PQCMC Proof of Concept current - Continuous Build

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Implementation Guide Home Page

As part of an effort intended to support future electronic acquisition and use of submitted information, a project was undertaken at FDA to identify and prioritize pharmaceutical quality/chemistry, manufacturing and controls (PQ/CMC) information that would benefit from a structured submission approach. This information would be submitted in the Common Technical Document as defined by the International Council for Harmonisation's (ICH) Common Technical Document (CTD) . The goals of this project were (a) to identify types of PQ/CMC information that are available in applications, information that is important to evaluate an application, information categories and elements that are common across the various application types, and (b) to provide recommendations for standardization of the categories and data types necessary for application review. This initiative will align, where comparable elements exist, with substance and product identifiers described by the International Organization of Standardization for the Identification of Medicinal Products (ISO IDMP) standards.

For consistency of product quality data across FDA centers, the draft standardized data elements and terminologies were created by an Agency workgroup comprised of Subject Matter Experts (SMEs) from Center for Drug Evaluation and Research (CDER), Center for Veterinary Medicine (CVM) and Center for Biologics Evaluation and Research (CBER). The draft data elements and terminologies associated with PQ/CMC subject areas and scoped to some of what is currently submitted in Module 3 of the electronic Common Technical Document (eCTD) submission, but is not intended to be comprehensive in covering all eCTD pharmaceutical quality information. FDA has developed limited structured data elements and supporting terminologies for PQ/CMC and has recently engaged in discussions with standard setting bodies to codify these data elements into a data exchange specification for the submission of PQ/CMC data.

At present FDA is exploring HL7 FHIR as a potential data exchange solution for submission of PQ/CMC structured data as part of Module 3 eCTD submission. Since this is an exploratory effort, FDA is conducting a tightly scoped Proof-of-Concept (PoC) with FHIR for just the Quality Specification domain of PQ/CMC. The PoC effort has created a DRAFT FHIR Profile called PQ/CMC Specification Profile. The DRAFT FHIR Profile is intended to be used by few sponsor organizations to create FHIR xml instances and submit test applications to the FDA Test Gateway.

For more information CTD see The Common Technical Document for the Registration of Pharmaceuticals for Human Use: Quality – M4Q(R1).
For more information on eCTD see Electronic Common Technical Document Specification V3.2.2.

Scope: Quality Specification

Quality specifications are submitted in several sections of the eCTD: 3.2.S.4.1, 3.2.P.4.1, and 3.2.P.5.1 for Control of Drug Substance, Control of Excipients, Control of Drug Product and respectively. This PoC is focused on Drug Substance and Drug Product specifications. Most specifications are submitted in a tabular format and for that reason considered amenable to standardization. The objective of the PoC is to test not only the structure that has been defined for quality specifications but also the FHIR standard as an exchange mechanism.

- Due to minor differences in the definition of Specification in CDER, CBER and CVM regulations we are including all three below:
  CDER & CBER - (314.3) Specification means the quality standard (i.e. , tests, analytical procedures, and acceptance criteria) provided in an approved application to confirm the quality of drug substances, drug products, intermediates, raw materials, reagents, components, in process materials, container closure systems, and other materials used in the production of a drug substance or drug product. For the purpose of this definition, acceptance criteria means numerical limits, ranges, or other criteria for the tests described.
- CVM - (514.8 (iv)) Specification means the quality standard (i.e., tests, analytical procedures, and acceptance criteria) provided in an approved application to confirm the quality of drugs including, for example, drug substances, Type A medicated articles, drug products, intermediates, raw materials, reagents, components, in-process materials, container closure systems, and other materials used in the production of a drug. For the purpose of this definition, the term "acceptance criteria" means numerical limits, ranges, or other criteria for the tests described.

- CBER & CDER - (600.3 (kk)) Specification, as used in 601.12 of this chapter, means the quality standard (i.e., tests, analytical procedures, and acceptancecriteria) provided in an approved application to confirm the quality of products, intermediates, raw materials, reagents, components, in-process materials, container closure systems, and other materials used in the production of a product. For the purpose of this definition, acceptance criteria means numerical limits, ranges, or other criteria for the tests described.

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Mapping the Quality Specification to FHIR

The Quality Specification data model was developed indent of FHIR. No new resources were developed for Quality Specification. A single profile has been defined on three resources: PlanDefinition, MedicationKnowledge and Substance. As of this writing the maturity of PlanDefinigion and Substance is 2 while MedicationKnowledge is 0. Always be aware that this is a PoC and that change is to be expected and any difficulty in describing a test with the existing model and mechanism should be communicated.

This implementation guide contains the standard FHIR IG pages, however since the naming of the elements in the FHIR resources does not reflect the PQ/CMC data model elements names a table has been provided here which contains the mapping and the path to the FHIR element and a xml code snippet. One important aspect of the Quality Specification profile is that MedicationKnowledge and Substance are included only to convey the information about the drug product and drug substance respectively. Only one of these resources will be present in any profile instance. While the data model for Quality Specification assigns acceptance criteria as a child element within the test structure, the PlanDefinition represents the acceptance as a goal id. This is a reference to a list of goals, AKA the acceptance criteria which are listed at the start of the file. A distinct goal is only listed once but can be referred to many time. For example, many impurities will have an acceptance criteria of <0.1%. The goal of <0.1% will occur exactly once and have a goal id. Every individual impurity that has and acceptance criteria of <0.1% will reference the goal's id value for the acceptance criteria. The human readable section in the XML examples readily illustrates this grouping of the goals, but the human readable section is not very readable for this reason. The reader must refer up and down between the tests and the acceptance criteria.

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PQ/CMC Elements Table

This table provides a mapping from the PQ/CMC elements to the FHIR Profile (Is it an element or class?) and provides the FHIR Path.

PQ/CMC Element	FHIR Profile Mapping	FHIR Path
DrugSubstance	PlanDefinition.subjectReference.resolve().where(extension("pqcmc-substanceType").valueCode="DrugSubstance")	/Bundle/entry/resource/MedicationKnowledge/extension/valueCode
DrugSubstance chemicalName	Substance.extension("pqcmc-chemicalName").valueString	/Bundle/entry/resource/MedicationKnowledge/code/text
DrugSubstance companyCode	Substance.code.coding.where(system={not one of the others}).code	/Bundle/entry/resource/MedicationKnowledge/code/coding/code
DrugSubstance INN	Substance.code.coding.where(system="...inn/en").code	/Bundle/entry/resource/MedicationKnowledge/code/coding/code
DrugSubstance IUPACName	Substance.code.coding.where(system="...iupac.org").code	/Bundle/entry/resource/MedicationKnowledge/code/coding/code
DrugSubstance USAN	Substance.code.coding.where(system="...united-states-adopted-names").code	/Bundle/entry/resource/MedicationKnowledge/code/coding/code
DrugSubstance UNII	Substance.code.coding.where(system="...UNII").code	/Bundle/entry/resource/MedicationKnowledge/code/coding/code
…	…	…
DrugProduct	PlanDefinition.subjectReference.resolve().where(extension("pqcmc-	/Bundle/entry/resource/MedicationKnowledge

	substanceType").valueCode="DrugProduct"); MedicationKnowledge.where(extension("pqcmc-substanceType").valueCode="Raw Material")	
DrugProduct dosageForm	MedicationKnowledge.doseForm	/Bundle/entry/resource/MedicationKnowledge/extension/valueCode
DrugProduct nonProprietaryName	MedicationKnowledge.synonym.where(extension("pqcmc-nameType").valueCode="nonProprietary")	/Bundle/entry/resource/MedicationKnowledge/code/text
DrugProduct proprietaryName	MedicationKnowledge.synonym.where(extension("pqcmc-nameType").valueCode="proprietary")	/Bundle/entry/resource/MedicationKnowledge/synonym
DrugProduct strength	MedicationKnowledge.ingredient.strength.	/Bundle/entry/resource/MedicationKnowledge/ingredient/strength
DrugProduct strength value	MedicationKnowledge.ingredient.strength.numerator.value	/Bundle/entry/resource/MedicationKnowledge/ingredient/strength/numerator/value
DrugProduct strength unitOfMeasure	MedicationKnowledge.ingredient.strength.numerator.code	/Bundle/entry/resource/MedicationKnowledge/ingredient/strength/numerator/code
…	…	…
QualitySpecification	PlanDefinition	/Bundle/entry/resource/PlanDefinition
QualitySpecification additionalInformation	PlanDefinition.description, PlanDefinition.purpose, PlanDefinition.usage or extension	/Bundle/entry/resource/PlanDefinition/goal/description/text
QualitySpecification status	PlanDefinition.extension("pqcmc-approval").extension("code").valueCode	/Bundle/entry/resource/PlanDefinition/extension/extension/valueCode
QualitySpecification statusDate	PlanDefinition.extension.extension	/Bundle/entry/resource/PlanDefinition/extension/extension/valueDate
QualitySpecification title	PlanDefinition.title	/Bundle/entry/resource/PlanDefinition/title
QualitySpecification type	PlanDefinition.subjectReference.resolve().extension("pqcmc-substanceType").valueCode	/Bundle/entry/resource/MedicationKnowledge/extension/valueCode
QualitySpecification version	PlanDefinition.version	/Bundle/entry/resource/PlanDefinition/version
QualitySpecification versionDate	PlanDefinition.date	/Bundle/entry/resource/PlanDefinition/date
QualitySpecification Test	PlanDefinition.action	/Bundle/entry/resource/PlanDefinition/action
Test/analyticalProcedure	PlanDefinition.action.code.text	/Bundle/entry/resource/PlanDefinition/action/code/text
Test category	PlanDefinition.action.code	/Bundle/entry/resource/PlanDefinition/action/code/coding/code

Test name	PlanDefinition.action.title	/Bundle/entry/resource/PlanDefinition/action/title
Test UnidentifiedImpuritybyRRT	PlanDefinition.action.extension("pqcmc-focus").valueCode.code	/Bundle/entry/resource/PlanDefinition/action/extension/valueDecimal
Test referenceToProcedure	PlanDefinition.action.extension("pqcmc-definitionUri").valueUri.code	/Bundle/entry/resource/PlanDefinition/action/extension/valueUri
Test testMethodOrigin	PlanDefinition.action.extension("pqcmc-origin")	/Bundle/entry/resource/PlanDefinition/action/extension/valueCode
Test usage	PlanDefinition.action.reason	/Bundle/entry/resource/PlanDefinition/action/reason/text
Test Stage	PlanDefinition.action.action	/Bundle/entry/resource/PlanDefinition/action/action
Stage name	PlanDefinition.action.action.title	/Bundle/entry/resource/PlanDefinition/action/action/title
Stage sequenceOrder	PlanDefinition.action.relatedAction.actionId & relationship	/Bundle/entry/resource/PlanDefinition/action/action/relatedAction
Stage AcceptanceCriteria	PlanDefinition.action.action.goalId	/Bundle/entry/resource/PlanDefinition/action/action/goalId
AcceptanceCriteria additionalInformation	PlanDefinition.goal.extension("pqcmc-annotation")	/Bundle/entry/resource/PlanDefinition/goal/extension
AcceptanceCriteria interpretationCode	**The interpretation Code are explaind below in Intrepretation Codes**	/Bundle/entry/resource/PlanDefinition/goal/target
AcceptanceCriteria literalText	PlanDefinition.goal.detail[x].extension("originalText")	/Bundle/entry/resource/PlanDefinition/goal/description/text
AcceptanceCriteria value	PlanDefinition.goal.detailQuantity.value or PlanDefinition.goal.detailRange.low.value and PlanDefinition.goal.detailRange.high.value	/Bundle/entry/resource/PlanDefinition/goal/target/detailRange/low/value OR /Bundle/entry/resource/PlanDefinition/goal/target/detailRange/high/value OR /Bundle/entry/resource/PlanDefinition/goal/target/detailRange/extension/range-lowExclusive/valueQuantity/value OR /Bundle/entry/resource/PlanDefinition/goal/target/detailRange/extension/range-highExclusive/valueQuantity/value
AcceptanceCriteria valueUnit	PlanDefinition.goal.detailQuantity.code or PlanDefinition.goal.detailRange.low.code and PlanDefinition.goal.detailRange.high.code	/Bundle/entry/resource/PlanDefinition/goal/target/detailRange/low/code OR /Bundle/entry/resource/PlanDefinition/goal/target/detailRange/high/code

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Patterns for Structuring Acceptance Criteria in a Quality Specification

Overview

This section is an initial draft to define patterns for structuring some common tests & acceptance criteria typically seen in Drug Product and Drug Substance Specifications. It also provides instructions on how a current unstructured specification data would be represented in a structured format. As FDA moves from unstructured quality specifications submitted as PDF documents in Module 3 of eCTD to structured and standardized quality specifications, we plan to work with the industry to define the best way to structure the various kinds of tests and their acceptance criteria. This section will evolve as new tests are added and existing structuring patterns are updated based on experience and industry feedback. Below are guidelines/instructions on how to structure some common tests.

Particle Size Distribution

Since there is variation in how particle size distribution techniques are presented in quality specifications, FDA is providing some instructions on standardizing the way these are submitted in the future.

Laser Diffraction

Guidance would be to send this data in the following format: d(0.1), d(0.5).

NOTE: d(0.1) – means the average diameter of 10% of the particles are less than the given value. For a values that says d(0.1) NMT 20 microns – this means 10% of the particles are less than or equal to 20 microns

Sieve Diameters

Guidance would be to send this data as the sieve microns rather than the Sieve Number. Sieve numbers are not standardized and therefore not useful for FDA reviewers.

Cascade Impactors (inhalers)

This will be addressed in future guidance. Will seek industry input in defining how this data should be structured.

Below are examples for two of the particle size distribution techniques:

Laser Diffraction

Figure 1: Laser Diffraction Example

Particle Size (By Malvern)		Laser diffraction Test Method – XX-0000	
D(0.1)	NMT 20 um		
d(0.5)	NMT[1] 50 µm		43 µm
d(0.9)	NMT[1] 100 µm		86 µm

In the above example, the data should be submitted as follows:

Test Category: *Physical Property*
Test Name: *Particle Size Distribution D (0.1)*
Stage Name: *Single Stage*
Acceptance Criteria (AC):
AC.literalText: *NMT 20 um*
AC.InterpretationCode: *NMT*
AC.Value: *20*
AC.ValueNumericUOM: *um*
Analytical Procedure (for all three tests): *Laser diffraction Test Method XX-0000*

Sieve Diameters

Figure 2: Sieve Dimeters Example

2. Total Particle Size	NMT 0.05%	0.00%	0.00%	NMT 0.05%	<0.01%	0.01%
1. #80 (180μm) US Std Sieve	NLT 80% thru	97%	95%	NLT 80% thru	96%	94%
2. #400 (38μm) US Std Sieve	NLT 25% thru	42%	41%	NLT 25% thru	40%	37%
Levoamphetamine	47.0 – 53.0%	50.0%	50.0%	47.0 – 53.0%	50.0%	49.9%

Test Category: *Physical Property*
Test Name: *Particle Size Distribution 180um*
Stage Name: *Single Stage*
Acceptance Criteria (AC):
AC.literalText: *NMT 80% thru*
AC.InterpretationCode: *NMT*
AC.Value: *80*
AC.ValueNumericUOM: *%*
Analytical Procedure: *Determination by Analytical Sieving*

Microbial Testing

Figure 3: Microbial Testing Example

14	Microbial enumeration tests:	
	Total aerobic microbial count	NMT 1000 cfu / g
	Total combined yeasts and molds count	NMT 100 cfu / g
	Test for specified microorganisms [E .coli, Salmonella spp., S. aureus, Pseudomonas aeruginosa]	Should be Absent / g

NOTE: In the above example, there are 6 Tests. Besides the Total Aerobic microbial count (TAMC) and Total combined yeasts and mold counts (TYMC), each of the 4 microorganisms should be built out as 4 separate Tests.

In the above example, for TAMC the data should be submitted as follows:

Test Category: *Biological Property*
Test Name: *Total Aerobic microbial count*
Stage Name: *Single Stage*
Acceptance Criteria (AC):
AC.literalText: *NMT 1000 cfu/g*
AC.InterpretationCode: *NMT*
AC.Value: *1000*
AC.ValueNumericUOM: *cfu/g*
Analytical Procedure (for all 6 tests): *USP<61>*

For each of the 4 microorganisms, the data should be submitted as shown below for E.Coli:

> **Test Category:** *Biological Property*
> **Test Name:** *E.Coli*
> **Stage Name:** *Single Stage*
> **Acceptance Criteria (AC):**
> **AC.literalText:** *Should be Absent/g*
> **AC.InterpretationCode:** *NA*
> **AC.Value** *Should be Absent*
> **AC.ValueNumericUOM:** *NA*
> **Analytical Procedure (for all 6 tests):** *USP<61>*

Dissolution Tests

Dissolution Tests can be either for Immediate or Modified (Delayed or Extended) Release.

- Example 1 below shows the structuring of an "Immediate release multi-substance product". The structured example just shows one of the substances.
- Example 2 below shows the structuring of a "Modified release product" that has both delayed and extended properties

The rationale for asking structured data at all Stages is because FDA would like to see if a Dissolution test always seems to go beyond Stage 1 and then pass. It would indicate that the Dissolution test is not adequate or maybe there is a problem in the manufacturing process.

Example 1 – Multi-substance product

Dissolution	NLT 80% (Q) of labeled amount of Substance A is dissolved in 30 minutes
(ABC 12345, HPLC)	NLT 80% (Q) of the labeled amount of Substance B is dissolved in 30 minutes
	NLT 80% (Q) of the labeled amount of Substance C is dissolved in 30 minutes
	Conforms to current USP <711>

This example for Dissolution Test is challenging for FDA because it does not specify the details of the subsequent steps. There is just a reference to USP <711>. Moving forward, FDA is considering that these kinds of representations should be submitted as follows:

Instead of one text based acceptance criteria for Substance A - **"NLT 80% (Q) of the labeled amount of Substance A dissolved in 30 minutes"**

Now this one acceptance criterion would be broken out as following six (6) acceptance criteria's:

1. First Stage: no one unit (of the 6) is NLT 85% dissolved in 30 minutes
2. Second Stage: (average of 12) NLT 80% dissolved in 30 minutes
3. Second Stage: no one unit is NLT 65% dissolved in 30 minutes

4. Third Stage: (average of 24) NLT 80% dissolved in 30 minutes

5. Third Stage: not more than 2 units are NLT 65% dissolved in 30 minutes

6. Third Stage: no one unit is NLT 55% dissolved in 30 minutes

Following is how this would be structured in the Test, Stage and Acceptance Criteria data elements for each of the three substances – Substance A, Substance B and Substance C. There will be a total of 18 records in Acceptance Criteria – 6 records for each of the three substances.

FIRST STAGE

- **no** one unit (of the 6) is NLT 85% dissolved in 30 minutes

> **Test Category:** *Assay*
> **Test Name:** *Dissolution for Substance A*
> **Stage Name:** *First Stage*
> **Acceptance Criteria (AC):**
> **AC.literalText:** *no one unit (of the 6) is NLT 85% dissolved in 30 minutes*
> **AC.InterpretationCode:** *NLT*
> **AC.Value:** *85*
> **AC.ValueNumericUOM:** *%*
> **Analytical Procedure :** *USP<711>*

SECOND STAGE

-
SECOND STAGE Second Stage: (average of 12) NLT 80%; Second Stage: no one unit is NLT 65%

> **Test Category:** *Assay*
> **Test Name:** *: Dissolution for Substance A*
> **Stage Name:** *Second Stage*
> **Acceptance Criteria (AC):**
> **AC.literalText:** *(average of 12) NLT 80% dissolved in 30 minutes*
> **AC.InterpretationCode:** *NLT*
> **AC.Value:** *80*
> **AC.ValueNumericUOM:** *%*
> **Analytical Procedacure :** *USP<711>*

> **Test Category:** *Assay*
> **Test Name:** *: Dissolution for Substance A*
> **Stage Name:** *Second Stage*
> **Acceptance Criteria (AC):**
> **AC.literalText:** *no one unit is NLT 65% dissolved in 30 minutes*
> **AC.InterpretationCode:** *NLT*
> **AC.Value:** *65*
> **AC.ValueNumericUOM:** *%*
> **Analytical Procedure :** *USP<711>*

THIRD STAGE

-
Third Stage: (average of 24) NLT 80%; Third Stage: not more than 2 units are NLT 65%; third Stage: no one unit is NLT 55%

> **Test Category:** *Assay*
> **Test Name:** *: Dissolution for Substance A*
> **Stage Name:** *Third Stage*

> **Test Category:** *Assay*
> **Test Name:** *: Dissolution for Substance A*
> **Stage Name:** *Third Stage*

> **Test Category:** *Assay*
> **Test Name:** *: Dissolution for Substance A*
> **Stage Name:** *Third Stage*

Acceptance Criteria (AC):
AC.literalText: *(average of 24) NLT 80% dissolved in 30 minutes*
AC.InterpretationCode: *NLT*
AC.Value: *80*
AC.ValueNumericUOM: *%*
Analytical Procedure : *USP<711>*

Acceptance Criteria (AC):
AC.literalText: *nnot more than 2 units are NLT 65% dissolved in 30 minutes*
AC.InterpretationCode: *NLT*
AC.Value: *65*
AC.ValueNumericUOM: *%*
Analytical Procedure : *USP<711>*

Acceptance Criteria (AC):
AC.literalText: *nno one unit is NLT 55% dissolved in 30 minutes*
AC.InterpretationCode: *NLT*
AC.Value: *55*
AC.ValueNumericUOM: *%*
Analytical Procedure : *USP<711>*

Example 2 - Modified Release

Dissolution USP <711>	Acid Stage: Time in hrs. 2	Amount Dissolved NMT 10%
	Base Stage: Time in hrs. 1	Amount Dissolved NMT 25%
	2	15% - 60%
	6	NLT 85%

- Two conditions: Acid and Buffer/Base. There will be total of 18 records in acceptance criteria for the above Example
- **Test Name: Dissolution in Acid Stage (2 hours)**
    1. First Stage: no one unit (of the 6) is NMT 10%
    2. Second Stage (average of 12) NMT 10%
    3. Second Stage no one unit is NMT 25%
    4. Third Stage (average of 24) NMT 10%
    5. Third Stage no one unit is NMT 25%
    6. Third Stage: NA
- **Test Name: Dissolution in Base (1 hour)**
    1. First Stage no one unit (of the 6) is NMT 20%
    2. Second Stage (average of 12) NMT 25%
    3. Second Stage no one unit is NMT 40%
    4. Third Stage (average of 24) NMT 25%
    5. Third Stage not more than 2 units are NMT 40%
    6. Third Stage no one unit is NMT 50%
- **Test Name: Dissolution in Base (2 hours)**
    1. First Stage no one unit (of the 6) is between 15% and 60%
    2. Second Stage: NA
    3. Second Stage: NA
    4. Third Stage: NA
    5. Third Stage: NA

6. Third Stage: NA

- **Test Name: Dissolution in Base (6 hours)**

    1. First Stage no one unit (of the 6) is NLT 90%

    2. Second Stage (average of 12) NLT 85%

    3. Second Stage no one unit is NLT 70%

    4. Third Stage (average of 24) NLT 85%

    5. Third Stage not more than 2 units are NLT 70%

    6. Third Stage no one unit is NLT 60%

Structuring of Test Name: Dissolution in Acid Stage (2 hours)

1. First Stage: no one unit (of the 6) is NMT 10%

2. Second Stage (average of 12) NMT 10%

3. Second Stage no one unit is NMT 25%

4. Third Stage (average of 24) NMT 10%

5. Third Stage no one unit is NMT 25%

6. Third Stage: NA

FIRST STAGE

- no one unit (of the 6) is more than 10%

> **Test Category:** *Assay*
> **Test Name:** *Dissolution in Acid Stage (2 hours)*
> **Stage Name:** *First Stage*
> **Acceptance Criteria (AC):**
> **AC.literalText:** *no one unit (of the 6) is NMT 10%*
> **AC.InterpretationCode:** *NMT*
> **AC.Value:** *10*
> **AC.ValueNumericUOM:** *%*
> **Analytical Procedure :** *USP<711>*

SECOND STAGE

- Second Stage: (average of 12) NMT 10%; Second Stage: no one unit is NMT 25%

> **Test Category:** *Assay*
> **Test Name:** *:: Dissolution in Acid Stage (2 hours)*
> **Stage Name:** *Second Stage*
> **Acceptance Criteria (AC):**
> **AC.literalText:** *(average of 12) NMT 10%*
> **AC.InterpretationCode:** *NMT*
> **AC.Value:** *10*
> **AC.ValueNumericUOM:** *%*
> **Analytical Procedure :** *USP<711>*

> **Test Category:** *Assay*
> **Test Name:** *:: Dissolution in Acid Stage (2 hours)*
> **Stage Name:** *Second Stage*
> **Acceptance Criteria (AC):**
> **AC.literalText:** *no one unit is NMT 25%*
> **AC.InterpretationCode:** *NMT*
> **AC.Value:** *25*
> **AC.ValueNumericUOM:** *%*
> **Analytical Procedure :** *USP<711>*

THIRD STAGE

- Third Stage: (average of 24) NMT 10%; Third Stage: no one unit is NMT 25%; Third Stage: NA

Test Category: *Assay* **Test Name:** *: Dissolution in Acid Stage (2 hours)* **Stage Name:** *Third Stage* **Acceptance Criteria (AC):** **AC.literalText:** *(average of 24) NMT 10%* **AC.InterpretationCode:** *NLT* **AC.Value:** *10* **AC.ValueNumericUOM:** *%* **Analytical Procedure :** *USP<711>*	**Test Category:** *Assay* **Test Name:** *:Dissolution in Acid Stage (2 hours)* **Stage Name:** *Third Stage* **Acceptance Criteria (AC):** **AC.literalText:** *no one unit is NMT 25%* **AC.InterpretationCode:** *NMT* **AC.Value:** *25* **AC.ValueNumericUOM:** *%* **Analytical Procedure :** *USP<711>*

Examples of dissoltuion tests in PQ/CMC FHIR Profile XML are shown in this example XML snippets.

Polymorphic Forms

Polymorphic Form tests are typically seen as Identification Tests or Assay Tests. Below are examples of both types. Depending on the kind of acceptance criteria that is needed, PQ/CMC will support both the text based criteria (example 1) or quantitative criteria (example 2).

Example 1

Figure 6: Identification Tests Example

In the above example, the acceptance criteria (AC) is the first sentence of the text. It basically tells you that the results should conform with the standard. The second part is just identifying the details of the standard and tells you exactly where the peaks are – these are also defined in the method/analytical procedure in eCTD.

Test Category: *Physical Property*
Test Name: *Polymorphic Forms*
Stage Name: *Single Stage*
Acceptance Criteria (AC):
AC.literalText: *The –Ray powder diffractogram is consistent with the reference diffractogram of Test Substance A. Characteristic XRD peak positions are 7,1,10.8, 14.2, 16.7, 17.2, 18.5, 21.4, 22.6, 23.2, 23.5, 24.0, 24.2, 28.5, 32.5, 32.5 within ±0.3 degrees*
AC.InterpretationCode: *NA*
AC.Value: *The x-Ray powder diffractogram Is consistent with the reference diffractogram of Test Substance A*
AC.ValueNumericUOM:
Analytical Procedure : *XRD*

Example 2

Figure 7: Polymorphic Form Example

Test	Analytical Procedure	Acceptance Criteria
Polymorph Form II (DSC)	ABC - 00004504 (K195202-003)	NMT 2.0%
Polymorph Form IV (XRD)	ABC - 000089891	Not detected

When Polymorphic Form is presented as numeric values, as shown above, the acceptance criteria will be structured as follows:

Test Category: *Physical Property*
Test Name: *Polymorphic Form II*
Stage Name: *Single Stage*
Acceptance Criteria (AC):
AC.literalText: *NMT 2.0%*
AC.InterpretationCode: *NMT*
AC.Value: *2.0*
AC.ValueNumericUOM: *%*
Analytical Procedure : *DSC*

Content Uniformity

Test	Specification	Analytical Procedure
Uniformity of dosage units (By content uniformity)[e]	The requirements for dosage uniformity are met if the acceptance value of the first 10 dosage units is less than or equal to L1. If the acceptance value is greater than L1, test the next 20 dosage units and calculate the acceptance value. The requirements are met if the final acceptance value of the 30 dosage units is less than or equal to L1 and no individual content of the dosage unit is less than $(1 - L2 \times 0.01)M$ nor more than $(1 + L2 \times 0.01)M$ in calculation of acceptance value. Unless otherwise specified, L1 is 15.0 and L2 is 25.0.	USP <905> (By HPLC)

The acceptance criteria for content uniformity tests is <u>not</u> intended to be parsed and structured in PQ/CMC.

In the above example, for Uniformity of dosage units Test, the data should be submitted as follows:

Test Category: *Assay*
Test Name: *Uniformity of dosage*
Stage Name: *Single Stage*

Acceptance Criteria (AC):
AC.literalText: *" the entire text in the Specification cell from above"*
AC.InterpretationCode: *NA*
AC.Value: *"the entire text in the Specification cell from above"*
AC.ValueNumericUOM:
Analytical Procedure : *USP <905> (by HPLC)*

Optical Rotation/Specific Rotation

Figure 8: Specific Rotation Test Example

		obtained under assay test.
4	Water % w/w (by KF)*	1.9 % - 2.5 %
5	Specific Rotation (1.0% solution in chloroform, on anhydrous basis)	Between -82° and -90°

FDA is recommending that Acceptance Criteria for Specific Rotation Test should always be presented as a quantitative value like in Example 1. This will be structured as following:

Test Category: *Physical Property*
Test Name: *Specific Rotation*
Stage Name: *Single Stage*
Acceptance Criteria (AC):
AC.literalText: *Between -82 and -90*
AC.InterpretationCode: *NMT*
AC.Value: *-82*
AC.ValueNumericUOM: *Degree*
Analytical Procedure:

Test Category: *Physical Property*
Test Name: *Specific Rotation*
Stage Name: *Single Stage*
Acceptance Criteria (AC):
AC.literalText: *Between -82 and -90*
AC.InterpretationCode: *NLT*
AC.Value: *-90*
AC.ValueNumericUOM: *Degree*
Analytical Procedure:

Example 2

Figure 9: Specific Rotation Test Example 2

pH	5.0 – 7.0	5.9	6.2	5.0 – 7.0
Specific Rotation	Optically Inactive	Conforms	Conforms	Inactive
Residue on Ignition	NMT 0.2%	0.0%	0.0%	NMT 0.2%

In the above example 2, Specific Rotation acceptance criteria is presented as text value of "Optically Inactive". FDA recommends that Specific Rotation criteria should always be presented as a numeric value. In the above example, it should say 0 degrees. It can then be structured as Example 1, with only one value of

Test Category: *Physical Property*

Test Name: *Specific Rotation*
Stage Name: *Single Stage*
Acceptance Criteria (AC):
AC.literalText: *0 Degree*
AC.InterpretationCode: *NA*
AC.Value: *0*
AC.ValueNumericUOM: *Degree*
Analytical Procedure:

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Interpretation Codes

Interpretation Codes describe how to relate the given value to an acceptance value.   The PQ/CMC data model has an element for the codes, however the FHIR exchange standard does not support codes or an ability to write extensions to contain the code. As shown the table above, the Interpretation code maps to PlanDefinition/goal/target, but the codes will not be found in any XML file. The target indicates what should be done and within what timeframe. Target have goals which are measured. The interpretation Codes are expressed in the relationships of the low and the high elements of the detailRange.   The unit and code/system elements of the low or high elements are required to match. A range can be incomplete. The low and the high values are inclusive. Two extensions have been added to the Quality Specification profile to account for exclusive range.

The **XML Template for a detailRange**

< **[name]** xmlns="http://hl7.org/fhir">

<!-- from Element: extension -->

 < **low** ><!-- **0..1** Quantity(SimpleQuantity) Low limit --></low>

 < **high** ><!-- **0..1** Quantity(SimpleQuantity) High limit --></high>

</[name]>

Numeric limits.

	INCLUSIVE	EXCLUSIVE
For an upper limit:	```<goal id="goal3"> <description> <text value="NMT 80 %"/> </description> <target> <measure> <text value=""/> </measure> <detailRange> <high> <value value="80"/> <system value="http://unitsofmeasure.org"/> <code value="%"/> </high> </detailRange> </target> </goal>```	```<goal id="goal3"> <description> <text value="LT 90 %"/> </description> <target> <measure> <text value=""/> </measure> <detailRange> <extension url="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/range-highExclusive"> <valueQuantity> <value value="90"/> <system value="http://unitsofmeasure.org"/> <code value="%"/> </valueQuantity> </extension> </detailRange> </target> </goal>```
For and upper and lower limit:	```<goal id="goal4"> <description> <text value="NLT 90 %;NLT 105 %;"/> </description> <target> <measure> <text value="no additional Information"/> </measure> <detailRange> <low> <value value="90"/> <system value="http://unitsofmeasure.org"/> <code value="%"/> </low> <high> <value value="105"/>```	```<goal id="goal4"> <description> <text value="GT 90 %;LT 105 %;"/> </description> <target> <measure> <text value="no additional Information"/> </measure> <detailRange> <extension url="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/range-lowExclusive"> <valueQuantity> <value value="90"/> <system value="http://unitsofmeasure.org"/> <code value="%"/> </valueQuantity> </extension>```

<table>
<tr>
<td colspan="2">

```xml
<system value="http://unitsofmeasure.org"/>
<code value="%"/>
</high>
</detailRange>
</target>
</goal>
```

</td>
<td>

```xml
<extension url="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/range-highExclusive">
<valueQuantity>
<value value="105"/>
<system value="http://unitsofmeasure.org"/>
<code value="%"/>
</valueQuantity>
</extension>
</detailRange>
</target>
</goal>
```

</td>
</tr>
<tr>
<td>For a lower limit:</td>
<td>

```xml
<goal id="goal2">
<description>
<text value="NLT 20 %"/>
</description>
<target>
<measure>
<text value="test"/>
</measure>
<detailRange>
<low>
<value value="20"/>
<system value="http://unitsofmeasure.org"/>
<code value="%"/>
</low>
</detailRange>
</target>
</goal>
```

</td>
<td>

```xml
<goal id="goal2">
<description>
<text value="GT 20 %"/>
</description>
<target>
<measure>
<text value=""/>
</measure>
<detailRange>
<extension url="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/range-lowExclusive">
<valueQuantity>
<value value="20"/>
<system value="http://unitsofmeasure.org"/>
<code value="%"/>
</valueQuantity>
</extension>
</detailRange>
</target>
</goal>
```

</td>
</tr>
</table>

For an Equal :

```xml
<goal id="goal4">
<description>
<text value="EQ 85 %"/>
</description>
<target>
<measure>
<text value=""/>
</measure>
<detailRange>
<valueQuantity>
<value value="28"/>
<system value="http://unitsofmeasure.org"/>
<code value="%"/>
</valueQuantity>
```

```
</detailRange>
</target>
</goal>
```

For a not applicable limit i.e. text:

```
<goal id="goal1">
<description>
<text value="White free of particles"/>
</description>
<target>
<measure>
<text value="test"/>
</measure>
<detailCodeableConcept>
<text value="White free of particles"/>
</detailCodeableConcept>
</target>
</goal>
```

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Codes and Terminology

Value Sets defined as part of the PQCMC implementation guide

The value sets used in the PQ/CMC PoC are listed below. In addition to these are the Unified Code for Units of Measure (UCUM) The PoC tool provides a lint of UCUM values but the PoC will not validate against UCUM.   The UCUM site is not a quick read, but the FHIR value set concept makes that unnecessary. Value sets are used to create a simple collection of codes suitable for use for the use case of the profile for data entry or validation.   UCUM is the only FHIR code system for units and is supported in the profile, but the PoC validator is not utilizing a FHIR terminology server.   In time, a value set for PQ/CMC will be developed and/or possibly extend the value sets in use for SPL.

- Dosage Form   Value set for Dosage Form
- Method Origin   Value set for Methods
- Specification Satus Value set for Specification Satus
- Test Categories   Value set for Test Categories
- Test Usage   Value set for Test Usage

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Artifact index

This page provides a list of the FHIR artifacts defined as part of this implementation guide.

Artifact Packages

Extensions

Extensions defined as part of the PQCMC implementation guide

• Approval Status	Information about the approval status and date associated with the PlanDefinition
• Comment	Additional text describing the item
• Method Origin	A coded value describing the source of a test method
• Definition URI	A reference to the formal definition for the test as a URI
• Focus	Indication of the focus of a particular testing step
• Name Type	Distinguishes between types of medication names
• Range lower bound exclusive	A lower-bound for the range that excludes the specified value(rather than the default assumption of inclusive of Range.low)
• Range upper bound exclusive	An upper-bound for the range that excludes the specified value(rather than the default assumption of inclusive of Range.high)
• Content Percent	Percentage by mass of the ingredient within the product
• Product Type	Distinguishes between Drug Product and Drug Substance

Profiles

Constraints on FHIR resources to be adhered to as part of the PQCMC implementation guide

• PQCMC Quality Specification	Defines the tests and stages for product testing
• PQCMC Drug Product	a finished dosage form, for example, tablet, capsule, or solution that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients. [21 CFR 314.3; Title 21; Chapter I; Subchapter D; Subpart A]
• PQCMC Drug Substance	Drug substance means "an active ingredient that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or any function of the human body, but does not include intermediates use in the synthesis of such ingredient. [21 CFR 314.3; Title 21; Chapter I; Subchapter D; Part 314; Subpart A]
• PQCMC Raw Ingredient	Out of scope for the PoC

Value Set

Value Sets defined as part of the PQCMC implementation guide

- Test Usage   Value set for Test Usage
- Method Origin   Value set for methods
- Specification Status Value set for Specification Status
- Test Categories   Value set for Test Categories
- Dosage Form   Value set for Dosage Form

Examples

Sample quality specifications

- ProductExample   FHIR XML illustrating a Drug Product
- SubstanceExample FHIR XML illustrating a Drug Substance

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Example - Dissolution

The example below shows the specifications for dissoltion in a FHIR XML file.

```xml
<?xml version="1.0"?>
<PlanDefinition>
<id value="POCABBV32805DrugProduct"/>
<meta>
<profile value="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/qualityspecification"/>
</meta>
<text>
<status value="generated"/>
<div xmlns="http://www.w3.org/1999/xhtml">
<p>
<b>Proof of Concept PC/CMC Quality Specification</b>
</p>
</div>
</text>
<extension url="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-approvalStatus">
<extension url="type">
<valueCode value="C134011"/>
</extension>
<extension url="date">
<valueDate value="2018-06-22"/>
</extension>
</extension>
<version value="2"/>
<title value="."/>
<status value="active"/>
<subjectReference>
<reference value="MedicationKnoweledge/idbvfb0l3guwhfomghwcvgw2tjrkdcnmmsn2fgbkpwqasyfwvqetob"/>
</subjectReference>
<date value="2018-08-31"/>
<usage value="a comment on product"/>
<goal id="goal1">
<description>
<text value="no one unit (of the 6) is NMT 10%"/>
</description>
<target>
<detailRange>
<high>
<value value="10"/>
<system value="http://unitsofmeasure.org"/>
<code value="%"/>
</high>
```

```xml
</detailRange>
</target>
</goal>
<goal id="goal2">
<description>
<text value="(average of 12) NMT 10%"/>
</description>
<target>
<detailRange>
<high>
<value value="10"/>
<system value="http://unitsofmeasure.org"/>
<code value="%"/>
</high>
</detailRange>
</target>
</goal>
<goal id="goal3">
<description>
<text value="no one unit is NMT 25%"/>
</description>
<target>
<detailRange>
<high>
<value value="25"/>
<system value="http://unitsofmeasure.org"/>
<code value="%"/>
</high>
</detailRange>
</target>
</goal>
<goal id="goal4">
<description>
<text value="(average of 24)"/>
</description>
<target>
<detailRange>
<high>
<value value="10"/>
<system value="http://unitsofmeasure.org"/>
<code value="%"/>
</high>
</detailRange>
</target>
</goal>
<goal id="goal5">
<description>
<text value="no one unit is NMT 25%"/>
</description>
<target>
<detailRange>
<high>
<value value="25"/>
<system value="http://unitsofmeasure.org"/>
<code value="%"/>
</high>
</detailRange>
```

```xml
</target>
</goal>
<goal id="goal6">
<description>
<text value="no one unit (of the 6) is NMT 20%"/>
</description>
<target>
<detailRange>
<high>
<value value="20"/>
<system value="http://unitsofmeasure.org"/>
<code value="%"/>
</high>
</detailRange>
</target>
</goal>
<goal id="goal8">
<description>
<text value="(average of 12) NMT 25%"/>
</description>
<target>
<detailRange>
<high>
<value value="25"/>
<system value="http://unitsofmeasure.org"/>
<code value="%"/>
</high>
</detailRange>
</target>
</goal>
<goal id="goal9">
<description>
<text value="no one unit is NMT 40%"/>
</description>
<target>
<detailRange>
<high>
<value value="40"/>
<system value="http://unitsofmeasure.org"/>
<code value="%"/>
</high>
</detailRange>
</target>
</goal>
<goal id="goal10">
<description>
<text value="(average of 24)"/>
</description>
<target>
<detailRange>
<high>
<value value="25"/>
<system value="http://unitsofmeasure.org"/>
<code value="%"/>
</high>
</detailRange>
</target>
```

```
</goal>
<goal id="goal11">
<description>
<text value="no one unit is NMT 40%"/>
</description>
<target>
<detailRange>
<high>
<value value="40"/>
<system value="http://unitsofmeasure.org"/>
<code value="%"/>
</high>
</detailRange>
</target>
</goal>
<goal id="goal12">
<description>
<text value="no one unit is NMT 50%"/>
</description>
<target>
<detailRange>
<high>
<value value="50"/>
<system value="http://unitsofmeasure.org"/>
<code value="%"/>
</high>
</detailRange>
</target>
</goal>
<goal id="goal13">
<description>
<text value="no one unit (of the 6) is NLT 15%; no one unit (of the 6) is NMT 60%;"/>
</description>
<target>
<detailRange>
<low>
<value value="15"/>
<system value="http://unitsofmeasure.org"/>
<code value="%"/>
</low>
<high>
<value value="60"/>
<system value="http://unitsofmeasure.org"/>
<code value="%"/>
</high>
</detailRange>
</target>
</goal>
<goal id="goal15">
<description>
<text value="on one unit (of the 6) is NLT 90%"/>
</description>
<target>
<detailRange>
<low>
<value value="90"/>
<system value="http://unitsofmeasure.org"/>
```

```
<code value="%"/>
</low>
</detailRange>
</target>
</goal>
<goal id="goal16">
<description>
<text value="(average of 12) NT 85%"/>
</description>
<target>
<detailRange>
<low>
<value value="85"/>
<system value="http://unitsofmeasure.org"/>
<code value="%"/>
</low>
</detailRange>
</target>
</goal>
<goal id="goal17">
<description>
<text value="no one unit is NLT 70%"/>
</description>
<target>
<detailRange>
<low>
<value value="70"/>
<system value="http://unitsofmeasure.org"/>
<code value="%"/>
</low>
</detailRange>
</target>
</goal>
<goal id="goal18">
<description>
<text value="(average of 24) is NLT 85%"/>
</description>
<target>
<detailRange>
<low>
<value value="85"/>
<system value="http://unitsofmeasure.org"/>
<code value="%"/>
</low>
</detailRange>
</target>
</goal>
<goal id="goal19">
<description>
<text value="not more than 2 units are NLT 70%"/>
</description>
<target>
<detailRange>
<low>
<value value="70"/>
<system value="http://unitsofmeasure.org"/>
<code value="%"/>
```

```xml
</low>
</detailRange>
</target>
</goal>
<goal id="goal20">
<description>
<text value="no one unit is NLT 60%"/>
</description>
<target>
<detailRange>
<low>
<value value="60"/>
<system value="http://unitsofmeasure.org"/>
<code value="%"/>
</low>
</detailRange>
</target>
</goal>
<action>
<extension url="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-methodOrigin">
<valueCode value="Compendial"/>
</extension>
<extension url="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-definitionUri">
<valueString value="ABBV32805/Product/ver_2/USP711.pdf"/>
</extension>
<title value="Dissolution in Acid Stage (2 hours)"/>
<code>
<coding>
<code value="C60819"/>
<display value="Assay"/>
</coding>
<text value="USP &amp;#60; 711&amp;#62;"/>
</code>
<reason>
<coding>
<code value="C134029"/>
<display value="Release"/>
</coding>
</reason>
<action id="idkdeec3xnopreczyb3auhxlm2nin13xwlodteogpiwqljqyxrc5fl">
<title value="First Stage"/>
<goalId value="goal1"/>
</action>
<action id="idcwlt3r4q11cebwekp44tn3epfoyqs0ejxqh4pdidhcdcuhqmfbgo">
<title value="Second Stage"/>
<goalId value="goal2"/>
<goalId value="goal3"/>
<relatedAction>
<actionId value="93281ae6-4421-453b-ba93-d9f78d56500f"/>
<relationship value="after"/>
</relatedAction>
</action>
<action id="iduawwbjjtk3ntdq02y2ovk4gdkdtry15p0nghkho3u3wv3yr3bddc">
<title value="Third Stage"/>
<goalId value="goal4"/>
<goalId value="goal5"/>
<relatedAction>
```

```
<actionId value="a1fc5481-4fd0-4489-a351-0a1e6479e233"/>
<relationship value="after"/>
</relatedAction>
</action>
</action>
<action>
<extension url="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-methodOrigin">
<valueCode value="Compendial"/>
</extension>
<extension url="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-definitionUri">
<valueString value="ABBV32805/Product/ver_2/USP711.pdf"/>
</extension>
<title value="Dissolution in Base (1 hour)"/>
<code>
<coding>
<code value="C60819"/>
<display value="Assay"/>
</coding>
<text value="USP &amp;#60; 711&amp;#62;"/>
</code>
<reason>
<coding>
<code value="C134029"/>
<display value="Release"/>
</coding>
</reason>
<action id="idj40wuvfechssmgyqjlw44j4amlxasrhltnm1y1kaia4owt25i2t">
<title value="First Stage"/>
<goalId value="goal6"/>
</action>
<action id="idlqaxirlqjp10c5rm15dq4ubsnfk3v0do3e5miylvwr3cnaspgy">
<title value="Second Stage"/>
<goalId value="goal8"/>
<goalId value="goal9"/>
<relatedAction>
<actionId value="6bb5c09c-39dd-4dbd-8d58-cb284986e03c"/>
<relationship value="after"/>
</relatedAction>
</action>
<action id="idftuyqxde4v4wp33jhun1u054blawfyyahvcqwwmchyqvfbfkmpfk">
<title value="Third Stage"/>
<goalId value="goal10"/>
<goalId value="goal11"/>
<goalId value="goal12"/>
<relatedAction>
<actionId value="de270050-c544-4ca7-aa91-b55fb8c0bb30"/>
<relationship value="after"/>
</relatedAction>
</action>
</action>
<action>
<extension url="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-methodOrigin">
<valueCode value="Compendial"/>
</extension>
<extension url="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-definitionUri">
<valueString value="ABBV32805/Product/ver_2/USP711.pdf"/>
</extension>
```

```xml
<title value="Dissolution in Base (2 hours)"/>
<code>
<coding>
<code value="C60819"/>
<display value="Assay"/>
</coding>
<text value="USP &amp;#60; 711&amp;#62;"/>
</code>
<reason>
<coding>
<code value="C134029"/>
<display value="Release"/>
</coding>
</reason>
<action id="idgfy50bs2spxkkk0e5cpvxxwhsk4z1kad1xsprzgfsvw1bhush1mf">
<title value="First Stage"/>
<goalId value="goal13"/>
</action>
</action>
<action>
<extension url="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-methodOrigin">
<valueCode value="Compendial"/>
</extension>
<extension url="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-definitionUri">
<valueString value="ABBV32805/Product/ver_2/USP711.pdf"/>
</extension>
<title value="Dissolution in Base (6 hours)"/>
<code>
<coding>
<code value="C60819"/>
<display value="Assay"/>
</coding>
<text value="USP&amp;#60;711&amp;#62;"/>
</code>
<reason>
<coding>
<code value="C134029"/>
<display value="Release"/>
</coding>
</reason>
<action id="idxo0fqoujfsj5fdvnm2oi4i4eombqqnzojotxuvfiej3jvoiamfxk">
<title value="First Stage"/>
<goalId value="goal15"/>
</action>
<action id="idq4cg3ixjjsydnmi41el13z4kjnbcqyntkxdbpzmgbovs5jv2h4xg">
<title value="Second Stage"/>
<goalId value="goal16"/>
<goalId value="goal17"/>
<relatedAction>
<actionId value="8e992279-4189-4097-9d4b-f180c59dc934"/>
<relationship value="after"/>
</relatedAction>
</action>
<action id="id3pakysj14xs5o5ulwsxtw4lugdprcvkyduyff5dupjvc0yeoft5k">
<title value="Third Stage"/>
<goalId value="goal18"/>
<goalId value="goal19"/>
```

```
<goalId value="goal20"/>
<relatedAction>
<actionId value="246f1d7e-2eee-4b71-abee-431e7fc03ef2"/>
<relationship value="after"/>
</relatedAction>
</action>
</action>
</PlanDefinition>
```

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Value Set /ValueSet/DoseForm

Summary

Defining URL:	http://fda.gov/cder/fhir/pqcmc/ValueSet/DoseForm
Version:	current
Name:	cmcDose
Definition:	This is the physical form of the product as presented to the individual. For example: tablet, capsule, liquid or ointment. NCI concept code for pharmaceutical dosage form: C42636
Source Resource:	XML

This value set is not used

Content Logical Definition
cmcDose

This is the physical form of the product as presented to the individual. For example: tablet, capsule, liquid or ointment. NCI concept code for pharmaceutical dosage form: C42636

This value set includes codes from the following code systems:

- Include all codes defined in `http://fda.gov/cder/fhir/pqcmc/CodeSystem/DoseForm`

Expansion

This value set contains 156 concepts

> Expansion based on http://fda.gov/cder/fhir/pqcmc/CodeSystem/DoseForm version current

All codes from system `http://fda.gov/cder/fhir/pqcmc/CodeSystem/DoseForm`

Code	Display	Definition
C42887	AEROSOL	
C42888	AEROSOL, FOAM	
C42960	AEROSOL, METERED	
C42971	AEROSOL, POWDER	
C42889	AEROSOL, SPRAY	
C42892	BAR, CHEWABLE	
C42890	BEAD	

C25158	CAPSULE	
C42895	CAPSULE, COATED	
C42896	CAPSULE, COATED PELLETS	
C42917	CAPSULE, COATED, EXTENDED RELEASE	
C42902	CAPSULE, DELAYED RELEASE	
C42904	CAPSULE, DELAYED RELEASE PELLETS	
C42916	CAPSULE, EXTENDED RELEASE	
C42928	CAPSULE, FILM COATED, EXTENDED RELEASE	
C42936	CAPSULE, GELATIN COATED	
C42954	CAPSULE, LIQUID FILLED	
C100103	CELLULAR SHEET	
C134876	CHEWABLE GEL	
C60884	CLOTH	
C60891	CONCENTRATE	
C28944	CREAM	
C60897	CREAM, AUGMENTED	
C42901	CRYSTAL	
C43525	DISC	
C42679	DOUCHE	
C42763	DRESSING	
C42912	ELIXIR	
C42913	EMULSION	
C42915	ENEMA	
C42929	EXTRACT	
C60926	FIBER, EXTENDED RELEASE	
C42932	FILM	
C42920	FILM, EXTENDED RELEASE	
C42984	FILM, SOLUBLE	
C60927	FOR SOLUTION	
C60928	FOR SUSPENSION	
C60929	FOR SUSPENSION, EXTENDED RELEASE	
C42933	GAS	
C42934	GEL	
C42906	GEL, DENTIFRICE	
C60930	GEL, METERED	
C42937	GLOBULE	
C42938	GRANULE	
C42903	GRANULE, DELAYED RELEASE	
C42909	GRANULE, EFFERVESCENT	
C42939	GRANULE, FOR SOLUTION	
C42940	GRANULE, FOR SUSPENSION	
C42921	GRANULE, FOR SUSPENSION, EXTENDED RELEASE	

C42894	GUM, CHEWING	
C42942	IMPLANT	
C42944	INHALANT	
C113106	INJECTABLE FOAM	
C60931	INJECTABLE, LIPOSOMAL	
C42946	INJECTION	
C42914	INJECTION, EMULSION	
C42950	INJECTION, LIPID COMPLEX	
C42974	INJECTION, POWDER, FOR SOLUTION	
C42976	INJECTION, POWDER, FOR SUSPENSION	
C42977	INJECTION, POWDER, FOR SUSPENSION, EXTENDED RELEASE	
C42959	INJECTION, POWDER, LYOPHILIZED, FOR LIPOSOMAL SUSPENSION	
C42957	INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION	
C42958	INJECTION, POWDER, LYOPHILIZED, FOR SUSPENSION	
C42956	INJECTION, POWDER, LYOPHILIZED, FOR SUSPENSION, EXTENDED RELEASE	
C42945	INJECTION, SOLUTION	
C42899	INJECTION, SOLUTION, CONCENTRATE	
C42995	INJECTION, SUSPENSION	
C42926	INJECTION, SUSPENSION, EXTENDED RELEASE	
C42951	INJECTION, SUSPENSION, LIPOSOMAL	
C42988	INJECTION, SUSPENSION, SONICATED	
C60933	INSERT	
C42922	INSERT, EXTENDED RELEASE	
C47915	INTRAUTERINE DEVICE	
C42947	IRRIGANT	
C42948	JELLY	
C47916	KIT	
C42949	LINIMENT	
C42952	LIPSTICK	
C42953	LIQUID	
C60934	LIQUID, EXTENDED RELEASE	
C29167	LOTION	
C60957	LOTION, AUGMENTED	
C60958	LOTION/SHAMPOO	
C42955	LOZENGE	
C29269	MOUTHWASH	
C48624	NOT APPLICABLE	
C42965	OIL	
C42966	OINTMENT	
C60984	OINTMENT, AUGMENTED	
C42967	PASTE	
C42907	PASTE, DENTIFRICE	

C60985	PASTILLE	
C42968	PATCH	
C42923	PATCH, EXTENDED RELEASE	
C42911	PATCH, EXTENDED RELEASE, ELECTRICALLY CONTROLLED	
C42969	PELLET	
C42943	PELLET, IMPLANTABLE	
C42918	PELLETS, COATED, EXTENDED RELEASE	
C25394	PILL	
C42970	PLASTER	
C47913	POULTICE	
C42972	POWDER	
C42908	POWDER, DENTIFRICE	
C42973	POWDER, FOR SOLUTION	
C42975	POWDER, FOR SUSPENSION	
C42961	POWDER, METERED	
C60988	RING	
C42979	RINSE	
C42980	SALVE	
C42981	SHAMPOO	
C42982	SHAMPOO, SUSPENSION	
C42983	SOAP	
C42986	SOLUTION	
C42898	SOLUTION, CONCENTRATE	
C42987	SOLUTION, FOR SLUSH	
C60994	SOLUTION, GEL FORMING / DROPS	
C42935	SOLUTION, GEL FORMING, EXTENDED RELEASE	
C60992	SOLUTION/ DROPS	
C47912	SPONGE	
C42989	SPRAY	
C42962	SPRAY, METERED	
C42990	SPRAY, SUSPENSION	
C42991	STICK	
C47914	STRIP	
C42993	SUPPOSITORY	
C42924	SUPPOSITORY, EXTENDED RELEASE	
C42994	SUSPENSION	
C42925	SUSPENSION, EXTENDED RELEASE	
C60995	SUSPENSION/ DROPS	
C47898	SWAB	
C42996	SYRUP	
C42998	TABLET	
C42893	TABLET, CHEWABLE	

C124794	TABLET, CHEWABLE, EXTENDED RELEASE
C42897	TABLET, COATED
C60997	TABLET, COATED PARTICLES
C42905	TABLET, DELAYED RELEASE
C42997	TABLET, DELAYED RELEASE PARTICLES
C42910	TABLET, EFFERVESCENT
C42927	TABLET, EXTENDED RELEASE
C42931	TABLET, FILM COATED
C42930	TABLET, FILM COATED, EXTENDED RELEASE
C61004	TABLET, FOR SOLUTION
C61005	TABLET, FOR SUSPENSION
C42964	TABLET, MULTILAYER
C42963	TABLET, MULTILAYER, EXTENDED RELEASE
C42999	TABLET, ORALLY DISINTEGRATING
C61006	TABLET, ORALLY DISINTEGRATING, DELAYED RELEASE
C42985	TABLET, SOLUBLE
C42992	TABLET, SUGAR COATED
C147579	TABLET WITH SENSOR
C47892	TAMPON
C47897	TAPE
C43000	TINCTURE
C43001	TROCHE
C43003	WAFER

Explanation of the columns that may appear on this page:

Level	A few code lists that FHIR defines are hierarchical - each code is assigned a level. In this scheme, some codes are under other codes, and imply that the code they are under also applies
Source	The source of the definition of the code (when the value set draws in codes defined elsewhere)
Code	The code (used as the code in the resource instance)
Display	The display (used in the *display* element of a Coding). If there is no display, implementers should not simply display the code, but map the concept into their application
Definition	An explanation of the meaning of the concept
Comments	Additional notes about how to use the code

Table of Contents > Artifact index > Method Origin

Value Set /ValueSet/methodOrig

Summary

Defining URL:	http://fda.gov/cder/fhir/pqcmc/ValueSet/methodOrig
Version:	current
Name:	MethodOrigin
Definition:	Codes specifying the source of the method.
Source Resource:	XML

This value set is not used

Content Logical Definition
MethodOrigin

Codes specifying the source of the method.

This value set includes codes from the following code systems:

- Include all codes defined in `http://fda.gov/cder/fhir/pqcmc/CodeSystem/methodOrig`

Expansion

This value set contains 3 concepts

> Expansion based on http://fda.gov/cder/fhir/pqcmc/CodeSystem/methodOrig version current

All codes from system `http://fda.gov/cder/fhir/pqcmc/CodeSystem/methodOrig`

Code	Display	Definition
C96102	Compendial	Method defined in any recognized compendium (e.g., USP, PharmEU, JP, etc.).
C96103	Proprietary	Method defined by the sponsor (not recognized in CFR or any compendium)
C96164	CFR	Method defined in the Code of Federal Regulation (CFR)

Explanation of the columns that may appear on this page:

Level	A few code lists that FHIR defines are hierarchical - each code is assigned a level. In this scheme, some codes are under other codes, and imply that the code they are under also applies
Source	The source of the definition of the code (when the value set draws in codes defined elsewhere)
Code	The code (used as the code in the resource instance)
Display	The display (used in the *display* element of a Coding). If there is no display, implementers should not

	simply display the code, but map the concept into their application
Definition	An explanation of the meaning of the concept
Comments	Additional notes about how to use the code

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IG Home   Artifact Index   FHIR Spec

Table of Contents > **Artifact index** > **Specification Status**

Value Set /ValueSet/SpecStat

Summary

Defining URL:	http://fda.gov/cder/fhir/pqcmc/ValueSet/SpecStat
Version:	current
Name:	SpecStatus
Definition:	Code indicating the current FDA regulatory status of the specification
Source Resource:	XML

This value set is not used

Content Logical Definition
SpecStatus

Code indicating the current FDA regulatory status of the specification

This value set includes codes from the following code systems:

- Include all codes defined in `http://fda.gov/cder/fhir/pqcmc/CodeSystem/SpecStat`

Expansion

This value set contains 4 concepts

Expansion based on http://fda.gov/cder/fhir/pqcmc/CodeSystem/SpecStat version current

All codes from system `http://fda.gov/cder/fhir/pqcmc/CodeSystem/SpecStat`

Code	Display	Definition
C134010	Tentatively Approved	A specification that met the requirements for approval but the application could not be approved for reasons such as patents and exclusivity.
C134011	Not Approved	A specification that has not yet been approved.
C134012	Reported in a CBE or AR	The specification may be used without prior approval, and was submitted in a changes being effected (CBE) supplement or an annual report (AR).
C25425	Approved	A specification that has met the requirements for approval

Explanation of the columns that may appear on this page:

Level	A few code lists that FHIR defines are hierarchical - each code is assigned a level. In this scheme, some codes are under other codes, and imply that the code they are under also applies
Source	The source of the definition of the code (when the value set draws in codes defined elsewhere)

Code	The code (used as the code in the resource instance)
Display	The display (used in the *display* element of a Coding). If there is no display, implementers should not simply display the code, but map the concept into their application
Definition	An explanation of the meaning of the concept
Comments	Additional notes about how to use the code

Table of Contents > **Artifact index** > **Test Categories**

Value Set /ValueSet/testCat

Summary

Defining URL:	http://fda.gov/cder/fhir/pqcmc/ValueSet/testCat
Version:	current
Name:	TestCategory
Definition:	List of test categories allowable values for the Test Category data element
Source Resource:	XML

This value set is not used

Content Logical Definition
TestCategory

List of test categories allowable values for the Test Category data element

This value set includes codes from the following code systems:

- Include all codes defined in `http://fda.gov/cder/fhir/pqcmc/CodeSystem/testCat`

Expansion

This value set contains 7 concepts

> Expansion based on http://fda.gov/cder/fhir/pqcmc/CodeSystem/testCat version current

All codes from system `http://fda.gov/cder/fhir/pqcmc/CodeSystem/testCat`

Code	Display	Definition
C60819	Assay	Tests which measure the content of the active ingredient in the drug substance or drug product. Synonymous with strength or purity which is commonly used of define the content of the active ingredient in a drug product. [Source: Adapted from ICH Q6A and Q6B] Note: chiral purity, preservative content, Anti-Oxidant Concentration, Chelate Concentration, isomeric ratio.
C138990	Description	An assessment of the physical state (e.g., color, shape, size) of the drug substance or product. [Source: Adapted from ICH Q6A]
C138993	Identification	Tests that establishes the characteristic and uniqueness of the substance of interest and should be able to discriminate between compounds of closely related structures which are likely to be present. [Source: ICH Q6A]
C158424	Physical Properties	Assessments of the characteristics of a material that are not associated with a change in its composition and basic nature, including but not limited to its texture, smell, freezing point, boiling point, melting point, opacity, viscosity and density.

C158425	Biological Properties	Any effect a given material has on a living organism (e.g., microbial limits, endotoxin).
C17771	Chemical Properties	A characteristic of a material that is observed during a reaction in which the chemical composition or identity of the material is changed (e.g., combustibility, solubility, acidity/basicity).
C158423	Impurities	Analytical procedures that determine the presence of a component of the material that is not the chemical entity defined as the material.

Explanation of the columns that may appear on this page:

Level	A few code lists that FHIR defines are hierarchical - each code is assigned a level. In this scheme, some codes are under other codes, and imply that the code they are under also applies
Source	The source of the definition of the code (when the value set draws in codes defined elsewhere)
Code	The code (used as the code in the resource instance)
Display	The display (used in the *display* element of a Coding). If there is no display, implementers should not simply display the code, but map the concept into their application
Definition	An explanation of the meaning of the concept
Comments	Additional notes about how to use the code

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Table of Contents > **Artifact index** > **Test Usage**

Value Set /ValueSet/pqcmcUsage

Summary

Defining URL:	http://fda.gov/cder/fhir/pqcmc/ValueSet/pqcmcUsage
Version:	current
Name:	TestUsage
Definition:	List of codes specifying the time point during the manufacturing process of a substance or product when a particular analytical procedure or measurement is being performed
Source Resource:	XML

This value set is not used

Content Logical Definition
TestUsage

List of codes specifying the time point during the manufacturing process of a substance or product when a particular analytical procedure or measurement is being performed

This value set includes codes from the following code systems:

- Include all codes defined in `http://fda.gov/cder/fhir/pqcmc/CodeSystem/pqcmcUsage`

Expansion

This value set contains 3 concepts

Expansion based on http://fda.gov/cder/fhir/pqcmc/CodeSystem/pqcmcUsage version current

All codes from system `http://fda.gov/cder/fhir/pqcmc/CodeSystem/pqcmcUsage`

Code	Display	Definition
C134029	Release	For determination of acceptability for use of a material, drug or a drug substance. NOTE: The "use" could be for distribution, marketing, further manufacturing stages, etc.
C134030	Stability	For determination of maintained performance parameters on storage over time, of a material, drug or a drug substance.
C134031	Release and Stability	For determination at release and on stability when test and acceptance criteria are the same in both cases.

Explanation of the columns that may appear on this page:

Level	A few code lists that FHIR defines are hierarchical - each code is assigned a level. In this scheme, some codes are under other codes, and imply that the code they are under also applies
Source	The source of the definition of the code (when the value set draws in codes defined elsewhere)
Code	The code (used as the code in the resource instance)
Display	The display (used in the *display* element of a Coding). If there is no display, implementers should not simply display the code, but map the concept into their application
Definition	An explanation of the meaning of the concept
Comments	Additional notes about how to use the code

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Table of Contents > Artifact index > **Approval Status**

Content | Detailed Descriptions | Mappings | XML

Extension: approvalStatus

The official URL for this extension is:

```
http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-approvalStatus
```

Status: **draft**
Extension maintained by: U.S. FDA - CDER division

Context of Use

This extension may be used on the following element(s):

- {"type"=>"PlanDefinition"}

Usage info

Yet to be done: xref

Formal Views of Extension Content

Description of Profiles, Differentials, Snapshots, and how the XML and JSON presentations work.

- Text Summary
- Differential Table
- Snapshot Table
- All

This structure is derived from Extension

Summary

Mandatory: 2 elements
Fixed Value: 3 elements
Prohibited: 1 element

This structure is derived from Extension

Name	Flags	Card.	Type	Description & Constraints	?
Extension		0..1		Approval Status	
extension	⭐	1..1	Extension	Type of approval	
url		1..1		"type"	
valueCode		0..1	code		
extension		1..1	Extension	Date of approval	

⭐				
📁 url	1..1			"date"
▭ valueDate	0..1	date		
📁 url	1..1	uri		"http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-approvalStatus"
📁 ~~value[x]~~	~~0..0~~			

❓ Documentation for this format

Name	Flags	Card.	Type	Description & Constraints	❓
📁 Extension	I	0..1		Approval Status	
▭ id		0..1	string	Unique id for inter-element referencing	
⭐ extension		0..*	Extension	Additional content defined by implementations **Slice:** Unordered, Open by value:url	
⭐ extension		1..1	Extension	Type of approval	
▭ id		0..1	string	Unique id for inter-element referencing	
⭐ extension		0..*	Extension	Additional content defined by implementations **Slice:** Unordered, Open by value:url	
📁 url		1..1		"type"	
▭ valueCode		0..1	code	Value of extension	
⭐ extension		1..1	Extension	Date of approval	
▭ id		0..1	string	Unique id for inter-element referencing	
⭐ extension		0..*	Extension	Additional content defined by implementations **Slice:** Unordered, Open by value:url	
📁 url		1..1		"date"	
▭ valueDate		0..1	date	Value of extension	
▭ url		1..1	uri	"http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-approvalStatus"	

❓ Documentation for this format

This structure is derived from Extension

Summary

Mandatory: 2 elements
Fixed Value: 3 elements
Prohibited: 1 element

Differential View

This structure is derived from Extension

Name	Flags	Card.	Type	Description & Constraints	❓
📁 Extension		0..1		Approval Status	
⭐ extension		1..1	Extension	Type of approval	
📁 url		1..1		"type"	
▭ valueCode		0..1	code		
⭐ extension		1..1	Extension	Date of approval	
📁 url		1..1		"date"	
▭ valueDate		0..1	date		
▭ url		1..1	uri	"http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-approvalStatus"	
📁 ~~value[x]~~		~~0..0~~			

? Documentation for this format

Snapshot View

Name	Flags	Card.	Type	Description & Constraints	?
📁 Extension	I	0..1		Approval Status	
📇 id		0..1	string	Unique id for inter-element referencing	
⭐ extension		0..*	Extension	Additional content defined by implementations **Slice:** Unordered, Open by value:url	
⭐ extension		1..1	Extension	Type of approval	
📇 id		0..1	string	Unique id for inter-element referencing	
⭐ extension		0..*	Extension	Additional content defined by implementations **Slice:** Unordered, Open by value:url	
🔒 url		1..1		"type"	
📇 valueCode		0..1	code	Value of extension	
⭐ extension		1..1	Extension	Date of approval	
📇 id		0..1	string	Unique id for inter-element referencing	
⭐ extension		0..*	Extension	Additional content defined by implementations **Slice:** Unordered, Open by value:url	
🔒 url		1..1		"date"	
📇 valueDate		0..1	date	Value of extension	
📇 url		1..1	uri	"http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-approvalStatus"	

? Documentation for this format

Other representations of extension: Schematron

Terminology Bindings
Constraints

Id	Path	Details	Requirements
ele-1	Extension	All FHIR elements must have a @value or children : hasValue() or (children().count() > id.count())	
ext-1	Extension	Must have either extensions or value[x], not both : extension.exists() != value.exists()	

Links: Table of Contents | QA Report | Version History | (○) PUBLIC DOMAIN | Propose a change FDA

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Table of Contents > **Artifact index** > **Comment**

Content   Detailed Descriptions   Mappings   XML

Extension: Additional comment

The official URL for this extension is:

http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-comment

Status: **draft**
Extension maintained by: U.S. FDA - CDER division

Context of Use

This extension may be used on the following element(s):

- {"type"=>"Element"}

Usage info

Yet to be done: xref

Formal Views of Extension Content

Description of Profiles, Differentials, Snapshots, and how the XML and JSON presentations work.

- Text Summary
- Differential Table
- Snapshot Table
- All

This structure is derived from Extension

Summary

Fixed Value: 1 element

This structure is derived from Extension

Name	Flags	Card.	Type	Description & Constraints	?
📁 Extension		1..*		Additional comment	
⌐ url		1..1	uri	"http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-comment"	
⌐ valueString		0..1	string		

? Documentation for this format

Name	Flags	Card.	Type	Description & Constraints	?

📁 Extension	I	1..*			Additional comment
⬜ id		0..1	string		Unique id for inter-element referencing
⭐ extension		0..*	Extension		Additional content defined by implementations **Slice:** Unordered, Open by value:url
⬜ url		1..1	uri		"http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-comment"
⬜ valueString		0..1	string		Value of extension

❓ Documentation for this format

This structure is derived from Extension

Summary

Fixed Value: 1 element

Differential View

This structure is derived from Extension

Name	Flags	Card.	Type	Description & Constraints ❓
📁 Extension		1..*		Additional comment
⬜ url		1..1	uri	"http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-comment"
⬜ valueString		0..1	string	

❓ Documentation for this format

Snapshot View

Name	Flags	Card.	Type	Description & Constraints ❓
📁 Extension	I	1..*		Additional comment
⬜ id		0..1	string	Unique id for inter-element referencing
⭐ extension		0..*	Extension	Additional content defined by implementations **Slice:** Unordered, Open by value:url
⬜ url		1..1	uri	"http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-comment"
⬜ valueString		0..1	string	Value of extension

❓ Documentation for this format

Other representations of extension: Schematron

Terminology Bindings

Constraints

Id	Path	Details	Requirements
ele-1	Extension	All FHIR elements must have a @value or children : hasValue() or (children().count() > id.count())	
ext-1	Extension	Must have either extensions or value[x], not both : extension.exists() != value.exists()	

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Content   Detailed Descriptions   Mappings   XML

Extension: Method origin

The official URL for this extension is:

```
http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-methodOrigin
```

Status: **draft**
Extension maintained by: U.S. FDA - CDER division

Context of Use

This extension may be used on the following element(s):

- {"type"=>"PlanDefinition.action"}

Usage info

Yet to be done: xref

Formal Views of Extension Content

Description of Profiles, Differentials, Snapshots, and how the XML and JSON presentations work.

- Text Summary
- Differential Table
- Snapshot Table
- All

This structure is derived from Extension

Summary

Fixed Value: 1 element

This structure is derived from Extension

Name	Flags	Card.	Type	Description & Constraints	?
📁 Extension		0..1		Method origin	
└─ 📄 url		1..1	uri	"http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-methodOrigin"	
└─ 📄 valueCode		0..1	code		

❓ Documentation for this format

Name	Flags	Card.	Type	Description & Constraints	?

📁 Extension	I	0..1		Method origin
id		0..1	string	Unique id for inter-element referencing
⭐ extension		0..*	Extension	Additional content defined by implementations
				Slice: Unordered, Open by value:url
url		1..1	uri	"http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-methodOrigin"
valueCode		0..1	code	Value of extension

❓ Documentation for this format

This structure is derived from Extension

Summary

Fixed Value: 1 element

Differential View

This structure is derived from Extension

Name	Flags	Card.	Type	Description & Constraints ❓
📁 Extension		0..1		Method origin
url		1..1	uri	"http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-methodOrigin"
valueCode		0..1	code	

❓ Documentation for this format

Snapshot View

Name	Flags	Card.	Type	Description & Constraints ❓
📁 Extension	I	0..1		Method origin
id		0..1	string	Unique id for inter-element referencing
⭐ extension		0..*	Extension	Additional content defined by implementations
				Slice: Unordered, Open by value:url
url		1..1	uri	"http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-methodOrigin"
valueCode		0..1	code	Value of extension

❓ Documentation for this format

Other representations of extension: Schematron

Terminology Bindings
Constraints

Id	Path	Details	Requirements
ele-1	Extension	All FHIR elements must have a @value or children : hasValue() or (children().count() > id.count())	
ext-1	Extension	Must have either extensions or value[x], not both : extension.exists() != value.exists()	

Content | Detailed Descriptions | Mappings | XML

Extension: Analytic Procedure URL

The official URL for this extension is:

> http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-definitionUri

Status: **draft**
Extension maintained by: U.S. FDA - CDER division

Context of Use

This extension may be used on the following element(s):

- {"type"=>"PlanDefinition.action"}

Usage info

Yet to be done: xref

Formal Views of Extension Content

Description of Profiles, Differentials, Snapshots, and how the XML and JSON presentations work.

- Text Summary
- Differential Table
- Snapshot Table
- All

This structure is derived from Extension

Summary

Fixed Value: 1 element

This structure is derived from Extension

Name	Flags	Card.	Type	Description & Constraints	?
📁 Extension		0..1		Analytic Procedure URL	
📄 url		1..1	uri	"http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-definitionUri"	
📄 valueString		0..1	string		

? Documentation for this format

Name	Flags	Card.	Type	Description & Constraints	?

📁 Extension	I	0..1		Analytic Procedure URL
id		0..1	string	Unique id for inter-element referencing
⭐ extension		0..*	Extension	Additional content defined by implementations **Slice:** Unordered, Open by value:url
url		1..1	uri	"http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-definitionUri"
valueString		0..1	string	Value of extension

❓ Documentation for this format

This structure is derived from Extension

Summary

Fixed Value: 1 element

Differential View

This structure is derived from Extension

Name	Flags	Card.	Type	Description & Constraints ❓
📁 Extension		0..1		Analytic Procedure URL
url		1..1	uri	"http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-definitionUri"
valueString		0..1	string	

❓ Documentation for this format

Snapshot View

Name	Flags	Card.	Type	Description & Constraints ❓
📁 Extension	I	0..1		Analytic Procedure URL
id		0..1	string	Unique id for inter-element referencing
⭐ extension		0..*	Extension	Additional content defined by implementations **Slice:** Unordered, Open by value:url
url		1..1	uri	"http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-definitionUri"
valueString		0..1	string	Value of extension

❓ Documentation for this format

Other representations of extension: Schematron

Terminology Bindings

Constraints

Id	Path	Details	Requirements
ele-1	Extension	All FHIR elements must have a @value or children : hasValue() or (children().count() > id.count())	
ext-1	Extension	Must have either extensions or value[x], not both : extension.exists() != value.exists()	

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Table of Contents > **Artifact index** > **Focus**

Content	Detailed Descriptions	Mappings	XML

Extension: Activity focus

The official URL for this extension is:

```
http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-focus
```

Status: **draft**
Extension maintained by: U.S. FDA - CDER division

Context of Use

This extension may be used on the following element(s):

- {"type"=>"PlanDefinition.action"}

Usage info

Yet to be done: xref

Formal Views of Extension Content

Description of Profiles, Differentials, Snapshots, and how the XML and JSON presentations work.

- Text Summary
- Differential Table
- Snapshot Table
- All

This structure is derived from Extension

Summary

Fixed Value: 1 element

This structure is derived from Extension

Name	Flags	Card.	Type	Description & Constraints	❓
📁 Extension		0..1		Activity focus	
└ 📁 url		1..1	uri	"http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-focus"	
└ ⬡ valueCodeableConcept		0..1	CodeableConcept		

❓ Documentation for this format

Name	Flags	Card.	Type	Description & Constraints	❓

📁 Extension		I	0..1		Activity focus
id			0..1	string	Unique id for inter-element referencing
⭐ extension			0..*	Extension	Additional content defined by implementations **Slice:** Unordered, Open by value:url
url			1..1	uri	"http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-focus"
valueCodeableConcept			0..1	CodeableConcept	Value of extension

❓ Documentation for this format

This structure is derived from Extension

Summary

Fixed Value: 1 element

Differential View

This structure is derived from Extension

Name	Flags	Card.	Type	Description & Constraints ❓
📁 Extension		0..1		Activity focus
url		1..1	uri	"http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-focus"
valueCodeableConcept		0..1	CodeableConcept	

❓ Documentation for this format

Snapshot View

Name	Flags	Card.	Type	Description & Constraints ❓
📁 Extension	I	0..1		Activity focus
id		0..1	string	Unique id for inter-element referencing
⭐ extension		0..*	Extension	Additional content defined by implementations **Slice:** Unordered, Open by value:url
url		1..1	uri	"http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-focus"
valueCodeableConcept		0..1	CodeableConcept	Value of extension

❓ Documentation for this format

Other representations of extension: Schematron

Terminology Bindings

Constraints

Id	Path	Details	Requirements
ele-1	Extension	All FHIR elements must have a @value or children : hasValue() or (children().count() > id.count())	
ext-1	Extension	Must have either extensions or value[x], not both : extension.exists() != value.exists()	

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Table of Contents > Artifact index > **Name Type**

| Content | Detailed Descriptions | Mappings | XML |

Extension: nameType

The official URL for this extension is:

```
http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-nameType
```

Status: **draft**
Extension maintained by: U.S. FDA - CDER division

Context of Use

This extension may be used on the following element(s):

- {"type"=>"MedicationKnowledge.synonym"}

Usage info

Yet to be done: xref

Formal Views of Extension Content

Description of Profiles, Differentials, Snapshots, and how the XML and JSON presentations work.

- Text Summary
- Differential Table
- Snapshot Table
- All

This structure is derived from Extension

Summary

Fixed Value: 1 element

This structure is derived from Extension

Name	Flags	Card.	Type	Description & Constraints	?
📁 Extension		0..1		Type of synonym	
└ 📁 url		1..1	uri	"http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-nameType"	

? Documentation for this format

Name	Flags	Card.	Type	Description & Constraints	?
📁 Extension	I	0..1		Type of synonym	

id	0..1	string	Unique id for inter-element referencing	
extension	0..*	Extension	Additional content defined by implementations **Slice:** Unordered, Open by value:url	
url	1..1	uri	"http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-nameType"	
value[x]	0..1	base64Binary, boolean, canonical(), code, date, dateTime, decimal, id, instant, integer, markdown, oid, positiveInt, string, time, unsignedInt, uri, url, uuid, Address, Age, Annotation, Attachment, CodeableConcept, Coding, ContactPoint, Count, Distance, Duration, HumanName, Identifier, Money, Period, Quantity, Range, Ratio, Reference(), SampledData, Signature, Timing, ContactDetail, Contributor, DataRequirement, Expression, ParameterDefinition, RelatedArtifact, TriggerDefinition, UsageContext, Dosage	Value of extension	

Documentation for this format

This structure is derived from Extension

Summary

Fixed Value: 1 element

Differential View

This structure is derived from Extension

Name	Flags	Card.	Type	Description & Constraints	
Extension		0..1		Type of synonym	
url		1..1	uri	"http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-nameType"	

Documentation for this format

Snapshot View

Name	Flags	Card.	Type	Description & Constraints	
Extension	I	0..1		Type of synonym	
id		0..1	string	Unique id for inter-element referencing	
extension		0..*	Extension	Additional content defined by implementations	

url		1..1	uri		**Slice:** Unordered, Open by value:url "http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-nameType"
value[x]		0..1	base64Binary, boolean, canonical(), code, date, dateTime, decimal, id, instant, integer, markdown, oid, positiveInt, string, time, unsignedInt, uri, url, uuid, Address, Age, Annotation, Attachment, CodeableConcept, Coding, ContactPoint, Count, Distance, Duration, HumanName, Identifier, Money, Period, Quantity, Range, Ratio, Reference(), SampledData, Signature, Timing, ContactDetail, Contributor, DataRequirement, Expression, ParameterDefinition, RelatedArtifact, TriggerDefinition, UsageContext, Dosage		Value of extension

Documentation for this format

Other representations of extension: Schematron

Terminology Bindings
Constraints

Id	Path	Details	Requirements
ele-1	Extension	All FHIR elements must have a @value or children : hasValue() or (children().count() > id.count())	
ext-1	Extension	Must have either extensions or value[x], not both : extension.exists() != value.exists()	

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Content   Detailed Descriptions   Mappings   XML

Extension: RangeLowExclusive

The official URL for this extension is:

```
http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-range-lowExclusive
```

Status: **draft**
Extension maintained by:

A lower-bound for the range that excludes the specified value(rather than the default assumption of inclusive of Range.low)

Context of Use

This extension may be used on the following element(s):

- {"type"=>"Range"}

Usage info

Yet to be done: xref

Formal Views of Extension Content

Description of Profiles, Differentials, Snapshots, and how the XML and JSON presentations work.

- Text Summary
- Differential Table
- Snapshot Table
- All

This structure is derived from Extension

Summary

Mandatory: 1 element
Fixed Value: 1 element
Prohibited: 1 element

Structures

This structure refers to these other structures:

- http://hl7.org/fhir/StructureDefinition/SimpleQuantity

This structure is derived from Extension

Name	Flags	Card.	Type	Description & Constraints	?
📁 Extension		0..*		Range exclusive lower-bound	
⭐ ~~extension~~		~~0..0~~			
📁 url		1..1		"http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-range-lowExclusive"	
🔷 valueQuantity		0..1	SimpleQuantity	Value of lower exclusive boundary	

❓ Documentation for this format

Name	Flags	Card.	Type	Description & Constraints	?
📁 Extension	I	0..*		Range exclusive lower-bound	
🔲 id		0..1	string	Unique id for inter-element referencing	
⭐ extension		0..0			
🔒 url		1..1		"http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-range-lowExclusive"	
🔷 valueQuantity	I	0..1	SimpleQuantity	Value of lower exclusive boundary	

❓ Documentation for this format

This structure is derived from Extension

Summary

Mandatory: 1 element
Fixed Value: 1 element
Prohibited: 1 element

Structures

This structure refers to these other structures:

- http://hl7.org/fhir/StructureDefinition/SimpleQuantity

Differential View

This structure is derived from Extension

Name	Flags	Card.	Type	Description & Constraints	?
📁 Extension		0..*		Range exclusive lower-bound	
⭐ ~~extension~~		~~0..0~~			
📁 url		1..1		"http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-range-lowExclusive"	
🔷 valueQuantity		0..1	SimpleQuantity	Value of lower exclusive boundary	

❓ Documentation for this format

Snapshot View

Name	Flags	Card.	Type	Description & Constraints	?
📁 Extension	I	0..*		Range exclusive lower-bound	
🔲 id		0..1	string	Unique id for inter-element referencing	
⭐ extension		0..0			
🔒 url		1..1		"http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-range-lowExclusive"	
🔷 valueQuantity	I	0..1	SimpleQuantity	Value of lower exclusive boundary	

❓ Documentation for this format

Other representations of extension: Schematron

Terminology Bindings
Constraints

Id	Path	Details	Requirements
ele-1	Extension	All FHIR elements must have a @value or children : hasValue() or (children().count() > id.count())	
ext-1	Extension	Must have either extensions or value[x], not both : extension.exists() != value.exists()	
ele-1	Extension.valueQuantity	All FHIR elements must have a @value or children : hasValue() or (children().count() > id.count())	
qty-3	Extension.valueQuantity	If a code for the unit is present, the system SHALL also be present : code.empty() or system.exists()	
sqty-1	Extension.valueQuantity	The comparator is not used on a SimpleQuantity : comparator.empty()	

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Table of Contents > Artifact index > **Range upper bound exclusive**

Content | Detailed Descriptions | Mappings | XML

Extension: RangeHighExclusive

The official URL for this extension is:

```
http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-range-highExclusive
```

Status: **draft**
Extension maintained by:

An upper-bound for the range that excludes the specified value(rather than the default assumption of inclusive of Range.high)

Context of Use

This extension may be used on the following element(s):

- {"type"=>"Range"}

Usage info

Yet to be done: xref

Formal Views of Extension Content

Description of Profiles, Differentials, Snapshots, and how the XML and JSON presentations work.

- Text Summary
- Differential Table
- Snapshot Table
- All

This structure is derived from Extension

Summary

Mandatory: 1 element
Fixed Value: 1 element
Prohibited: 1 element

Structures

This structure refers to these other structures:

- http://hl7.org/fhir/StructureDefinition/SimpleQuantity

This structure is derived from Extension

Name	Flags	Card.	Type	Description & Constraints	?
📁 Extension		0..*		Range exclusive upper-bound	
⭐ extension		0..0			
📁 url		1..1		"http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-range-highExclusive"	
🔶 valueQuantity		0..1	SimpleQuantity	Value of upper exclusive boundary	

❓ Documentation for this format

Name	Flags	Card.	Type	Description & Constraints	?
📁 Extension	I	0..*		Range exclusive upper-bound	
▭ id		0..1	string	Unique id for inter-element referencing	
⭐ extension		0..0			
📁 url		1..1		"http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-range-highExclusive"	
🔶 valueQuantity	I	0..1	SimpleQuantity	Value of upper exclusive boundary	

❓ Documentation for this format

This structure is derived from Extension

Summary

Mandatory: 1 element
Fixed Value: 1 element
Prohibited: 1 element

Structures

This structure refers to these other structures:

- http://hl7.org/fhir/StructureDefinition/SimpleQuantity

Differential View

This structure is derived from Extension

Name	Flags	Card.	Type	Description & Constraints	?
📁 Extension		0..*		Range exclusive upper-bound	
⭐ extension		0..0			
📁 url		1..1		"http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-range-highExclusive"	
🔶 valueQuantity		0..1	SimpleQuantity	Value of upper exclusive boundary	

❓ Documentation for this format

Snapshot View

Name	Flags	Card.	Type	Description & Constraints	?
📁 Extension	I	0..*		Range exclusive upper-bound	
▭ id		0..1	string	Unique id for inter-element referencing	
⭐ extension		0..0			
📁 url		1..1		"http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-range-highExclusive"	
🔶 valueQuantity	I	0..1	SimpleQuantity	Value of upper exclusive boundary	

❓ Documentation for this format

Other representations of extension: Schematron

Terminology Bindings
Constraints

Id	Path	Details	Requirements
ele-1	Extension	All FHIR elements must have a @value or children : hasValue() or (children().count() > id.count())	
ext-1	Extension	Must have either extensions or value[x], not both : extension.exists() != value.exists()	
ele-1	Extension.valueQuantity	All FHIR elements must have a @value or children : hasValue() or (children().count() > id.count())	
qty-3	Extension.valueQuantity	If a code for the unit is present, the system SHALL also be present : code.empty() or system.exists()	
sqty-1	Extension.valueQuantity	The comparator is not used on a SimpleQuantity : comparator.empty()	

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Table of Contents > **Artifact index** > **Content Percent**

Content   Detailed Descriptions   Mappings   XML

Extension: contentPercent

The official URL for this extension is:

```
http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-contentPercent
```

Status: **draft**
Extension maintained by: U.S. FDA - CDER division

Context of Use

This extension may be used on the following element(s):

- {"type"=>"MedicationKnowledge.ingredient"}

Usage info

Yet to be done: xref

Formal Views of Extension Content

Description of Profiles, Differentials, Snapshots, and how the XML and JSON presentations work.

- Text Summary
- Differential Table
- Snapshot Table
- All

This structure is derived from Extension

Summary

Fixed Value: 1 element

This structure is derived from Extension

Name	Flags	Card.	Type	Description & Constraints	?
📁 Extension		0..1		Ingredient percentage by mass (0-100)	
┄📁 url		1..1	uri	"http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-contentPercent"	
┄📁 valueDecimal		0..1	decimal		

❓ Documentation for this format

Name	Flags	Card.	Type	Description & Constraints	?

📁 Extension	I	0..1		Ingredient percentage by mass (0-100)
id		0..1	string	Unique id for inter-element referencing
⭐ extension		0..*	Extension	Additional content defined by implementations **Slice:** Unordered, Open by value:url
url		1..1	uri	"http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-contentPercent"
valueDecimal		0..1	decimal	Value of extension

❓ Documentation for this format

This structure is derived from Extension

Summary

Fixed Value: 1 element

Differential View

This structure is derived from Extension

Name	Flags	Card.	Type	Description & Constraints	❓
📁 Extension		0..1		Ingredient percentage by mass (0-100)	
url		1..1	uri	"http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-contentPercent"	
valueDecimal		0..1	decimal		

❓ Documentation for this format

Snapshot View

Name	Flags	Card.	Type	Description & Constraints	❓
📁 Extension	I	0..1		Ingredient percentage by mass (0-100)	
id		0..1	string	Unique id for inter-element referencing	
⭐ extension		0..*	Extension	Additional content defined by implementations **Slice:** Unordered, Open by value:url	
url		1..1	uri	"http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-contentPercent"	
valueDecimal		0..1	decimal	Value of extension	

❓ Documentation for this format

Other representations of extension: Schematron

Terminology Bindings
Constraints

Id	Path	Details	Requirements
ele-1	Extension	All FHIR elements must have a @value or children : hasValue() or (children().count() > id.count())	
ext-1	Extension	Must have either extensions or value[x], not both : extension.exists() != value.exists()	

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Table of Contents > **Artifact index** > **Product Type**

| Content | Detailed Descriptions | Mappings | XML |

Extension: productType

The official URL for this extension is:

```
http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-productType
```

Status: **draft**
Extension maintained by: U.S. FDA - CDER division

Context of Use

This extension may be used on the following element(s):

- {"type"=>"MedicationKnowledge"}

Usage info

Yet to be done: xref

Formal Views of Extension Content

Description of Profiles, Differentials, Snapshots, and how the XML and JSON presentations work.

- Text Summary
- Differential Table
- Snapshot Table
- All

This structure is derived from Extension

Summary

Fixed Value: 1 element

This structure is derived from Extension

Name	Flags	Card.	Type	Description & Constraints	?
📁 Extension		0..1		product | substance	
📁 url		1..1	uri	"http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-productType"	
📁 valueCode		0..1	code		

❓ Documentation for this format

Name	Flags	Card.	Type	Description & Constraints	?

📁 Extension	I	0..1		product | substance
└─ id		0..1	string	Unique id for inter-element referencing
└─ ⭐ extension		0..*	Extension	Additional content defined by implementations **Slice:** Unordered, Open by value:url
└─ url		1..1	uri	"http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-productType"
└─ valueCode		0..1	code	Value of extension

❓ Documentation for this format

This structure is derived from Extension

Summary

Fixed Value: 1 element

Differential View

This structure is derived from Extension

Name	Flags	Card.	Type	Description & Constraints ❓
📁 Extension		0..1		product | substance
└─ url		1..1	uri	"http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-productType"
└─ valueCode		0..1	code	

❓ Documentation for this format

Snapshot View

Name	Flags	Card.	Type	Description & Constraints ❓
📁 Extension	I	0..1		product | substance
└─ id		0..1	string	Unique id for inter-element referencing
└─ ⭐ extension		0..*	Extension	Additional content defined by implementations **Slice:** Unordered, Open by value:url
└─ url		1..1	uri	"http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-productType"
└─ valueCode		0..1	code	Value of extension

❓ Documentation for this format

Other representations of extension: Schematron

Terminology Bindings
Constraints

Id	Path	Details	Requirements
ele-1	Extension	All FHIR elements must have a @value or children : hasValue() or (children().count() > id.count())	
ext-1	Extension	Must have either extensions or value[x], not both : extension.exists() != value.exists()	

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Table of Contents > Artifact index > PQCMC Quality Specification

Content   Detailed Descriptions

StructureDefinition: Quality Specification

The official URL for this profile is:

```
http://fda.gov/cder/fhir/pqcmc/StructureDefinition/qualityspecification
```

Formal Views of Profile Content

Description of Profiles, Differentials, Snapshots and how the different presentations work.

This structure is derived from PlanDefinition

Name	Flags	Card.	Type	Description & Constraints
PlanDefinition		0..*		Quality Specification
ext-approvalStatus	S	0..1	(Complex)	Approval Status **URL:** http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-approvalStatus **Binding:** SpecStatus (required)
extension	S	1..1	Extension	Specification Type
extension	S	1..1	Extension	Approval Status Date
version	S	1..1	string	Quality Specification Version
title	S	1..1	string	Quality Specification Title
status	S	1..1	code	**Fixed Value:** active
subjectReference	S	1..1	Reference(MedicationKnowledge | Substance)	Tested Product or Substance
date	S	1..1	dateTime	Version Date
usage	S	0..1	string	Additional Information
goal	S	1..*	BackboneElement	Acceptance criteria
ext-comment	S	0..1	string	Additional Information **URL:** http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-comment
description	S	1..1	CodeableConcept	
text	S	1..1	string	Literal text
target	S	1..1	BackboneElement	
data-absent-reason	S	0..1	code	unknown | asked | temp | notasked | masked | unsupported | astext | error **URL:** http://hl7.org/fhir/StructureDefinition/data-absent-reason **Binding:** DataAbsentReason (required)
valueCode	S	1..1	code	**Fixed Value:** not-applicable
detail[x]	S		*Quantity, Range, CodeableConcept*	***Slice:*** *Unordered, Open by value:@Type*
detailQuantity	S	0..1	Quantity	
value	S	1..1	decimal	
system	S	1..1	uri	**Fixed Value:** http://unitsofmeasure.org

Element		Card.	Type	Notes
code	S	1..1	code	
detailRange		0..1	Range	
ext-range-lowExclusive	S	0..1	SimpleQuantity	interpretationCode= GT **URL:** http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-range-lowExclusive
valueQuantity		0..1	Quantity	
value	S	1..1	decimal	valueNumeric
system	S	1..1	uri	Unit **Fixed Value:** http://unitsofmeasure.org
ext-range-highExclusive	S	0..1	SimpleQuantity	interpretationCode= LT **URL:** http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-range-highExclusive
valueQuantity		0..1	Quantity	
value	S	1..1	decimal	valueNumeric
system	S	1..1	uri	Unit **Fixed Value:** http://unitsofmeasure.org
low	S	0..1	SimpleQuantity	interpretationCode=NLT
value	S	1..1	decimal	valueNumeric
system	S	1..1	uri	**Fixed Value:** http://unitsofmeasure.org
code	S	1..1	code	Unit
high	S	0..1	SimpleQuantity	interpretationCode=NMT
value	S	1..1	decimal	valueNumeric
system	S	1..1	uri	**Fixed Value:** http://unitsofmeasure.org
code	S	1..1	code	Unit
detailCodeableConcept	S	0..1	CodeableConcept	
text	S	1..1	string	value
action	S	1..*	BackboneElement	Test
ext-methodOrigin	S	0..1	code	Test method origin **URL:** http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-methodOrigin
ext-definitionUri	S	0..1	string	Reference to procedure (url) **URL:** http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-definitionUri
ext-focus	S	0..1	CodeableConcept	Relative retention time **URL:** http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-focus
title	S	1..1	string	Test Name
code	S	1..1	CodeableConcept	QualitySpecification Test category
coding	S	1..1	Coding	Test category
text	S	1..1	string	Analytical Procedure
reason	S	1..1	CodeableConcept	Usage
definitionUri	S	0..1	canonical(ActivityDefinition | PlanDefinition | Questionnaire), uri	referenceToProcedure (FHIR)
action	S	1..*	BackboneElement	Stage
title	S	1..1	string	Stage name
goalId	S	1..*	id	Acceptance criteria
relatedAction	S	0..1	BackboneElement	Indicates relative sequence
actionId	S	1..1	id	GUID identifer for related stage
relationship	S	1..1	code	Sequence reference

❓ Documentation for this format

Other representations of profile: Schematron

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Based on FHIR version (4.0.0). IG generated on Thu, Apr 18, 2019 17:50-0400.
Links: Table of Contents | QA Report | Version History | (●) PUBLICDOMAIN | Propose a change FDA

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Table of Contents > **Artifact index** > **PQCMC Drug Product**

Content | Detailed Descriptions

StructureDefinition: PQCMC_MedicationKnowledge

The official URL for this profile is:

```
http://fda.gov/cder/fhir/pqcmc/StructureDefinition/drugproduct
```

Formal Views of Profile Content

Description of Profiles, Differentials, Snapshots and how the different presentations work.

This structure is derived from MedicationKnowledge

Name	Flags	Card.	Type	Description & Constraints
MedicationKnowledge		0..*		
ext-productType	S	1..1	code	Specification Type **URL:** http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-productType
valueCode	S	1..1	code	Drug Product **Fixed Value:** product
code	S	1..1	CodeableConcept	
text	S	1..1	string	Non-proprietary Name
doseForm	S	1..1	CodeableConcept	Dosage Form
synonym	S		string	*Slice: Unordered, Open by value:extension('http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-nameType').valueCode*
ext-nameType	S	1..1	base64Binary, boolean, canonical(), code, date, dateTime, decimal, id, instant, integer, markdown, oid, positiveInt, string, time, unsignedInt, uri, url, uuid, Address, Age, Annotation, Attachment, CodeableConcept, Coding, ContactPoint, Count, Distance, Duration, HumanName, Identifier, Money, Period, Quantity, Range, Ratio, Reference(), SampledData, Signature, Timing, ContactDetail, Contributor, DataRequirement,	Proprietary Name **URL:** http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-nameType

			Expression, ParameterDefinition, RelatedArtifact, TriggerDefinition, UsageContext, Dosage	
valueCode	S	1..1	code	**Fixed Value:** proprietary
ingredient	S	1..*	BackboneElement	Product Component Name
ext-contentPercent	S	0..1	decimal	Content percent **URL:** http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-contentPercent
itemReference	S	1..1	CodeableConcept, Reference(Substance)	
strength	S	1..*	Ratio	Strength
numerator	S	0..1	Quantity	Strength Unit
value	S	1..1	decimal	
system	S	1..1	uri	**Fixed Value:** http://unitsofmeasure.org
code	S	1..1	code	Strength Unit of Measure
denominator	S	0..1	Quantity	
value		0..1	decimal	**Fixed Value:** 1

 Documentation for this format

Other representations of profile: Schematron

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StructureDefinition: PQCMC_MedicationKnowledge

The official URL for this profile is:

```
http://fda.gov/cder/fhir/pqcmc/StructureDefinition/drugsubstance
```

Formal Views of Profile Content

Description of Profiles, Differentials, Snapshots and how the different presentations work.

This structure is derived from MedicationKnowledge

Name	Flags	Card.	Type	Description & Constraints
MedicationKnowledge		0..*		
ext-productType	S	1..1	code	Specification Type **URL:** http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-productType
valueCode	S		code	*Drug Substance* **Slice:** *Unordered, Open by value:@valueCode* **Fixed Value:** *substance*
code	S	1..*	CodeableConcept	
coding	S		Coding	**Slice:** *Unordered, Open by value:system*
coding	S	1..1	Coding	UNII code
system	S	1..1	uri	**Fixed Value:** http://www.fda.gov/ForIndustry/DataStandards/SubstanceRegistrationSystem-UniqueIngredientIdentifierUNII/default.html
code	S	1..1	code	
coding	S	0..1	Coding	CAS number
system	S	1..1	uri	**Fixed Value:** https://www.cas.org/
code	S	1..1	code	
coding	S	0..1	Coding	INN
system	S	1..1	uri	**Fixed Value:** https://www.who.int/medicines/services/inn/en/
code	S	1..1	code	
coding	S	0..1	Coding	USAN
system	S	1..1	uri	**Fixed Value:** https://www.ama-assn.org/about-ama/united-states-adopted-names
code	S	1..1	code	
coding	S	0..1	Coding	IUPAC Name
system	S	1..1	uri	**Fixed Value:** https://iupac.org/who-we-are/divisions/division-details/inchi/
code	S	1..1	code	
coding	S	0..*	Coding	
code	S	1..1	code	Company code
text	S	1..1	string	Chemical Name
ingredient	S	0..*	BackboneElement	
itemReference	S	1..1	Reference(PQCMC_Substance)	

Documentation for this format

Other representations of profile: Schematron

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Based on FHIR version (4.0.0). IG generated on Thu, Apr 18, 2019 17:50-0400.

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Content   Detailed Descriptions

StructureDefinition: PQCMC_Substance

The official URL for this profile is:

```
http://fda.gov/cder/fhir/pqcmc/StructureDefinition/rawingredient
```

Formal Views of Profile Content

Description of Profiles, Differentials, Snapshots and how the different presentations work.

This structure is derived from MedicationKnowledge

Name	Flags	Card.	Type	Description & Constraints	?
MedicationKnowledge		0..*			
code	S	1..*	CodeableConcept		
coding	S		Coding	**Slice:** Unordered, Open by value:system	
coding	S	1..1	Coding		
system	S	1..1	uri	**Fixed Value:** http://todo.org/CodeSystem/UNII	
code	S	1..1	code	UNII code	
coding	S	1..1	Coding		
system	S	1..1	uri	**Fixed Value:** http://todo.org/CodeSystem/CASNumber	
code	S	1..1	code	CAS number	
text	S	1..1	string	Name	

? Documentation for this format

Other representations of profile: Schematron

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Table of Contents > **Artifact index** > **ProductExample**

ProductExample

Format(s):

- XML

Narrative view

Bundle POC32801 of type collection

Entry 1 - Full URL = http://fda.gov/cder/fhir/pqcmc/POC32801.xml

Resource PlanDefinition:

Proof of Concept PC/CMC Quality Specification

Entry 2 - Full URL = urn:uuid:idigwqdhk4lkudoiwttzesqs5lugq0mu2rsd0xqekd1ptktqxadunl

Resource MedicationKnowledge:

Drug Product section

Table of Contents > **Artifact index** > **SubstanceExample**

SubstanceExample

Format(s):

- XML

Narrative view

Bundle POC32802 of type collection

Entry 1 - Full URL = http://fda.gov/cder/fhir/pqcmc/POC32802.xml

Resource PlanDefinition:

Proof of Concept PC/CMC Quality Specification

Entry 2 - Full URL = urn:uuid:idb2fkhte2ctyuos5kunitness0j0okowtvcur2kk0rlcbzuk0wcgo

Resource MedicationKnowledge:

Drug Substance section

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Table of Contents > Artifact index > **Dosage Form**

cmcDose - xml

Raw xml

Narrative view of the Value Set

```
<ValueSet xmlns="http://hl7.org/fhir">
  <id value="DoseForm"/>
  <meta>
    <profile value="http://hl7.org/fhir/StructureDefinition/shareablevalueset"/>
  </meta>
  <text>
    <status value="generated"/>
    <div xmlns="http://www.w3.org/1999/xhtml"><h2>cmcDose</h2><div><p>This is the physica
l form of the product as presented to the individual. For example: tablet, capsule, liqui
d or ointment. NCI concept code for pharmaceutical dosage form: C42636</p>
</div><p>This value set includes codes from the following code systems:</p><ul><li>Includ
e all codes defined in <a href="DoseForm.html"><code>http://fda.gov/cder/fhir/pqcmc/CodeS
ystem/DoseForm</code></a></li></ul></div>
  </text>
  <url value="http://fda.gov/cder/fhir/pqcmc/ValueSet/DoseForm"/>
  <version value="current"/>
  <name value="cmcDose"/>
  <status value="draft"/>
  <experimental value="false"/>
  <date value="2019-04-18T17:50:12-04:00"/>
  <contact>
    <telecom>
      <system value="url"/>
    </telecom>
    <telecom>
      <system value="email"/>
    </telecom>
  </contact>
  <description
            value="This is the physical form of the product as presented to the indivi
dual. For example: tablet, capsule, liquid or ointment. NCI concept code for pharmaceutic
al dosage form: C42636"/>
  <immutable value="true"/>
  <compose>
    <include>
      <system value="http://fda.gov/cder/fhir/pqcmc/CodeSystem/DoseForm"/>
    </include>
  </compose>
</ValueSet>
```

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Format(s):

- XML

Narrative view

cmcDose

This is the physical form of the product as presented to the individual. For example: tablet, capsule, liquid or ointment. NCI concept code for pharmaceutical dosage form: C42636

This code system http://fda.gov/cder/fhir/pqcmc/CodeSystem/DoseForm defines the following codes:

Code	Display	Definition
C42887	AEROSOL	
C42888	AEROSOL, FOAM	
C42960	AEROSOL, METERED	
C42971	AEROSOL, POWDER	
C42889	AEROSOL, SPRAY	
C42892	BAR, CHEWABLE	
C42890	BEAD	
C25158	CAPSULE	
C42895	CAPSULE, COATED	
C42896	CAPSULE, COATED PELLETS	
C42917	CAPSULE, COATED, EXTENDED RELEASE	
C42902	CAPSULE, DELAYED RELEASE	
C42904	CAPSULE, DELAYED RELEASE PELLETS	
C42916	CAPSULE, EXTENDED RELEASE	
C42928	CAPSULE, FILM COATED, EXTENDED RELEASE	
C42936	CAPSULE, GELATIN COATED	
C42954	CAPSULE, LIQUID FILLED	
C100103	CELLULAR SHEET	
C134876	CHEWABLE GEL	
C60884	CLOTH	
C60891	CONCENTRATE	
C28944	CREAM	
C60897	CREAM, AUGMENTED	
C42901	CRYSTAL	
C43525	DISC	

C42679	DOUCHE	
C42763	DRESSING	
C42912	ELIXIR	
C42913	EMULSION	
C42915	ENEMA	
C42929	EXTRACT	
C60926	FIBER, EXTENDED RELEASE	
C42932	FILM	
C42920	FILM, EXTENDED RELEASE	
C42984	FILM, SOLUBLE	
C60927	FOR SOLUTION	
C60928	FOR SUSPENSION	
C60929	FOR SUSPENSION, EXTENDED RELEASE	
C42933	GAS	
C42934	GEL	
C42906	GEL, DENTIFRICE	
C60930	GEL, METERED	
C42937	GLOBULE	
C42938	GRANULE	
C42903	GRANULE, DELAYED RELEASE	
C42909	GRANULE, EFFERVESCENT	
C42939	GRANULE, FOR SOLUTION	
C42940	GRANULE, FOR SUSPENSION	
C42921	GRANULE, FOR SUSPENSION, EXTENDED RELEASE	
C42894	GUM, CHEWING	
C42942	IMPLANT	
C42944	INHALANT	
C113106	INJECTABLE FOAM	
C60931	INJECTABLE, LIPOSOMAL	
C42946	INJECTION	
C42914	INJECTION, EMULSION	
C42950	INJECTION, LIPID COMPLEX	
C42974	INJECTION, POWDER, FOR SOLUTION	
C42976	INJECTION, POWDER, FOR SUSPENSION	
C42977	INJECTION, POWDER, FOR SUSPENSION, EXTENDED RELEASE	
C42959	INJECTION, POWDER, LYOPHILIZED, FOR LIPOSOMAL SUSPENSION	
C42957	INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION	
C42958	INJECTION, POWDER, LYOPHILIZED, FOR SUSPENSION	
C42956	INJECTION, POWDER, LYOPHILIZED, FOR SUSPENSION, EXTENDED RELEASE	
C42945	INJECTION, SOLUTION	
C42899	INJECTION, SOLUTION, CONCENTRATE	
C42995	INJECTION, SUSPENSION	

C42926	INJECTION, SUSPENSION, EXTENDED RELEASE	
C42951	INJECTION, SUSPENSION, LIPOSOMAL	
C42988	INJECTION, SUSPENSION, SONICATED	
C60933	INSERT	
C42922	INSERT, EXTENDED RELEASE	
C47915	INTRAUTERINE DEVICE	
C42947	IRRIGANT	
C42948	JELLY	
C47916	KIT	
C42949	LINIMENT	
C42952	LIPSTICK	
C42953	LIQUID	
C60934	LIQUID, EXTENDED RELEASE	
C29167	LOTION	
C60957	LOTION, AUGMENTED	
C60958	LOTION/SHAMPOO	
C42955	LOZENGE	
C29269	MOUTHWASH	
C48624	NOT APPLICABLE	
C42965	OIL	
C42966	OINTMENT	
C60984	OINTMENT, AUGMENTED	
C42967	PASTE	
C42907	PASTE, DENTIFRICE	
C60985	PASTILLE	
C42968	PATCH	
C42923	PATCH, EXTENDED RELEASE	
C42911	PATCH, EXTENDED RELEASE, ELECTRICALLY CONTROLLED	
C42969	PELLET	
C42943	PELLET, IMPLANTABLE	
C42918	PELLETS, COATED, EXTENDED RELEASE	
C25394	PILL	
C42970	PLASTER	
C47913	POULTICE	
C42972	POWDER	
C42908	POWDER, DENTIFRICE	
C42973	POWDER, FOR SOLUTION	
C42975	POWDER, FOR SUSPENSION	
C42961	POWDER, METERED	
C60988	RING	
C42979	RINSE	
C42980	SALVE	

C42981	SHAMPOO	
C42982	SHAMPOO, SUSPENSION	
C42983	SOAP	
C42986	SOLUTION	
C42898	SOLUTION, CONCENTRATE	
C42987	SOLUTION, FOR SLUSH	
C60994	SOLUTION, GEL FORMING / DROPS	
C42935	SOLUTION, GEL FORMING, EXTENDED RELEASE	
C60992	SOLUTION/ DROPS	
C47912	SPONGE	
C42989	SPRAY	
C42962	SPRAY, METERED	
C42990	SPRAY, SUSPENSION	
C42991	STICK	
C47914	STRIP	
C42993	SUPPOSITORY	
C42924	SUPPOSITORY, EXTENDED RELEASE	
C42994	SUSPENSION	
C42925	SUSPENSION, EXTENDED RELEASE	
C60995	SUSPENSION/ DROPS	
C47898	SWAB	
C42996	SYRUP	
C42998	TABLET	
C42893	TABLET, CHEWABLE	
C124794	TABLET, CHEWABLE, EXTENDED RELEASE	
C42897	TABLET, COATED	
C60997	TABLET, COATED PARTICLES	
C42905	TABLET, DELAYED RELEASE	
C42997	TABLET, DELAYED RELEASE PARTICLES	
C42910	TABLET, EFFERVESCENT	
C42927	TABLET, EXTENDED RELEASE	
C42931	TABLET, FILM COATED	
C42930	TABLET, FILM COATED, EXTENDED RELEASE	
C61004	TABLET, FOR SOLUTION	
C61005	TABLET, FOR SUSPENSION	
C42964	TABLET, MULTILAYER	
C42963	TABLET, MULTILAYER, EXTENDED RELEASE	
C42999	TABLET, ORALLY DISINTEGRATING	
C61006	TABLET, ORALLY DISINTEGRATING, DELAYED RELEASE	
C42985	TABLET, SOLUBLE	
C42992	TABLET, SUGAR COATED	
C147579	TABLET WITH SENSOR	

C47892	TAMPON	
C47897	TAPE	
C43000	TINCTURE	
C43001	TROCHE	
C43003	WAFER	

MethodOrigin - xml

Raw xml

Narrative view of the Value Set

```xml
<ValueSet xmlns="http://hl7.org/fhir">
  <id value="methodOrig"/>
  <meta>
    <profile value="http://hl7.org/fhir/StructureDefinition/shareablevalueset"/>
  </meta>
  <text>
    <status value="generated"/>
    <div xmlns="http://www.w3.org/1999/xhtml"><h2>MethodOrigin</h2><div><p>Codes  specify
ing the source of the method.</p>
</div><p>This value set includes codes from the following code systems:</p><ul><li>Includ
e all codes defined in <a href="methodOrig.html"><code>http://fda.gov/cder/fhir/pqcmc/Cod
eSystem/methodOrig</code></a></li></ul></div>
  </text>
  <url value="http://fda.gov/cder/fhir/pqcmc/ValueSet/methodOrig"/>
  <version value="current"/>
  <name value="MethodOrigin"/>
  <status value="draft"/>
  <experimental value="false"/>
  <date value="2019-04-18T17:50:12-04:00"/>
  <contact>
    <telecom>
      <system value="url"/>
    </telecom>
    <telecom>
      <system value="email"/>
    </telecom>
  </contact>
  <description value="Codes  specifying the source of the method."/>
  <immutable value="true"/>
  <compose>
    <include>
      <system value="http://fda.gov/cder/fhir/pqcmc/CodeSystem/methodOrig"/>
    </include>
  </compose>
</ValueSet>
```

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Format(s):

- XML

Narrative view

MethodOrigin

Codes specifying the source of the method.

This code system http://fda.gov/cder/fhir/pqcmc/CodeSystem/methodOrig defines the following codes:

Code	Display	Definition
C96102	Compendial	Method defined in any recognized compendium (e.g., USP, PharmEU, JP, etc.).
C96103	Proprietary	Method defined by the sponsor (not recognized in CFR or any compendium)
C96164	CFR	Method defined in the Code of Federal Regulation (CFR)

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SpecStatus - xml

Raw xml

Narrative view of the Value Set

```
<ValueSet xmlns="http://hl7.org/fhir">
  <id value="SpecStat"/>
  <meta>
    <profile value="http://hl7.org/fhir/StructureDefinition/shareablevalueset"/>
  </meta>
  <text>
    <status value="generated"/>
    <div xmlns="http://www.w3.org/1999/xhtml"><h2>SpecStatus</h2><div><p>Code indicating
the current FDA regulatory status of the specification</p>
</div><p>This value set includes codes from the following code systems:</p><ul><li>Includ
e all codes defined in <a href="SpecStat.html"><code>http://fda.gov/cder/fhir/pqcmc/CodeS
ystem/SpecStat</code></a></li></ul></div>
  </text>
  <url value="http://fda.gov/cder/fhir/pqcmc/ValueSet/SpecStat"/>
  <version value="current"/>
  <name value="SpecStatus"/>
  <status value="draft"/>
  <experimental value="false"/>
  <date value="2019-04-18T17:50:12-04:00"/>
  <contact>
    <telecom>
      <system value="url"/>
    </telecom>
    <telecom>
      <system value="email"/>
    </telecom>
  </contact>
  <description
            value="Code indicating the current FDA regulatory status of the specificat
ion"/>
  <immutable value="true"/>
  <compose>
    <include>
      <system value="http://fda.gov/cder/fhir/pqcmc/CodeSystem/SpecStat"/>
    </include>
  </compose>
</ValueSet>
```

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Format(s):

- XML

Narrative view

SpecStatus

Code indicating the current FDA regulatory status of the specification

This code system http://fda.gov/cder/fhir/pqcmc/CodeSystem/SpecStat defines the following codes:

Code	Display	Definition
C134010	Tentatively Approved	A specification that met the requirements for approval but the application could not be approved for reasons such as patents and exclusivity.
C134011	Not Approved	A specification that has not yet been approved.
C134012	Reported in a CBE or AR	The specification may be used without prior approval, and was submitted in a changes being effected (CBE) supplement or an annual report (AR).
C25425	Approved	A specification that has met the requirements for approval

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TestCategory - xml

Raw xml

Narrative view of the Value Set

```
<ValueSet xmlns="http://hl7.org/fhir">
  <id value="testCat"/>
  <meta>
    <profile value="http://hl7.org/fhir/StructureDefinition/shareablevalueset"/>
  </meta>
  <text>
    <status value="generated"/>
    <div xmlns="http://www.w3.org/1999/xhtml"><h2>TestCategory</h2><div><p>List of test c
ategories allowable values for the Test Category data element</p>
</div><p>This value set includes codes from the following code systems:</p><ul><li>Includ
e all codes defined in <a href="testCat.html"><code>http://fda.gov/cder/fhir/pqcmc/CodeSy
stem/testCat</code></a></li></ul></div>
  </text>
  <url value="http://fda.gov/cder/fhir/pqcmc/ValueSet/testCat"/>
  <version value="current"/>
  <name value="TestCategory"/>
  <status value="draft"/>
  <experimental value="false"/>
  <date value="2019-04-18T17:50:12-04:00"/>
  <contact>
    <telecom>
      <system value="url"/>
    </telecom>
    <telecom>
      <system value="email"/>
    </telecom>
  </contact>
  <description
            value="List of test categories allowable values for the Test Category data
 element"/>
  <immutable value="true"/>
  <compose>
    <include>
      <system value="http://fda.gov/cder/fhir/pqcmc/CodeSystem/testCat"/>
    </include>
  </compose>
</ValueSet>
```

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Format(s):

- XML

Narrative view

TestCategory

List of test categories allowable values for the Test Category data element

This code system http://fda.gov/cder/fhir/pqcmc/CodeSystem/testCat defines the following codes:

Code	Display	Definition
C60819	Assay	Tests which measure the content of the active ingredient in the drug substance or drug product. Synonymous with strength or purity which is commonly used of define the content of the active ingredient in a drug product. [Source: Adapted from ICH Q6A and Q6B] Note: chiral purity, preservative content, Anti-Oxidant Concentration, Chelate Concentration, isomeric ratio.
C138990	Description	An assessment of the physical state (e.g., color, shape, size) of the drug substance or product. [Source: Adapted from ICH Q6A]
C138993	Identification	Tests that establishes the characteristic and uniqueness of the substance of interest and should be able to discriminate between compounds of closely related structures which are likely to be present. [Source: ICH Q6A]
C158424	Physical Properties	Assessments of the characteristics of a material that are not associated with a change in its composition and basic nature, including but not limited to its texture, smell, freezing point, boiling point, melting point, opacity, viscosity and density.
C158425	Biological Properties	Any effect a given material has on a living organism (e.g., microbial limits, endotoxin).
C17771	Chemical Properties	A characteristic of a material that is observed during a reaction in which the chemical composition or identity of the material is changed (e.g., combustibility, solubility, acidity/basicity).
C158423	Impurities	Analytical procedures that determine the presence of a component of the material that is not the chemical entity defined as the material.

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Table of Contents > **Artifact index** > **Test Usage**

TestUsage - xml

Raw xml

Narrative view of the Value Set

```
<ValueSet xmlns="http://hl7.org/fhir">
  <id value="pqcmcUsage"/>
  <meta>
    <profile value="http://hl7.org/fhir/StructureDefinition/shareablevalueset"/>
  </meta>
  <text>
    <status value="generated"/>
    <div xmlns="http://www.w3.org/1999/xhtml"><h2>TestUsage</h2><div><p>List of codes spe
cifying the time point during the manufacturing process of a substance or product when a
particular analytical procedure or measurement is being performed</p>
</div><p>This value set includes codes from the following code systems:</p><ul><li>Includ
e all codes defined in <a href="pqcmcUsage.html"><code>http://fda.gov/cder/fhir/pqcmc/Cod
eSystem/pqcmcUsage</code></a></li></ul></div>
  </text>
  <url value="http://fda.gov/cder/fhir/pqcmc/ValueSet/pqcmcUsage"/>
  <version value="current"/>
  <name value="TestUsage"/>
  <status value="draft"/>
  <experimental value="false"/>
  <date value="2019-04-18T17:50:12-04:00"/>
  <contact>
    <telecom>
      <system value="url"/>
    </telecom>
    <telecom>
      <system value="email"/>
    </telecom>
  </contact>
  <description
            value="List of codes specifying the time point during the manufacturing pr
ocess of a substance or product when a particular analytical procedure or measurement is
being performed"/>
  <immutable value="true"/>
  <compose>
    <include>
      <system value="http://fda.gov/cder/fhir/pqcmc/CodeSystem/pqcmcUsage"/>
    </include>
  </compose>
</ValueSet>
```

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Format(s):

- XML

Narrative view

TestUsage

List of codes specifying the time point during the manufacturing process of a substance or product when a particular analytical procedure or measurement is being performed

This code system http://fda.gov/cder/fhir/pqcmc/CodeSystem/pqcmcUsage defines the following codes:

Code	Display	Definition
C134029	Release	For determination of acceptability for use of a material, drug or a drug substance. NOTE: The "use" could be for distribution, marketing, further manufacturing stages, etc.
C134030	Stability	For determination of maintained performance parameters on storage over time, of a material, drug or a drug substance.
C134031	Release and Stability	For determination at release and on stability when test and acceptance criteria are the same in both cases.

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Content | **Detailed Descriptions** | Mappings | XML

Extension: approvalStatus - Detailed Descriptions

Definitions for the ext-approvalStatus Extension

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Extension: approvalStatus - Mappings

Mappings for the Extension

Mappings for RIM Mapping (http://hl7.org/v3)

approvalStatus	
Extension	
id	n/a
extension	n/a
extension (type)	
id	n/a
extension	n/a
url	N/A
valueCode	N/A
extension (date)	
id	n/a
extension	n/a
url	N/A
valueDate	N/A
url	N/A

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Content   Detailed Descriptions   Mappings   XML

Extension: approvalStatus - XML Profile

XML representation of the ext-approvalStatus Extension

```
<StructureDefinition xmlns="http://hl7.org/fhir">
  <id value="ext-approvalStatus"/>
  <text>
    <status value="generated"/>
    <div xmlns="http://www.w3.org/1999/xhtml"><table border="0" cellpadding="0" cellspaci
ng="0" style="border: 0px #F0F0F0 solid; font-size: 11px; font-family: verdana; vertical-
align: top;"><tr style="border: 1px #F0F0F0 solid; font-size: 11px; font-family: verdana;
 vertical-align: top;"><th style="vertical-align: top; text-align : left; background-colo
r: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><a href="
http://build.fhir.org/formats.html#table" title="The logical name of the element">Name</a
></th><th style="vertical-align: top; text-align : left; background-color: white; border:
 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><a href="http://build.fhir
.org/formats.html#table" title="Information about the use of the element">Flags</a></th><
th style="vertical-align: top; text-align : left; background-color: white; border: 0px #F
0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><a href="http://build.fhir.org/fo
rmats.html#table" title="Minimum and Maximum # of times the the element can appear in the
 instance">Card.</a></th><th style="width: 100px" class="hierarchy"><a href="http://build
.fhir.org/formats.html#table" title="Reference to the type of the element">Type</a></th><
th style="vertical-align: top; text-align : left; background-color: white; border: 0px #F
0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><a href="http://build.fhir.org/fo
rmats.html#table" title="Additional information about the element">Description &amp; Cons
traints</a><span style="float: right"><a href="http://build.fhir.org/formats.html#table"
title="Legend for this format"><img src="http://build.fhir.org/help16.png" alt="doco" sty
le="background-color: inherit"/></a></span></th></tr><tr style="border: 0px #F0F0F0 solid
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top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4
px 0px 4px; white-space: nowrap; background-image: url(tbl_bck1.png)" class="hierarchy"><
img src="tbl_spacer.png" alt="." style="background-color: inherit" class="hierarchy"/><im
g src="icon_element.gif" alt="." style="background-color: white; background-color: inheri
t" title="Element" class="hierarchy"/> <a href="extension-ext-approvalStatus-definitions.
html#Extension">Extension</a><a name="Extension"> </a></td><td style="vertical-align: top
; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px
0px 4px" class="hierarchy"/><td style="vertical-align: top; text-align : left; background
-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy">0..1
</td><td style="vertical-align: top; text-align : left; background-color: white; border:
0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"/><td style="vertical-align:
 top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px
4px 0px 4px" class="hierarchy">Approval Status</td></tr>
<tr style="border: 0px #F0F0F0 solid; padding:0px; vertical-align: top; background-color:
```

```
white;"><td style="vertical-align: top; text-align : left; background-color: white; bord
er: 0px #F0F0F0 solid; padding:0px 4px 0px 4px; white-space: nowrap; background-image: ur
l(tbl_bck15.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="background-c
olor: inherit" class="hierarchy"/><img src="tbl_vjoin.png" alt="." style="background-colo
r: inherit" class="hierarchy"/><img src="icon_extension_simple.png" alt="." style="backgr
ound-color: white; background-color: inherit" title="Simple Extension" class="hierarchy"/
> <a href="extension-ext-approvalStatus-definitions.html#Extension.extension:type" title=
"Slice type: ">extension</a><a name="Extension.extension"> </a></td><td style="vertical-a
lign: top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding
:0px 4px 0px 4px" class="hierarchy"/><td style="vertical-align: top; text-align : left; b
ackground-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierar
chy">1..1</td><td style="vertical-align: top; text-align : left; background-color: white;
 border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><a href="http://bu
ild.fhir.org/datatypes.html#Extension">Extension</a></td><td style="vertical-align: top;
text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0p
x 4px" class="hierarchy">Type of approval</td></tr>
<tr style="border: 0px #F0F0F0 solid; padding:0px; vertical-align: top; background-color:
 white;"><td style="vertical-align: top; text-align : left; background-color: white; bord
er: 0px #F0F0F0 solid; padding:0px 4px 0px 4px; white-space: nowrap; background-image: ur
l(tbl_bck150.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="background-
color: inherit" class="hierarchy"/><img src="tbl_vline.png" alt="." style="background-col
or: inherit" class="hierarchy"/><img src="tbl_vjoin_slice.png" alt="." style="background-
color: inherit" class="hierarchy"/><img src="icon_element.gif" alt="." style="background-
color: white; background-color: inherit" title="Element" class="hierarchy"/> <a href="ext
ension-ext-approvalStatus-definitions.html#Extension.extension:type.url" title="null">url
</a><a name="Extension.extension.url"> </a></td><td style="vertical-align: top; text-alig
n : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" cl
ass="hierarchy"/><td style="vertical-align: top; text-align : left; background-color: whi
te; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"/><td style="ver
tical-align: top; text-align : left; background-color: white; border: 0px #F0F0F0 solid;
padding:0px 4px 0px 4px" class="hierarchy"/><td style="vertical-align: top; text-align :
left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class=
"hierarchy"><span style="color: darkgreen">&quot;type&quot;</span></td></tr>
<tr style="border: 0px #F0F0F0 solid; padding:0px; vertical-align: top; background-color:
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er: 0px #F0F0F0 solid; padding:0px 4px 0px 4px; white-space: nowrap; background-image: ur
l(tbl_bck140.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="background-
color: inherit" class="hierarchy"/><img src="tbl_vline.png" alt="." style="background-col
or: inherit" class="hierarchy"/><img src="tbl_vjoin_end_slice.png" alt="." style="backgro
und-color: inherit" class="hierarchy"/><img src="icon_primitive.png" alt="." style="backg
round-color: white; background-color: inherit" title="Primitive Data Type" class="hierarc
hy"/> <a href="extension-ext-approvalStatus-definitions.html#Extension.extension:type.val
ueCode" title="null">valueCode</a><a name="Extension.extension.valueCode"> </a></td><td s
tyle="vertical-align: top; text-align : left; background-color: white; border: 0px #F0F0F
0 solid; padding:0px 4px 0px 4px" class="hierarchy"/><td style="vertical-align: top; text
-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4p
x" class="hierarchy"/><td style="vertical-align: top; text-align : left; background-color
: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><a href="h
ttp://build.fhir.org/datatypes.html#code">code</a></td><td style="vertical-align: top; te
xt-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px
4px" class="hierarchy"/></tr>
<tr style="border: 0px #F0F0F0 solid; padding:0px; vertical-align: top; background-color:
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er: 0px #F0F0F0 solid; padding:0px 4px 0px 4px; white-space: nowrap; background-image: ur
l(tbl_bck15.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="background-c
olor: inherit" class="hierarchy"/><img src="tbl_vjoin.png" alt="." style="background-colo
r: inherit" class="hierarchy"/><img src="icon_extension_simple.png" alt="." style="backgr
```

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ound-color: white; background-color: inherit" title="Simple Extension" class="hierarchy"/
> <a href="extension-ext-approvalStatus-definitions.html#Extension.extension:date" title=
"Slice date: ">extension</a><a name="Extension.extension"> </a></td><td style="vertical-a
lign: top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding
:0px 4px 0px 4px" class="hierarchy"/><td style="vertical-align: top; text-align : left; b
ackground-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierar
chy">1..1</td><td style="vertical-align: top; text-align : left; background-color: white;
 border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><a href="http://bu
ild.fhir.org/datatypes.html#Extension">Extension</a></td><td style="vertical-align: top;
text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0p
x 4px" class="hierarchy">Date of approval</td></tr>
<tr style="border: 0px #F0F0F0 solid; padding:0px; vertical-align: top; background-color:
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l(tbl_bck150.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="background-
color: inherit" class="hierarchy"/><img src="tbl_vline.png" alt="." style="background-col
or: inherit" class="hierarchy"/><img src="tbl_vjoin_slice.png" alt="." style="background-
color: inherit" class="hierarchy"/><img src="icon_element.gif" alt="." style="background-
color: white; background-color: inherit" title="Element" class="hierarchy"/> <a href="ext
ension-ext-approvalStatus-definitions.html#Extension.extension:date.url" title="null">url
</a><a name="Extension.extension.url"> </a></td><td style="vertical-align: top; text-alig
n : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" cl
ass="hierarchy"/><td style="vertical-align: top; text-align : left; background-color: whi
te; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"/><td style="ver
tical-align: top; text-align : left; background-color: white; border: 0px #F0F0F0 solid;
padding:0px 4px 0px 4px" class="hierarchy"/><td style="vertical-align: top; text-align :
left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class=
"hierarchy"><span style="color: darkgreen">&quot;date&quot;</span></td></tr>
<tr style="border: 0px #F0F0F0 solid; padding:0px; vertical-align: top; background-color:
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er: 0px #F0F0F0 solid; padding:0px 4px 0px 4px; white-space: nowrap; background-image: ur
l(tbl_bck140.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="background-
color: inherit" class="hierarchy"/><img src="tbl_vline.png" alt="." style="background-col
or: inherit" class="hierarchy"/><img src="tbl_vjoin_end_slice.png" alt="." style="backgro
und-color: inherit" class="hierarchy"/><img src="icon_primitive.png" alt="." style="backg
round-color: white; background-color: inherit" title="Primitive Data Type" class="hierarc
hy"/> <a href="extension-ext-approvalStatus-definitions.html#Extension.extension:date.val
ueDate" title="null">valueDate</a><a name="Extension.extension.valueDate"> </a></td><td s
tyle="vertical-align: top; text-align : left; background-color: white; border: 0px #F0F0F
0 solid; padding:0px 4px 0px 4px" class="hierarchy"/><td style="vertical-align: top; text
-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4p
x" class="hierarchy"/><td style="vertical-align: top; text-align : left; background-color
: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><a href="h
ttp://build.fhir.org/datatypes.html#date">date</a></td><td style="vertical-align: top; te
xt-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px
4px" class="hierarchy"/></tr>
<tr style="border: 0px #F0F0F0 solid; padding:0px; vertical-align: top; background-color:
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er: 0px #F0F0F0 solid; padding:0px 4px 0px 4px; white-space: nowrap; background-image: ur
l(tbl_bck10.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="background-c
olor: inherit" class="hierarchy"/><img src="tbl_vjoin.png" alt="." style="background-colo
r: inherit" class="hierarchy"/><img src="icon_primitive.png" alt="." style="background-co
lor: white; background-color: inherit" title="Primitive Data Type" class="hierarchy"/> <a
 href="extension-ext-approvalStatus-definitions.html#Extension.url" title="null">url</a><
a name="Extension.url"> </a></td><td style="vertical-align: top; text-align : left; backg
round-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"
/><td style="vertical-align: top; text-align : left; background-color: white; border: 0px
```

```
       #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"/><td style="vertical-align: to
p; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px
 0px 4px" class="hierarchy"><a href="http://build.fhir.org/datatypes.html#uri">uri</a></t
d><td style="vertical-align: top; text-align : left; background-color: white; border: 0px
 #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><span style="color: darkgreen"
>&quot;http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-approvalStatus&quot;</span>
</td></tr>
<tr style="border: 0px #F0F0F0 solid; padding:0px; vertical-align: top; background-color:
 white;"><td style="vertical-align: top; text-align : left; background-color: white; bord
er: 0px #F0F0F0 solid; padding:0px 4px 0px 4px; white-space: nowrap; background-image: ur
l(tbl_bck00.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="background-c
olor: inherit" class="hierarchy"/><img src="tbl_vjoin_end.png" alt="." style="background-
color: inherit" class="hierarchy"/><img src="icon_element.gif" alt="." style="background-
color: white; background-color: inherit" title="Element" class="hierarchy"/> <span style=
"text-decoration:line-through" title="null">value[x]</span><a name="Extension.value_x_">
</a></td><td style="vertical-align: top; text-align : left; background-color: white; bord
er: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"/><td style="vertical-al
ign: top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:
0px 4px 0px 4px" class="hierarchy"><span style="text-decoration:line-through"/><span styl
e="text-decoration:line-through"></span><span style="text-decoration:line-through">..</sp
an><span style="text-decoration:line-through">0</span></td><td style="vertical-align: top
; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px
0px 4px" class="hierarchy"/><td style="vertical-align: top; text-align : left; background
-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"/></t
r>
<tr><td colspan="5" class="hierarchy"><br/><a href="http://build.fhir.org/formats.html#ta
ble" title="Legend for this format"><img src="http://build.fhir.org/help16.png" alt="doco
" style="background-color: inherit"/> Documentation for this format</a></td></tr></table>
</div>
  </text>
  <url
      value="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-approvalStatus"/>
  <version value="current"/>
  <name value="approvalStatus"/>
  <title value="Approval status"/>
  <status value="draft"/>
  <experimental value="false"/>
  <date value="2018-10-05T00:00:00-04:00"/>
  <publisher value="U.S. FDA - CDER division"/>
  <contact>
    <telecom>
      <system value="url"/>
      <value
           value="https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsan
dtobacco/cder"/>
    </telecom>
  </contact>
  <fhirVersion value="4.0.0"/>
  <mapping>
    <identity value="rim"/>
    <uri value="http://hl7.org/v3"/>
    <name value="RIM Mapping"/>
  </mapping>
  <kind value="complex-type"/>
  <abstract value="false"/>
  <context>
    <type value="element"/>
```

```xml
      <expression value="PlanDefinition"/>
    </context>
    <type value="Extension"/>
    <baseDefinition value="http://hl7.org/fhir/StructureDefinition/Extension"/>
    <derivation value="constraint"/>
    <snapshot>
      <element id="Extension">
        <extension
                url="http://hl7.org/fhir/StructureDefinition/structuredefinition-standar
ds-status">
          <valueCode value="normative"/>
        </extension>
        <extension
                url="http://hl7.org/fhir/StructureDefinition/structuredefinition-normati
ve-version">
          <valueCode value="4.0.0"/>
        </extension>
        <path value="Extension"/>
        <short value="Approval Status"/>
        <definition value="An Extension"/>
        <comment
                value="Indicates that the form has been designed with an expectation that
it will be submitted to the specified URI.  If multiple endpoints are specified, expectat
ion is that answers are submitted to all endpoints.

If no end-point is specified, then the form is not exclusively designed to be submitted t
o a specific site.  If and where the form needs to be submitted or how the form should be
 internally processed must be inferred from external context or system business rules."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Extension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <condition value="ele-1"/>
        <constraint>
          <key value="ele-1"/>
          <severity value="error"/>
          <human value="All FHIR elements must have a @value or children"/>
          <expression value="hasValue() or (children().count() &gt; id.count())"/>
          <xpath value="@value|f:*|h:div"/>
          <source value="Element"/>
        </constraint>
        <constraint>
          <key value="ext-1"/>
          <severity value="error"/>
          <human value="Must have either extensions or value[x], not both"/>
          <expression value="extension.exists() != value.exists()"/>
          <xpath
                value="exists(f:extension)!=exists(f:*[starts-with(local-name(.), &#39;val
ue&#39;)])"/>
          <source value="Extension"/>
        </constraint>
        <isModifier value="false"/>
      </element>
      <element id="Extension.id">
```

```
      <path value="Extension.id"/>
      <representation value="xmlAttr"/>
      <short value="Unique id for inter-element referencing"/>
      <definition
                 value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="Element.id"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="string"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="n/a"/>
      </mapping>
    </element>
    <element id="Extension.extension">
      <path value="Extension.extension"/>
      <slicing>
        <discriminator>
          <type value="value"/>
          <path value="url"/>
        </discriminator>
        <description value="Extensions are always sliced by (at least) url"/>
        <rules value="open"/>
      </slicing>
      <short value="Additional content defined by implementations"/>
      <definition
                 value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
      <comment
                value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
      <alias value="extensions"/>
      <alias value="user content"/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="Element.extension"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Extension"/>
      </type>
```

```xml
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="Extension.extension:type">
        <path value="Extension.extension"/>
        <sliceName value="type"/>
        <short value="Type of approval"/>
        <definition value="An Extension"/>
        <min value="1"/>
        <max value="1"/>
        <base>
          <path value="Element.extension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="Extension.extension:type.id">
        <path value="Extension.extension.id"/>
        <representation value="xmlAttr"/>
        <short value="Unique id for inter-element referencing"/>
        <definition
                  value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Element.id"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="string"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="Extension.extension:type.extension">
        <path value="Extension.extension.extension"/>
        <slicing>
          <discriminator>
            <type value="value"/>
            <path value="url"/>
          </discriminator>
          <description value="Extensions are always sliced by (at least) url"/>
```

```
            <rules value="open"/>
        </slicing>
        <short value="Additional content defined by implementations"/>
        <definition
                    value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
        <comment
                value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
        <alias value="extensions"/>
        <alias value="user content"/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="Element.extension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="Extension.extension:type.url">
        <path value="Extension.extension.url"/>
        <representation value="xmlAttr"/>
        <short value="identifies the meaning of the extension"/>
        <definition
                    value="Source of the definition for the extension code - a logical name
 or a URL."/>
        <comment
                value="The definition may point directly to a computable or human-readable
 definition of the extensibility codes, or it may be a logical URI as declared in some ot
her specification. The definition SHALL be a URI for the Structure Definition defining th
e extension."/>
        <min value="1"/>
        <max value="1"/>
        <base>
          <path value="Extension.url"/>
          <min value="1"/>
          <max value="1"/>
        </base>
        <type>
          <code>
            <extension
                      url="http://hl7.org/fhir/StructureDefinition/structuredefinition-jso
n-type">
```

```xml
                    <valueString value="string"/>
                </extension>
                <extension
                        url="http://hl7.org/fhir/StructureDefinition/structuredefinition-xml
-type">
                    <valueString value="xsd:string"/>
                </extension>
                <extension
                        url="http://hl7.org/fhir/StructureDefinition/structuredefinition-rdf
-type">
                    <valueString value="xsd:string"/>
                </extension>
                <extension url="http://hl7.org/fhir/StructureDefinition/regex">
                    <valueString
                            value="((http|https)://([A-Za-z0-9\\\.\:\%\$]*\/)*)?(Account|Act
ivityDefinition|AdverseEvent|AllergyIntolerance|Appointment|AppointmentResponse|AuditEven
t|Basic|Binary|BiologicallyDerivedProduct|BodyStructure|Bundle|CapabilityStatement|CarePl
an|CareTeam|CatalogEntry|ChargeItem|ChargeItemDefinition|Claim|ClaimResponse|ClinicalImpr
ession|CodeSystem|Communication|CommunicationRequest|CompartmentDefinition|Composition|Co
nceptMap|Condition|Consent|Contract|Coverage|CoverageEligibilityRequest|CoverageEligibili
tyResponse|DetectedIssue|Device|DeviceDefinition|DeviceMetric|DeviceRequest|DeviceUseStat
ement|DiagnosticReport|DocumentManifest|DocumentReference|EffectEvidenceSynthesis|Encount
er|Endpoint|EnrollmentRequest|EnrollmentResponse|EpisodeOfCare|EventDefinition|Evidence|E
videnceVariable|ExampleScenario|ExplanationOfBenefit|FamilyMemberHistory|Flag|Goal|GraphD
efinition|Group|GuidanceResponse|HealthcareService|ImagingStudy|Immunization|Immunization
Evaluation|ImmunizationRecommendation|ImplementationGuide|InsurancePlan|Invoice|Library|L
inkage|List|Location|Measure|MeasureReport|Media|Medication|MedicationAdministration|Medi
cationDispense|MedicationKnowledge|MedicationRequest|MedicationStatement|MedicinalProduct
|MedicinalProductAuthorization|MedicinalProductContraindication|MedicinalProductIndicatio
n|MedicinalProductIngredient|MedicinalProductInteraction|MedicinalProductManufactured|Med
icinalProductPackaged|MedicinalProductPharmaceutical|MedicinalProductUndesirableEffect|Me
ssageDefinition|MessageHeader|MolecularSequence|NamingSystem|NutritionOrder|Observation|O
bservationDefinition|OperationDefinition|OperationOutcome|Organization|OrganizationAffili
ation|Patient|PaymentNotice|PaymentReconciliation|Person|PlanDefinition|Practitioner|Prac
titionerRole|Procedure|Provenance|Questionnaire|QuestionnaireResponse|RelatedPerson|Reque
stGroup|ResearchDefinition|ResearchElementDefinition|ResearchStudy|ResearchSubject|RiskAs
sessment|RiskEvidenceSynthesis|Schedule|SearchParameter|ServiceRequest|Slot|Specimen|Spec
imenDefinition|StructureDefinition|StructureMap|Subscription|Substance|SubstanceNucleicAc
id|SubstancePolymer|SubstanceProtein|SubstanceReferenceInformation|SubstanceSourceMateria
l|SubstanceSpecification|SupplyDelivery|SupplyRequest|Task|TerminologyCapabilities|TestRe
port|TestScript|ValueSet|VerificationResult|VisionPrescription)\/[A-Za-z0-9\-\.]{1,64}(\/
_history\/[A-Za-z0-9\-\.]{1,64})?"/>
                </extension>
            </code>
        </type>
        <fixedUri value="type"/>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
            <identity value="rim"/>
            <map value="N/A"/>
        </mapping>
    </element>
    <element id="Extension.extension:type.valueCode">
        <path value="Extension.extension.valueCode"/>
        <short value="Value of extension"/>
        <definition
```

```
                    value="Value of extension - must be one of a constrained set of the dat
a types (see [Extensibility](http://build.fhir.org/extensibility.html) for a list)."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="Extension.value[x]"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="code"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="N/A"/>
      </mapping>
    </element>
    <element id="Extension.extension:date">
      <path value="Extension.extension"/>
      <sliceName value="date"/>
      <short value="Date of approval"/>
      <definition value="An Extension"/>
      <min value="1"/>
      <max value="1"/>
      <base>
        <path value="Element.extension"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Extension"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="Extension.extension:date.id">
      <path value="Extension.extension.id"/>
      <representation value="xmlAttr"/>
      <short value="Unique id for inter-element referencing"/>
      <definition
                    value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="Element.id"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="string"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
```

```
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="Extension.extension:date.extension">
        <path value="Extension.extension.extension"/>
        <slicing>
          <discriminator>
            <type value="value"/>
            <path value="url"/>
          </discriminator>
          <description value="Extensions are always sliced by (at least) url"/>
          <rules value="open"/>
        </slicing>
        <short value="Additional content defined by implementations"/>
        <definition
                   value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
        <comment
                value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
        <alias value="extensions"/>
        <alias value="user content"/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="Element.extension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="Extension.extension:date.url">
        <path value="Extension.extension.url"/>
        <representation value="xmlAttr"/>
        <short value="identifies the meaning of the extension"/>
        <definition
                   value="Source of the definition for the extension code - a logical name
 or a URL."/>
        <comment
                value="The definition may point directly to a computable or human-readable
 definition of the extensibility codes, or it may be a logical URI as declared in some ot
her specification. The definition SHALL be a URI for the Structure Definition defining th
e extension."/>
```

```xml
        <min value="1"/>
        <max value="1"/>
        <base>
          <path value="Extension.url"/>
          <min value="1"/>
          <max value="1"/>
        </base>
        <type>
          <code>
            <extension
                    url="http://hl7.org/fhir/StructureDefinition/structuredefinition-json-type">
              <valueString value="string"/>
            </extension>
            <extension
                    url="http://hl7.org/fhir/StructureDefinition/structuredefinition-xml-type">
              <valueString value="xsd:string"/>
            </extension>
            <extension
                    url="http://hl7.org/fhir/StructureDefinition/structuredefinition-rdf-type">
              <valueString value="xsd:string"/>
            </extension>
            <extension url="http://hl7.org/fhir/StructureDefinition/regex">
              <valueString
                        value="((http|https)://([A-Za-z0-9\\\.\:\%\$]*\/)*)?(Account|ActivityDefinition|AdverseEvent|AllergyIntolerance|Appointment|AppointmentResponse|AuditEvent|Basic|Binary|BiologicallyDerivedProduct|BodyStructure|Bundle|CapabilityStatement|CarePlan|CareTeam|CatalogEntry|ChargeItem|ChargeItemDefinition|Claim|ClaimResponse|ClinicalImpression|CodeSystem|Communication|CommunicationRequest|CompartmentDefinition|Composition|ConceptMap|Condition|Consent|Contract|Coverage|CoverageEligibilityRequest|CoverageEligibilityResponse|DetectedIssue|Device|DeviceDefinition|DeviceMetric|DeviceRequest|DeviceUseStatement|DiagnosticReport|DocumentManifest|DocumentReference|EffectEvidenceSynthesis|Encounter|Endpoint|EnrollmentRequest|EnrollmentResponse|EpisodeOfCare|EventDefinition|Evidence|EvidenceVariable|ExampleScenario|ExplanationOfBenefit|FamilyMemberHistory|Flag|Goal|GraphDefinition|Group|GuidanceResponse|HealthcareService|ImagingStudy|Immunization|ImmunizationEvaluation|ImmunizationRecommendation|ImplementationGuide|InsurancePlan|Invoice|Library|Linkage|List|Location|Measure|MeasureReport|Media|Medication|MedicationAdministration|MedicationDispense|MedicationKnowledge|MedicationRequest|MedicationStatement|MedicinalProduct|MedicinalProductAuthorization|MedicinalProductContraindication|MedicinalProductIndication|MedicinalProductIngredient|MedicinalProductInteraction|MedicinalProductManufactured|MedicinalProductPackaged|MedicinalProductPharmaceutical|MedicinalProductUndesirableEffect|MessageDefinition|MessageHeader|MolecularSequence|NamingSystem|NutritionOrder|Observation|ObservationDefinition|OperationDefinition|OperationOutcome|Organization|OrganizationAffiliation|Patient|PaymentNotice|PaymentReconciliation|Person|PlanDefinition|Practitioner|PractitionerRole|Procedure|Provenance|Questionnaire|QuestionnaireResponse|RelatedPerson|RequestGroup|ResearchDefinition|ResearchElementDefinition|ResearchStudy|ResearchSubject|RiskAssessment|RiskEvidenceSynthesis|Schedule|SearchParameter|ServiceRequest|Slot|Specimen|SpecimenDefinition|StructureDefinition|StructureMap|Subscription|Substance|SubstanceNucleicAcid|SubstancePolymer|SubstanceProtein|SubstanceReferenceInformation|SubstanceSourceMaterial|SubstanceSpecification|SupplyDelivery|SupplyRequest|Task|TerminologyCapabilities|TestReport|TestScript|ValueSet|VerificationResult|VisionPrescription)\/[A-Za-z0-9\-\.]{1,64}(\/_history\/[A-Za-z0-9\-\.]{1,64})?"/>
            </extension>
          </code>
        </type>
```

```xml
          <fixedUri value="date"/>
          <isModifier value="false"/>
          <isSummary value="false"/>
          <mapping>
            <identity value="rim"/>
            <map value="N/A"/>
          </mapping>
        </element>
        <element id="Extension.extension:date.valueDate">
          <path value="Extension.extension.valueDate"/>
          <short value="Value of extension"/>
          <definition
                    value="Value of extension - must be one of a constrained set of the dat
a types (see [Extensibility](http://build.fhir.org/extensibility.html) for a list)."/>
          <min value="0"/>
          <max value="1"/>
          <base>
            <path value="Extension.value[x]"/>
            <min value="0"/>
            <max value="1"/>
          </base>
          <type>
            <code value="date"/>
          </type>
          <isModifier value="false"/>
          <isSummary value="false"/>
          <mapping>
            <identity value="rim"/>
            <map value="N/A"/>
          </mapping>
        </element>
        <element id="Extension.url">
          <path value="Extension.url"/>
          <representation value="xmlAttr"/>
          <short value="identifies the meaning of the extension"/>
          <definition
                    value="Source of the definition for the extension code - a logical name
 or a URL."/>
          <comment
                value="The definition may point directly to a computable or human-readable
 definition of the extensibility codes, or it may be a logical URI as declared in some ot
her specification. The definition SHALL be a URI for the Structure Definition defining th
e extension."/>
          <min value="1"/>
          <max value="1"/>
          <base>
            <path value="Extension.url"/>
            <min value="1"/>
            <max value="1"/>
          </base>
          <type>
            <code value="uri"/>
          </type>
          <fixedUri
                    value="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-approvalSta
tus"/>
          <isModifier value="false"/>
```

```xml
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="N/A"/>
        </mapping>
      </element>
      <element id="Extension.value[x]">
        <path value="Extension.value[x]"/>
        <short value="Value of extension"/>
        <definition
                    value="Value of extension - must be one of a constrained set of the dat
a types (see [Extensibility](http://build.fhir.org/extensibility.html) for a list)."/>
        <min value="0"/>
        <max value="0"/>
        <base>
          <path value="Extension.value[x]"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="base64Binary"/>
        </type>
        <type>
          <code value="boolean"/>
        </type>
        <type>
          <code value="canonical"/>
        </type>
        <type>
          <code value="code"/>
        </type>
        <type>
          <code value="date"/>
        </type>
        <type>
          <code value="dateTime"/>
        </type>
        <type>
          <code value="decimal"/>
        </type>
        <type>
          <code value="id"/>
        </type>
        <type>
          <code value="instant"/>
        </type>
        <type>
          <code value="integer"/>
        </type>
        <type>
          <code value="markdown"/>
        </type>
        <type>
          <code value="oid"/>
        </type>
        <type>
          <code value="positiveInt"/>
```

```xml
    </type>
    <type>
      <code value="string"/>
    </type>
    <type>
      <code value="time"/>
    </type>
    <type>
      <code value="unsignedInt"/>
    </type>
    <type>
      <code value="uri"/>
    </type>
    <type>
      <code value="url"/>
    </type>
    <type>
      <code value="uuid"/>
    </type>
    <type>
      <code value="Address"/>
    </type>
    <type>
      <code value="Age"/>
    </type>
    <type>
      <code value="Annotation"/>
    </type>
    <type>
      <code value="Attachment"/>
    </type>
    <type>
      <code value="CodeableConcept"/>
    </type>
    <type>
      <code value="Coding"/>
    </type>
    <type>
      <code value="ContactPoint"/>
    </type>
    <type>
      <code value="Count"/>
    </type>
    <type>
      <code value="Distance"/>
    </type>
    <type>
      <code value="Duration"/>
    </type>
    <type>
      <code value="HumanName"/>
    </type>
    <type>
      <code value="Identifier"/>
    </type>
    <type>
      <code value="Money"/>
```

```xml
      </type>
      <type>
        <code value="Period"/>
      </type>
      <type>
        <code value="Quantity"/>
      </type>
      <type>
        <code value="Range"/>
      </type>
      <type>
        <code value="Ratio"/>
      </type>
      <type>
        <code value="Reference"/>
      </type>
      <type>
        <code value="SampledData"/>
      </type>
      <type>
        <code value="Signature"/>
      </type>
      <type>
        <code value="Timing"/>
      </type>
      <type>
        <code value="ContactDetail"/>
      </type>
      <type>
        <code value="Contributor"/>
      </type>
      <type>
        <code value="DataRequirement"/>
      </type>
      <type>
        <code value="Expression"/>
      </type>
      <type>
        <code value="ParameterDefinition"/>
      </type>
      <type>
        <code value="RelatedArtifact"/>
      </type>
      <type>
        <code value="TriggerDefinition"/>
      </type>
      <type>
        <code value="UsageContext"/>
      </type>
      <type>
        <code value="Dosage"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="N/A"/>
```

```
        </mapping>
      </element>
    </snapshot>
    <differential>
      <element id="Extension">
        <path value="Extension"/>
        <short value="Approval Status"/>
        <comment
                  value="Indicates that the form has been designed with an expectation that
it will be submitted to the specified URI.  If multiple endpoints are specified, expectat
ion is that answers are submitted to all endpoints.

If no end-point is specified, then the form is not exclusively designed to be submitted t
o a specific site.  If and where the form needs to be submitted or how the form should be
 internally processed must be inferred from external context or system business rules."/>
        <min value="0"/>
        <max value="1"/>
        <isModifier value="false"/>
      </element>
      <element id="Extension.extension:type">
        <path value="Extension.extension"/>
        <sliceName value="type"/>
        <short value="Type of approval"/>
        <min value="1"/>
        <max value="1"/>
        <type>
          <code value="Extension"/>
        </type>
        <isModifier value="false"/>
      </element>
      <element id="Extension.extension:type.url">
        <path value="Extension.extension.url"/>
        <fixedUri value="type"/>
      </element>
      <element id="Extension.extension:type.valueCode">
        <path value="Extension.extension.valueCode"/>
        <type>
          <code value="code"/>
        </type>
      </element>
      <element id="Extension.extension:date">
        <path value="Extension.extension"/>
        <sliceName value="date"/>
        <short value="Date of approval"/>
        <min value="1"/>
        <max value="1"/>
        <type>
          <code value="Extension"/>
        </type>
        <isModifier value="false"/>
      </element>
      <element id="Extension.extension:date.url">
        <path value="Extension.extension.url"/>
        <fixedUri value="date"/>
      </element>
      <element id="Extension.extension:date.valueDate">
        <path value="Extension.extension.valueDate"/>
```

```xml
            <type>
              <code value="date"/>
            </type>
          </element>
          <element id="Extension.url">
            <path value="Extension.url"/>
            <type>
              <code value="uri"/>
            </type>
            <fixedUri
                   value="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-approvalSta
tus"/>
          </element>
          <element id="Extension.value[x]">
            <path value="Extension.value[x]"/>
            <max value="0"/>
          </element>
        </differential>
</StructureDefinition>
```

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f:Extension extension with URL = 'type': minimum cardinality of 'extension' is 1 extension with URL = 'type': maximum cardinality of 'extension' is 1 extension with URL = 'date': minimum cardinality of 'extension' is 1 extension with URL = 'date': maximum cardinality of 'extension' is 1 value[x]: maximum cardinality of 'value[x]' is 0 Extension All FHIR elements must have a @value or children (inherited) Must have either extensions or value[x], not both (inherited) f:Extension/f:extension id: maximum cardinality of 'id' is 1 url: minimum cardinality of 'url' is 1 url: maximum cardinality of 'url' is 1 valueCode: maximum cardinality of 'valueCode' is 1 id: maximum cardinality of 'id' is 1 url: minimum cardinality of 'url' is 1 url: maximum cardinality of 'url' is 1 valueDate: maximum cardinality of 'valueDate' is 1

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| Content | **Detailed Descriptions** | Mappings | XML |

Extension: Additional comment - Detailed Descriptions

Definitions for the ext-comment Extension

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Table of Contents > Artifact index > **Comment**

| Content | Detailed Descriptions | Mappings | XML |

Extension: Additional comment - Mappings

Mappings for the Extension

Mappings for RIM Mapping (http://hl7.org/v3)

Additional comment	
Extension	
id	n/a
extension	n/a
url	N/A
valueString	N/A

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Table of Contents > **Artifact index** > **Comment**

Content   Detailed Descriptions   Mappings   XML

Extension: Additional comment - XML Profile

XML representation of the ext-comment Extension

```
<StructureDefinition xmlns="http://hl7.org/fhir">
  <id value="ext-comment"/>
  <text>
    <status value="generated"/>
    <div xmlns="http://www.w3.org/1999/xhtml"><table border="0" cellpadding="0" cellspaci
ng="0" style="border: 0px #F0F0F0 solid; font-size: 11px; font-family: verdana; vertical-
align: top;"><tr style="border: 1px #F0F0F0 solid; font-size: 11px; font-family: verdana;
 vertical-align: top;"><th style="vertical-align: top; text-align : left; background-colo
r: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><a href="
http://build.fhir.org/formats.html#table" title="The logical name of the element">Name</a
></th><th style="vertical-align: top; text-align : left; background-color: white; border:
 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><a href="http://build.fhir
.org/formats.html#table" title="Information about the use of the element">Flags</a></th><
th style="vertical-align: top; text-align : left; background-color: white; border: 0px #F
0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><a href="http://build.fhir.org/fo
rmats.html#table" title="Minimum and Maximum # of times the the element can appear in the
 instance">Card.</a></th><th style="width: 100px" class="hierarchy"><a href="http://build
.fhir.org/formats.html#table" title="Reference to the type of the element">Type</a></th><
th style="vertical-align: top; text-align : left; background-color: white; border: 0px #F
0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><a href="http://build.fhir.org/fo
rmats.html#table" title="Additional information about the element">Description &amp; Cons
traints</a><span style="float: right"><a href="http://build.fhir.org/formats.html#table"
title="Legend for this format"><img src="http://build.fhir.org/help16.png" alt="doco" sty
le="background-color: inherit"/></a></span></th></tr><tr style="border: 0px #F0F0F0 solid
; padding:0px; vertical-align: top; background-color: white;"><td style="vertical-align:
top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4
px 0px 4px; white-space: nowrap; background-image: url(tbl_bck1.png)" class="hierarchy"><
img src="tbl_spacer.png" alt="." style="background-color: inherit" class="hierarchy"/><im
g src="icon_element.gif" alt="." style="background-color: white; background-color: inheri
t" title="Element" class="hierarchy"/> <a href="extension-ext-comment-definitions.html#Ex
tension">Extension</a><a name="Extension"> </a></td><td style="vertical-align: top; text-
align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px
" class="hierarchy"/><td style="vertical-align: top; text-align : left; background-color:
 white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy">1..*</td><t
d style="vertical-align: top; text-align : left; background-color: white; border: 0px #F0
F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"/><td style="vertical-align: top; t
ext-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px
 4px" class="hierarchy">Additional comment<br/></td></tr>
<tr style="border: 0px #F0F0F0 solid; padding:0px; vertical-align: top; background-color:
```

```
 white;"><td style="vertical-align: top; text-align : left; background-color: white; bord
er: 0px #F0F0F0 solid; padding:0px 4px 0px 4px; white-space: nowrap; background-image: ur
l(tbl_bck10.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="background-c
olor: inherit" class="hierarchy"/><img src="tbl_vjoin.png" alt="." style="background-colo
r: inherit" class="hierarchy"/><img src="icon_primitive.png" alt="." style="background-co
lor: white; background-color: inherit" title="Primitive Data Type" class="hierarchy"/> <a
 href="extension-ext-comment-definitions.html#Extension.url" title="null">url</a><a name=
"Extension.url"> </a></td><td style="vertical-align: top; text-align : left; background-c
olor: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"/><td s
tyle="vertical-align: top; text-align : left; background-color: white; border: 0px #F0F0F
0 solid; padding:0px 4px 0px 4px" class="hierarchy"/><td style="vertical-align: top; text
-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4p
x" class="hierarchy"><a href="http://build.fhir.org/datatypes.html#uri">uri</a></td><td s
tyle="vertical-align: top; text-align : left; background-color: white; border: 0px #F0F0F
0 solid; padding:0px 4px 0px 4px" class="hierarchy"><span style="color: darkgreen">&quot;
http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-comment&quot;</span></td></tr>
<tr style="border: 0px #F0F0F0 solid; padding:0px; vertical-align: top; background-color:
 white;"><td style="vertical-align: top; text-align : left; background-color: white; bord
er: 0px #F0F0F0 solid; padding:0px 4px 0px 4px; white-space: nowrap; background-image: ur
l(tbl_bck00.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="background-c
olor: inherit" class="hierarchy"/><img src="tbl_vjoin_end.png" alt="." style="background-
color: inherit" class="hierarchy"/><img src="icon_primitive.png" alt="." style="backgroun
d-color: white; background-color: inherit" title="Primitive Data Type" class="hierarchy"/
> <a href="extension-ext-comment-definitions.html#Extension.valueString" title="null">val
ueString</a><a name="Extension.valueString"> </a></td><td style="vertical-align: top; tex
t-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4
px" class="hierarchy"/><td style="vertical-align: top; text-align : left; background-colo
r: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"/><td styl
e="vertical-align: top; text-align : left; background-color: white; border: 0px #F0F0F0 s
olid; padding:0px 4px 0px 4px" class="hierarchy"><a href="http://build.fhir.org/datatypes
.html#string">string</a></td><td style="vertical-align: top; text-align : left; backgroun
d-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"/></
tr>
<tr><td colspan="5" class="hierarchy"><br/><a href="http://build.fhir.org/formats.html#ta
ble" title="Legend for this format"><img src="http://build.fhir.org/help16.png" alt="doco
" style="background-color: inherit"/> Documentation for this format</a></td></tr></table>
</div>
  </text>
  <url value="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-comment"/>
  <version value="current"/>
  <name value="Additional comment"/>
  <status value="draft"/>
  <experimental value="false"/>
  <date value="2018-10-05T00:00:00-04:00"/>
  <publisher value="U.S. FDA - CDER division"/>
  <contact>
    <telecom>
      <system value="url"/>
      <value
            value="https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsan
dtobacco/cder"/>
    </telecom>
  </contact>
  <fhirVersion value="4.0.0"/>
  <mapping>
    <identity value="rim"/>
    <uri value="http://hl7.org/v3"/>
```

```xml
      <name value="RIM Mapping"/>
    </mapping>
    <kind value="complex-type"/>
    <abstract value="false"/>
    <context>
      <type value="element"/>
      <expression value="Element"/>
    </context>
    <type value="Extension"/>
    <baseDefinition value="http://hl7.org/fhir/StructureDefinition/Extension"/>
    <derivation value="constraint"/>
    <snapshot>
      <element id="Extension">
        <extension
                   url="http://hl7.org/fhir/StructureDefinition/structuredefinition-standar
ds-status">
          <valueCode value="normative"/>
        </extension>
        <extension
                   url="http://hl7.org/fhir/StructureDefinition/structuredefinition-normati
ve-version">
          <valueCode value="4.0.0"/>
        </extension>
        <path value="Extension"/>
        <short value="Additional comment"/>
        <definition value="An Extension"/>
        <min value="1"/>
        <max value="*"/>
        <base>
          <path value="Extension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <condition value="ele-1"/>
        <constraint>
          <key value="ele-1"/>
          <severity value="error"/>
          <human value="All FHIR elements must have a @value or children"/>
          <expression value="hasValue() or (children().count() &gt; id.count())"/>
          <xpath value="@value|f:*|h:div"/>
          <source value="Element"/>
        </constraint>
        <constraint>
          <key value="ext-1"/>
          <severity value="error"/>
          <human value="Must have either extensions or value[x], not both"/>
          <expression value="extension.exists() != value.exists()"/>
          <xpath
                 value="exists(f:extension)!=exists(f:*[starts-with(local-name(.), &#39;val
ue&#39;)])"/>
          <source value="Extension"/>
        </constraint>
        <isModifier value="false"/>
      </element>
      <element id="Extension.id">
        <path value="Extension.id"/>
        <representation value="xmlAttr"/>
```

```
      <short value="Unique id for inter-element referencing"/>
      <definition
                  value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="Element.id"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="string"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="n/a"/>
      </mapping>
    </element>
    <element id="Extension.extension">
      <path value="Extension.extension"/>
      <slicing>
        <discriminator>
          <type value="value"/>
          <path value="url"/>
        </discriminator>
        <description value="Extensions are always sliced by (at least) url"/>
        <rules value="open"/>
      </slicing>
      <short value="Additional content defined by implementations"/>
      <definition
                  value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
      <comment
                value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
      <alias value="extensions"/>
      <alias value="user content"/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="Element.extension"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Extension"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
```

```xml
      <mapping>
        <identity value="rim"/>
        <map value="n/a"/>
      </mapping>
    </element>
    <element id="Extension.url">
      <path value="Extension.url"/>
      <representation value="xmlAttr"/>
      <short value="identifies the meaning of the extension"/>
      <definition
                  value="Source of the definition for the extension code - a logical name
 or a URL."/>
      <comment
                value="The definition may point directly to a computable or human-readable
 definition of the extensibility codes, or it may be a logical URI as declared in some ot
her specification. The definition SHALL be a URI for the Structure Definition defining th
e extension."/>
      <min value="1"/>
      <max value="1"/>
      <base>
        <path value="Extension.url"/>
        <min value="1"/>
        <max value="1"/>
      </base>
      <type>
        <code value="uri"/>
      </type>
      <fixedUri
                  value="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-comment"/>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="N/A"/>
      </mapping>
    </element>
    <element id="Extension.valueString">
      <path value="Extension.valueString"/>
      <short value="Value of extension"/>
      <definition
                  value="Value of extension - must be one of a constrained set of the dat
a types (see [Extensibility](http://build.fhir.org/extensibility.html) for a list)."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="Extension.value[x]"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="string"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="N/A"/>
```

```
        </mapping>
      </element>
    </snapshot>
    <differential>
      <element id="Extension">
        <path value="Extension"/>
        <short value="Additional comment"/>
        <min value="1"/>
        <max value="*"/>
        <isModifier value="false"/>
      </element>
      <element id="Extension.url">
        <path value="Extension.url"/>
        <type>
          <code value="uri"/>
        </type>
        <fixedUri
                 value="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-comment"/>
      </element>
      <element id="Extension.valueString">
        <path value="Extension.valueString"/>
        <type>
          <code value="string"/>
        </type>
      </element>
    </differential>
</StructureDefinition>
```

Extension All FHIR elements must have a @value or children (inherited) Must have either extensions or value[x], not both (inherited)

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Content | **Detailed Descriptions** | Mappings | XML

Extension: Method origin - Detailed Descriptions

Definitions for the ext-methodOrigin Extension

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| Content | Detailed Descriptions | Mappings | XML |

Extension: Method origin - Mappings

Mappings for the Extension

Mappings for RIM Mapping (http://hl7.org/v3)

Method origin	
Extension	
id	n/a
extension	n/a
url	N/A
valueCode	N/A

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Table of Contents > **Artifact index** > **Method Origin**

Content   Detailed Descriptions   Mappings   XML

Extension: Method origin - XML Profile

XML representation of the ext-methodOrigin Extension

```
<StructureDefinition xmlns="http://hl7.org/fhir">
  <id value="ext-methodOrigin"/>
  <text>
    <status value="generated"/>
    <div xmlns="http://www.w3.org/1999/xhtml"><table border="0" cellpadding="0" cellspaci
ng="0" style="border: 0px #F0F0F0 solid; font-size: 11px; font-family: verdana; vertical-
align: top;"><tr style="border: 1px #F0F0F0 solid; font-size: 11px; font-family: verdana;
 vertical-align: top;"><th style="vertical-align: top; text-align : left; background-colo
r: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><a href="
http://build.fhir.org/formats.html#table" title="The logical name of the element">Name</a
></th><th style="vertical-align: top; text-align : left; background-color: white; border:
 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><a href="http://build.fhir
.org/formats.html#table" title="Information about the use of the element">Flags</a></th><
th style="vertical-align: top; text-align : left; background-color: white; border: 0px #F
0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><a href="http://build.fhir.org/fo
rmats.html#table" title="Minimum and Maximum # of times the the element can appear in the
 instance">Card.</a></th><th style="width: 100px" class="hierarchy"><a href="http://build
.fhir.org/formats.html#table" title="Reference to the type of the element">Type</a></th><
th style="vertical-align: top; text-align : left; background-color: white; border: 0px #F
0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><a href="http://build.fhir.org/fo
rmats.html#table" title="Additional information about the element">Description &amp; Cons
traints</a><span style="float: right"><a href="http://build.fhir.org/formats.html#table"
title="Legend for this format"><img src="http://build.fhir.org/help16.png" alt="doco" sty
le="background-color: inherit"/></a></span></th></tr><tr style="border: 0px #F0F0F0 solid
; padding:0px; vertical-align: top; background-color: white;"><td style="vertical-align:
top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4
px 0px 4px; white-space: nowrap; background-image: url(tbl_bck1.png)" class="hierarchy"><
img src="tbl_spacer.png" alt="." style="background-color: inherit" class="hierarchy"/><im
g src="icon_element.gif" alt="." style="background-color: white; background-color: inheri
t" title="Element" class="hierarchy"/> <a href="extension-ext-methodOrigin-definitions.ht
ml#Extension">Extension</a><a name="Extension"> </a></td><td style="vertical-align: top;
text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0p
x 4px" class="hierarchy"/><td style="vertical-align: top; text-align : left; background-c
olor: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy">0..1</
td><td style="vertical-align: top; text-align : left; background-color: white; border: 0p
x #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"/><td style="vertical-align: t
op; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4p
x 0px 4px" class="hierarchy">Method origin</td></tr>
<tr style="border: 0px #F0F0F0 solid; padding:0px; vertical-align: top; background-color:
```

```
 white;"><td style="vertical-align: top; text-align : left; background-color: white; bord
er: 0px #F0F0F0 solid; padding:0px 4px 0px 4px; white-space: nowrap; background-image: ur
l(tbl_bck10.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="background-c
olor: inherit" class="hierarchy"/><img src="tbl_vjoin.png" alt="." style="background-colo
r: inherit" class="hierarchy"/><img src="icon_primitive.png" alt="." style="background-co
lor: white; background-color: inherit" title="Primitive Data Type" class="hierarchy"/> <a
 href="extension-ext-methodOrigin-definitions.html#Extension.url" title="null">url</a><a
name="Extension.url"> </a></td><td style="vertical-align: top; text-align : left; backgro
und-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"/>
<td style="vertical-align: top; text-align : left; background-color: white; border: 0px #
F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"/><td style="vertical-align: top;
 text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0
px 4px" class="hierarchy"><a href="http://build.fhir.org/datatypes.html#uri">uri</a></td>
<td style="vertical-align: top; text-align : left; background-color: white; border: 0px #
F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><span style="color: darkgreen">&
quot;http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-methodOrigin&quot;</span></td
></tr>
<tr style="border: 0px #F0F0F0 solid; padding:0px; vertical-align: top; background-color:
 white;"><td style="vertical-align: top; text-align : left; background-color: white; bord
er: 0px #F0F0F0 solid; padding:0px 4px 0px 4px; white-space: nowrap; background-image: ur
l(tbl_bck00.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="background-c
olor: inherit" class="hierarchy"/><img src="tbl_vjoin_end.png" alt="." style="background-
color: inherit" class="hierarchy"/><img src="icon_primitive.png" alt="." style="backgroun
d-color: white; background-color: inherit" title="Primitive Data Type" class="hierarchy"/
> <a href="extension-ext-methodOrigin-definitions.html#Extension.valueCode" title="null">
valueCode</a><a name="Extension.valueCode"> </a></td><td style="vertical-align: top; text
-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4p
x" class="hierarchy"/><td style="vertical-align: top; text-align : left; background-color
: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"/><td style
="vertical-align: top; text-align : left; background-color: white; border: 0px #F0F0F0 so
lid; padding:0px 4px 0px 4px" class="hierarchy"><a href="http://build.fhir.org/datatypes.
html#code">code</a></td><td style="vertical-align: top; text-align : left; background-col
or: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"/></tr>
<tr><td colspan="5" class="hierarchy"><br/><a href="http://build.fhir.org/formats.html#ta
ble" title="Legend for this format"><img src="http://build.fhir.org/help16.png" alt="doco
" style="background-color: inherit"/> Documentation for this format</a></td></tr></table>
</div>
  </text>
  <url
      value="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-methodOrigin"/>
  <version value="current"/>
  <name value="Method origin"/>
  <status value="draft"/>
  <experimental value="false"/>
  <date value="2018-10-05T00:00:00-04:00"/>
  <publisher value="U.S. FDA - CDER division"/>
  <contact>
    <telecom>
      <system value="url"/>
      <value
            value="https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsan
dtobacco/cder"/>
    </telecom>
  </contact>
  <fhirVersion value="4.0.0"/>
  <mapping>
    <identity value="rim"/>
```

```xml
      <uri value="http://hl7.org/v3"/>
      <name value="RIM Mapping"/>
    </mapping>
    <kind value="complex-type"/>
    <abstract value="false"/>
    <context>
      <type value="element"/>
      <expression value="PlanDefinition.action"/>
    </context>
    <type value="Extension"/>
    <baseDefinition value="http://hl7.org/fhir/StructureDefinition/Extension"/>
    <derivation value="constraint"/>
    <snapshot>
      <element id="Extension">
        <extension
                  url="http://hl7.org/fhir/StructureDefinition/structuredefinition-standar
ds-status">
          <valueCode value="normative"/>
        </extension>
        <extension
                  url="http://hl7.org/fhir/StructureDefinition/structuredefinition-normati
ve-version">
          <valueCode value="4.0.0"/>
        </extension>
        <path value="Extension"/>
        <short value="Method origin"/>
        <definition value="An Extension"/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Extension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <condition value="ele-1"/>
        <constraint>
          <key value="ele-1"/>
          <severity value="error"/>
          <human value="All FHIR elements must have a @value or children"/>
          <expression value="hasValue() or (children().count() &gt; id.count())"/>
          <xpath value="@value|f:*|h:div"/>
          <source value="Element"/>
        </constraint>
        <constraint>
          <key value="ext-1"/>
          <severity value="error"/>
          <human value="Must have either extensions or value[x], not both"/>
          <expression value="extension.exists() != value.exists()"/>
          <xpath
                value="exists(f:extension)!=exists(f:*[starts-with(local-name(.), &#39;val
ue&#39;)])"/>
          <source value="Extension"/>
        </constraint>
        <isModifier value="false"/>
      </element>
      <element id="Extension.id">
        <path value="Extension.id"/>
```

```
        <representation value="xmlAttr"/>
        <short value="Unique id for inter-element referencing"/>
        <definition
                   value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Element.id"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="string"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="Extension.extension">
        <path value="Extension.extension"/>
        <slicing>
          <discriminator>
            <type value="value"/>
            <path value="url"/>
          </discriminator>
          <description value="Extensions are always sliced by (at least) url"/>
          <rules value="open"/>
        </slicing>
        <short value="Additional content defined by implementations"/>
        <definition
                   value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
        <comment
                value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
        <alias value="extensions"/>
        <alias value="user content"/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="Element.extension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
        </type>
        <isModifier value="false"/>
```

```xml
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="n/a"/>
      </mapping>
    </element>
    <element id="Extension.url">
      <path value="Extension.url"/>
      <representation value="xmlAttr"/>
      <short value="identifies the meaning of the extension"/>
      <definition
                  value="Source of the definition for the extension code - a logical name
 or a URL."/>
      <comment
              value="The definition may point directly to a computable or human-readable
 definition of the extensibility codes, or it may be a logical URI as declared in some ot
her specification. The definition SHALL be a URI for the Structure Definition defining th
e extension."/>
      <min value="1"/>
      <max value="1"/>
      <base>
        <path value="Extension.url"/>
        <min value="1"/>
        <max value="1"/>
      </base>
      <type>
        <code value="uri"/>
      </type>
      <fixedUri
                value="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-methodOrigi
n"/>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="N/A"/>
      </mapping>
    </element>
    <element id="Extension.valueCode">
      <path value="Extension.valueCode"/>
      <short value="Value of extension"/>
      <definition
                  value="Value of extension - must be one of a constrained set of the dat
a types (see [Extensibility](http://build.fhir.org/extensibility.html) for a list)."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="Extension.value[x]"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="code"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
```

```
            <identity value="rim"/>
            <map value="N/A"/>
          </mapping>
        </element>
      </snapshot>
      <differential>
        <element id="Extension">
          <path value="Extension"/>
          <short value="Method origin"/>
          <min value="0"/>
          <max value="1"/>
          <isModifier value="false"/>
        </element>
        <element id="Extension.url">
          <path value="Extension.url"/>
          <type>
            <code value="uri"/>
          </type>
          <fixedUri
                  value="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-methodOrigi
n"/>
        </element>
        <element id="Extension.valueCode">
          <path value="Extension.valueCode"/>
          <type>
            <code value="code"/>
          </type>
        </element>
      </differential>
</StructureDefinition>
```

f:Extension valueCode: maximum cardinality of 'valueCode' is 1 Extension All FHIR elements must have a @value or children (inherited) Must have either extensions or value[x], not both (inherited)

Content   **Detailed Descriptions**   Mappings   XML

Extension: Analytic Procedure URL - Detailed Descriptions

Definitions for the ext-definitionUri Extension

| Content | Detailed Descriptions | Mappings | XML |

Extension: Analytic Procedure URL - Mappings

Mappings for the Extension

Mappings for RIM Mapping (http://hl7.org/v3)

Analytic Procedure URL	
Extension	
id	n/a
extension	n/a
url	N/A
valueString	N/A

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Extension: Analytic Procedure URL - XML Profile

XML representation of the ext-definitionUri Extension

```
<StructureDefinition xmlns="http://hl7.org/fhir">
  <id value="ext-definitionUri"/>
  <text>
    <status value="generated"/>
    <div xmlns="http://www.w3.org/1999/xhtml"><table border="0" cellpadding="0" cellspaci
ng="0" style="border: 0px #F0F0F0 solid; font-size: 11px; font-family: verdana; vertical-
align: top;"><tr style="border: 1px #F0F0F0 solid; font-size: 11px; font-family: verdana;
 vertical-align: top;"><th style="vertical-align: top; text-align : left; background-colo
r: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><a href="
http://build.fhir.org/formats.html#table" title="The logical name of the element">Name</a
></th><th style="vertical-align: top; text-align : left; background-color: white; border:
 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><a href="http://build.fhir
.org/formats.html#table" title="Information about the use of the element">Flags</a></th><
th style="vertical-align: top; text-align : left; background-color: white; border: 0px #F
0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><a href="http://build.fhir.org/fo
rmats.html#table" title="Minimum and Maximum # of times the the element can appear in the
 instance">Card.</a></th><th style="width: 100px" class="hierarchy"><a href="http://build
.fhir.org/formats.html#table" title="Reference to the type of the element">Type</a></th><
th style="vertical-align: top; text-align : left; background-color: white; border: 0px #F
0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><a href="http://build.fhir.org/fo
rmats.html#table" title="Additional information about the element">Description &amp; Cons
traints</a><span style="float: right"><a href="http://build.fhir.org/formats.html#table"
title="Legend for this format"><img src="http://build.fhir.org/help16.png" alt="doco" sty
le="background-color: inherit"/></a></span></th></tr><tr style="border: 0px #F0F0F0 solid
; padding:0px; vertical-align: top; background-color: white;"><td style="vertical-align:
top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4
px 0px 4px; white-space: nowrap; background-image: url(tbl_bck1.png)" class="hierarchy"><
img src="tbl_spacer.png" alt="." style="background-color: inherit" class="hierarchy"/><im
g src="icon_element.gif" alt="." style="background-color: white; background-color: inheri
t" title="Element" class="hierarchy"/> <a href="extension-ext-definitionUri-definitions.h
tml#Extension">Extension</a><a name="Extension"> </a></td><td style="vertical-align: top;
 text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0
px 4px" class="hierarchy"/><td style="vertical-align: top; text-align : left; background-
color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy">0..1<
/td><td style="vertical-align: top; text-align : left; background-color: white; border: 0
px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"/><td style="vertical-align:
top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4
px 0px 4px" class="hierarchy">Analytic Procedure URL</td></tr>
<tr style="border: 0px #F0F0F0 solid; padding:0px; vertical-align: top; background-color:
```

```
 white;"><td style="vertical-align: top; text-align : left; background-color: white; bord
er: 0px #F0F0F0 solid; padding:0px 4px 0px 4px; white-space: nowrap; background-image: ur
l(tbl_bck10.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="background-c
olor: inherit" class="hierarchy"/><img src="tbl_vjoin.png" alt="." style="background-colo
r: inherit" class="hierarchy"/><img src="icon_primitive.png" alt="." style="background-co
lor: white; background-color: inherit" title="Primitive Data Type" class="hierarchy"/> <a
 href="extension-ext-definitionUri-definitions.html#Extension.url" title="null">url</a><a
 name="Extension.url"> </a></td><td style="vertical-align: top; text-align : left; backgr
ound-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"/
><td style="vertical-align: top; text-align : left; background-color: white; border: 0px
#F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"/><td style="vertical-align: top
; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px
0px 4px" class="hierarchy"><a href="http://build.fhir.org/datatypes.html#uri">uri</a></td
><td style="vertical-align: top; text-align : left; background-color: white; border: 0px
#F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><span style="color: darkgreen">
&quot;http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-definitionUri&quot;</span></
td></tr>
<tr style="border: 0px #F0F0F0 solid; padding:0px; vertical-align: top; background-color:
 white;"><td style="vertical-align: top; text-align : left; background-color: white; bord
er: 0px #F0F0F0 solid; padding:0px 4px 0px 4px; white-space: nowrap; background-image: ur
l(tbl_bck00.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="background-c
olor: inherit" class="hierarchy"/><img src="tbl_vjoin_end.png" alt="." style="background-
color: inherit" class="hierarchy"/><img src="icon_primitive.png" alt="." style="backgroun
d-color: white; background-color: inherit" title="Primitive Data Type" class="hierarchy"/
> <a href="extension-ext-definitionUri-definitions.html#Extension.valueString" title="nul
l">valueString</a><a name="Extension.valueString"> </a></td><td style="vertical-align: to
p; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px
 0px 4px" class="hierarchy"/><td style="vertical-align: top; text-align : left; backgroun
d-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"/><t
d style="vertical-align: top; text-align : left; background-color: white; border: 0px #F0
F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><a href="http://build.fhir.org/dat
atypes.html#string">string</a></td><td style="vertical-align: top; text-align : left; bac
kground-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarch
y"/></tr>
<tr><td colspan="5" class="hierarchy"><br/><a href="http://build.fhir.org/formats.html#ta
ble" title="Legend for this format"><img src="http://build.fhir.org/help16.png" alt="doco
" style="background-color: inherit"/> Documentation for this format</a></td></tr></table>
</div>
  </text>
  <url
      value="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-definitionUri"/>
  <version value="current"/>
  <name value="Analytic Procedure URL"/>
  <status value="draft"/>
  <experimental value="false"/>
  <date value="2018-10-05T00:00:00-04:00"/>
  <publisher value="U.S. FDA - CDER division"/>
  <contact>
    <telecom>
      <system value="url"/>
      <value
            value="https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsan
dtobacco/cder"/>
    </telecom>
  </contact>
  <fhirVersion value="4.0.0"/>
  <mapping>
```

```xml
      <identity value="rim"/>
      <uri value="http://hl7.org/v3"/>
      <name value="RIM Mapping"/>
  </mapping>
  <kind value="complex-type"/>
  <abstract value="false"/>
  <context>
    <type value="element"/>
    <expression value="PlanDefinition.action"/>
  </context>
  <type value="Extension"/>
  <baseDefinition value="http://hl7.org/fhir/StructureDefinition/Extension"/>
  <derivation value="constraint"/>
  <snapshot>
    <element id="Extension">
      <extension
                url="http://hl7.org/fhir/StructureDefinition/structuredefinition-standar
ds-status">
        <valueCode value="normative"/>
      </extension>
      <extension
                url="http://hl7.org/fhir/StructureDefinition/structuredefinition-normati
ve-version">
        <valueCode value="4.0.0"/>
      </extension>
      <path value="Extension"/>
      <short value="Analytic Procedure URL"/>
      <definition value="An Extension"/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="Extension"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <condition value="ele-1"/>
      <constraint>
        <key value="ele-1"/>
        <severity value="error"/>
        <human value="All FHIR elements must have a @value or children"/>
        <expression value="hasValue() or (children().count() &gt; id.count())"/>
        <xpath value="@value|f:*|h:div"/>
        <source value="Element"/>
      </constraint>
      <constraint>
        <key value="ext-1"/>
        <severity value="error"/>
        <human value="Must have either extensions or value[x], not both"/>
        <expression value="extension.exists() != value.exists()"/>
        <xpath
              value="exists(f:extension)!=exists(f:*[starts-with(local-name(.), &#39;val
ue&#39;)])"/>
        <source value="Extension"/>
      </constraint>
      <isModifier value="false"/>
    </element>
    <element id="Extension.id">
```

```xml
        <path value="Extension.id"/>
        <representation value="xmlAttr"/>
        <short value="Unique id for inter-element referencing"/>
        <definition
                    value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Element.id"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="string"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="Extension.extension">
        <path value="Extension.extension"/>
        <slicing>
          <discriminator>
            <type value="value"/>
            <path value="url"/>
          </discriminator>
          <description value="Extensions are always sliced by (at least) url"/>
          <rules value="open"/>
        </slicing>
        <short value="Additional content defined by implementations"/>
        <definition
                    value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
        <comment
                value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
        <alias value="extensions"/>
        <alias value="user content"/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="Element.extension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
        </type>
```

```xml
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="n/a"/>
      </mapping>
    </element>
    <element id="Extension.url">
      <path value="Extension.url"/>
      <representation value="xmlAttr"/>
      <short value="identifies the meaning of the extension"/>
      <definition
                  value="Source of the definition for the extension code - a logical name
 or a URL."/>
      <comment
              value="The definition may point directly to a computable or human-readable
 definition of the extensibility codes, or it may be a logical URI as declared in some ot
her specification. The definition SHALL be a URI for the Structure Definition defining th
e extension."/>
      <min value="1"/>
      <max value="1"/>
      <base>
        <path value="Extension.url"/>
        <min value="1"/>
        <max value="1"/>
      </base>
      <type>
        <code value="uri"/>
      </type>
      <fixedUri
              value="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-definitionU
ri"/>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="N/A"/>
      </mapping>
    </element>
    <element id="Extension.valueString">
      <path value="Extension.valueString"/>
      <short value="Value of extension"/>
      <definition
                  value="Value of extension - must be one of a constrained set of the dat
a types (see [Extensibility](http://build.fhir.org/extensibility.html) for a list)."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="Extension.value[x]"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="string"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
```

```
        <mapping>
          <identity value="rim"/>
          <map value="N/A"/>
        </mapping>
      </element>
    </snapshot>
    <differential>
      <element id="Extension">
        <path value="Extension"/>
        <short value="Analytic Procedure URL"/>
        <min value="0"/>
        <max value="1"/>
        <isModifier value="false"/>
      </element>
      <element id="Extension.url">
        <path value="Extension.url"/>
        <type>
          <code value="uri"/>
        </type>
        <fixedUri
                value="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-definitionU
ri"/>
      </element>
      <element id="Extension.valueString">
        <path value="Extension.valueString"/>
        <type>
          <code value="string"/>
        </type>
      </element>
    </differential>
</StructureDefinition>
```

Extension All FHIR elements must have a @value or children (inherited) Must have either extensions or value[x], not both (inherited)

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Extension: Activity focus - Detailed Descriptions

Definitions for the ext-focus Extension

Implementation Guide © 2018+ U.S. Federal Drug Administration - Center for Drug Evaluation and Research. Based on FHIR version (4.0.0). IG generated on Thu, Apr 18, 2019 17:50-0400.

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Extension: Activity focus - Mappings

Mappings for the Extension

Mappings for RIM Mapping (http://hl7.org/v3)

Activity focus	
Extension	
id	n/a
extension	n/a
url	N/A
valueCodeableConcept	N/A

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Extension: Activity focus - XML Profile

XML representation of the ext-focus Extension

```xml
<StructureDefinition xmlns="http://hl7.org/fhir">
  <id value="ext-focus"/>
  <text>
    <status value="generated"/>
    <div xmlns="http://www.w3.org/1999/xhtml"><table border="0" cellpadding="0" cellspacing="0" style="border: 0px #F0F0F0 solid; font-size: 11px; font-family: verdana; vertical-align: top;"><tr style="border: 1px #F0F0F0 solid; font-size: 11px; font-family: verdana; vertical-align: top;"><th style="vertical-align: top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><a href="http://build.fhir.org/formats.html#table" title="The logical name of the element">Name</a></th><th style="vertical-align: top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><a href="http://build.fhir.org/formats.html#table" title="Information about the use of the element">Flags</a></th><th style="vertical-align: top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><a href="http://build.fhir.org/formats.html#table" title="Minimum and Maximum # of times the the element can appear in the instance">Card.</a></th><th style="width: 100px" class="hierarchy"><a href="http://build.fhir.org/formats.html#table" title="Reference to the type of the element">Type</a></th><th style="vertical-align: top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><a href="http://build.fhir.org/formats.html#table" title="Additional information about the element">Description &amp; Constraints</a><span style="float: right"><a href="http://build.fhir.org/formats.html#table" title="Legend for this format"><img src="http://build.fhir.org/help16.png" alt="doco" style="background-color: inherit"/></a></span></th></tr><tr style="border: 0px #F0F0F0 solid; padding:0px; vertical-align: top; background-color: white;"><td style="vertical-align: top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px; white-space: nowrap; background-image: url(tbl_bck1.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="background-color: inherit" class="hierarchy"/><img src="icon_element.gif" alt="." style="background-color: white; background-color: inherit" title="Element" class="hierarchy"/> <a href="extension-ext-focus-definitions.html#Extension">Extension</a><a name="Extension"> </a></td><td style="vertical-align: top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"/><td style="vertical-align: top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy">0..1</td><td style="vertical-align: top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"/><td style="vertical-align: top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy">Activity focus</td></tr>
<tr style="border: 0px #F0F0F0 solid; padding:0px; vertical-align: top; background-color:
```

```
 white;"><td style="vertical-align: top; text-align : left; background-color: white; bord
er: 0px #F0F0F0 solid; padding:0px 4px 0px 4px; white-space: nowrap; background-image: ur
l(tbl_bck10.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="background-c
olor: inherit" class="hierarchy"/><img src="tbl_vjoin.png" alt="." style="background-colo
r: inherit" class="hierarchy"/><img src="icon_primitive.png" alt="." style="background-co
lor: white; background-color: inherit" title="Primitive Data Type" class="hierarchy"/> <a
 href="extension-ext-focus-definitions.html#Extension.url" title="null">url</a><a name="E
xtension.url"> </a></td><td style="vertical-align: top; text-align : left; background-col
or: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"/><td sty
le="vertical-align: top; text-align : left; background-color: white; border: 0px #F0F0F0
solid; padding:0px 4px 0px 4px" class="hierarchy"/><td style="vertical-align: top; text-a
lign : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px"
 class="hierarchy"><a href="http://build.fhir.org/datatypes.html#uri">uri</a></td><td sty
le="vertical-align: top; text-align : left; background-color: white; border: 0px #F0F0F0
solid; padding:0px 4px 0px 4px" class="hierarchy"><span style="color: darkgreen">&quot;ht
tp://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-focus&quot;</span></td></tr>
<tr style="border: 0px #F0F0F0 solid; padding:0px; vertical-align: top; background-color:
 white;"><td style="vertical-align: top; text-align : left; background-color: white; bord
er: 0px #F0F0F0 solid; padding:0px 4px 0px 4px; white-space: nowrap; background-image: ur
l(tbl_bck00.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="background-c
olor: inherit" class="hierarchy"/><img src="tbl_vjoin_end.png" alt="." style="background-
color: inherit" class="hierarchy"/><img src="icon_datatype.gif" alt="." style="background
-color: white; background-color: inherit" title="Data Type" class="hierarchy"/> <a href="
extension-ext-focus-definitions.html#Extension.valueCodeableConcept" title="null">valueCo
deableConcept</a><a name="Extension.valueCodeableConcept"> </a></td><td style="vertical-a
lign: top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding
:0px 4px 0px 4px" class="hierarchy"/><td style="vertical-align: top; text-align : left; b
ackground-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierar
chy"/><td style="vertical-align: top; text-align : left; background-color: white; border:
 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><a href="http://build.fhir
.org/datatypes.html#CodeableConcept">CodeableConcept</a></td><td style="vertical-align: t
op; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4p
x 0px 4px" class="hierarchy"/></tr>
<tr><td colspan="5" class="hierarchy"><br/><a href="http://build.fhir.org/formats.html#ta
ble" title="Legend for this format"><img src="http://build.fhir.org/help16.png" alt="doco
" style="background-color: inherit"/> Documentation for this format</a></td></tr></table>
</div>
  </text>
  <url value="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-focus"/>
  <version value="current"/>
  <name value="Activity focus"/>
  <status value="draft"/>
  <experimental value="false"/>
  <date value="2018-10-05T00:00:00-04:00"/>
  <publisher value="U.S. FDA - CDER division"/>
  <contact>
    <telecom>
      <system value="url"/>
      <value
            value="https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsan
dtobacco/cder"/>
    </telecom>
  </contact>
  <fhirVersion value="4.0.0"/>
  <mapping>
    <identity value="rim"/>
    <uri value="http://hl7.org/v3"/>
```

```
      <name value="RIM Mapping"/>
    </mapping>
    <kind value="complex-type"/>
    <abstract value="false"/>
    <context>
      <type value="element"/>
      <expression value="PlanDefinition.action"/>
    </context>
    <type value="Extension"/>
    <baseDefinition value="http://hl7.org/fhir/StructureDefinition/Extension"/>
    <derivation value="constraint"/>
    <snapshot>
      <element id="Extension">
        <extension
                 url="http://hl7.org/fhir/StructureDefinition/structuredefinition-standar
ds-status">
          <valueCode value="normative"/>
        </extension>
        <extension
                 url="http://hl7.org/fhir/StructureDefinition/structuredefinition-normati
ve-version">
          <valueCode value="4.0.0"/>
        </extension>
        <path value="Extension"/>
        <short value="Activity focus"/>
        <definition value="An Extension"/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Extension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <condition value="ele-1"/>
        <constraint>
          <key value="ele-1"/>
          <severity value="error"/>
          <human value="All FHIR elements must have a @value or children"/>
          <expression value="hasValue() or (children().count() &gt; id.count())"/>
          <xpath value="@value|f:*|h:div"/>
          <source value="Element"/>
        </constraint>
        <constraint>
          <key value="ext-1"/>
          <severity value="error"/>
          <human value="Must have either extensions or value[x], not both"/>
          <expression value="extension.exists() != value.exists()"/>
          <xpath
                value="exists(f:extension)!=exists(f:*[starts-with(local-name(.), &#39;val
ue&#39;)])"/>
          <source value="Extension"/>
        </constraint>
        <isModifier value="false"/>
      </element>
      <element id="Extension.id">
        <path value="Extension.id"/>
        <representation value="xmlAttr"/>
```

```
      <short value="Unique id for inter-element referencing"/>
      <definition
                  value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="Element.id"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="string"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="n/a"/>
      </mapping>
    </element>
    <element id="Extension.extension">
      <path value="Extension.extension"/>
      <slicing>
        <discriminator>
          <type value="value"/>
          <path value="url"/>
        </discriminator>
        <description value="Extensions are always sliced by (at least) url"/>
        <rules value="open"/>
      </slicing>
      <short value="Additional content defined by implementations"/>
      <definition
                  value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
      <comment
               value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
      <alias value="extensions"/>
      <alias value="user content"/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="Element.extension"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Extension"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
```

```xml
      <mapping>
        <identity value="rim"/>
        <map value="n/a"/>
      </mapping>
    </element>
    <element id="Extension.url">
      <path value="Extension.url"/>
      <representation value="xmlAttr"/>
      <short value="identifies the meaning of the extension"/>
      <definition
                   value="Source of the definition for the extension code - a logical name
 or a URL."/>
      <comment
                value="The definition may point directly to a computable or human-readable
 definition of the extensibility codes, or it may be a logical URI as declared in some ot
her specification. The definition SHALL be a URI for the Structure Definition defining th
e extension."/>
      <min value="1"/>
      <max value="1"/>
      <base>
        <path value="Extension.url"/>
        <min value="1"/>
        <max value="1"/>
      </base>
      <type>
        <code value="uri"/>
      </type>
      <fixedUri
                 value="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-focus"/>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="N/A"/>
      </mapping>
    </element>
    <element id="Extension.valueCodeableConcept">
      <path value="Extension.valueCodeableConcept"/>
      <short value="Value of extension"/>
      <definition
                   value="Value of extension - must be one of a constrained set of the dat
a types (see [Extensibility](http://build.fhir.org/extensibility.html) for a list)."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="Extension.value[x]"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="CodeableConcept"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="N/A"/>
```

```
          </mapping>
        </element>
      </snapshot>
      <differential>
        <element id="Extension">
          <path value="Extension"/>
          <short value="Activity focus"/>
          <min value="0"/>
          <max value="1"/>
          <isModifier value="false"/>
        </element>
        <element id="Extension.url">
          <path value="Extension.url"/>
          <type>
            <code value="uri"/>
          </type>
          <fixedUri
                  value="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-focus"/>
        </element>
        <element id="Extension.valueCodeableConcept">
          <path value="Extension.valueCodeableConcept"/>
          <type>
            <code value="CodeableConcept"/>
          </type>
        </element>
      </differential>
    </StructureDefinition>
```

Extension All FHIR elements must have a @value or children (inherited) Must have either extensions or value[x], not both (inherited)

Table of Contents > **Artifact index** > **Name Type**

Content | Detailed Descriptions | Mappings | XML

Extension: nameType - Detailed Descriptions

Definitions for the ext-nameType Extension

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Table of Contents > **Artifact index** > **Name Type**

| Content | Detailed Descriptions | Mappings | XML |

Extension: nameType - Mappings

Mappings for the Extension

Mappings for RIM Mapping (http://hl7.org/v3)

nameType	
Extension	
id	n/a
extension	n/a
url	N/A
value[x]	N/A

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Content   Detailed Descriptions   Mappings   XML

Extension: nameType - XML Profile

XML representation of the ext-nameType Extension

```
<StructureDefinition xmlns="http://hl7.org/fhir">
  <id value="ext-nameType"/>
  <text>
    <status value="generated"/>
    <div xmlns="http://www.w3.org/1999/xhtml"><table border="0" cellpadding="0" cellspaci
ng="0" style="border: 0px #F0F0F0 solid; font-size: 11px; font-family: verdana; vertical-
align: top;"><tr style="border: 1px #F0F0F0 solid; font-size: 11px; font-family: verdana;
 vertical-align: top;"><th style="vertical-align: top; text-align : left; background-colo
r: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><a href="
http://build.fhir.org/formats.html#table" title="The logical name of the element">Name</a
></th><th style="vertical-align: top; text-align : left; background-color: white; border:
 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><a href="http://build.fhir
.org/formats.html#table" title="Information about the use of the element">Flags</a></th><
th style="vertical-align: top; text-align : left; background-color: white; border: 0px #F
0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><a href="http://build.fhir.org/fo
rmats.html#table" title="Minimum and Maximum # of times the the element can appear in the
 instance">Card.</a></th><th style="width: 100px" class="hierarchy"><a href="http://build
.fhir.org/formats.html#table" title="Reference to the type of the element">Type</a></th><
th style="vertical-align: top; text-align : left; background-color: white; border: 0px #F
0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><a href="http://build.fhir.org/fo
rmats.html#table" title="Additional information about the element">Description &amp; Cons
traints</a><span style="float: right"><a href="http://build.fhir.org/formats.html#table"
title="Legend for this format"><img src="http://build.fhir.org/help16.png" alt="doco" sty
le="background-color: inherit"/></a></span></th></tr><tr style="border: 0px #F0F0F0 solid
; padding:0px; vertical-align: top; background-color: white;"><td style="vertical-align:
top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4
px 0px 4px; white-space: nowrap; background-image: url(tbl_bck1.png)" class="hierarchy"><
img src="tbl_spacer.png" alt="." style="background-color: inherit" class="hierarchy"/><im
g src="icon_element.gif" alt="." style="background-color: white; background-color: inheri
t" title="Element" class="hierarchy"/> <a href="extension-ext-nameType-definitions.html#E
xtension">Extension</a><a name="Extension"> </a></td><td style="vertical-align: top; text
-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4p
x" class="hierarchy"/><td style="vertical-align: top; text-align : left; background-color
: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy">0..1</td><
td style="vertical-align: top; text-align : left; background-color: white; border: 0px #F
0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"/><td style="vertical-align: top;
text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0p
x 4px" class="hierarchy">Type of synonym</td></tr>
<tr style="border: 0px #F0F0F0 solid; padding:0px; vertical-align: top; background-color:
```

```
 white;"><td style="vertical-align: top; text-align : left; background-color: white; bord
er: 0px #F0F0F0 solid; padding:0px 4px 0px 4px; white-space: nowrap; background-image: ur
l(tbl_bck00.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="background-c
olor: inherit" class="hierarchy"/><img src="tbl_vjoin_end.png" alt="." style="background-
color: inherit" class="hierarchy"/><img src="icon_primitive.png" alt="." style="backgroun
d-color: white; background-color: inherit" title="Primitive Data Type" class="hierarchy"/
> <a href="extension-ext-nameType-definitions.html#Extension.url" title="null">url</a><a
name="Extension.url"> </a></td><td style="vertical-align: top; text-align : left; backgro
und-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"/>
<td style="vertical-align: top; text-align : left; background-color: white; border: 0px #
F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"/><td style="vertical-align: top;
 text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0
px 4px" class="hierarchy"><a href="http://build.fhir.org/datatypes.html#uri">uri</a></td>
<td style="vertical-align: top; text-align : left; background-color: white; border: 0px #
F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><span style="color: darkgreen">&
quot;http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-nameType&quot;</span></td></t
r>
<tr><td colspan="5" class="hierarchy"><br/><a href="http://build.fhir.org/formats.html#ta
ble" title="Legend for this format"><img src="http://build.fhir.org/help16.png" alt="doco
" style="background-color: inherit"/> Documentation for this format</a></td></tr></table>
</div>
  </text>
  <url value="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-nameType"/>
  <version value="current"/>
  <name value="nameType"/>
  <title value="Name Type"/>
  <status value="draft"/>
  <experimental value="false"/>
  <date value="2018-10-05T00:00:00-04:00"/>
  <publisher value="U.S. FDA - CDER division"/>
  <contact>
    <telecom>
      <system value="url"/>
      <value value="https://www.fda.gov/Drugs/default.htm"/>
    </telecom>
  </contact>
  <fhirVersion value="4.0.0"/>
  <mapping>
    <identity value="rim"/>
    <uri value="http://hl7.org/v3"/>
    <name value="RIM Mapping"/>
  </mapping>
  <kind value="complex-type"/>
  <abstract value="false"/>
  <context>
    <type value="element"/>
    <expression value="MedicationKnowledge.synonym"/>
  </context>
  <type value="Extension"/>
  <baseDefinition value="http://hl7.org/fhir/StructureDefinition/Extension"/>
  <derivation value="constraint"/>
  <snapshot>
    <element id="Extension">
      <extension
               url="http://hl7.org/fhir/StructureDefinition/structuredefinition-standar
ds-status">
        <valueCode value="normative"/>
```

```
        </extension>
        <extension
                 url="http://hl7.org/fhir/StructureDefinition/structuredefinition-normati
ve-version">
          <valueCode value="4.0.0"/>
        </extension>
        <path value="Extension"/>
        <short value="Type of synonym"/>
        <definition value="An Extension"/>
        <comment
                 value="Indicates that the form has been designed with an expectation that
it will be submitted to the specified URI.  If multiple endpoints are specified, expectat
ion is that answers are submitted to all endpoints.

If no end-point is specified, then the form is not exclusively designed to be submitted t
o a specific site.  If and where the form needs to be submitted or how the form should be
 internally processed must be inferred from external context or system business rules."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Extension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <condition value="ele-1"/>
        <constraint>
          <key value="ele-1"/>
          <severity value="error"/>
          <human value="All FHIR elements must have a @value or children"/>
          <expression value="hasValue() or (children().count() &gt; id.count())"/>
          <xpath value="@value|f:*|h:div"/>
          <source value="Element"/>
        </constraint>
        <constraint>
          <key value="ext-1"/>
          <severity value="error"/>
          <human value="Must have either extensions or value[x], not both"/>
          <expression value="extension.exists() != value.exists()"/>
          <xpath
                 value="exists(f:extension)!=exists(f:*[starts-with(local-name(.), &#39;val
ue&#39;)])"/>
          <source value="Extension"/>
        </constraint>
        <isModifier value="false"/>
      </element>
      <element id="Extension.id">
        <path value="Extension.id"/>
        <representation value="xmlAttr"/>
        <short value="Unique id for inter-element referencing"/>
        <definition
                 value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Element.id"/>
          <min value="0"/>
```

```
          <max value="1"/>
        </base>
        <type>
          <code value="string"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="Extension.extension">
        <path value="Extension.extension"/>
        <slicing>
          <discriminator>
            <type value="value"/>
            <path value="url"/>
          </discriminator>
          <description value="Extensions are always sliced by (at least) url"/>
          <rules value="open"/>
        </slicing>
        <short value="Additional content defined by implementations"/>
        <definition
                    value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
        <comment
                value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
        <alias value="extensions"/>
        <alias value="user content"/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="Element.extension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="Extension.url">
        <path value="Extension.url"/>
        <representation value="xmlAttr"/>
        <short value="identifies the meaning of the extension"/>
```

```xml
          <definition
                    value="Source of the definition for the extension code - a logical name
 or a URL."/>
          <comment
                   value="The definition may point directly to a computable or human-readable
 definition of the extensibility codes, or it may be a logical URI as declared in some ot
her specification. The definition SHALL be a URI for the Structure Definition defining th
e extension."/>
          <min value="1"/>
          <max value="1"/>
          <base>
            <path value="Extension.url"/>
            <min value="1"/>
            <max value="1"/>
          </base>
          <type>
            <code value="uri"/>
          </type>
          <fixedUri
                    value="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-nameType"/>
          <isModifier value="false"/>
          <isSummary value="false"/>
          <mapping>
            <identity value="rim"/>
            <map value="N/A"/>
          </mapping>
        </element>
        <element id="Extension.value[x]">
          <path value="Extension.value[x]"/>
          <short value="Value of extension"/>
          <definition
                    value="Value of extension - must be one of a constrained set of the dat
a types (see [Extensibility](http://build.fhir.org/extensibility.html) for a list)."/>
          <min value="0"/>
          <max value="1"/>
          <base>
            <path value="Extension.value[x]"/>
            <min value="0"/>
            <max value="1"/>
          </base>
          <type>
            <code value="base64Binary"/>
          </type>
          <type>
            <code value="boolean"/>
          </type>
          <type>
            <code value="canonical"/>
          </type>
          <type>
            <code value="code"/>
          </type>
          <type>
            <code value="date"/>
          </type>
          <type>
            <code value="dateTime"/>
```

```xml
    </type>
    <type>
      <code value="decimal"/>
    </type>
    <type>
      <code value="id"/>
    </type>
    <type>
      <code value="instant"/>
    </type>
    <type>
      <code value="integer"/>
    </type>
    <type>
      <code value="markdown"/>
    </type>
    <type>
      <code value="oid"/>
    </type>
    <type>
      <code value="positiveInt"/>
    </type>
    <type>
      <code value="string"/>
    </type>
    <type>
      <code value="time"/>
    </type>
    <type>
      <code value="unsignedInt"/>
    </type>
    <type>
      <code value="uri"/>
    </type>
    <type>
      <code value="url"/>
    </type>
    <type>
      <code value="uuid"/>
    </type>
    <type>
      <code value="Address"/>
    </type>
    <type>
      <code value="Age"/>
    </type>
    <type>
      <code value="Annotation"/>
    </type>
    <type>
      <code value="Attachment"/>
    </type>
    <type>
      <code value="CodeableConcept"/>
    </type>
    <type>
      <code value="Coding"/>
```

```xml
    </type>
    <type>
      <code value="ContactPoint"/>
    </type>
    <type>
      <code value="Count"/>
    </type>
    <type>
      <code value="Distance"/>
    </type>
    <type>
      <code value="Duration"/>
    </type>
    <type>
      <code value="HumanName"/>
    </type>
    <type>
      <code value="Identifier"/>
    </type>
    <type>
      <code value="Money"/>
    </type>
    <type>
      <code value="Period"/>
    </type>
    <type>
      <code value="Quantity"/>
    </type>
    <type>
      <code value="Range"/>
    </type>
    <type>
      <code value="Ratio"/>
    </type>
    <type>
      <code value="Reference"/>
    </type>
    <type>
      <code value="SampledData"/>
    </type>
    <type>
      <code value="Signature"/>
    </type>
    <type>
      <code value="Timing"/>
    </type>
    <type>
      <code value="ContactDetail"/>
    </type>
    <type>
      <code value="Contributor"/>
    </type>
    <type>
      <code value="DataRequirement"/>
    </type>
    <type>
      <code value="Expression"/>
```

```xml
        </type>
        <type>
          <code value="ParameterDefinition"/>
        </type>
        <type>
          <code value="RelatedArtifact"/>
        </type>
        <type>
          <code value="TriggerDefinition"/>
        </type>
        <type>
          <code value="UsageContext"/>
        </type>
        <type>
          <code value="Dosage"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="N/A"/>
        </mapping>
      </element>
    </snapshot>
    <differential>
      <element id="Extension">
        <path value="Extension"/>
        <short value="Type of synonym"/>
        <comment
                value="Indicates that the form has been designed with an expectation that
it will be submitted to the specified URI.  If multiple endpoints are specified, expectat
ion is that answers are submitted to all endpoints.

If no end-point is specified, then the form is not exclusively designed to be submitted t
o a specific site.  If and where the form needs to be submitted or how the form should be
 internally processed must be inferred from external context or system business rules."/>
        <min value="0"/>
        <max value="1"/>
        <isModifier value="false"/>
      </element>
      <element id="Extension.url">
        <path value="Extension.url"/>
        <type>
          <code value="uri"/>
        </type>
        <fixedUri
                value="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-nameType"/>
      </element>
    </differential>
</StructureDefinition>
```

Extension All FHIR elements must have a @value or children (inherited) Must have either extensions or value[x], not both (inherited)

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| Content | Detailed Descriptions | Mappings | XML |

Extension: RangeLowExclusive - Detailed Descriptions

Definitions for the ext-range-lowExclusive Extension

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Table of Contents > Artifact index > **Range lower bound exclusive**

| Content | Detailed Descriptions | Mappings | XML |

Extension: RangeLowExclusive - Mappings

Mappings for the Extension

Mappings for RIM Mapping (http://hl7.org/v3)

RangeLowExclusive	
Extension	
id	n/a
url	N/A
valueQuantity	n/a

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Content   Detailed Descriptions   Mappings   XML

Extension: RangeLowExclusive - XML Profile

XML representation of the ext-range-lowExclusive Extension

```xml
<StructureDefinition xmlns="http://hl7.org/fhir">
  <id value="ext-range-lowExclusive"/>
  <text>
    <status value="generated"/>
    <div xmlns="http://www.w3.org/1999/xhtml"><table border="0" cellpadding="0" cellspaci
ng="0" style="border: 0px #F0F0F0 solid; font-size: 11px; font-family: verdana; vertical-
align: top;"><tr style="border: 1px #F0F0F0 solid; font-size: 11px; font-family: verdana;
 vertical-align: top;"><th style="vertical-align: top; text-align : left; background-colo
r: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><a href="
http://build.fhir.org/formats.html#table" title="The logical name of the element">Name</a
></th><th style="vertical-align: top; text-align : left; background-color: white; border:
 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><a href="http://build.fhir
.org/formats.html#table" title="Information about the use of the element">Flags</a></th><
th style="vertical-align: top; text-align : left; background-color: white; border: 0px #F
0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><a href="http://build.fhir.org/fo
rmats.html#table" title="Minimum and Maximum # of times the the element can appear in the
 instance">Card.</a></th><th style="width: 100px" class="hierarchy"><a href="http://build
.fhir.org/formats.html#table" title="Reference to the type of the element">Type</a></th><
th style="vertical-align: top; text-align : left; background-color: white; border: 0px #F
0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><a href="http://build.fhir.org/fo
rmats.html#table" title="Additional information about the element">Description &amp; Cons
traints</a><span style="float: right"><a href="http://build.fhir.org/formats.html#table"
title="Legend for this format"><img src="http://build.fhir.org/help16.png" alt="doco" sty
le="background-color: inherit"/></a></span></th></tr><tr style="border: 0px #F0F0F0 solid
; padding:0px; vertical-align: top; background-color: white;"><td style="vertical-align:
top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4
px 0px 4px; white-space: nowrap; background-image: url(tbl_bck1.png)" class="hierarchy"><
img src="tbl_spacer.png" alt="." style="background-color: inherit" class="hierarchy"/><im
g src="icon_element.gif" alt="." style="background-color: white; background-color: inheri
t" title="Element" class="hierarchy"/> <a href="extension-ext-range-lowExclusive-definiti
ons.html#Extension" title="A lower-bound for the range that excludes the specified value(
rather than the default assumption of inclusive of Range.low)">Extension</a><a name="Exte
nsion"> </a></td><td style="vertical-align: top; text-align : left; background-color: whi
te; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"/><td style="ver
tical-align: top; text-align : left; background-color: white; border: 0px #F0F0F0 solid;
padding:0px 4px 0px 4px" class="hierarchy"/><td style="vertical-align: top; text-align :
left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class=
"hierarchy"/><td style="vertical-align: top; text-align : left; background-color: white;
border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy">Range exclusive low
```

```
er-bound</td></tr>
<tr style="border: 0px #F0F0F0 solid; padding:0px; vertical-align: top; background-color:
 white;"><td style="vertical-align: top; text-align : left; background-color: white; bord
er: 0px #F0F0F0 solid; padding:0px 4px 0px 4px; white-space: nowrap; background-image: ur
l(tbl_bck10.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="background-c
olor: inherit" class="hierarchy"/><img src="tbl_vjoin.png" alt="." style="background-colo
r: inherit" class="hierarchy"/><img src="icon_extension_simple.png" alt="." style="backgr
ound-color: white; background-color: inherit" title="Simple Extension" class="hierarchy"/
> <span style="text-decoration:line-through" title="null">extension</span><a name="Extens
ion.extension"> </a></td><td style="vertical-align: top; text-align : left; background-co
lor: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"/><td st
yle="vertical-align: top; text-align : left; background-color: white; border: 0px #F0F0F0
 solid; padding:0px 4px 0px 4px" class="hierarchy"><span style="text-decoration:line-thro
ugh"/><span style="text-decoration:line-through"></span><span style="text-decoration:line
-through">..</span><span style="text-decoration:line-through">0</span></td><td style="ver
tical-align: top; text-align : left; background-color: white; border: 0px #F0F0F0 solid;
padding:0px 4px 0px 4px" class="hierarchy"/><td style="vertical-align: top; text-align :
left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class=
"hierarchy"/></tr>
<tr style="border: 0px #F0F0F0 solid; padding:0px; vertical-align: top; background-color:
 white;"><td style="vertical-align: top; text-align : left; background-color: white; bord
er: 0px #F0F0F0 solid; padding:0px 4px 0px 4px; white-space: nowrap; background-image: ur
l(tbl_bck10.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="background-c
olor: inherit" class="hierarchy"/><img src="tbl_vjoin.png" alt="." style="background-colo
r: inherit" class="hierarchy"/><img src="icon_element.gif" alt="." style="background-colo
r: white; background-color: inherit" title="Element" class="hierarchy"/> <a href="extensi
on-ext-range-lowExclusive-definitions.html#Extension.url" title="null">url</a><a name="Ex
tension.url"> </a></td><td style="vertical-align: top; text-align : left; background-colo
r: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"/><td styl
e="vertical-align: top; text-align : left; background-color: white; border: 0px #F0F0F0 s
olid; padding:0px 4px 0px 4px" class="hierarchy">1..</td><td style="vertical-align: top;
text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0p
x 4px" class="hierarchy"/><td style="vertical-align: top; text-align : left; background-c
olor: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><span
style="color: darkgreen">&quot;http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-ran
ge-lowExclusive&quot;</span></td></tr>
<tr style="border: 0px #F0F0F0 solid; padding:0px; vertical-align: top; background-color:
 white;"><td style="vertical-align: top; text-align : left; background-color: white; bord
er: 0px #F0F0F0 solid; padding:0px 4px 0px 4px; white-space: nowrap; background-image: ur
l(tbl_bck00.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="background-c
olor: inherit" class="hierarchy"/><img src="tbl_vjoin_end.png" alt="." style="background-
color: inherit" class="hierarchy"/><img src="icon_datatype.gif" alt="." style="background
-color: white; background-color: inherit" title="Data Type" class="hierarchy"/> <a href="
extension-ext-range-lowExclusive-definitions.html#Extension.valueQuantity" title="null">v
alueQuantity</a><a name="Extension.valueQuantity"> </a></td><td style="vertical-align: to
p; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px
 0px 4px" class="hierarchy"/><td style="vertical-align: top; text-align : left; backgroun
d-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"/><t
d style="vertical-align: top; text-align : left; background-color: white; border: 0px #F0
F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><a href="http://build.fhir.org/dat
atypes.html#SimpleQuantity" title="Quantity">SimpleQuantity</a></td><td style="vertical-a
lign: top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding
:0px 4px 0px 4px" class="hierarchy">Value of lower exclusive boundary</td></tr>
<tr><td colspan="5" class="hierarchy"><br/><a href="http://build.fhir.org/formats.html#ta
ble" title="Legend for this format"><img src="http://build.fhir.org/help16.png" alt="doco
" style="background-color: inherit"/> Documentation for this format</a></td></tr></table>
</div>
```

```xml
    </text>
    <url
        value="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-range-lowExclusive"/
>
    <version value="current"/>
    <name value="RangeLowExclusive"/>
    <title value="Range exclusive lower-bound"/>
    <status value="draft"/>
    <date value="2019-03-05T11:52:49-05:00"/>
    <description
                value="A lower-bound for the range that excludes the specified value(rathe
r than the default assumption of inclusive of Range.low)"/>
    <fhirVersion value="4.0.0"/>
    <mapping>
      <identity value="rim"/>
      <uri value="http://hl7.org/v3"/>
      <name value="RIM Mapping"/>
    </mapping>
    <kind value="complex-type"/>
    <abstract value="false"/>
    <context>
      <type value="element"/>
      <expression value="Range"/>
    </context>
    <type value="Extension"/>
    <baseDefinition value="http://hl7.org/fhir/StructureDefinition/Extension"/>
    <derivation value="constraint"/>
    <snapshot>
      <element id="Extension">
        <extension
                  url="http://hl7.org/fhir/StructureDefinition/structuredefinition-standar
ds-status">
          <valueCode value="normative"/>
        </extension>
        <extension
                  url="http://hl7.org/fhir/StructureDefinition/structuredefinition-normati
ve-version">
          <valueCode value="4.0.0"/>
        </extension>
        <path value="Extension"/>
        <short value="Range exclusive lower-bound"/>
        <definition
                    value="A lower-bound for the range that excludes the specified value(ra
ther than the default assumption of inclusive of Range.low)"/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="Extension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <condition value="ele-1"/>
        <constraint>
          <key value="ele-1"/>
          <severity value="error"/>
          <human value="All FHIR elements must have a @value or children"/>
          <expression value="hasValue() or (children().count() &gt; id.count())"/>
```

```
          <xpath value="@value|f:*|h:div"/>
          <source value="Element"/>
      </constraint>
      <constraint>
          <key value="ext-1"/>
          <severity value="error"/>
          <human value="Must have either extensions or value[x], not both"/>
          <expression value="extension.exists() != value.exists()"/>
          <xpath
                  value="exists(f:extension)!=exists(f:*[starts-with(local-name(.), &#39;val
ue&#39;)])"/>
          <source value="Extension"/>
      </constraint>
      <isModifier value="false"/>
    </element>
    <element id="Extension.id">
      <path value="Extension.id"/>
      <representation value="xmlAttr"/>
      <short value="Unique id for inter-element referencing"/>
      <definition
                  value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="Element.id"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="string"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="n/a"/>
      </mapping>
    </element>
    <element id="Extension.extension">
      <path value="Extension.extension"/>
      <slicing>
        <discriminator>
          <type value="value"/>
          <path value="url"/>
        </discriminator>
        <description value="Extensions are always sliced by (at least) url"/>
        <rules value="open"/>
      </slicing>
      <short value="Extension"/>
      <definition value="An Extension"/>
      <min value="0"/>
      <max value="0"/>
      <base>
        <path value="Element.extension"/>
        <min value="0"/>
        <max value="*"/>
```

```
        </base>
        <type>
          <code value="Extension"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="Extension.url">
        <path value="Extension.url"/>
        <representation value="xmlAttr"/>
        <short value="identifies the meaning of the extension"/>
        <definition
                   value="Source of the definition for the extension code - a logical name
 or a URL."/>
        <comment
                value="The definition may point directly to a computable or human-readable
 definition of the extensibility codes, or it may be a logical URI as declared in some ot
her specification. The definition SHALL be a URI for the Structure Definition defining th
e extension."/>
        <min value="1"/>
        <max value="1"/>
        <base>
          <path value="Extension.url"/>
          <min value="1"/>
          <max value="1"/>
        </base>
        <type>
          <code>
            <extension
                      url="http://hl7.org/fhir/StructureDefinition/structuredefinition-jso
n-type">
              <valueString value="string"/>
            </extension>
            <extension
                      url="http://hl7.org/fhir/StructureDefinition/structuredefinition-xml
-type">
              <valueString value="xsd:string"/>
            </extension>
            <extension
                      url="http://hl7.org/fhir/StructureDefinition/structuredefinition-rdf
-type">
              <valueString value="xsd:string"/>
            </extension>
            <extension url="http://hl7.org/fhir/StructureDefinition/regex">
              <valueString
                          value="((http|https)://([A-Za-z0-9\\\.\:\%\$]*\/)*)?(Account|Act
ivityDefinition|AdverseEvent|AllergyIntolerance|Appointment|AppointmentResponse|AuditEven
t|Basic|Binary|BiologicallyDerivedProduct|BodyStructure|Bundle|CapabilityStatement|CarePl
an|CareTeam|CatalogEntry|ChargeItem|ChargeItemDefinition|Claim|ClaimResponse|ClinicalImpr
ession|CodeSystem|Communication|CommunicationRequest|CompartmentDefinition|Composition|Co
nceptMap|Condition|Consent|Contract|Coverage|CoverageEligibilityRequest|CoverageEligibili
tyResponse|DetectedIssue|Device|DeviceDefinition|DeviceMetric|DeviceRequest|DeviceUseStat
ement|DiagnosticReport|DocumentManifest|DocumentReference|EffectEvidenceSynthesis|Encount
er|Endpoint|EnrollmentRequest|EnrollmentResponse|EpisodeOfCare|EventDefinition|Evidence|E
videnceVariable|ExampleScenario|ExplanationOfBenefit|FamilyMemberHistory|Flag|Goal|GraphD
efinition|Group|GuidanceResponse|HealthcareService|ImagingStudy|Immunization|Immunization
Evaluation|ImmunizationRecommendation|ImplementationGuide|InsurancePlan|Invoice|Library|L
```

```
inkage|List|Location|Measure|MeasureReport|Media|Medication|MedicationAdministration|Medi
cationDispense|MedicationKnowledge|MedicationRequest|MedicationStatement|MedicinalProduct
|MedicinalProductAuthorization|MedicinalProductContraindication|MedicinalProductIndicatio
n|MedicinalProductIngredient|MedicinalProductInteraction|MedicinalProductManufactured|Med
icinalProductPackaged|MedicinalProductPharmaceutical|MedicinalProductUndesirableEffect|Me
ssageDefinition|MessageHeader|MolecularSequence|NamingSystem|NutritionOrder|Observation|O
bservationDefinition|OperationDefinition|OperationOutcome|Organization|OrganizationAffili
ation|Patient|PaymentNotice|PaymentReconciliation|Person|PlanDefinition|Practitioner|Prac
titionerRole|Procedure|Provenance|Questionnaire|QuestionnaireResponse|RelatedPerson|Reque
stGroup|ResearchDefinition|ResearchElementDefinition|ResearchStudy|ResearchSubject|RiskAs
sessment|RiskEvidenceSynthesis|Schedule|SearchParameter|ServiceRequest|Slot|Specimen|Spec
imenDefinition|StructureDefinition|StructureMap|Subscription|Substance|SubstanceNucleicAc
id|SubstancePolymer|SubstanceProtein|SubstanceReferenceInformation|SubstanceSourceMateria
l|SubstanceSpecification|SupplyDelivery|SupplyRequest|Task|TerminologyCapabilities|TestRe
port|TestScript|ValueSet|VerificationResult|VisionPrescription)\/[A-Za-z0-9\-\.]{1,64}(\/
_history\/[A-Za-z0-9\-\.]{1,64})?"/>
                </extension>
            </code>
        </type>
        <fixedUri
                value="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-range-lowEx
clusive"/>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="N/A"/>
        </mapping>
    </element>
    <element id="Extension.valueQuantity">
        <extension
                url="http://hl7.org/fhir/StructureDefinition/structuredefinition-standar
ds-status">
          <valueCode value="normative"/>
        </extension>
        <extension
                url="http://hl7.org/fhir/StructureDefinition/structuredefinition-normati
ve-version">
          <valueCode value="4.0.0"/>
        </extension>
        <path value="Extension.valueQuantity"/>
        <short value="Value of lower exclusive boundary"/>
        <definition value="The comparator is not used on a SimpleQuantity"/>
        <comment
                value="The context of use may frequently define what kind of quantity this
 is and therefore what kind of units can be used. The context of use may also restrict th
e values for the comparator."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Extension.value[x]"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="Quantity"/>
          <profile value="http://hl7.org/fhir/StructureDefinition/SimpleQuantity"/>
```

```
        </type>
        <condition value="ele-1"/>
        <constraint>
          <key value="ele-1"/>
          <severity value="error"/>
          <human value="All FHIR elements must have a @value or children"/>
          <expression value="hasValue() or (children().count() &gt; id.count())"/>
          <xpath value="@value|f:*|h:div"/>
          <source value="Element"/>
        </constraint>
        <constraint>
          <key value="qty-3"/>
          <severity value="error"/>
          <human
                value="If a code for the unit is present, the system SHALL also be present
"/>
          <expression value="code.empty() or system.exists()"/>
          <xpath value="not(exists(f:code)) or exists(f:system)"/>
          <source value="Quantity"/>
        </constraint>
        <constraint>
          <key value="sqty-1"/>
          <severity value="error"/>
          <human value="The comparator is not used on a SimpleQuantity"/>
          <expression value="comparator.empty()"/>
          <xpath value="not(exists(f:comparator))"/>
          <source value="Quantity"/>
        </constraint>
        <isModifier value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
        <mapping>
          <identity value="v2"/>
          <map value="SN (see also Range) or CQ"/>
        </mapping>
        <mapping>
          <identity value="rim"/>
          <map value="PQ, IVL&lt;PQ&gt;, MO, CO, depending on the values"/>
        </mapping>
      </element>
    </snapshot>
    <differential>
      <element id="Extension">
        <path value="Extension"/>
        <short value="Range exclusive lower-bound"/>
        <definition
                    value="A lower-bound for the range that excludes the specified value(ra
ther than the default assumption of inclusive of Range.low)"/>
      </element>
      <element id="Extension.extension">
        <path value="Extension.extension"/>
        <max value="0"/>
      </element>
      <element id="Extension.url">
        <path value="Extension.url"/>
```

```xml
          <min value="1"/>
          <fixedUri
                  value="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-range-lowEx
clusive"/>
      </element>
      <element id="Extension.valueQuantity">
        <path value="Extension.valueQuantity"/>
        <short value="Value of lower exclusive boundary"/>
        <type>
          <code value="Quantity"/>
          <profile value="http://hl7.org/fhir/StructureDefinition/SimpleQuantity"/>
        </type>
      </element>
  </differential>
</StructureDefinition>
```

Extension All FHIR elements must have a @value or children (inherited) Must have either extensions or value[x], not both (inherited) Extension.valueQuantity All FHIR elements must have a @value or children (inherited) If a code for the unit is present, the system SHALL also be present (inherited) The comparator is not used on a SimpleQuantity (inherited)

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Content | Detailed Descriptions | Mappings | XML

Extension: RangeHighExclusive - Detailed Descriptions

Definitions for the ext-range-highExclusive Extension

Table of Contents > Artifact index > **Range upper bound exclusive**

Content | Detailed Descriptions | Mappings | XML

Extension: RangeHighExclusive - Mappings

Mappings for the Extension

Mappings for RIM Mapping (http://hl7.org/v3)

RangeHighExclusive	
Extension	
id	n/a
url	N/A
valueQuantity	n/a

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IG Home   Artifact Index   FHIR Spec

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| Content | Detailed Descriptions | Mappings | XML |

Extension: RangeHighExclusive - XML Profile

XML representation of the ext-range-highExclusive Extension

```xml
<StructureDefinition xmlns="http://hl7.org/fhir">
  <id value="ext-range-highExclusive"/>
  <text>
    <status value="generated"/>
    <div xmlns="http://www.w3.org/1999/xhtml"><table border="0" cellpadding="0" cellspaci
ng="0" style="border: 0px #F0F0F0 solid; font-size: 11px; font-family: verdana; vertical-
align: top;"><tr style="border: 1px #F0F0F0 solid; font-size: 11px; font-family: verdana;
 vertical-align: top;"><th style="vertical-align: top; text-align : left; background-colo
r: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><a href="
http://build.fhir.org/formats.html#table" title="The logical name of the element">Name</a
></th><th style="vertical-align: top; text-align : left; background-color: white; border:
 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><a href="http://build.fhir
.org/formats.html#table" title="Information about the use of the element">Flags</a></th><
th style="vertical-align: top; text-align : left; background-color: white; border: 0px #F
0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><a href="http://build.fhir.org/fo
rmats.html#table" title="Minimum and Maximum # of times the the element can appear in the
 instance">Card.</a></th><th style="width: 100px" class="hierarchy"><a href="http://build
.fhir.org/formats.html#table" title="Reference to the type of the element">Type</a></th><
th style="vertical-align: top; text-align : left; background-color: white; border: 0px #F
0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><a href="http://build.fhir.org/fo
rmats.html#table" title="Additional information about the element">Description &amp; Cons
traints</a><span style="float: right"><a href="http://build.fhir.org/formats.html#table"
title="Legend for this format"><img src="http://build.fhir.org/help16.png" alt="doco" sty
le="background-color: inherit"/></a></span></th></tr><tr style="border: 0px #F0F0F0 solid
; padding:0px; vertical-align: top; background-color: white;"><td style="vertical-align:
top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4
px 0px 4px; white-space: nowrap; background-image: url(tbl_bck1.png)" class="hierarchy"><
img src="tbl_spacer.png" alt="." style="background-color: inherit" class="hierarchy"/><im
g src="icon_element.gif" alt="." style="background-color: white; background-color: inheri
t" title="Element" class="hierarchy"/> <a href="extension-ext-range-highExclusive-definit
ions.html#Extension" title="An upper-bound for the range that excludes the specified valu
e(rather than the default assumption of inclusive of Range.high)">Extension</a><a name="E
xtension"> </a></td><td style="vertical-align: top; text-align : left; background-color:
white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"/><td style="
vertical-align: top; text-align : left; background-color: white; border: 0px #F0F0F0 soli
d; padding:0px 4px 0px 4px" class="hierarchy"/><td style="vertical-align: top; text-align
 : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" cla
ss="hierarchy"/><td style="vertical-align: top; text-align : left; background-color: whit
e; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy">Range exclusive
```

```
upper-bound</td></tr>
<tr style="border: 0px #F0F0F0 solid; padding:0px; vertical-align: top; background-color:
 white;"><td style="vertical-align: top; text-align : left; background-color: white; bord
er: 0px #F0F0F0 solid; padding:0px 4px 0px 4px; white-space: nowrap; background-image: ur
l(tbl_bck10.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="background-c
olor: inherit" class="hierarchy"/><img src="tbl_vjoin.png" alt="." style="background-colo
r: inherit" class="hierarchy"/><img src="icon_extension_simple.png" alt="." style="backgr
ound-color: white; background-color: inherit" title="Simple Extension" class="hierarchy"/
> <span style="text-decoration:line-through" title="null">extension</span><a name="Extens
ion.extension"> </a></td><td style="vertical-align: top; text-align : left; background-co
lor: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"/><td st
yle="vertical-align: top; text-align : left; background-color: white; border: 0px #F0F0F0
 solid; padding:0px 4px 0px 4px" class="hierarchy"><span style="text-decoration:line-thro
ugh"/><span style="text-decoration:line-through"></span><span style="text-decoration:line
-through">..</span><span style="text-decoration:line-through">0</span></td><td style="ver
tical-align: top; text-align : left; background-color: white; border: 0px #F0F0F0 solid;
padding:0px 4px 0px 4px" class="hierarchy"/><td style="vertical-align: top; text-align :
left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class=
"hierarchy"/></tr>
<tr style="border: 0px #F0F0F0 solid; padding:0px; vertical-align: top; background-color:
 white;"><td style="vertical-align: top; text-align : left; background-color: white; bord
er: 0px #F0F0F0 solid; padding:0px 4px 0px 4px; white-space: nowrap; background-image: ur
l(tbl_bck10.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="background-c
olor: inherit" class="hierarchy"/><img src="tbl_vjoin.png" alt="." style="background-colo
r: inherit" class="hierarchy"/><img src="icon_element.gif" alt="." style="background-colo
r: white; background-color: inherit" title="Element" class="hierarchy"/> <a href="extensi
on-ext-range-highExclusive-definitions.html#Extension.url" title="null">url</a><a name="E
xtension.url"> </a></td><td style="vertical-align: top; text-align : left; background-col
or: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"/><td sty
le="vertical-align: top; text-align : left; background-color: white; border: 0px #F0F0F0
solid; padding:0px 4px 0px 4px" class="hierarchy">1..</td><td style="vertical-align: top;
 text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0
px 4px" class="hierarchy"/><td style="vertical-align: top; text-align : left; background-
color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><span
 style="color: darkgreen">&quot;http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-ra
nge-highExclusive&quot;</span></td></tr>
<tr style="border: 0px #F0F0F0 solid; padding:0px; vertical-align: top; background-color:
 white;"><td style="vertical-align: top; text-align : left; background-color: white; bord
er: 0px #F0F0F0 solid; padding:0px 4px 0px 4px; white-space: nowrap; background-image: ur
l(tbl_bck00.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="background-c
olor: inherit" class="hierarchy"/><img src="tbl_vjoin_end.png" alt="." style="background-
color: inherit" class="hierarchy"/><img src="icon_datatype.gif" alt="." style="background
-color: white; background-color: inherit" title="Data Type" class="hierarchy"/> <a href="
extension-ext-range-highExclusive-definitions.html#Extension.valueQuantity" title="null">
valueQuantity</a><a name="Extension.valueQuantity"> </a></td><td style="vertical-align: t
op; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4p
x 0px 4px" class="hierarchy"/><td style="vertical-align: top; text-align : left; backgrou
nd-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"/><
td style="vertical-align: top; text-align : left; background-color: white; border: 0px #F
0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><a href="http://build.fhir.org/da
tatypes.html#SimpleQuantity" title="Quantity">SimpleQuantity</a></td><td style="vertical-
align: top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; paddin
g:0px 4px 0px 4px" class="hierarchy">Value of upper exclusive boundary</td></tr>
<tr><td colspan="5" class="hierarchy"><br/><a href="http://build.fhir.org/formats.html#ta
ble" title="Legend for this format"><img src="http://build.fhir.org/help16.png" alt="doco
" style="background-color: inherit"/> Documentation for this format</a></td></tr></table>
</div>
```

```
    </text>
    <url
        value="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-range-highExclusive"
/>
    <version value="current"/>
    <name value="RangeHighExclusive"/>
    <title value="Range exclusive upper-bound"/>
    <status value="draft"/>
    <date value="2019-03-05T11:52:49-05:00"/>
    <description
                value="An upper-bound for the range that excludes the specified value(rath
er than the default assumption of inclusive of Range.high)"/>
    <fhirVersion value="4.0.0"/>
    <mapping>
      <identity value="rim"/>
      <uri value="http://hl7.org/v3"/>
      <name value="RIM Mapping"/>
    </mapping>
    <kind value="complex-type"/>
    <abstract value="false"/>
    <context>
      <type value="element"/>
      <expression value="Range"/>
    </context>
    <type value="Extension"/>
    <baseDefinition value="http://hl7.org/fhir/StructureDefinition/Extension"/>
    <derivation value="constraint"/>
    <snapshot>
      <element id="Extension">
        <extension
                  url="http://hl7.org/fhir/StructureDefinition/structuredefinition-standar
ds-status">
          <valueCode value="normative"/>
        </extension>
        <extension
                  url="http://hl7.org/fhir/StructureDefinition/structuredefinition-normati
ve-version">
          <valueCode value="4.0.0"/>
        </extension>
        <path value="Extension"/>
        <short value="Range exclusive upper-bound"/>
        <definition
                    value="An upper-bound for the range that excludes the specified value(r
ather than the default assumption of inclusive of Range.high)"/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="Extension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <condition value="ele-1"/>
        <constraint>
          <key value="ele-1"/>
          <severity value="error"/>
          <human value="All FHIR elements must have a @value or children"/>
          <expression value="hasValue() or (children().count() &gt; id.count())"/>
```

```xml
        <xpath value="@value|f:*|h:div"/>
        <source value="Element"/>
      </constraint>
      <constraint>
        <key value="ext-1"/>
        <severity value="error"/>
        <human value="Must have either extensions or value[x], not both"/>
        <expression value="extension.exists() != value.exists()"/>
        <xpath
              value="exists(f:extension)!=exists(f:*[starts-with(local-name(.), &#39;val
ue&#39;)])"/>
        <source value="Extension"/>
      </constraint>
      <isModifier value="false"/>
    </element>
    <element id="Extension.id">
      <path value="Extension.id"/>
      <representation value="xmlAttr"/>
      <short value="Unique id for inter-element referencing"/>
      <definition
                value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="Element.id"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="string"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="n/a"/>
      </mapping>
    </element>
    <element id="Extension.extension">
      <path value="Extension.extension"/>
      <slicing>
        <discriminator>
          <type value="value"/>
          <path value="url"/>
        </discriminator>
        <description value="Extensions are always sliced by (at least) url"/>
        <rules value="open"/>
      </slicing>
      <short value="Extension"/>
      <definition value="An Extension"/>
      <min value="0"/>
      <max value="0"/>
      <base>
        <path value="Element.extension"/>
        <min value="0"/>
        <max value="*"/>
```

```xml
      </base>
      <type>
        <code value="Extension"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="Extension.url">
      <path value="Extension.url"/>
      <representation value="xmlAttr"/>
      <short value="identifies the meaning of the extension"/>
      <definition
                  value="Source of the definition for the extension code - a logical name
 or a URL."/>
      <comment
               value="The definition may point directly to a computable or human-readable
 definition of the extensibility codes, or it may be a logical URI as declared in some ot
her specification. The definition SHALL be a URI for the Structure Definition defining th
e extension."/>
      <min value="1"/>
      <max value="1"/>
      <base>
        <path value="Extension.url"/>
        <min value="1"/>
        <max value="1"/>
      </base>
      <type>
        <code>
          <extension
                     url="http://hl7.org/fhir/StructureDefinition/structuredefinition-jso
n-type">
            <valueString value="string"/>
          </extension>
          <extension
                     url="http://hl7.org/fhir/StructureDefinition/structuredefinition-xml
-type">
            <valueString value="xsd:string"/>
          </extension>
          <extension
                     url="http://hl7.org/fhir/StructureDefinition/structuredefinition-rdf
-type">
            <valueString value="xsd:string"/>
          </extension>
          <extension url="http://hl7.org/fhir/StructureDefinition/regex">
            <valueString
                         value="((http|https)://([A-Za-z0-9\\\.\:\%\$]*\/)*)?(Account|Act
ivityDefinition|AdverseEvent|AllergyIntolerance|Appointment|AppointmentResponse|AuditEven
t|Basic|Binary|BiologicallyDerivedProduct|BodyStructure|Bundle|CapabilityStatement|CarePl
an|CareTeam|CatalogEntry|ChargeItem|ChargeItemDefinition|Claim|ClaimResponse|ClinicalImpr
ession|CodeSystem|Communication|CommunicationRequest|CompartmentDefinition|Composition|Co
nceptMap|Condition|Consent|Contract|Coverage|CoverageEligibilityRequest|CoverageEligibili
tyResponse|DetectedIssue|Device|DeviceDefinition|DeviceMetric|DeviceRequest|DeviceUseStat
ement|DiagnosticReport|DocumentManifest|DocumentReference|EffectEvidenceSynthesis|Encount
er|Endpoint|EnrollmentRequest|EnrollmentResponse|EpisodeOfCare|EventDefinition|Evidence|E
videnceVariable|ExampleScenario|ExplanationOfBenefit|FamilyMemberHistory|Flag|Goal|GraphD
efinition|Group|GuidanceResponse|HealthcareService|ImagingStudy|Immunization|Immunization
Evaluation|ImmunizationRecommendation|ImplementationGuide|InsurancePlan|Invoice|Library|L
```

```
inkage|List|Location|Measure|MeasureReport|Media|Medication|MedicationAdministration|Medi
cationDispense|MedicationKnowledge|MedicationRequest|MedicationStatement|MedicinalProduct
|MedicinalProductAuthorization|MedicinalProductContraindication|MedicinalProductIndicatio
n|MedicinalProductIngredient|MedicinalProductInteraction|MedicinalProductManufactured|Med
icinalProductPackaged|MedicinalProductPharmaceutical|MedicinalProductUndesirableEffect|Me
ssageDefinition|MessageHeader|MolecularSequence|NamingSystem|NutritionOrder|Observation|O
bservationDefinition|OperationDefinition|OperationOutcome|Organization|OrganizationAffili
ation|Patient|PaymentNotice|PaymentReconciliation|Person|PlanDefinition|Practitioner|Prac
titionerRole|Procedure|Provenance|Questionnaire|QuestionnaireResponse|RelatedPerson|Reque
stGroup|ResearchDefinition|ResearchElementDefinition|ResearchStudy|ResearchSubject|RiskAs
sessment|RiskEvidenceSynthesis|Schedule|SearchParameter|ServiceRequest|Slot|Specimen|Spec
imenDefinition|StructureDefinition|StructureMap|Subscription|Substance|SubstanceNucleicAc
id|SubstancePolymer|SubstanceProtein|SubstanceReferenceInformation|SubstanceSourceMateria
l|SubstanceSpecification|SupplyDelivery|SupplyRequest|Task|TerminologyCapabilities|TestRe
port|TestScript|ValueSet|VerificationResult|VisionPrescription)\/[A-Za-z0-9\-\.]{1,64}(\/
_history\/[A-Za-z0-9\-\.]{1,64})?"/>
              </extension>
          </code>
        </type>
        <fixedUri
                value="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-range-highE
xclusive"/>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="N/A"/>
        </mapping>
      </element>
      <element id="Extension.valueQuantity">
        <extension
                url="http://hl7.org/fhir/StructureDefinition/structuredefinition-standar
ds-status">
          <valueCode value="normative"/>
        </extension>
        <extension
                url="http://hl7.org/fhir/StructureDefinition/structuredefinition-normati
ve-version">
          <valueCode value="4.0.0"/>
        </extension>
        <path value="Extension.valueQuantity"/>
        <short value="Value of upper exclusive boundary"/>
        <definition value="The comparator is not used on a SimpleQuantity"/>
        <comment
                value="The context of use may frequently define what kind of quantity this
 is and therefore what kind of units can be used. The context of use may also restrict th
e values for the comparator."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Extension.value[x]"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="Quantity"/>
          <profile value="http://hl7.org/fhir/StructureDefinition/SimpleQuantity"/>
```

```xml
        </type>
        <condition value="ele-1"/>
        <constraint>
          <key value="ele-1"/>
          <severity value="error"/>
          <human value="All FHIR elements must have a @value or children"/>
          <expression value="hasValue() or (children().count() &gt; id.count())"/>
          <xpath value="@value|f:*|h:div"/>
          <source value="Element"/>
        </constraint>
        <constraint>
          <key value="qty-3"/>
          <severity value="error"/>
          <human
                  value="If a code for the unit is present, the system SHALL also be present
"/>
          <expression value="code.empty() or system.exists()"/>
          <xpath value="not(exists(f:code)) or exists(f:system)"/>
          <source value="Quantity"/>
        </constraint>
        <constraint>
          <key value="sqty-1"/>
          <severity value="error"/>
          <human value="The comparator is not used on a SimpleQuantity"/>
          <expression value="comparator.empty()"/>
          <xpath value="not(exists(f:comparator))"/>
          <source value="Quantity"/>
        </constraint>
        <isModifier value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
        <mapping>
          <identity value="v2"/>
          <map value="SN (see also Range) or CQ"/>
        </mapping>
        <mapping>
          <identity value="rim"/>
          <map value="PQ, IVL&lt;PQ&gt;, MO, CO, depending on the values"/>
        </mapping>
      </element>
    </snapshot>
    <differential>
      <element id="Extension">
        <path value="Extension"/>
        <short value="Range exclusive upper-bound"/>
        <definition
                    value="An upper-bound for the range that excludes the specified value(r
ather than the default assumption of inclusive of Range.high)"/>
      </element>
      <element id="Extension.extension">
        <path value="Extension.extension"/>
        <max value="0"/>
      </element>
      <element id="Extension.url">
        <path value="Extension.url"/>
```

```
          <min value="1"/>
          <fixedUri
                  value="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-range-highE
xclusive"/>
      </element>
      <element id="Extension.valueQuantity">
        <path value="Extension.valueQuantity"/>
        <short value="Value of upper exclusive boundary"/>
        <type>
          <code value="Quantity"/>
          <profile value="http://hl7.org/fhir/StructureDefinition/SimpleQuantity"/>
        </type>
      </element>
    </differential>
</StructureDefinition>
```

Extension All FHIR elements must have a @value or children (inherited) Must have either extensions or value[x], not both (inherited) Extension.valueQuantity All FHIR elements must have a @value or children (inherited) If a code for the unit is present, the system SHALL also be present (inherited) The comparator is not used on a SimpleQuantity (inherited)

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Table of Contents > **Artifact index** > **Content Percent**

| Content | **Detailed Descriptions** | Mappings | XML |

Extension: contentPercent - Detailed Descriptions

Definitions for the ext-contentPercent Extension

PQCMC **Proof of Concept** current - Continuous Build

Table of Contents > Artifact index > Content Percent

| Content | Detailed Descriptions | Mappings | XML |

Extension: contentPercent - Mappings

Mappings for the Extension

Mappings for RIM Mapping (http://hl7.org/v3)

contentPercent	
Extension	
id	n/a
extension	n/a
url	N/A
valueDecimal	N/A

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Table of Contents > **Artifact index** > **Content Percent**

Content | Detailed Descriptions | Mappings | XML

Extension: contentPercent - XML Profile

XML representation of the ext-contentPercent Extension

```
<StructureDefinition xmlns="http://hl7.org/fhir">
  <id value="ext-contentPercent"/>
  <text>
    <status value="generated"/>
    <div xmlns="http://www.w3.org/1999/xhtml"><table border="0" cellpadding="0" cellspaci
ng="0" style="border: 0px #F0F0F0 solid; font-size: 11px; font-family: verdana; vertical-
align: top;"><tr style="border: 1px #F0F0F0 solid; font-size: 11px; font-family: verdana;
 vertical-align: top;"><th style="vertical-align: top; text-align : left; background-colo
r: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><a href="
http://build.fhir.org/formats.html#table" title="The logical name of the element">Name</a
></th><th style="vertical-align: top; text-align : left; background-color: white; border:
 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><a href="http://build.fhir
.org/formats.html#table" title="Information about the use of the element">Flags</a></th><
th style="vertical-align: top; text-align : left; background-color: white; border: 0px #F
0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><a href="http://build.fhir.org/fo
rmats.html#table" title="Minimum and Maximum # of times the the element can appear in the
 instance">Card.</a></th><th style="width: 100px" class="hierarchy"><a href="http://build
.fhir.org/formats.html#table" title="Reference to the type of the element">Type</a></th><
th style="vertical-align: top; text-align : left; background-color: white; border: 0px #F
0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><a href="http://build.fhir.org/fo
rmats.html#table" title="Additional information about the element">Description &amp; Cons
traints</a><span style="float: right"><a href="http://build.fhir.org/formats.html#table"
title="Legend for this format"><img src="http://build.fhir.org/help16.png" alt="doco" sty
le="background-color: inherit"/></a></span></th></tr><tr style="border: 0px #F0F0F0 solid
; padding:0px; vertical-align: top; background-color: white;"><td style="vertical-align:
top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4
px 0px 4px; white-space: nowrap; background-image: url(tbl_bck1.png)" class="hierarchy"><
img src="tbl_spacer.png" alt="." style="background-color: inherit" class="hierarchy"/><im
g src="icon_element.gif" alt="." style="background-color: white; background-color: inheri
t" title="Element" class="hierarchy"/> <a href="extension-ext-contentPercent-definitions.
html#Extension">Extension</a><a name="Extension"> </a></td><td style="vertical-align: top
; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px
0px 4px" class="hierarchy"/><td style="vertical-align: top; text-align : left; background
-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy">0..1
</td><td style="vertical-align: top; text-align : left; background-color: white; border:
0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"/><td style="vertical-align:
 top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px
4px 0px 4px" class="hierarchy">Ingredient percentage by mass (0-100)</td></tr>
<tr style="border: 0px #F0F0F0 solid; padding:0px; vertical-align: top; background-color:
```

```
 white;"><td style="vertical-align: top; text-align : left; background-color: white; bord
er: 0px #F0F0F0 solid; padding:0px 4px 0px 4px; white-space: nowrap; background-image: ur
l(tbl_bck10.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="background-c
olor: inherit" class="hierarchy"/><img src="tbl_vjoin.png" alt="." style="background-colo
r: inherit" class="hierarchy"/><img src="icon_primitive.png" alt="." style="background-co
lor: white; background-color: inherit" title="Primitive Data Type" class="hierarchy"/> <a
 href="extension-ext-contentPercent-definitions.html#Extension.url" title="null">url</a><
a name="Extension.url"> </a></td><td style="vertical-align: top; text-align : left; backg
round-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"
/><td style="vertical-align: top; text-align : left; background-color: white; border: 0px
 #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"/><td style="vertical-align: to
p; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px
 0px 4px" class="hierarchy"><a href="http://build.fhir.org/datatypes.html#uri">uri</a></t
d><td style="vertical-align: top; text-align : left; background-color: white; border: 0px
 #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><span style="color: darkgreen"
>&quot;http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-contentPercent&quot;</span>
</td></tr>
<tr style="border: 0px #F0F0F0 solid; padding:0px; vertical-align: top; background-color:
 white;"><td style="vertical-align: top; text-align : left; background-color: white; bord
er: 0px #F0F0F0 solid; padding:0px 4px 0px 4px; white-space: nowrap; background-image: ur
l(tbl_bck00.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="background-c
olor: inherit" class="hierarchy"/><img src="tbl_vjoin_end.png" alt="." style="background-
color: inherit" class="hierarchy"/><img src="icon_primitive.png" alt="." style="backgroun
d-color: white; background-color: inherit" title="Primitive Data Type" class="hierarchy"/
> <a href="extension-ext-contentPercent-definitions.html#Extension.valueDecimal" title="n
ull">valueDecimal</a><a name="Extension.valueDecimal"> </a></td><td style="vertical-align
: top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px
 4px 0px 4px" class="hierarchy"/><td style="vertical-align: top; text-align : left; backg
round-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"
/><td style="vertical-align: top; text-align : left; background-color: white; border: 0px
 #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><a href="http://build.fhir.org
/datatypes.html#decimal">decimal</a></td><td style="vertical-align: top; text-align : lef
t; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hi
erarchy"/></tr>
<tr><td colspan="5" class="hierarchy"><br/><a href="http://build.fhir.org/formats.html#ta
ble" title="Legend for this format"><img src="http://build.fhir.org/help16.png" alt="doco
" style="background-color: inherit"/> Documentation for this format</a></td></tr></table>
</div>
  </text>
  <url
      value="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-contentPercent"/>
  <version value="current"/>
  <name value="contentPercent"/>
  <title value="Content Percent"/>
  <status value="draft"/>
  <experimental value="false"/>
  <date value="2018-10-05T00:00:00-04:00"/>
  <publisher value="U.S. FDA - CDER division"/>
  <contact>
    <telecom>
      <system value="url"/>
      <value value="https://www.fda.gov/Drugs/default.htm"/>
    </telecom>
  </contact>
  <fhirVersion value="4.0.0"/>
  <mapping>
    <identity value="rim"/>
```

```
    <uri value="http://hl7.org/v3"/>
    <name value="RIM Mapping"/>
  </mapping>
  <kind value="complex-type"/>
  <abstract value="false"/>
  <context>
    <type value="element"/>
    <expression value="MedicationKnowledge.ingredient"/>
  </context>
  <type value="Extension"/>
  <baseDefinition value="http://hl7.org/fhir/StructureDefinition/Extension"/>
  <derivation value="constraint"/>
  <snapshot>
    <element id="Extension">
      <extension
               url="http://hl7.org/fhir/StructureDefinition/structuredefinition-standar
ds-status">
        <valueCode value="normative"/>
      </extension>
      <extension
               url="http://hl7.org/fhir/StructureDefinition/structuredefinition-normati
ve-version">
        <valueCode value="4.0.0"/>
      </extension>
      <path value="Extension"/>
      <short value="Ingredient percentage by mass (0-100)"/>
      <definition value="An Extension"/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="Extension"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <condition value="ele-1"/>
      <constraint>
        <key value="ele-1"/>
        <severity value="error"/>
        <human value="All FHIR elements must have a @value or children"/>
        <expression value="hasValue() or (children().count() &gt; id.count())"/>
        <xpath value="@value|f:*|h:div"/>
        <source value="Element"/>
      </constraint>
      <constraint>
        <key value="ext-1"/>
        <severity value="error"/>
        <human value="Must have either extensions or value[x], not both"/>
        <expression value="extension.exists() != value.exists()"/>
        <xpath
              value="exists(f:extension)!=exists(f:*[starts-with(local-name(.), &#39;val
ue&#39;)])"/>
        <source value="Extension"/>
      </constraint>
      <isModifier value="false"/>
    </element>
    <element id="Extension.id">
      <path value="Extension.id"/>
```

```xml
        <representation value="xmlAttr"/>
        <short value="Unique id for inter-element referencing"/>
        <definition
                   value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Element.id"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="string"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="Extension.extension">
        <path value="Extension.extension"/>
        <slicing>
          <discriminator>
            <type value="value"/>
            <path value="url"/>
          </discriminator>
          <description value="Extensions are always sliced by (at least) url"/>
          <rules value="open"/>
        </slicing>
        <short value="Additional content defined by implementations"/>
        <definition
                   value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
        <comment
                value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
        <alias value="extensions"/>
        <alias value="user content"/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="Element.extension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
        </type>
        <isModifier value="false"/>
```

```xml
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="Extension.url">
        <path value="Extension.url"/>
        <representation value="xmlAttr"/>
        <short value="identifies the meaning of the extension"/>
        <definition
                    value="Source of the definition for the extension code - a logical name
 or a URL."/>
        <comment
                 value="The definition may point directly to a computable or human-readable
 definition of the extensibility codes, or it may be a logical URI as declared in some ot
her specification. The definition SHALL be a URI for the Structure Definition defining th
e extension."/>
        <min value="1"/>
        <max value="1"/>
        <base>
          <path value="Extension.url"/>
          <min value="1"/>
          <max value="1"/>
        </base>
        <type>
          <code value="uri"/>
        </type>
        <fixedUri
                  value="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-contentPerc
ent"/>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="N/A"/>
        </mapping>
      </element>
      <element id="Extension.valueDecimal">
        <path value="Extension.valueDecimal"/>
        <short value="Value of extension"/>
        <definition
                    value="Value of extension - must be one of a constrained set of the dat
a types (see [Extensibility](http://build.fhir.org/extensibility.html) for a list)."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Extension.value[x]"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="decimal"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
```

```xml
                <identity value="rim"/>
                <map value="N/A"/>
            </mapping>
        </element>
    </snapshot>
    <differential>
        <element id="Extension">
            <path value="Extension"/>
            <short value="Ingredient percentage by mass (0-100)"/>
            <min value="0"/>
            <max value="1"/>
            <isModifier value="false"/>
        </element>
        <element id="Extension.url">
            <path value="Extension.url"/>
            <type>
                <code value="uri"/>
            </type>
            <fixedUri
                    value="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-contentPerc
ent"/>
        </element>
        <element id="Extension.valueDecimal">
            <path value="Extension.valueDecimal"/>
            <type>
                <code value="decimal"/>
            </type>
        </element>
    </differential>
</StructureDefinition>
```

Extension All FHIR elements must have a @value or children (inherited) Must have either extensions or value[x], not both (inherited)

PQCMC Proof of Concept current - Continuous Build

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Extension: productType - Detailed Descriptions

Definitions for the ext-productType Extension

Table of Contents > **Artifact index** > **Product Type**

Content | Detailed Descriptions | Mappings | XML

Extension: productType - Mappings

Mappings for the Extension

Mappings for RIM Mapping (http://hl7.org/v3)

productType	
Extension	
id	n/a
extension	n/a
url	N/A
valueCode	N/A

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Extension: productType - XML Profile

XML representation of the ext-productType Extension

```
<StructureDefinition xmlns="http://hl7.org/fhir">
  <id value="ext-productType"/>
  <text>
    <status value="generated"/>
    <div xmlns="http://www.w3.org/1999/xhtml"><table border="0" cellpadding="0" cellspaci
ng="0" style="border: 0px #F0F0F0 solid; font-size: 11px; font-family: verdana; vertical-
align: top;"><tr style="border: 1px #F0F0F0 solid; font-size: 11px; font-family: verdana;
 vertical-align: top;"><th style="vertical-align: top; text-align : left; background-colo
r: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><a href="
http://build.fhir.org/formats.html#table" title="The logical name of the element">Name</a
></th><th style="vertical-align: top; text-align : left; background-color: white; border:
 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><a href="http://build.fhir
.org/formats.html#table" title="Information about the use of the element">Flags</a></th><
th style="vertical-align: top; text-align : left; background-color: white; border: 0px #F
0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><a href="http://build.fhir.org/fo
rmats.html#table" title="Minimum and Maximum # of times the the element can appear in the
 instance">Card.</a></th><th style="width: 100px" class="hierarchy"><a href="http://build
.fhir.org/formats.html#table" title="Reference to the type of the element">Type</a></th><
th style="vertical-align: top; text-align : left; background-color: white; border: 0px #F
0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><a href="http://build.fhir.org/fo
rmats.html#table" title="Additional information about the element">Description &amp; Cons
traints</a><span style="float: right"><a href="http://build.fhir.org/formats.html#table"
title="Legend for this format"><img src="http://build.fhir.org/help16.png" alt="doco" sty
le="background-color: inherit"/></a></span></th></tr><tr style="border: 0px #F0F0F0 solid
; padding:0px; vertical-align: top; background-color: white;"><td style="vertical-align:
top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4
px 0px 4px; white-space: nowrap; background-image: url(tbl_bck1.png)" class="hierarchy"><
img src="tbl_spacer.png" alt="." style="background-color: inherit" class="hierarchy"/><im
g src="icon_element.gif" alt="." style="background-color: white; background-color: inheri
t" title="Element" class="hierarchy"/> <a href="extension-ext-productType-definitions.htm
l#Extension">Extension</a><a name="Extension"> </a></td><td style="vertical-align: top; t
ext-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px
 4px" class="hierarchy"/><td style="vertical-align: top; text-align : left; background-co
lor: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy">0..1</t
d><td style="vertical-align: top; text-align : left; background-color: white; border: 0px
 #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"/><td style="vertical-align: to
p; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px
 0px 4px" class="hierarchy">product | substance</td></tr>
<tr style="border: 0px #F0F0F0 solid; padding:0px; vertical-align: top; background-color:
```

```
white;"><td style="vertical-align: top; text-align : left; background-color: white; bord
er: 0px #F0F0F0 solid; padding:0px 4px 0px 4px; white-space: nowrap; background-image: ur
l(tbl_bck10.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="background-c
olor: inherit" class="hierarchy"/><img src="tbl_vjoin.png" alt="." style="background-colo
r: inherit" class="hierarchy"/><img src="icon_primitive.png" alt="." style="background-co
lor: white; background-color: inherit" title="Primitive Data Type" class="hierarchy"/> <a
 href="extension-ext-productType-definitions.html#Extension.url" title="null">url</a><a n
ame="Extension.url"> </a></td><td style="vertical-align: top; text-align : left; backgrou
nd-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"/><
td style="vertical-align: top; text-align : left; background-color: white; border: 0px #F
0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"/><td style="vertical-align: top;
text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0p
x 4px" class="hierarchy"><a href="http://build.fhir.org/datatypes.html#uri">uri</a></td><
td style="vertical-align: top; text-align : left; background-color: white; border: 0px #F
0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><span style="color: darkgreen">&q
uot;http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-productType&quot;</span></td><
/tr>
<tr style="border: 0px #F0F0F0 solid; padding:0px; vertical-align: top; background-color:
 white;"><td style="vertical-align: top; text-align : left; background-color: white; bord
er: 0px #F0F0F0 solid; padding:0px 4px 0px 4px; white-space: nowrap; background-image: ur
l(tbl_bck00.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="background-c
olor: inherit" class="hierarchy"/><img src="tbl_vjoin_end.png" alt="." style="background-
color: inherit" class="hierarchy"/><img src="icon_primitive.png" alt="." style="backgroun
d-color: white; background-color: inherit" title="Primitive Data Type" class="hierarchy"/
> <a href="extension-ext-productType-definitions.html#Extension.valueCode" title="null">v
alueCode</a><a name="Extension.valueCode"> </a></td><td style="vertical-align: top; text-
align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px
" class="hierarchy"/><td style="vertical-align: top; text-align : left; background-color:
 white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"/><td style=
"vertical-align: top; text-align : left; background-color: white; border: 0px #F0F0F0 sol
id; padding:0px 4px 0px 4px" class="hierarchy"><a href="http://build.fhir.org/datatypes.h
tml#code">code</a></td><td style="vertical-align: top; text-align : left; background-colo
r: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"/></tr>
<tr><td colspan="5" class="hierarchy"><br/><a href="http://build.fhir.org/formats.html#ta
ble" title="Legend for this format"><img src="http://build.fhir.org/help16.png" alt="doco
" style="background-color: inherit"/> Documentation for this format</a></td></tr></table>
</div>
  </text>
  <url
      value="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-productType"/>
  <version value="current"/>
  <name value="productType"/>
  <title value="Product Type"/>
  <status value="draft"/>
  <experimental value="false"/>
  <date value="2018-10-05T00:00:00-04:00"/>
  <publisher value="U.S. FDA - CDER division"/>
  <contact>
    <telecom>
      <system value="url"/>
      <value value="https://www.fda.gov/Drugs/default.htm"/>
    </telecom>
  </contact>
  <fhirVersion value="4.0.0"/>
  <mapping>
    <identity value="rim"/>
    <uri value="http://hl7.org/v3"/>
```

```
    <name value="RIM Mapping"/>
  </mapping>
  <kind value="complex-type"/>
  <abstract value="false"/>
  <context>
    <type value="element"/>
    <expression value="MedicationKnowledge"/>
  </context>
  <type value="Extension"/>
  <baseDefinition value="http://hl7.org/fhir/StructureDefinition/Extension"/>
  <derivation value="constraint"/>
  <snapshot>
    <element id="Extension">
      <extension
                 url="http://hl7.org/fhir/StructureDefinition/structuredefinition-standar
ds-status">
        <valueCode value="normative"/>
      </extension>
      <extension
                 url="http://hl7.org/fhir/StructureDefinition/structuredefinition-normati
ve-version">
        <valueCode value="4.0.0"/>
      </extension>
      <path value="Extension"/>
      <short value="product | substance"/>
      <definition value="An Extension"/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="Extension"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <condition value="ele-1"/>
      <constraint>
        <key value="ele-1"/>
        <severity value="error"/>
        <human value="All FHIR elements must have a @value or children"/>
        <expression value="hasValue() or (children().count() &gt; id.count())"/>
        <xpath value="@value|f:*|h:div"/>
        <source value="Element"/>
      </constraint>
      <constraint>
        <key value="ext-1"/>
        <severity value="error"/>
        <human value="Must have either extensions or value[x], not both"/>
        <expression value="extension.exists() != value.exists()"/>
        <xpath
               value="exists(f:extension)!=exists(f:*[starts-with(local-name(.), &#39;val
ue&#39;)])"/>
        <source value="Extension"/>
      </constraint>
      <isModifier value="false"/>
    </element>
    <element id="Extension.id">
      <path value="Extension.id"/>
      <representation value="xmlAttr"/>
```

```xml
        <short value="Unique id for inter-element referencing"/>
        <definition
                    value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Element.id"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="string"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="Extension.extension">
        <path value="Extension.extension"/>
        <slicing>
          <discriminator>
            <type value="value"/>
            <path value="url"/>
          </discriminator>
          <description value="Extensions are always sliced by (at least) url"/>
          <rules value="open"/>
        </slicing>
        <short value="Additional content defined by implementations"/>
        <definition
                    value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
        <comment
                value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
        <alias value="extensions"/>
        <alias value="user content"/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="Element.extension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
```

```
      <mapping>
        <identity value="rim"/>
        <map value="n/a"/>
      </mapping>
    </element>
    <element id="Extension.url">
      <path value="Extension.url"/>
      <representation value="xmlAttr"/>
      <short value="identifies the meaning of the extension"/>
      <definition
                  value="Source of the definition for the extension code - a logical name
 or a URL."/>
      <comment
                value="The definition may point directly to a computable or human-readable
 definition of the extensibility codes, or it may be a logical URI as declared in some ot
her specification. The definition SHALL be a URI for the Structure Definition defining th
e extension."/>
      <min value="1"/>
      <max value="1"/>
      <base>
        <path value="Extension.url"/>
        <min value="1"/>
        <max value="1"/>
      </base>
      <type>
        <code value="uri"/>
      </type>
      <fixedUri
                value="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-productType
"/>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="N/A"/>
      </mapping>
    </element>
    <element id="Extension.valueCode">
      <path value="Extension.valueCode"/>
      <short value="Value of extension"/>
      <definition
                  value="Value of extension - must be one of a constrained set of the dat
a types (see [Extensibility](http://build.fhir.org/extensibility.html) for a list)."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="Extension.value[x]"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="code"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
```

```xml
                <map value="N/A"/>
            </mapping>
        </element>
    </snapshot>
    <differential>
        <element id="Extension">
            <path value="Extension"/>
            <short value="product | substance"/>
            <min value="0"/>
            <max value="1"/>
            <isModifier value="false"/>
        </element>
        <element id="Extension.url">
            <path value="Extension.url"/>
            <type>
                <code value="uri"/>
            </type>
            <fixedUri
                    value="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-productType
"/>
        </element>
        <element id="Extension.valueCode">
            <path value="Extension.valueCode"/>
            <type>
                <code value="code"/>
            </type>
        </element>
    </differential>
</StructureDefinition>
```

f:Extension valueCode: maximum cardinality of 'valueCode' is 1 Extension All FHIR elements must have a @value or children (inherited) Must have either extensions or value[x], not both (inherited)

Table of Contents > **Artifact index** > **PQCMC Quality Specification**

| Content | Detailed Descriptions | Mappings | Examples | XML |

StructureDefinition: Quality Specification - Detailed Descriptions

Definitions for the qualityspecification Profile.

1. PlanDefinition (Quality Specification)

Definition	Specification means the quality standard (i.e. , tests, analytical procedures, and acceptance criteria) provided in an approved application to confirm the quality of drug substances, drug products, intermediates, raw materials, reagents, components, in-process materials, container closure systems, and other materials used in the production of a drug substance or drug product. For the purpose of this definition, acceptance criteria means numerical limits, ranges, or other criteria for the tests described.
Control	0..*
Invariants	**Defined on this element** **dom-2**: If the resource is contained in another resource, it SHALL NOT contain nested Resources (: contained.contained.empty()) **dom-3**: If the resource is contained in another resource, it SHALL be referred to from elsewhere in the resource or SHALL refer to the containing resource (: contained.where((('#'+id in (%resource.descendants().reference | %resource.descendants().as(canonical) | %resource.descendants().as(uri) | %resource.descendants().as(url))) or descendants().where(reference = '#').exists() or descendants().where(as(canonical) = '#').exists() or descendants().where(as(canonical) = '#').exists()).not()).trace('unmatched', id).empty()) **dom-4**: If a resource is contained in another resource, it SHALL NOT have a meta.versionId or a meta.lastUpdated (: contained.meta.versionId.empty() and contained.meta.lastUpdated.empty()) **dom-5**: If a resource is contained in another resource, it SHALL NOT have a security label (: contained.meta.security.empty()) **dom-6**: A resource should have narrative for robust management (: text.div.exists()) **pdf-0**: Name should be usable as an identifier for the module by machine processing applications such as code generation (: name.matches('[A-Z]([A-Za-z0-9_]){0,254}'))

8. PlanDefinition.extension (Approval Status)

Definition	An Extension
Control	0..*
Type	Extension

27. PlanDefinition.version (Quality Specification Version)

Definition	The alphanumeric text assigned by the sponsor to a particular edition of a specification. [Source: SME Defined] Examples: 2.1, 13.2, ST1, 00001, 00002, <companyname>001, etc.
Note	This is a business versionId, not a resource version id (see discussion)
Control	1..1
Type	string
Must Support	true
Comments	There may be different plan definition instances that have the same identifier but different versions. The version can be appended to the url in a reference to allow a reference to a particular business version of the plan definition with the format [url]|[version].

29. PlanDefinition.title (Quality Specification Title)

Definition	The textual identification for the specification. [Source: SME Defined] Example: <drug name> 75 mg chewable

tablets Note: This may include the name of the drug substance, product or the raw material/excipients.

Control	1..1
Type	string
Must Support	true
Comments	This name does not need to be machine-processing friendly and may contain punctuation, white-space, etc.

32. PlanDefinition.status

Definition	The status of this plan definition. Enables tracking the life-cycle of the content.
Control	1..1
Binding	The lifecycle status of an artifact. The codes SHALL be taken from PublicationStatus
Type	code
Is Modifier	true
Must Support	true
Comments	Allows filtering of plan definitions that are appropriate for use versus not.
Fixed Value	active

34. PlanDefinition.subjectReference (Tested Product or Substance)

Definition	A classification of specification related to the kind of the entity it is referencing. [Source: SME Defined].
Control	1..1
Type	Reference(MedicationKnowledge | Substance)
Must Support	true
Meaning if Missing	Patient

35. PlanDefinition.date (Version Date)

Definition	The date when the sponsor assigned a date to a specific version. [Source: SME Defined].
Control	1..1
Type	dateTime
Must Support	true
Alternate Names	Revision Date
Comments	Note that this is not the same as the resource last-modified-date, since the resource may be a secondary representation of the plan definition. Additional specific dates may be added as extensions or be found by consulting Provenances associated with past versions of the resource.

42. PlanDefinition.usage (Additional Information)

Definition	Placeholder for providing any comments that are relevant to the specification. [Source: SME Defined] Examples: replaces method ABC, using the XYZ facility, etc.
Control	0..1
Type	string
Must Support	true

54. PlanDefinition.goal (Acceptance criteria)

Definition	Numerical limits, ranges, or other criteria for the tests described. [Source: 21 CFR 314.3, 514.3 and 600.3].
Control	1..*
Type	BackboneElement
Must Support	true
Requirements	Goal information needs to be captured for order sets, protocols, and care plan definitions to better describe the

objectives of the protocol activities and to guide the creation of specific goals within the derived care plans and orders.

Invariants	**Defined on this element** **ele-1**: All FHIR elements must have a @value or children (: hasValue() or (children().count() > id.count()))

56. PlanDefinition.goal.extension (Additional Information)

Definition	An Extension
Control	0..*
Type	Extension

60. PlanDefinition.goal.description

Definition	Human-readable and/or coded description of a specific desired objective of care, such as "control blood pressure" or "negotiate an obstacle course" or "dance with child at wedding".
Control	1..1
Binding	Describes goals that can be achieved. For example codes, see SNOMEDCTClinicalFindings
Type	CodeableConcept
Must Support	true
Comments	If no code is available, use CodeableConcept.text.

64. PlanDefinition.goal.description.text (Literal text)

Definition	The text of the acceptance criteria as provided in the specification. [Source: SME Defined] Examples: White to off-white cake; 22.5 -27.5 mg/ml Note: This is the text as it appears in the Specification.
Control	1..1
Type	string
Must Support	true
Requirements	The codes from the terminologies do not always capture the correct meaning with all the nuances of the human using them, or sometimes there is no appropriate code at all. In these cases, the text is used to capture the full meaning of the source.
Comments	Very often the text is the same as a displayName of one of the codings.

69. PlanDefinition.goal.target

Definition	Indicates what should be done and within what timeframe.
Control	1..1
Type	BackboneElement
Must Support	true
Invariants	**Defined on this element** **ele-1**: All FHIR elements must have a @value or children (: hasValue() or (children().count() > id.count()))

71. PlanDefinition.goal.target.extension

Definition	An Extension
Control	0..*
Type	Extension

79. PlanDefinition.goal.target.detail[x]

Definition	The target value of the measure to be achieved to signify fulfillment of the goal, e.g. 150 pounds or 7.0%. Either the high or low or both values of the range can be specified. When a low value is missing, it indicates that the goal is achieved at any value at or below the high value. Similarly, if the high value is missing, it indicates that the goal is achieved at any value at or above the low value.
Control	0..1

Type	Choice of: Quantity, Range, CodeableConcept
[x] Note	See Choice of Data Types for further information about how to use [x]
Must Support	true
Alternate Names	Quantity, Range, CodeableConcept

137. PlanDefinition.action (Test)

Definition	A determination of a physical, chemical or biological property. [Source: SME Defined].
Control	1..*
Type	BackboneElement
Must Support	true
Comments	Note that there is overlap between many of the elements defined here and the ActivityDefinition resource. When an ActivityDefinition is referenced (using the definition element), the overlapping elements in the plan override the content of the referenced ActivityDefinition unless otherwise documented in the specific elements. See the PlanDefinition resource for more detailed information.
Invariants	**Defined on this element** **ele-1**: All FHIR elements must have a @value or children (: hasValue() or (children().count() > id.count()))

139. PlanDefinition.action.extension (Test method origin)

Definition	An Extension
Control	0..*
Type	Extension

145. PlanDefinition.action.title (Test Name)

Definition	The textual description of a procedure or analytical method. [Source: SME Defined].
Control	1..1
Type	string
Must Support	true

149. PlanDefinition.action.code (QualitySpecification Test category)

Definition	A code that provides meaning for the action or action group. For example, a section may have a LOINC code for the section of a documentation template.
Control	1..1
Type	CodeableConcept
Must Support	true

152. PlanDefinition.action.code.coding (Test category)

Definition	A high level grouping of product quality attributes. [Source: SME Defined] Examples: Appearance, Physical Properties, etc.
Control	1..1
Type	Coding
Must Support	true
Requirements	Allows for alternative encodings within a code system, and translations to other code systems.
Comments	Codes may be defined very casually in enumerations, or code lists, up to very formal definitions such as SNOMED CT - see the HL7 v3 Core Principles for more information. Ordering of codings is undefined and SHALL NOT be used to infer meaning. Generally, at most only one of the coding values will be labeled as UserSelected = true.

153. PlanDefinition.action.code.text (Analytical Procedure)

Definition	A technique used to determine the nature of a characteristic. [Source: SME Defined] Examples: HPLC, Capillary Electrophoresis, etc.
Control	1..1

Type	string
Must Support	true
Requirements	The codes from the terminologies do not always capture the correct meaning with all the nuances of the human using them, or sometimes there is no appropriate code at all. In these cases, the text is used to capture the full meaning of the source.
Comments	Very often the text is the same as a displayName of one of the codings.

154. PlanDefinition.action.reason (Usage)

Definition	A coded value specifying the time point during the manufacturing process of a substance or product when a particular analytical procedure or measurement is being performed. [Source: SME Defined].
Control	1..1
Type	CodeableConcept
Must Support	true
Comments	This is different than the clinical evidence documentation, it's an actual business description of the reason for performing the action.

195. PlanDefinition.action.action (Stage)

Definition	A set of discrete sequential steps performed on a given test. [Source: SME Defined] Note: Level and Tier could be synonyms for Stage. A Test can have many stages.
Control	1..*
Type	BackboneElement
Must Support	true

200. PlanDefinition.action.action.title (Stage name)

Definition	A textual description and/or a number that identifies a level within a sequential test. [Source: SME Defined] Examples – Single Stage, Stage 1, Stage 2 (sometimes referred to as L1, L2 L3 or A1, A2 as in USP <711>) Note: A Stage may or may not provide a conditional sequence with associated acceptance criteria. [Source: SME Defined] (e.g., dissolution test, pyrogen test -USP <151>; 21 CFR 610.13(b) Test for pyrogenic substances).
Control	1..1
Type	string
Must Support	true

207. PlanDefinition.action.action.goalId (Acceptance criteria)

Definition	Identifies goals that this action supports. The reference must be to a goal element defined within this plan definition.
Control	1..*
Type	id
Must Support	true

218. PlanDefinition.action.action.relatedAction (Indicates relative sequence)

Definition	The order of the stages in regular succession. [Source: SME Defined] Examples: 1, 2, 3, etc. This is not a direct mapping in FHIR.
Control	0..1
Type	BackboneElement
Must Support	true
Comments	When an action depends on multiple actions, the meaning is that all actions are dependencies, rather than that any of the actions are a dependency.
Invariants	**Defined on this element** **ele-1**: All FHIR elements must have a @value or children (: hasValue() or (children().count() > id.count()))

222. PlanDefinition.action.action.relatedAction.actionId (GUID identifer for related stage)

Definition	The identifier of the previous stage.
Control	1..1
Type	id
Must Support	true

223. PlanDefinition.action.action.relatedAction.relationship (Sequence reference)

Definition	The relationship of this action to the related action.
Control	1..1
Binding	Defines the types of relationships between actions. The codes SHALL be taken from ActionRelationshipType
Type	code
Must Support	true

f:PlanDefinition extension with URL = 'http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-approvalStatus': maximum cardinality of 'extension' is 1 version: minimum cardinality of 'version' is 1 title: minimum cardinality of 'title' is 1 subjectReference: minimum cardinality of 'subjectReference' is 1 date: minimum cardinality of 'date' is 1 goal: minimum cardinality of 'goal' is 1 action: minimum cardinality of 'action' is 1 PlanDefinition If the resource is contained in another resource, it SHALL NOT contain nested Resources (inherited) If a resource is contained in another resource, it SHALL NOT have a meta.versionId or a meta.lastUpdated (inherited) If the resource is contained in another resource, it SHALL be referred to from elsewhere in the resource or SHALL refer to the containing resource (inherited) A resource should have narrative for robust management (inherited) If a resource is contained in another resource, it SHALL NOT have a security label (inherited) Name should be usable as an identifier for the module by machine processing applications such as code generation (inherited) f:PlanDefinition/f:extension id: maximum cardinality of 'id' is 1 extension with URL = 'type': minimum cardinality of 'extension' is 1 extension with URL = 'type': maximum cardinality of 'extension' is 1 extension with URL = 'date': minimum cardinality of 'extension' is 1 extension with URL = 'date': maximum cardinality of 'extension' is 1 url: minimum cardinality of 'url' is 1 url: maximum cardinality of 'url' is 1 value[x]: maximum cardinality of 'value[x]' is 0 PlanDefinition.extension All FHIR elements must have a @value or children (inherited) Must have either extensions or value[x], not both (inherited) f:PlanDefinition/f:extension/f:extension id: maximum cardinality of 'id' is 1 url: minimum cardinality of 'url' is 1 url: maximum cardinality of 'url' is 1 valueCode: maximum cardinality of 'valueCode' is 1 id: maximum cardinality of 'id' is 1 url: minimum cardinality of 'url' is 1 url: maximum cardinality of 'url' is 1 valueDate: maximum cardinality of 'valueDate' is 1 f:PlanDefinition/f:goal extension with URL = 'http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-comment': maximum cardinality of 'extension' is 1 target: minimum cardinality of 'target' is 1 target: maximum cardinality of 'target' is 1 PlanDefinition.goal All FHIR elements must have a @value or children (inherited) PlanDefinition.goal.extension All FHIR elements must have a @value or children (inherited) Must have either extensions or value[x], not both (inherited) f:PlanDefinition/f:goal/f:description id: maximum cardinality of 'id' is 1 text: minimum cardinality of 'text' is 1 text: maximum cardinality of 'text' is 1 f:PlanDefinition/f:goal/f:target extension with URL = 'http://hl7.org/fhir/StructureDefinition/data-absent-reason': maximum cardinality of 'extension' is 1 detailRange: maximum cardinality of 'detailRange' is 1 PlanDefinition.goal.target All FHIR elements must have a @value or children (inherited) f:PlanDefinition/f:goal/f:target/f:extension id: maximum cardinality of 'id' is 1 url: minimum cardinality of 'url' is 1 url: maximum cardinality of 'url' is 1 valueCode: minimum cardinality of 'valueCode' is 1 valueCode: maximum cardinality of 'valueCode' is 1 PlanDefinition.goal.target.extension All FHIR elements must have a @value or children (inherited) Must have either extensions or value[x], not both (inherited) f:PlanDefinition/f:goal/f:target/f:detailQuantity value: minimum cardinality of 'value' is 1 system: minimum cardinality of 'system' is 1 code: minimum cardinality of 'code' is 1 f:PlanDefinition/f:goal/f:target/f:detailRange/f:extension url: minimum cardinality of 'url' is 1 url: minimum cardinality of 'url' is 1 f:PlanDefinition/f:goal/f:target/f:detailRange/f:extension/f:value[x] 1 value: minimum cardinality of 'value' is 1 system: minimum cardinality of 'system' is 1 value: minimum cardinality of 'value' is 1 system: minimum cardinality of 'system' is 1 f:PlanDefinition/f:goal/f:target/f:detailRange/f:low value: minimum cardinality of 'value' is 1 comparator: maximum cardinality of 'comparator' is 0 system: minimum cardinality of 'system' is 1 code: minimum cardinality of 'code' is 1 f:PlanDefinition/f:goal/f:target/f:detailRange/f:high value: minimum cardinality of 'value' is 1 comparator: maximum cardinality of 'comparator' is 0 system: minimum cardinality of 'system' is 1 code: minimum cardinality of 'code' is 1 f:PlanDefinition/f:goal/f:target/f:detailCodeableConcept text: minimum cardinality of 'text' is 1 f:PlanDefinition/f:action extension with URL = 'http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-methodOrigin': maximum cardinality of 'extension' is 1 extension with URL = 'http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-definitionUri': maximum cardinality of 'extension' is 1 extension with URL = 'http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-focus': maximum cardinality of 'extension' is 1 title: minimum cardinality of 'title' is 1 code: minimum cardinality of 'code' is 1 code: maximum cardinality of 'code' is 1 reason: minimum cardinality of 'reason' is 1 reason: maximum cardinality of 'reason' is 1 action: minimum cardinality of 'action' is 1 PlanDefinition.action All FHIR elements must have a @value or children (inherited) PlanDefinition.action.extension All FHIR elements must have a @value or children (inherited) Must have either extensions or value[x], not both (inherited) All FHIR elements must have a @value or children (inherited) Must have either extensions or value[x], not both (inherited) All FHIR elements must have a @value or children (inherited) Must have either extensions or value[x], not both (inherited) f:PlanDefinition/f:action/f:code id: maximum cardinality of 'id' is 1 coding: minimum cardinality of 'coding' is 1 coding: maximum cardinality of 'coding' is 1 text: minimum cardinality of 'text' is 1 text: maximum cardinality of 'text' is 1 PlanDefinition.action.condition All FHIR elements must have a @value or children (inherited) PlanDefinition.action.relatedAction All FHIR elements must have a @value or children

(inherited) PlanDefinition.action.participant All FHIR elements must have a @value or children (inherited) PlanDefinition.action.dynamicValue All FHIR elements must have a @value or children (inherited) f:PlanDefinition/f:action/f:action id: maximum cardinality of 'id' is 1 prefix: maximum cardinality of 'prefix' is 1 title: minimum cardinality of 'title' is 1 title: maximum cardinality of 'title' is 1 description: maximum cardinality of 'description' is 1 textEquivalent: maximum cardinality of 'textEquivalent' is 1 priority: maximum cardinality of 'priority' is 1 goalId: minimum cardinality of 'goalId' is 1 subject[x]: maximum cardinality of 'subject[x]' is 1 relatedAction: maximum cardinality of 'relatedAction' is 1 timing[x]: maximum cardinality of 'timing[x]' is 1 type: maximum cardinality of 'type' is 1 groupingBehavior: maximum cardinality of 'groupingBehavior' is 1 selectionBehavior: maximum cardinality of 'selectionBehavior' is 1 requiredBehavior: maximum cardinality of 'requiredBehavior' is 1 precheckBehavior: maximum cardinality of 'precheckBehavior' is 1 cardinalityBehavior: maximum cardinality of 'cardinalityBehavior' is 1 definition[x]: maximum cardinality of 'definition[x]' is 1 transform: maximum cardinality of 'transform' is 1 f:PlanDefinition/f:action/f:action/f:condition id: maximum cardinality of 'id' is 1 kind: minimum cardinality of 'kind' is 1 kind: maximum cardinality of 'kind' is 1 expression: maximum cardinality of 'expression' is 1 PlanDefinition.action.action.condition All FHIR elements must have a @value or children (inherited) f:PlanDefinition/f:action/f:action/f:relatedAction id: maximum cardinality of 'id' is 1 actionId: minimum cardinality of 'actionId' is 1 actionId: maximum cardinality of 'actionId' is 1 relationship: minimum cardinality of 'relationship' is 1 relationship: maximum cardinality of 'relationship' is 1 offset[x]: maximum cardinality of 'offset[x]' is 1 PlanDefinition.action.action.relatedAction All FHIR elements must have a @value or children (inherited) f:PlanDefinition/f:action/f:action/f:participant id: maximum cardinality of 'id' is 1 type: minimum cardinality of 'type' is 1 type: maximum cardinality of 'type' is 1 role: maximum cardinality of 'role' is 1 PlanDefinition.action.action.participant All FHIR elements must have a @value or children (inherited) f:PlanDefinition/f:action/f:action/f:dynamicValue id: maximum cardinality of 'id' is 1 path: maximum cardinality of 'path' is 1 expression: maximum cardinality of 'expression' is 1 PlanDefinition.action.action.dynamicValue All FHIR elements must have a @value or children (inherited)

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Content | Detailed Descriptions | Mappings | Examples | XML

StructureDefinition: PQCMC_MedicationKnowledge - Detailed Descriptions

Definitions for the drugproduct Profile.

1. MedicationKnowledge

Definition	Information about a medication that is used to support knowledge.
Control	0..*
Invariants	**Defined on this element** **dom-2**: If the resource is contained in another resource, it SHALL NOT contain nested Resources (: contained.contained.empty()) **dom-3**: If the resource is contained in another resource, it SHALL be referred to from elsewhere in the resource or SHALL refer to the containing resource (: contained.where(((('#'+id in (%resource.descendants().reference | %resource.descendants().as(canonical) | %resource.descendants().as(uri) | %resource.descendants().as(url))) or descendants().where(reference = '#').exists() or descendants().where(as(canonical) = '#').exists() or descendants().where(as(canonical) = '#').exists()).not()).trace('unmatched', id).empty()) **dom-4**: If a resource is contained in another resource, it SHALL NOT have a meta.versionId or a meta.lastUpdated (: contained.meta.versionId.empty() and contained.meta.lastUpdated.empty()) **dom-5**: If a resource is contained in another resource, it SHALL NOT have a security label (: contained.meta.security.empty()) **dom-6**: A resource should have narrative for robust management (: text.div.exists())

8. MedicationKnowledge.extension (Specification Type)

Definition	An Extension
Control	0..*
Type	Extension

15. MedicationKnowledge.code

Definition	A code that specifies this medication, or a textual description if no code is available. Usage note: This could be a standard medication code such as a code from RxNorm, SNOMED CT, IDMP etc. It could also be a national or local formulary code, optionally with translations to other code systems.
Control	1..1
Binding	A coded concept that defines the type of a medication. For example codes, see SNOMEDCTMedicationCodes
Type	CodeableConcept
Must Support	true
Comments	Depending on the context of use, the code that was actually selected by the user (prescriber, dispenser, etc.) will have the coding.userSelected set to true. As described in the coding datatype: "A coding may be marked as a "userSelected" if a user selected the particular coded value in a user interface (e.g. the user selects an item in a pick-list). If a user selected coding exists, it is the preferred choice for performing translations etc. Other codes can only be literal translations to alternative code systems, or codes at a lower level of granularity (e.g. a generic code for a vendor-specific primary one).

19. MedicationKnowledge.code.text (Non-proprietary Name)

Definition	A name unprotected by trademark rights that is entirely in the public domain. It may be used without restriction by the public at large, both lay and professional. [Source: http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/DataStandardsManualmonographs/ucm071638.htm].
Control	1..1
Type	string
Must Support	true
Requirements	The codes from the terminologies do not always capture the correct meaning with all the nuances of the human using them, or sometimes there is no appropriate code at all. In these cases, the text is used to capture the full meaning of the source.
Comments	Very often the text is the same as a displayName of one of the codings.

22. MedicationKnowledge.doseForm (Dosage Form)

Definition	The form in which active and/or inert ingredient(s) are physically presented. [Source: NCI EVS - C42636] Examples: tablet, capsule, solution, cream, etc. that contains a drug substance generally, but not necessarily, in association with excipients. [Source: ICH Q1A(R2)] Note: If there is a new dosage form that does not exist in the controlled terminology, then propose register this new dosage form during sponsor meetings with FDA.
Control	1..1
Binding	A coded concept defining the form of a medication. For example codes, see SNOMEDCTFormCodes
Type	CodeableConcept
Must Support	true
Comments	When Medication is referenced from MedicationRequest, this is the ordered form. When Medication is referenced within MedicationDispense, this is the dispensed form. When Medication is referenced within MedicationAdministration, this is administered form.

24. MedicationKnowledge.synonym	
Definition	Additional names for a medication, for example, the name(s) given to a medication in different countries. For example, acetaminophen and paracetamol or salbutamol and albuterol.
Control	0..*
Type	string
Must Support	true

39. MedicationKnowledge.ingredient (Product Component Name)	
Definition	Any ingredient intended for use in the manufacture of a drug product, including those that may not appear in such drug product. [Source: (21 CFR 210.3(b)(3)) PAC-ATLS 1998].
Control	1..*
Type	BackboneElement
Must Support	true
Invariants	**Defined on this element** **ele-1**: All FHIR elements must have a @value or children (: hasValue() or (children().count() > id.count()))

41. MedicationKnowledge.ingredient.extension (Content percent)	
Definition	An Extension
Control	0..*
Type	Extension

46. MedicationKnowledge.ingredient.strength (Strength)	
Definition	The content of an active ingredient expressed quantitatively per dosage unit, per unit of volume, or per unit of weight, according to the pharmaceutical dosage form. This should be the strength as listed on the label. [Source: Adapted from NCI EVS C53294] Note: Strength can also be referred to as potency in biologics and other products. This information may be captured on the label.
Control	1..*
Type	Ratio
Must Support	true

49. MedicationKnowledge.ingredient.strength.numerator (Strength Unit)	
Definition	The labeled unit of measure for the content of an active ingredient, expressed quantitatively per dosage unit. [Source: Adapted for NCI EVS C117055].
Control	0..1
Type	Quantity
Must Support	true

52. MedicationKnowledge.ingredient.strength.numerator.value	
Definition	The value of the measured amount. The value includes an implicit precision in the presentation of the value.
Control	1..1
Type	decimal
Must Support	true
Requirements	Precision is handled implicitly in almost all cases of measurement.
Comments	The implicit precision in the value should always be honored. Monetary values have their own rules for handling precision (refer to standard accounting text books).

55. MedicationKnowledge.ingredient.strength.numerator.system	
Definition	UCUM.
Control	1..1 This element is affected by the following invariants: qty-3
Type	uri
Must Support	true
Requirements	Need to know the system that defines the coded form of the unit.
Fixed Value	http://unitsofmeasure.org

56. MedicationKnowledge.ingredient.strength.numerator.code (Strength Unit of Measure)	
Definition	The labeled unit of measure for the content of an active ingredient, expressed quantitatively per dosage unit. [Source: Adapted for NCI EVS C117055] Examples: mg, g, mL, etc.
Control	1..1
Type	code
Must Support	true
Requirements	Need a computable form of the unit that is fixed across all forms. UCUM provides this for quantities, but SNOMED CT provides many units of interest.
Comments	The preferred system is UCUM, but SNOMED CT can also be used (for customary units) or ISO 4217 for currency. The context of use may additionally require a code from a particular system.

57. MedicationKnowledge.ingredient.strength.denominator	
Definition	The value of the denominator.

Control	0..1
Type	Quantity
Must Support	true

60. MedicationKnowledge.ingredient.strength.denominator.value

Definition	The value of the measured amount. The value includes an implicit precision in the presentation of the value.
Control	0..1
Type	decimal
Requirements	Precision is handled implicitly in almost all cases of measurement.
Comments	The implicit precision in the value should always be honored. Monetary values have their own rules for handling precision (refer to standard accounting text books).
Fixed Value	1

f:MedicationKnowledge extension with URL = 'http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-productType': minimum cardinality of 'extension' is 1 extension with URL = 'http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-productType': maximum cardinality of 'extension' is 1 code: minimum cardinality of 'code' is 1 doseForm: minimum cardinality of 'doseForm' is 1 ingredient: minimum cardinality of 'ingredient' is 1 MedicationKnowledge If the resource is contained in another resource, it SHALL NOT contain nested Resources (inherited) If a resource is contained in another resource, it SHALL NOT have a meta.versionId or a meta.lastUpdated (inherited) If the resource is contained in another resource, it SHALL be referred to from elsewhere in the resource or SHALL refer to the containing resource (inherited) A resource should have narrative for robust management (inherited) If a resource is contained in another resource, it SHALL NOT have a security label (inherited) f:MedicationKnowledge/f:extension id: maximum cardinality of 'id' is 1 url: minimum cardinality of 'url' is 1 url: maximum cardinality of 'url' is 1 valueCode: minimum cardinality of 'valueCode' is 1 valueCode: maximum cardinality of 'valueCode' is 1 MedicationKnowledge.extension All FHIR elements must have a @value or children (inherited) Must have either extensions or value[x], not both (inherited) f:MedicationKnowledge/f:code id: maximum cardinality of 'id' is 1 text: minimum cardinality of 'text' is 1 text: maximum cardinality of 'text' is 1 MedicationKnowledge.relatedMedicationKnowledge All FHIR elements must have a @value or children (inherited) MedicationKnowledge.monograph All FHIR elements must have a @value or children (inherited) f:MedicationKnowledge/f:ingredient extension with URL = 'http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-contentPercent': maximum cardinality of 'extension' is 1 strength: minimum cardinality of 'strength' is 1 MedicationKnowledge.ingredient All FHIR elements must have a @value or children (inherited) MedicationKnowledge.ingredient.extension All FHIR elements must have a @value or children (inherited) Must have either extensions or value[x], not both (inherited) f:MedicationKnowledge/f:ingredient/f:strength id: maximum cardinality of 'id' is 1 numerator: maximum cardinality of 'numerator' is 1 denominator: maximum cardinality of 'denominator' is 1 f:MedicationKnowledge/f:ingredient/f:strength/f:numerator id: maximum cardinality of 'id' is 1 value: minimum cardinality of 'value' is 1 value: maximum cardinality of 'value' is 1 comparator: maximum cardinality of 'comparator' is 1 unit: maximum cardinality of 'unit' is 1 system: minimum cardinality of 'system' is 1 system: maximum cardinality of 'system' is 1 code: minimum cardinality of 'code' is 1 code: maximum cardinality of 'code' is 1 f:MedicationKnowledge/f:ingredient/f:strength/f:denominator id: maximum cardinality of 'id' is 1 value: maximum cardinality of 'value' is 1 comparator: maximum cardinality of 'comparator' is 1 unit: maximum cardinality of 'unit' is 1 system: maximum cardinality of 'system' is 1 code: maximum cardinality of 'code' is 1 MedicationKnowledge.cost All FHIR elements must have a @value or children (inherited) MedicationKnowledge.monitoringProgram All FHIR elements must have a @value or children (inherited) MedicationKnowledge.administrationGuidelines All FHIR elements must have a @value or children (inherited) MedicationKnowledge.administrationGuidelines.dosage All FHIR elements must have a @value or children (inherited) MedicationKnowledge.administrationGuidelines.patientCharacteristics All FHIR elements must have a @value or children (inherited) MedicationKnowledge.medicineClassification All FHIR elements must have a @value or children (inherited) MedicationKnowledge.packaging All FHIR elements must have a @value or children (inherited) MedicationKnowledge.drugCharacteristic All FHIR elements must have a @value or children (inherited) MedicationKnowledge.regulatory All FHIR elements must have a @value or children (inherited) MedicationKnowledge.regulatory.substitution All FHIR elements must have a @value or children (inherited) MedicationKnowledge.regulatory.schedule All FHIR elements must have a @value or children (inherited) MedicationKnowledge.regulatory.maxDispense All FHIR elements must have a @value or children (inherited) MedicationKnowledge.kinetics All FHIR elements must have a @value or children (inherited)

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PQCMC Proof of Concept current - Continuous Build

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| Content | **Detailed Descriptions** | Mappings | Examples | XML |

StructureDefinition: PQCMC_MedicationKnowledge - Detailed Descriptions

Definitions for the drugsubstance Profile.

1. MedicationKnowledge

Definition	Information about a medication that is used to support knowledge.
Control	0..*
Invariants	**Defined on this element** **dom-2**: If the resource is contained in another resource, it SHALL NOT contain nested Resources (: contained.contained.empty()) **dom-3**: If the resource is contained in another resource, it SHALL be referred to from elsewhere in the resource or SHALL refer to the containing resource (: contained.where((('#'+id in (%resource.descendants().reference | %resource.descendants().as(canonical) | %resource.descendants().as(uri) | %resource.descendants().as(url))) or descendants().where(reference = '#').exists() or descendants().where(as(canonical) = '#').exists() or descendants().where(as(canonical) = '#').exists()).not()).trace('unmatched', id).empty()) **dom-4**: If a resource is contained in another resource, it SHALL NOT have a meta.versionId or a meta.lastUpdated (: contained.meta.versionId.empty() and contained.meta.lastUpdated.empty()) **dom-5**: If a resource is contained in another resource, it SHALL NOT have a security label (: contained.meta.security.empty()) **dom-6**: A resource should have narrative for robust management (: text.div.exists())

8. MedicationKnowledge.extension (Specification Type)

Definition	An Extension
Control	0..*
Type	Extension

15. MedicationKnowledge.code

Definition	A code that specifies this medication, or a textual description if no code is available. Usage note: This could be a standard medication code such as a code from RxNorm, SNOMED CT, IDMP etc. It could also be a national or local formulary code, optionally with translations to other code systems.
Control	1..*
Binding	A coded concept that defines the type of a medication. For example codes, see SNOMEDCTMedicationCodes
Type	CodeableConcept
Must Support	true
Comments	Depending on the context of use, the code that was actually selected by the user (prescriber, dispenser, etc.) will have the coding.userSelected set to true. As described in the coding datatype: "A coding may be marked as a "userSelected" if a user selected the particular coded value in a user interface (e.g. the user selects an item in a pick-list). If a user selected coding exists, it is the preferred choice for performing translations etc. Other codes can only be literal translations to alternative code systems, or codes at a lower level of granularity (e.g. a generic code for a vendor-specific primary one).

18. MedicationKnowledge.code.coding

Definition	A reference to a code defined by a terminology system.
Control	0..*
Type	Coding
Must Support	true
Requirements	Allows for alternative encodings within a code system, and translations to other code systems.
Comments	Codes may be defined very casually in enumerations, or code lists, up to very formal definitions such as SNOMED CT - see the HL7 v3 Core Principles for more information. Ordering of codings is undefined and SHALL NOT be used to infer meaning. Generally, at most only one of the coding values will be labeled as UserSelected = true.

67. MedicationKnowledge.code.text (Chemical Name)

Definition	A commonly used name or a systematic name assigned to the chemical or compound. [Source: SME Defined] Examples: acetaminophen; acetamide, N-(4-hydroxyphenyl)-; 4hydroxyacetanilide.
Control	1..1
Type	string
Must Support	true
Requirements	The codes from the terminologies do not always capture the correct meaning with all the nuances of the human using them, or sometimes there is no appropriate code at all. In these cases, the text is used to capture the full meaning of the source.
Comments	Very often the text is the same as a displayName of one of the codings.

87. MedicationKnowledge.ingredient

Definition	Identifies a particular constituent of interest in the product.
Control	0..*
Type	BackboneElement
Must Support	true
Invariants	**Defined on this element** **ele-1**: All FHIR elements must have a @value or children (: hasValue() or (children().count() > id.count()))

91. MedicationKnowledge.ingredient.itemReference

Definition	The actual ingredient - either a substance (simple ingredient) or another medication.
Control	1..1
Type	Reference(PQCMC_Substance)
Must Support	true

f:MedicationKnowledge extension with URL = 'http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-productType': minimum cardinality of 'extension' is 1 extension with URL = 'http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-productType': maximum cardinality of 'extension' is 1 code: minimum cardinality of 'code' is 1 MedicationKnowledge If the resource is contained in another resource, it SHALL NOT contain nested Resources (inherited) If a resource is contained in another resource, it SHALL NOT have a meta.versionId or a meta.lastUpdated (inherited) If the resource is contained in another resource, it SHALL be referred to from elsewhere in the resource or SHALL refer to the containing resource (inherited) A resource should have narrative for robust management (inherited) If a resource is contained in another resource, it SHALL NOT have a security label (inherited) f:MedicationKnowledge/f:extension id: maximum cardinality of 'id' is 1 url: minimum cardinality of 'url' is 1 url: maximum cardinality of 'url' is 1 MedicationKnowledge.extension All FHIR elements must have a @value or children (inherited) Must have either extensions or value[x], not both (inherited) f:MedicationKnowledge/f:code id: maximum cardinality of 'id' is 1 text: minimum cardinality of 'text' is 1 text: maximum cardinality of 'text' is 1 f:MedicationKnowledge/f:code/f:coding id: maximum cardinality of 'id' is 1 system: minimum cardinality of 'system' is 1 system: maximum cardinality of 'system' is 1 version: maximum cardinality of 'version' is 1 code: minimum cardinality of 'code' is 1 code: maximum cardinality of 'code' is 1 display: maximum cardinality of 'display' is 1 userSelected: maximum cardinality of 'userSelected' is 1 id: maximum cardinality of 'id' is 1 system: minimum cardinality of 'system' is 1 system: maximum cardinality of 'system' is 1 version: maximum cardinality of 'version' is 1 code: minimum cardinality of 'code' is 1 code: maximum cardinality of 'code' is 1 display: maximum cardinality of 'display' is 1 userSelected: maximum cardinality of 'userSelected' is 1 id: maximum cardinality of 'id' is 1 system: minimum cardinality of 'system' is 1 system: maximum cardinality of 'system' is 1 version: maximum cardinality of 'version' is 1 code: minimum cardinality of 'code' is 1 code: maximum cardinality of 'code' is 1 display: maximum cardinality of 'display' is 1 userSelected: maximum cardinality of 'userSelected' is 1 id: maximum cardinality of 'id' is 1 system: minimum cardinality of 'system' is 1 system: maximum cardinality of 'system' is 1 version: maximum cardinality of 'version' is 1 code: minimum cardinality of 'code' is 1 code: maximum cardinality of 'code' is 1 display: maximum cardinality of 'display' is 1 userSelected: maximum cardinality of 'userSelected' is 1 id: maximum cardinality of 'id' is 1 system: minimum cardinality of 'system' is 1 system: maximum cardinality of 'system' is 1 version: maximum cardinality of 'version' is 1 code: minimum cardinality of 'code' is 1 code: maximum cardinality of 'code' is 1 display: maximum cardinality of 'display' is 1 userSelected: maximum cardinality of 'userSelected' is 1 id: maximum cardinality of 'id' is 1 system: maximum cardinality of 'system' is 1 version: maximum cardinality of 'version' is 1 code: minimum cardinality of 'code' is 1 code: maximum cardinality of 'code' is 1 display: maximum cardinality of 'display' is 1 userSelected: maximum cardinality of 'userSelected' is 1

MedicationKnowledge.relatedMedicationKnowledge All FHIR elements must have a @value or children (inherited) MedicationKnowledge.monograph All FHIR elements must have a @value or children (inherited) MedicationKnowledge.ingredient All FHIR elements must have a @value or children (inherited) MedicationKnowledge.cost All FHIR elements must have a @value or children (inherited) MedicationKnowledge.monitoringProgram All FHIR elements must have a @value or children (inherited) MedicationKnowledge.administrationGuidelines All FHIR elements must have a @value or children (inherited) MedicationKnowledge.administrationGuidelines.dosage All FHIR elements must have a @value or children (inherited) MedicationKnowledge.administrationGuidelines.patientCharacteristics All FHIR elements must have a @value or children (inherited) MedicationKnowledge.medicineClassification All FHIR elements must have a @value or children (inherited) MedicationKnowledge.packaging All FHIR elements must have a @value or children (inherited) MedicationKnowledge.drugCharacteristic All FHIR elements must have a @value or children (inherited) MedicationKnowledge.regulatory All FHIR elements must have a @value or children (inherited) MedicationKnowledge.regulatory.substitution All FHIR elements must have a @value or children (inherited) MedicationKnowledge.regulatory.schedule All FHIR elements must have a @value or children (inherited) MedicationKnowledge.regulatory.maxDispense All FHIR elements must have a @value or children (inherited) MedicationKnowledge.kinetics All FHIR elements must have a @value or children (inherited)

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StructureDefinition: PQCMC_Substance - Detailed Descriptions

Definitions for the rawingredient Profile.

f:MedicationKnowledge code: minimum cardinality of 'code' is 1 MedicationKnowledge If the resource is contained in another resource, it SHALL NOT contain nested Resources (inherited) If a resource is contained in another resource, it SHALL NOT have a meta.versionId or a meta.lastUpdated (inherited) If the resource is contained in another resource, it SHALL be referred to from elsewhere in the resource or SHALL refer to the containing resource (inherited) A resource should have narrative for robust management (inherited) If a resource is contained in another resource, it SHALL NOT have a security label (inherited) f:MedicationKnowledge/f:code id: maximum cardinality of 'id' is 1 text: minimum cardinality of 'text' is 1 text: maximum cardinality of 'text' is 1 f:MedicationKnowledge/f:code/f:coding id: maximum cardinality of 'id' is 1 system: minimum cardinality of 'system' is 1 system: maximum cardinality of 'system' is 1 version: maximum cardinality of 'version' is 1 code: minimum cardinality of 'code' is 1 code: maximum cardinality of 'code' is 1 display: maximum cardinality of 'display' is 1 userSelected: maximum cardinality of 'userSelected' is 1 id: maximum cardinality of 'id' is 1 system: minimum cardinality of 'system' is 1 system: maximum cardinality of 'system' is 1 version: maximum cardinality of 'version' is 1 code: minimum cardinality of 'code' is 1 code: maximum cardinality of 'code' is 1 display: maximum cardinality of 'display' is 1 userSelected: maximum cardinality of 'userSelected' is 1
MedicationKnowledge.relatedMedicationKnowledge All FHIR elements must have a @value or children (inherited)
MedicationKnowledge.monograph All FHIR elements must have a @value or children (inherited)
MedicationKnowledge.ingredient All FHIR elements must have a @value or children (inherited)
MedicationKnowledge.cost All FHIR elements must have a @value or children (inherited)
MedicationKnowledge.monitoringProgram All FHIR elements must have a @value or children (inherited)
MedicationKnowledge.administrationGuidelines All FHIR elements must have a @value or children (inherited)
MedicationKnowledge.administrationGuidelines.dosage All FHIR elements must have a @value or children (inherited)
MedicationKnowledge.administrationGuidelines.patientCharacteristics All FHIR elements must have a @value or children (inherited) MedicationKnowledge.medicineClassification All FHIR elements must have a @value or children (inherited) MedicationKnowledge.packaging All FHIR elements must have a @value or children (inherited)
MedicationKnowledge.drugCharacteristic All FHIR elements must have a @value or children (inherited)
MedicationKnowledge.regulatory All FHIR elements must have a @value or children (inherited)
MedicationKnowledge.regulatory.substitution All FHIR elements must have a @value or children (inherited)
MedicationKnowledge.regulatory.schedule All FHIR elements must have a @value or children (inherited)
MedicationKnowledge.regulatory.maxDispense All FHIR elements must have a @value or children (inherited)
MedicationKnowledge.kinetics All FHIR elements must have a @value or children (inherited)

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ProductExample - XML Representation

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Raw xml

```xml
<Bundle xmlns="http://hl7.org/fhir">
  <id value="POC32801"/>
  <type value="collection"/>
  <entry>
    <fullUrl value="http://fda.gov/cder/fhir/pqcmc/POC32801.xml"/>
    <resource>
      <PlanDefinition>
        <id value="POC-POC32801-DrugProduct"/>
        <meta>
          <profile
                value="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/qualityspeci
fication"/>
        </meta>
        <text>
          <status value="generated"/>
          <div xmlns="http://www.w3.org/1999/xhtml">
                                        <p>
                                            <b>Proof of Concept PC/CMC Qualit
y Specification</b>
                                        </p>
                                </div>
        </text>
        <extension
                url="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-approvalSt
atus">
          <extension url="type">
            <valueCode value="C25425"/>
          </extension>
          <extension url="date">
            <valueDate value="2017-02-05"/>
          </extension>
        </extension>
        <version value="1.0"/>
        <title value="."/>
        <status value="active"/>
        <subjectReference>
          <reference
                value="MedicationKnoweledge/idigwqdhk4lkudoiwttzesqs5lugq0mu2rsd0xqe
kd1ptktqxadunl"/>
        </subjectReference>
```

```xml
          <date value="2016-09-24"/>
          <goal id="goal1">
            <description>
              <text value="Oval Pink Tablet"/>
            </description>
            <target>
              <detailCodeableConcept>
                <text value="Oval Pink"/>
              </detailCodeableConcept>
            </target>
          </goal>
          <goal id="goal2">
            <description>
              <text value="1.9% - 2.5%; 1.9%-2.5%;"/>
            </description>
            <target>
              <detailRange>
                <low>
                  <value value="1.9"/>
                  <system value="http://unitsofmeasure.org"/>
                  <code value="%"/>
                </low>
                <high>
                  <value value="2.5"/>
                  <system value="http://unitsofmeasure.org"/>
                  <code value="%"/>
                </high>
              </detailRange>
            </target>
          </goal>
          <goal id="goal4">
            <description>
              <text value="NMT 1000 cfu/g"/>
            </description>
            <target>
              <detailRange>
                <high>
                  <value value="1000"/>
                  <system value="http://unitsofmeasure.org"/>
                  <code value="cfu/g"/>
                </high>
              </detailRange>
            </target>
          </goal>
          <goal id="goal5">
            <description>
              <text value="Should be Absent/g"/>
            </description>
            <target>
              <detailCodeableConcept>
                <text value="Should be Absent/g"/>
              </detailCodeableConcept>
            </target>
          </goal>
          <goal id="goal6">
            <description>
              <text value="no one unit (of the 6) is NMT 10%"/>
```

```
        </description>
        <target>
          <detailRange>
            <high>
              <value value="10"/>
              <system value="http://unitsofmeasure.org"/>
              <code value="%"/>
            </high>
          </detailRange>
        </target>
      </goal>
      <goal id="goal7">
        <description>
          <text value="(average of 12) NMT 10%"/>
        </description>
        <target>
          <detailRange>
            <high>
              <value value="10"/>
              <system value="http://unitsofmeasure.org"/>
              <code value="%"/>
            </high>
          </detailRange>
        </target>
      </goal>
      <goal id="goal8">
        <description>
          <text value="no one unit is NMT 25%"/>
        </description>
        <target>
          <detailRange>
            <high>
              <value value="25"/>
              <system value="http://unitsofmeasure.org"/>
              <code value="%"/>
            </high>
          </detailRange>
        </target>
      </goal>
      <goal id="goal9">
        <description>
          <text value="(average of 24) NMT 10%"/>
        </description>
        <target>
          <detailRange>
            <high>
              <value value="10"/>
              <system value="http://unitsofmeasure.org"/>
              <code value="%"/>
            </high>
          </detailRange>
        </target>
      </goal>
      <goal id="goal10">
        <description>
          <text value="no one unit is NMT 25%"/>
        </description>
```

```xml
            <target>
              <detailRange>
                <high>
                  <value value="25"/>
                  <system value="http://unitsofmeasure.org"/>
                  <code value="%"/>
                </high>
              </detailRange>
            </target>
          </goal>
          <action>
            <extension
                    url="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-methodOr
igin">
              <valueCode value="Proprietary"/>
            </extension>
            <extension
                    url="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-definiti
onUri">
              <valueString value="POC32801/Product/ver_1.0/Visual"/>
            </extension>
            <title value="Description"/>
            <code>
              <coding>
                <code value="C138990"/>
                <display value="Description"/>
              </coding>
              <text value="Visual"/>
            </code>
            <reason>
              <coding>
                <code value="C134029"/>
                <display value="Release"/>
              </coding>
            </reason>
            <action id="idvnm0ta5zyl22fbg2qqxymlmljbbhngwtvwdl4dkgdd20ephziase">
              <title value="Single Stage"/>
              <goalId value="goal1"/>
            </action>
          </action>
          <action>
            <extension
                    url="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-methodOr
igin">
              <valueCode value="Compendial"/>
            </extension>
            <extension
                    url="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-definiti
onUri">
              <valueString value="POC32801/Product/ver_1.0/USP_&lt;921&gt;"/>
            </extension>
            <title value="Water % w/v by KF"/>
            <code>
              <coding>
                <code value="C17771"/>
                <display value="Chemical Properties"/>
              </coding>
```

```xml
          <text value="KF"/>
        </code>
        <reason>
          <coding>
            <code value="C134029"/>
            <display value="Release"/>
          </coding>
        </reason>
        <action id="idro5omudnrrx3elfnxt5su4q1geqlbm2t3jvzujdogwq1kggm24be">
          <title value="Single Stage"/>
          <goalId value="goal2"/>
        </action>
      </action>
      <action>
        <extension
                  url="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-methodOr
igin">
          <valueCode value="Proprietary"/>
        </extension>
        <extension
                  url="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-definiti
onUri">
          <valueString value="POC32801/Product/ver_1.0/MTE-2000"/>
        </extension>
        <title value="Total Aerobic microbial count"/>
        <code>
          <coding>
            <code value="C158425"/>
            <display value="Biological Properties"/>
          </coding>
          <text value="Microbial limits"/>
        </code>
        <reason>
          <coding>
            <code value="C134029"/>
            <display value="Release"/>
          </coding>
        </reason>
        <action id="id1pghkcl2wcoccmzsip3w32oomjvh1czjjud2uipbmevrklsiim1k">
          <title value="Single Stage"/>
          <goalId value="goal4"/>
        </action>
      </action>
      <action>
        <extension
                  url="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-methodOr
igin">
          <valueCode value="Proprietary"/>
        </extension>
        <extension
                  url="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-definiti
onUri">
          <valueString value="POC32801/Product/ver_1.0/MTE-20065"/>
        </extension>
        <title value="E.Coli"/>
        <code>
          <coding>
```

```
              <code value="C158425"/>
              <display value="Biological Properties"/>
            </coding>
            <text value="Microbial limits"/>
          </code>
          <reason>
            <coding>
              <code value="C134029"/>
              <display value="Release"/>
            </coding>
          </reason>
          <action id="idlu0pynrj324dnq3wyiapoafdokm2m3ub1ld1ohmxsjtsivnvs5g">
            <title value="Single Stage"/>
            <goalId value="goal5"/>
          </action>
        </action>
        <action>
          <extension
                    url="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-methodOr
igin">
            <valueCode value="Compendial"/>
          </extension>
          <extension
                    url="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-definiti
onUri">
            <valueString value="POC32801/Product/ver_1.0/USP&lt;711&gt;"/>
          </extension>
          <title value="Dissolution in Acid Stage (2 hours)"/>
          <code>
            <coding>
              <code value="C60819"/>
              <display value="Assay"/>
            </coding>
            <text value="711"/>
          </code>
          <reason>
            <coding>
              <code value="C134029"/>
              <display value="Release"/>
            </coding>
          </reason>
          <action id="idjsuiv3smxndoho0nb5y551juwdr31madwensw2bac2ngjaoyyo5e">
            <title value="First Stage"/>
            <goalId value="goal6"/>
          </action>
          <action id="iddqp5os1advhhgopfugbe2dgknqqhhugouvcdrohmdqac3oluwpm">
            <title value="Second Stage"/>
            <goalId value="goal7"/>
            <goalId value="goal8"/>
            <relatedAction>
              <actionId value="d39aeafc-901c-4386-9642-22438da8e444"/>
              <relationship value="after"/>
            </relatedAction>
          </action>
          <action id="idrwszgobaqa4lrnpqcgc32mzoeoikjurhtbcprk5lqmdlk0ieg3e">
            <title value="Third Stage"/>
            <goalId value="goal9"/>
```

```xml
                <goalId value="goal10"/>
                <relatedAction>
                  <actionId value="9fca490e-ef23-4fa4-922a-527956f60faf"/>
                  <relationship value="after"/>
                </relatedAction>
              </action>
            </action>
        </PlanDefinition>
      </resource>
    </entry>
    <entry>
      <fullUrl
              value="urn:uuid:idigwqdhk4lkudoiwttzesqs5lugq0mu2rsd0xqekd1ptktqxadunl"/>
      <resource>
        <MedicationKnowledge>
          <id value="idigwqdhk4lkudoiwttzesqs5lugq0mu2rsd0xqekd1ptktqxadunl"/>
          <meta>
            <profile
                    value="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/drugproduct"
/>
          </meta>
          <text>
            <status value="generated"/>
            <div xmlns="http://www.w3.org/1999/xhtml">
                                        <p>
                                                <b>Drug Product section</b>
                                        </p>
                                </div>
          </text>
          <extension
                    url="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-productTyp
e">
            <valueCode value="product"/>
          </extension>
          <code>
            <text value="Diphenhydramine Antihistamine"/>
          </code>
          <doseForm>
            <coding>
              <code value="C42998"/>
              <display value="TABLET"/>
            </coding>
          </doseForm>
          <synonym value="Benadryl HCL">
            <extension
                    url="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-nameType
">
              <valueCode value="proprietary"/>
            </extension>
          </synonym>
          <ingredient>
            <itemCodeableConcept>
              <coding>
                <display value="Diphenhydramine HCL"/>
              </coding>
            </itemCodeableConcept>
            <strength>
```

```
              <numerator>
                <value value="25"/>
                <system value="http://unitsofmeasure.org"/>
                <code value="mg"/>
              </numerator>
              <denominator>
                <value value="1"/>
              </denominator>
            </strength>
          </ingredient>
        </MedicationKnowledge>
      </resource>
    </entry>
  </Bundle>
```

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SubstanceExample - XML Representation

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Raw xml

```xml
<Bundle xmlns="http://hl7.org/fhir">
  <id value="POC32802"/>
  <type value="collection"/>
  <entry>
    <fullUrl value="http://fda.gov/cder/fhir/pqcmc/POC32802.xml"/>
    <resource>
      <PlanDefinition>
        <id value="POC-POC32802-DrugSubstance"/>
        <meta>
          <profile
                value="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/qualityspeci
fication"/>
        </meta>
        <text>
          <status value="generated"/>
          <div xmlns="http://www.w3.org/1999/xhtml">
                                        <p>
                                          <b>Proof of Concept PC/CMC Qualit
y Specification</b>
                                        </p>
                                </div>
        </text>
        <extension
                url="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-approvalSt
atus">
          <extension url="type">
            <valueCode value="C25425"/>
          </extension>
          <extension url="date">
            <valueDate value="2012-10-07"/>
          </extension>
        </extension>
        <version value="1.0"/>
        <title value="."/>
        <status value="active"/>
        <subjectReference>
          <reference
                value="MedicationKnoweledge/idb2fkhte2ctyuos5kunitness0j0okowtvcur2k
k0rlcbzuk0wcgo"/>
        </subjectReference>
```

```xml
            <date value="2008-05-17"/>
            <goal id="goal1">
              <description>
                <text value="White to off-White powder"/>
              </description>
              <target>
                <detailCodeableConcept>
                  <text value="White to off-White powder"/>
                </detailCodeableConcept>
              </target>
            </goal>
            <goal id="goal2">
              <description>
                <text value="169-170 Deg C; 169-170 Deg C;"/>
              </description>
              <target>
                <detailRange>
                  <low>
                    <value value="169"/>
                    <system value="http://unitsofmeasure.org"/>
                    <code value="Degree C"/>
                  </low>
                  <high>
                    <value value="170"/>
                    <system value="http://unitsofmeasure.org"/>
                    <code value="Degree C"/>
                  </high>
                </detailRange>
              </target>
            </goal>
            <goal id="goal4">
              <description>
                <text value="NMT 20 um"/>
              </description>
              <target>
                <detailRange>
                  <high>
                    <value value="20"/>
                    <system value="http://unitsofmeasure.org"/>
                    <code value="um"/>
                  </high>
                </detailRange>
              </target>
            </goal>
            <goal id="goal5">
              <description>
                <text value="NMT 50 um"/>
              </description>
              <target>
                <detailRange>
                  <high>
                    <value value="50"/>
                    <system value="http://unitsofmeasure.org"/>
                    <code value="um"/>
                  </high>
                </detailRange>
              </target>
```

```xml
            </goal>
            <goal id="goal6">
              <description>
                <text value="NMT 2.0%"/>
              </description>
              <target>
                <detailRange>
                  <high>
                    <value value="2"/>
                    <system value="http://unitsofmeasure.org"/>
                    <code value="%"/>
                  </high>
                </detailRange>
              </target>
            </goal>
            <action>
              <extension
                      url="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-methodOr
igin">
                <valueCode value="Proprietary"/>
              </extension>
              <extension
                      url="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-definiti
onUri">
                <valueString value="ABBV32805/Substance/ver_1.0/Visual"/>
              </extension>
              <title value="Description"/>
              <code>
                <coding>
                  <code value="C138990"/>
                  <display value="Description"/>
                </coding>
                <text value="Visual"/>
              </code>
              <reason>
                <coding>
                  <code value="C134029"/>
                  <display value="Release"/>
                </coding>
              </reason>
              <action id="idsvvyib4hb5zkhenmq0xswaydsejhbx0tswhu1qjy1r305ksjk30p">
                <title value="Single Stage"/>
                <goalId value="goal1"/>
              </action>
            </action>
            <action>
              <extension
                      url="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-methodOr
igin">
                <valueCode value="Proprietary"/>
              </extension>
              <extension
                      url="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-definiti
onUri">
                <valueString value="ABBV32805/Substance/ver_1.0/TXXQ-1234"/>
              </extension>
              <title value="Menting Range"/>
```

```xml
            <code>
              <coding>
                <code value="C158424"/>
                <display value="Physical Properties"/>
              </coding>
              <text value="Thiele Tube"/>
            </code>
            <reason>
              <coding>
                <code value="C134029"/>
                <display value="Release"/>
              </coding>
            </reason>
            <action id="idg0xeno3yzb5uhvzgefqwhjzm4ixlmwqbh31ovybaahacrnvqf12">
              <title value="Single Stage"/>
              <goalId value="goal2"/>
            </action>
          </action>
          <action>
            <extension
                    url="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-methodOr
igin">
              <valueCode value="Proprietary"/>
            </extension>
            <extension
                    url="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-definiti
onUri">
              <valueString value="ABBV32805/Substance/ver_1.0/XX-0000"/>
            </extension>
            <title value="Particle Size Distribution D (0.1)"/>
            <code>
              <coding>
                <code value="C158424"/>
                <display value="Physical Properties"/>
              </coding>
              <text value="Laser Diffraction"/>
            </code>
            <reason>
              <coding>
                <code value="C134029"/>
                <display value="Release"/>
              </coding>
            </reason>
            <action id="idwofubpdwv1q4jjqet02rbtby4gkixqg15tyu1ppumn5ufgeoauzg">
              <title value="Single Stage"/>
              <goalId value="goal4"/>
            </action>
          </action>
          <action>
            <extension
                    url="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-methodOr
igin">
              <valueCode value="Proprietary"/>
            </extension>
            <extension
                    url="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-definiti
onUri">
```

```xml
              <valueString value="ABBV32805/Substance/ver_1.0/XX-0000"/>
            </extension>
            <title value="Particle Size Distribution d (0.5)"/>
            <code>
              <coding>
                <code value="C158424"/>
                <display value="Physical Properties"/>
              </coding>
              <text value="Laser Diffraction"/>
            </code>
            <reason>
              <coding>
                <code value="C134029"/>
                <display value="Release"/>
              </coding>
            </reason>
            <action id="iddqp5os1advhhgopfugbe2dgknqqhhugouvcdrohmdqac3oluwpm">
              <title value="Single Stage"/>
              <goalId value="goal5"/>
            </action>
          </action>
          <action>
            <extension
                      url="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-methodOr
igin">
              <valueCode value="Proprietary"/>
            </extension>
            <extension
                      url="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-definiti
onUri">
              <valueString value="ABBV32805/Substance/ver_1.0/DEF-1122334455"/>
            </extension>
            <title value="Polymorphic Form II (DSC)"/>
            <code>
              <coding>
                <code value="C158424"/>
                <display value="Physical Properties"/>
              </coding>
              <text value="DSC"/>
            </code>
            <reason>
              <coding>
                <code value="C134029"/>
                <display value="Release"/>
              </coding>
            </reason>
            <action id="idysmxnbhdczfdca1vnukkdryq1inu0xmqyoohivmdyzwzy14kfhgb">
              <title value="Single Stage"/>
              <goalId value="goal6"/>
            </action>
          </action>
        </PlanDefinition>
      </resource>
    </entry>
    <entry>
      <fullUrl
              value="urn:uuid:idb2fkhte2ctyuos5kunitness0j0okowtvcur2kk0rlcbzuk0wcgo"/>
```

```xml
    <resource>
      <MedicationKnowledge>
        <id value="idb2fkhte2ctyuos5kunitness0j0okowtvcur2kk0rlcbzuk0wcgo"/>
        <meta>
          <profile
                value="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/drugsubstanc
e"/>
        </meta>
        <text>
          <status value="generated"/>
          <div xmlns="http://www.w3.org/1999/xhtml">
                                    <p>
                                        <b>Drug Substance section</b>
                                    </p>
                                </div>
        </text>
        <extension
                url="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-productTyp
e">
          <valueCode value="substance"/>
        </extension>
        <code>
          <coding>
            <system
                value="http://www.fda.gov/ForIndustry/DataStandards/SubstanceRegistra
tionSystem-UniqueIngredientIdentifierUNII/default.html"/>
            <code value="36209ITL9D"/>
          </coding>
          <coding>
            <system value="https://www.cas.org/"/>
            <code value="103-90-2"/>
          </coding>
          <coding>
            <system
                value="https://iupac.org/who-we-are/divisions/division-details/inchi/
"/>
            <code value="N-(4-hydroxyphenyl)acetamide"/>
          </coding>
          <text value="Acetominophen"/>
        </code>
      </MedicationKnowledge>
    </resource>
  </entry>
</Bundle>
```

```xml
<?xml version="1.0" encoding="UTF-8"?>

<ValueSet xmlns="http://hl7.org/fhir">
  <id value="DoseForm"/>
  <meta>
    <profile value="http://hl7.org/fhir/StructureDefinition/shareablevalueset"/>
  </meta>
  <text>
    <status value="generated"/><div xmlns="http://www.w3.org/1999/xhtml"><h2>cmcDose</h2><div><p>This is the
physical form of the product as presented to the individual. For example: tablet, capsule, liquid or ointment. NCI
concept code for pharmaceutical dosage form: C42636</p>
</div><p>This value set includes codes from the following code systems:</p><ul><li>Include all codes defined in <a
href="DoseForm.html"><code>http://fda.gov/cder/fhir/pqcmc/CodeSystem/DoseForm</code></a></li></ul></div>
  </text>
  <url value="http://fda.gov/cder/fhir/pqcmc/ValueSet/DoseForm"/>
  <version value="current"/>
  <name value="cmcDose"/>
  <status value="draft"/>
  <experimental value="false"/>
  <date value="2019-04-18T17:50:12-04:00"/>
  <contact>
    <telecom>
      <system value="url"/>
    </telecom>
    <telecom>
      <system value="email"/>
    </telecom>
  </contact>
  <description value="This is the physical form of the product as presented to the individual. For example: tablet,
capsule, liquid or ointment. NCI concept code for pharmaceutical dosage form: C42636"/>
  <immutable value="true"/>
  <compose>
    <include>
      <system value="http://fda.gov/cder/fhir/pqcmc/CodeSystem/DoseForm"/>
    </include>
  </compose>
</ValueSet>
```

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Raw xml

```
<CodeSystem xmlns="http://hl7.org/fhir">
  <id value="DoseForm"/>
  <text>
    <status value="generated"/>
    <div xmlns="http://www.w3.org/1999/xhtml"><h2>cmcDose</h2><div><p>This is the physica
l form of the product as presented to the individual. For example: tablet, capsule, liqui
d or ointment. NCI concept code for pharmaceutical dosage form: C42636</p>
</div><p>This code system http://fda.gov/cder/fhir/pqcmc/CodeSystem/DoseForm defines the
following codes:</p><table class="codes"><tr><td style="white-space:nowrap"><b>Code</b></
td><td><b>Display</b></td><td><b>Definition</b></td></tr><tr><td style="white-space:nowra
p">C42887<a name="DoseForm-C42887"> </a></td><td>AEROSOL</td><td/></tr><tr><td style="whi
te-space:nowrap">C42888<a name="DoseForm-C42888"> </a></td><td>AEROSOL, FOAM</td><td/></t
r><tr><td style="white-space:nowrap">C42960<a name="DoseForm-C42960"> </a></td><td>AEROSO
L, METERED</td><td/></tr><tr><td style="white-space:nowrap">C42971<a name="DoseForm-C4297
1"> </a></td><td>AEROSOL, POWDER</td><td/></tr><tr><td style="white-space:nowrap">C42889<
a name="DoseForm-C42889"> </a></td><td>AEROSOL, SPRAY</td><td/></tr><tr><td style="white-
space:nowrap">C42892<a name="DoseForm-C42892"> </a></td><td>BAR, CHEWABLE</td><td/></tr><
tr><td style="white-space:nowrap">C42890<a name="DoseForm-C42890"> </a></td><td>BEAD</td>
<td/></tr><tr><td style="white-space:nowrap">C25158<a name="DoseForm-C25158"> </a></td><t
d>CAPSULE</td><td/></tr><tr><td style="white-space:nowrap">C42895<a name="DoseForm-C42895
"> </a></td><td>CAPSULE, COATED</td><td/></tr><tr><td style="white-space:nowrap">C42896<a
 name="DoseForm-C42896"> </a></td><td>CAPSULE, COATED PELLETS</td><td/></tr><tr><td style
="white-space:nowrap">C42917<a name="DoseForm-C42917"> </a></td><td>CAPSULE, COATED, EXTE
NDED RELEASE</td><td/></tr><tr><td style="white-space:nowrap">C42902<a name="DoseForm-C42
902"> </a></td><td>CAPSULE, DELAYED RELEASE</td><td/></tr><tr><td style="white-space:nowr
ap">C42904<a name="DoseForm-C42904"> </a></td><td>CAPSULE, DELAYED RELEASE PELLETS</td><t
d/></tr><tr><td style="white-space:nowrap">C42916<a name="DoseForm-C42916"> </a></td><td>
CAPSULE, EXTENDED RELEASE</td><td/></tr><tr><td style="white-space:nowrap">C42928<a name=
"DoseForm-C42928"> </a></td><td>CAPSULE, FILM COATED, EXTENDED RELEASE</td><td/></tr><tr>
<td style="white-space:nowrap">C42936<a name="DoseForm-C42936"> </a></td><td>CAPSULE, GEL
ATIN COATED</td><td/></tr><tr><td style="white-space:nowrap">C42954<a name="DoseForm-C429
54"> </a></td><td>CAPSULE, LIQUID FILLED</td><td/></tr><tr><td style="white-space:nowrap"
>C100103<a name="DoseForm-C100103"> </a></td><td>CELLULAR SHEET</td><td/></tr><tr><td sty
le="white-space:nowrap">C134876<a name="DoseForm-C134876"> </a></td><td>CHEWABLE GEL</td>
<td/></tr><tr><td style="white-space:nowrap">C60884<a name="DoseForm-C60884"> </a></td><t
d>CLOTH</td><td/></tr><tr><td style="white-space:nowrap">C60891<a name="DoseForm-C60891">
 </a></td><td>CONCENTRATE</td><td/></tr><tr><td style="white-space:nowrap">C28944<a name=
"DoseForm-C28944"> </a></td><td>CREAM</td><td/></tr><tr><td style="white-space:nowrap">C6
0897<a name="DoseForm-C60897"> </a></td><td>CREAM, AUGMENTED</td><td/></tr><tr><td style=
"white-space:nowrap">C42901<a name="DoseForm-C42901"> </a></td><td>CRYSTAL</td><td/></tr>
<tr><td style="white-space:nowrap">C43525<a name="DoseForm-C43525"> </a></td><td>DISC</td
><td/></tr><tr><td style="white-space:nowrap">C42679<a name="DoseForm-C42679"> </a></td><
```

Code	Dose Form
	DOUCHE
C42763	DRESSING
C42912	ELIXIR
C42913	EMULSION
C42915	ENEMA
C42929	EXTRACT
C60926	FIBER, EXTENDED RELEASE
C42932	FILM
C42920	FILM, EXTENDED RELEASE
C42984	FILM, SOLUBLE
C60927	FOR SOLUTION
C60928	FOR SUSPENSION
C60929	FOR SUSPENSION, EXTENDED RELEASE
C42933	GAS
C42934	GEL
C42906	GEL, DENTIFRICE
C60930	GEL, METERED
C42937	GLOBULE
C42938	GRANULE
C42903	GRANULE, DELAYED RELEASE
C42909	GRANULE, EFFERVESCENT
C42939	GRANULE, FOR SOLUTION
C42940	GRANULE, FOR SUSPENSION
C42921	GRANULE, FOR SUSPENSION, EXTENDED RELEASE
C42894	GUM, CHEWING
C42942	IMPLANT
C42944	INHALANT
C113106	INJECTABLE FOAM
C60931	INJECTABLE, LIPOSOMAL
C42946	INJECTION
C42914	INJECTION, EMULSION
C42950	INJECTION, LIPID COMPLEX
C42974	INJECTION, POWDER, FOR SOLUTION
C42976	INJECTION, POWDER, FOR SUSPENSION
C42977	INJECTION, POWDER, FOR SUSPENSION, EXTENDED RELEASE
C42959	INJECTION, POWDER, LYOPHILIZED, FOR LIPOSOMAL SUSPENSION
C42957	INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION
C42958	INJECTION, POWDER, LYOPHILIZED, FOR SUSPENSION
C42956	INJECTION, POWDER, LYOPHILIZED, FOR SUSPENSION, EXTENDED RELEASE
C42945	INJECTION, SOLUTION
C42899	INJECTION, SOLUTION, CONCENTRATE
C42995	INJECTION, SUSPENSION
C42926	INJECTION, SUSPENSION, EXTENDED RELEASE
C42951	INJECTION, SUSPENSION, LIPOSOMAL

```
td style="white-space:nowrap">C42988<a name="DoseForm-C42988"> </a></td><td>INJECTION, SU
SPENSION, SONICATED</td><td/></tr><tr><td style="white-space:nowrap">C60933<a name="DoseF
orm-C60933"> </a></td><td>INSERT</td><td/></tr><tr><td style="white-space:nowrap">C42922<
a name="DoseForm-C42922"> </a></td><td>INSERT, EXTENDED RELEASE</td><td/></tr><tr><td sty
le="white-space:nowrap">C47915<a name="DoseForm-C47915"> </a></td><td>INTRAUTERINE DEVICE
</td><td/></tr><tr><td style="white-space:nowrap">C42947<a name="DoseForm-C42947"> </a></
td><td>IRRIGANT</td><td/></tr><tr><td style="white-space:nowrap">C42948<a name="DoseForm-
C42948"> </a></td><td>JELLY</td><td/></tr><tr><td style="white-space:nowrap">C47916<a nam
e="DoseForm-C47916"> </a></td><td>KIT</td><td/></tr><tr><td style="white-space:nowrap">C4
2949<a name="DoseForm-C42949"> </a></td><td>LINIMENT</td><td/></tr><tr><td style="white-s
pace:nowrap">C42952<a name="DoseForm-C42952"> </a></td><td>LIPSTICK</td><td/></tr><tr><td
 style="white-space:nowrap">C42953<a name="DoseForm-C42953"> </a></td><td>LIQUID</td><td/
></tr><tr><td style="white-space:nowrap">C60934<a name="DoseForm-C60934"> </a></td><td>LI
QUID, EXTENDED RELEASE</td><td/></tr><tr><td style="white-space:nowrap">C29167<a name="Do
seForm-C29167"> </a></td><td>LOTION</td><td/></tr><tr><td style="white-space:nowrap">C609
57<a name="DoseForm-C60957"> </a></td><td>LOTION, AUGMENTED</td><td/></tr><tr><td style="
white-space:nowrap">C60958<a name="DoseForm-C60958"> </a></td><td>LOTION/SHAMPOO</td><td/
></tr><tr><td style="white-space:nowrap">C42955<a name="DoseForm-C42955"> </a></td><td>LO
ZENGE</td><td/></tr><tr><td style="white-space:nowrap">C29269<a name="DoseForm-C29269"> <
/a></td><td>MOUTHWASH</td><td/></tr><tr><td style="white-space:nowrap">C48624<a name="Dos
eForm-C48624"> </a></td><td>NOT APPLICABLE</td><td/></tr><tr><td style="white-space:nowra
p">C42965<a name="DoseForm-C42965"> </a></td><td>OIL</td><td/></tr><tr><td style="white-s
pace:nowrap">C42966<a name="DoseForm-C42966"> </a></td><td>OINTMENT</td><td/></tr><tr><td
 style="white-space:nowrap">C60984<a name="DoseForm-C60984"> </a></td><td>OINTMENT, AUGME
NTED</td><td/></tr><tr><td style="white-space:nowrap">C42967<a name="DoseForm-C42967"> </
a></td><td>PASTE</td><td/></tr><tr><td style="white-space:nowrap">C42907<a name="DoseForm
-C42907"> </a></td><td>PASTE, DENTIFRICE</td><td/></tr><tr><td style="white-space:nowrap"
>C60985<a name="DoseForm-C60985"> </a></td><td>PASTILLE</td><td/></tr><tr><td style="whit
e-space:nowrap">C42968<a name="DoseForm-C42968"> </a></td><td>PATCH</td><td/></tr><tr><td
 style="white-space:nowrap">C42923<a name="DoseForm-C42923"> </a></td><td>PATCH, EXTENDED
 RELEASE</td><td/></tr><tr><td style="white-space:nowrap">C42911<a name="DoseForm-C42911"
> </a></td><td>PATCH, EXTENDED RELEASE, ELECTRICALLY CONTROLLED</td><td/></tr><tr><td sty
le="white-space:nowrap">C42969<a name="DoseForm-C42969"> </a></td><td>PELLET</td><td/></t
r><tr><td style="white-space:nowrap">C42943<a name="DoseForm-C42943"> </a></td><td>PELLET
, IMPLANTABLE</td><td/></tr><tr><td style="white-space:nowrap">C42918<a name="DoseForm-C4
2918"> </a></td><td>PELLETS, COATED, EXTENDED RELEASE</td><td/></tr><tr><td style="white-
space:nowrap">C25394<a name="DoseForm-C25394"> </a></td><td>PILL</td><td/></tr><tr><td st
yle="white-space:nowrap">C42970<a name="DoseForm-C42970"> </a></td><td>PLASTER</td><td/><
/tr><tr><td style="white-space:nowrap">C47913<a name="DoseForm-C47913"> </a></td><td>POUL
TICE</td><td/></tr><tr><td style="white-space:nowrap">C42972<a name="DoseForm-C42972"> </
a></td><td>POWDER</td><td/></tr><tr><td style="white-space:nowrap">C42908<a name="DoseFor
m-C42908"> </a></td><td>POWDER, DENTIFRICE</td><td/></tr><tr><td style="white-space:nowra
p">C42973<a name="DoseForm-C42973"> </a></td><td>POWDER, FOR SOLUTION</td><td/></tr><tr><
td style="white-space:nowrap">C42975<a name="DoseForm-C42975"> </a></td><td>POWDER, FOR S
USPENSION</td><td/></tr><tr><td style="white-space:nowrap">C42961<a name="DoseForm-C42961
"> </a></td><td>POWDER, METERED</td><td/></tr><tr><td style="white-space:nowrap">C60988<a
 name="DoseForm-C60988"> </a></td><td>RING</td><td/></tr><tr><td style="white-space:nowra
p">C42979<a name="DoseForm-C42979"> </a></td><td>RINSE</td><td/></tr><tr><td style="white
-space:nowrap">C42980<a name="DoseForm-C42980"> </a></td><td>SALVE</td><td/></tr><tr><td
style="white-space:nowrap">C42981<a name="DoseForm-C42981"> </a></td><td>SHAMPOO</td><td/
></tr><tr><td style="white-space:nowrap">C42982<a name="DoseForm-C42982"> </a></td><td>SH
AMPOO, SUSPENSION</td><td/></tr><tr><td style="white-space:nowrap">C42983<a name="DoseFor
m-C42983"> </a></td><td>SOAP</td><td/></tr><tr><td style="white-space:nowrap">C42986<a na
me="DoseForm-C42986"> </a></td><td>SOLUTION</td><td/></tr><tr><td style="white-space:nowr
ap">C42898<a name="DoseForm-C42898"> </a></td><td>SOLUTION, CONCENTRATE</td><td/></tr><tr
><td style="white-space:nowrap">C42987<a name="DoseForm-C42987"> </a></td><td>SOLUTION, F
OR SLUSH</td><td/></tr><tr><td style="white-space:nowrap">C60994<a name="DoseForm-C60994"
```

```
> </a></td><td>SOLUTION, GEL FORMING / DROPS</td><td/></tr><tr><td style="white-space:now
rap">C42935<a name="DoseForm-C42935"> </a></td><td>SOLUTION, GEL FORMING, EXTENDED RELEAS
E</td><td/></tr><tr><td style="white-space:nowrap">C60992<a name="DoseForm-C60992"> </a><
/td><td>SOLUTION/ DROPS</td><td/></tr><tr><td style="white-space:nowrap">C47912<a name="D
oseForm-C47912"> </a></td><td>SPONGE</td><td/></tr><tr><td style="white-space:nowrap">C42
989<a name="DoseForm-C42989"> </a></td><td>SPRAY</td><td/></tr><tr><td style="white-space
:nowrap">C42962<a name="DoseForm-C42962"> </a></td><td>SPRAY, METERED</td><td/></tr><tr><
td style="white-space:nowrap">C42990<a name="DoseForm-C42990"> </a></td><td>SPRAY, SUSPEN
SION</td><td/></tr><tr><td style="white-space:nowrap">C42991<a name="DoseForm-C42991"> </
a></td><td>STICK</td><td/></tr><tr><td style="white-space:nowrap">C47914<a name="DoseForm
-C47914"> </a></td><td>STRIP</td><td/></tr><tr><td style="white-space:nowrap">C42993<a na
me="DoseForm-C42993"> </a></td><td>SUPPOSITORY</td><td/></tr><tr><td style="white-space:n
owrap">C42924<a name="DoseForm-C42924"> </a></td><td>SUPPOSITORY, EXTENDED RELEASE</td><t
d/></tr><tr><td style="white-space:nowrap">C42994<a name="DoseForm-C42994"> </a></td><td>
SUSPENSION</td><td/></tr><tr><td style="white-space:nowrap">C42925<a name="DoseForm-C4292
5"> </a></td><td>SUSPENSION, EXTENDED RELEASE</td><td/></tr><tr><td style="white-space:no
wrap">C60995<a name="DoseForm-C60995"> </a></td><td>SUSPENSION/ DROPS</td><td/></tr><tr><
td style="white-space:nowrap">C47898<a name="DoseForm-C47898"> </a></td><td>SWAB</td><td/
></tr><tr><td style="white-space:nowrap">C42996<a name="DoseForm-C42996"> </a></td><td>SY
RUP</td><td/></tr><tr><td style="white-space:nowrap">C42998<a name="DoseForm-C42998"> </a
></td><td>TABLET</td><td/></tr><tr><td style="white-space:nowrap">C42893<a name="DoseForm
-C42893"> </a></td><td>TABLET, CHEWABLE</td><td/></tr><tr><td style="white-space:nowrap">
C124794<a name="DoseForm-C124794"> </a></td><td>TABLET, CHEWABLE, EXTENDED RELEASE</td><t
d/></tr><tr><td style="white-space:nowrap">C42897<a name="DoseForm-C42897"> </a></td><td>
TABLET, COATED</td><td/></tr><tr><td style="white-space:nowrap">C60997<a name="DoseForm-C
60997"> </a></td><td>TABLET, COATED PARTICLES</td><td/></tr><tr><td style="white-space:no
wrap">C42905<a name="DoseForm-C42905"> </a></td><td>TABLET, DELAYED RELEASE</td><td/></tr
><tr><td style="white-space:nowrap">C42997<a name="DoseForm-C42997"> </a></td><td>TABLET,
 DELAYED RELEASE PARTICLES</td><td/></tr><tr><td style="white-space:nowrap">C42910<a name
="DoseForm-C42910"> </a></td><td>TABLET, EFFERVESCENT</td><td/></tr><tr><td style="white-
space:nowrap">C42927<a name="DoseForm-C42927"> </a></td><td>TABLET, EXTENDED RELEASE</td>
<td/></tr><tr><td style="white-space:nowrap">C42931<a name="DoseForm-C42931"> </a></td><t
d>TABLET, FILM COATED</td><td/></tr><tr><td style="white-space:nowrap">C42930<a name="Dos
eForm-C42930"> </a></td><td>TABLET, FILM COATED, EXTENDED RELEASE</td><td/></tr><tr><td s
tyle="white-space:nowrap">C61004<a name="DoseForm-C61004"> </a></td><td>TABLET, FOR SOLUT
ION</td><td/></tr><tr><td style="white-space:nowrap">C61005<a name="DoseForm-C61005"> </a
></td><td>TABLET, FOR SUSPENSION</td><td/></tr><tr><td style="white-space:nowrap">C42964<
a name="DoseForm-C42964"> </a></td><td>TABLET, MULTILAYER</td><td/></tr><tr><td style="wh
ite-space:nowrap">C42963<a name="DoseForm-C42963"> </a></td><td>TABLET, MULTILAYER, EXTEN
DED RELEASE</td><td/></tr><tr><td style="white-space:nowrap">C42999<a name="DoseForm-C429
99"> </a></td><td>TABLET, ORALLY DISINTEGRATING</td><td/></tr><tr><td style="white-space:
nowrap">C61006<a name="DoseForm-C61006"> </a></td><td>TABLET, ORALLY DISINTEGRATING, DELA
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><td>TAMPON</td><td/></tr><tr><td style="white-space:nowrap">C47897<a name="DoseForm-C478
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seForm-C43000"> </a></td><td>TINCTURE</td><td/></tr><tr><td style="white-space:nowrap">C4
3001<a name="DoseForm-C43001"> </a></td><td>TROCHE</td><td/></tr><tr><td style="white-spa
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        <system value="email"/>
      </telecom>
    </contact>
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dual. For example: tablet, capsule, liquid or ointment. NCI concept code for pharmaceutic
al dosage form: C42636"/>
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```xml
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    <concept>
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    <concept>
      <code value="C43001"/>
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```

```xml
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<ValueSet xmlns="http://hl7.org/fhir">
  <id value="methodOrig"/>
  <meta>
    <profile value="http://hl7.org/fhir/StructureDefinition/shareablevalueset"/>
  </meta>
  <text>
    <status value="generated"/><div xmlns="http://www.w3.org/1999/xhtml"><h2>MethodOrigin</h2><div><p>Codes
specifying the source of the method.</p>
</div><p>This value set includes codes from the following code systems:</p><ul><li>Include all codes defined in <a
href="methodOrig.html"><code>http://fda.gov/cder/fhir/pqcmc/CodeSystem/methodOrig</code></a></li></ul></div>
  </text>
  <url value="http://fda.gov/cder/fhir/pqcmc/ValueSet/methodOrig"/>
  <version value="current"/>
  <name value="MethodOrigin"/>
  <status value="draft"/>
  <experimental value="false"/>
  <date value="2019-04-18T17:50:12-04:00"/>
  <contact>
    <telecom>
      <system value="url"/>
    </telecom>
    <telecom>
      <system value="email"/>
    </telecom>
  </contact>
  <description value="Codes  specifying the source of the method."/>
  <immutable value="true"/>
  <compose>
    <include>
      <system value="http://fda.gov/cder/fhir/pqcmc/CodeSystem/methodOrig"/>
    </include>
  </compose>
</ValueSet>
```

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Raw xml

```xml
<CodeSystem xmlns="http://hl7.org/fhir">
  <id value="methodOrig"/>
  <text>
    <status value="generated"/>
    <div xmlns="http://www.w3.org/1999/xhtml"><h2>MethodOrigin</h2><div><p>Codes  specify
ing the source of the method.</p>
</div><p>This code system http://fda.gov/cder/fhir/pqcmc/CodeSystem/methodOrig defines th
e following codes:</p><table class="codes"><tr><td style="white-space:nowrap"><b>Code</b>
</td><td><b>Display</b></td><td><b>Definition</b></td></tr><tr><td style="white-space:now
rap">C96102<a name="methodOrig-C96102"> </a></td><td>Compendial</td><td>Method defined in
 any recognized compendium (e.g., USP, PharmEU, JP, etc.).</td></tr><tr><td style="white-
space:nowrap">C96103<a name="methodOrig-C96103"> </a></td><td>Proprietary</td><td>Method
defined by the sponsor (not recognized in CFR or any compendium)</td></tr><tr><td style="
white-space:nowrap">C96164<a name="methodOrig-C96164"> </a></td><td>CFR</td><td>Method de
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  <name value="MethodOrigin"/>
  <status value="draft"/>
  <experimental value="false"/>
  <date value="2019-04-18T17:50:12-04:00"/>
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    <telecom>
      <system value="url"/>
    </telecom>
    <telecom>
      <system value="email"/>
    </telecom>
  </contact>
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  <caseSensitive value="true"/>
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  <content value="complete"/>
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    <display value="Compendial"/>
    <definition
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  <concept>
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dium)"/>
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    <concept>
        <code value="C96164"/>
        <display value="CFR"/>
        <definition value="Method defined in the Code of Federal Regulation (CFR)"/>
    </concept>
</CodeSystem>
```

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```xml
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<ValueSet xmlns="http://hl7.org/fhir">
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  <meta>
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  </meta>
  <text>
    <status value="generated"/><div xmlns="http://www.w3.org/1999/xhtml"><h2>SpecStatus</h2><div><p>Code
indicating the current FDA regulatory status of the specification</p>
</div><p>This value set includes codes from the following code systems:</p><ul><li>Include all codes defined in <a
href="SpecStat.html"><code>http://fda.gov/cder/fhir/pqcmc/CodeSystem/SpecStat</code></a></li></ul></div>
  </text>
  <url value="http://fda.gov/cder/fhir/pqcmc/ValueSet/SpecStat"/>
  <version value="current"/>
  <name value="SpecStatus"/>
  <status value="draft"/>
  <experimental value="false"/>
  <date value="2019-04-18T17:50:12-04:00"/>
  <contact>
    <telecom>
      <system value="url"/>
    </telecom>
    <telecom>
      <system value="email"/>
    </telecom>
  </contact>
  <description value="Code indicating the current FDA regulatory status of the specification"/>
  <immutable value="true"/>
  <compose>
    <include>
      <system value="http://fda.gov/cder/fhir/pqcmc/CodeSystem/SpecStat"/>
    </include>
  </compose>
</ValueSet>
```

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Raw xml

```
<CodeSystem xmlns="http://hl7.org/fhir">
  <id value="SpecStat"/>
  <text>
    <status value="generated"/>
    <div xmlns="http://www.w3.org/1999/xhtml"><h2>SpecStatus</h2><div><p>Code indicating
the current FDA regulatory status of the specification</p>
</div><p>This code system http://fda.gov/cder/fhir/pqcmc/CodeSystem/SpecStat defines the
following codes:</p><table class="codes"><tr><td style="white-space:nowrap"><b>Code</b></
td><td><b>Display</b></td><td><b>Definition</b></td></tr><tr><td style="white-space:nowra
p">C134010<a name="SpecStat-C134010"> </a></td><td>Tentatively Approved</td><td>A specifi
cation that met the requirements for approval but the application could not be approved f
or reasons such as patents and exclusivity.</td></tr><tr><td style="white-space:nowrap">C
134011<a name="SpecStat-C134011"> </a></td><td>Not Approved</td><td>A specification that
has not yet been approved.</td></tr><tr><td style="white-space:nowrap">C134012<a name="Sp
ecStat-C134012"> </a></td><td>Reported in a CBE or AR</td><td>The specification may be us
ed without prior approval, and was submitted in a changes being effected (CBE) supplement
 or an annual report (AR).</td></tr><tr><td style="white-space:nowrap">C25425<a name="Spe
cStat-C25425"> </a></td><td>Approved</td><td>A specification that has met the requirement
s for approval</td></tr></table></div>
  </text>
  <url value="http://fda.gov/cder/fhir/pqcmc/CodeSystem/SpecStat"/>
  <version value="current"/>
  <name value="SpecStatus"/>
  <status value="draft"/>
  <experimental value="false"/>
  <date value="2019-04-18T17:50:12-04:00"/>
  <contact>
    <telecom>
      <system value="url"/>
    </telecom>
    <telecom>
      <system value="email"/>
    </telecom>
  </contact>
  <description
            value="Code indicating the current FDA regulatory status of the specificat
ion"/>
  <caseSensitive value="true"/>
  <valueSet value="http://fda.gov/cder/fhir/pqcmc/ValueSet/SpecStat"/>
  <content value="complete"/>
  <concept>
    <code value="C134010"/>
```

```
        <display value="Tentatively Approved"/>
        <definition
                value="A specification that met the requirements for approval but the app
lication could not be approved for reasons such as patents and exclusivity."/>
    </concept>
    <concept>
        <code value="C134011"/>
        <display value="Not Approved"/>
        <definition value="A specification that has not yet been approved."/>
    </concept>
    <concept>
        <code value="C134012"/>
        <display value="Reported in a CBE or AR"/>
        <definition
                value="The specification may be used without prior approval, and was subm
itted in a changes being effected (CBE) supplement or an annual report (AR)."/>
    </concept>
    <concept>
        <code value="C25425"/>
        <display value="Approved"/>
        <definition
                value="A specification that has met the requirements for approval"/>
    </concept>
</CodeSystem>
```

```xml
<?xml version="1.0" encoding="UTF-8"?>

<ValueSet xmlns="http://hl7.org/fhir">
  <id value="testCat"/>
  <meta>
    <profile value="http://hl7.org/fhir/StructureDefinition/shareablevalueset"/>
  </meta>
  <text>
    <status value="generated"/><div xmlns="http://www.w3.org/1999/xhtml"><h2>TestCategory</h2><div><p>List of
test categories allowable values for the Test Category data element</p>
</div><p>This value set includes codes from the following code systems:</p><ul><li>Include all codes defined in <a
href="testCat.html"><code>http://fda.gov/cder/fhir/pqcmc/CodeSystem/testCat</code></a></li></ul></div>
  </text>
  <url value="http://fda.gov/cder/fhir/pqcmc/ValueSet/testCat"/>
  <version value="current"/>
  <name value="TestCategory"/>
  <status value="draft"/>
  <experimental value="false"/>
  <date value="2019-04-18T17:50:12-04:00"/>
  <contact>
    <telecom>
      <system value="url"/>
    </telecom>
    <telecom>
      <system value="email"/>
    </telecom>
  </contact>
  <description value="List of test categories allowable values for the Test Category data element"/>
  <immutable value="true"/>
  <compose>
    <include>
      <system value="http://fda.gov/cder/fhir/pqcmc/CodeSystem/testCat"/>
    </include>
  </compose>
</ValueSet>
```

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Raw xml

```
<CodeSystem xmlns="http://hl7.org/fhir">
  <id value="testCat"/>
  <text>
    <status value="generated"/>
    <div xmlns="http://www.w3.org/1999/xhtml"><h2>TestCategory</h2><div><p>List of test c
ategories allowable values for the Test Category data element</p>
</div><p>This code system http://fda.gov/cder/fhir/pqcmc/CodeSystem/testCat defines the f
ollowing codes:</p><table class="codes"><tr><td style="white-space:nowrap"><b>Code</b></t
d><td><b>Display</b></td><td><b>Definition</b></td></tr><tr><td style="white-space:nowrap
">C60819<a name="testCat-C60819"> </a></td><td>Assay</td><td>Tests which measure the cont
ent of the active ingredient in the drug substance or drug product. Synonymous with stren
gth or purity which is commonly used of define the content of the active ingredient in a
drug product. [Source: Adapted from ICH Q6A and Q6B]  Note:  chiral purity, preservative
content, Anti-Oxidant Concentration, Chelate Concentration, isomeric ratio.</td></tr><tr>
<td style="white-space:nowrap">C138990<a name="testCat-C138990"> </a></td><td>Description
</td><td>An assessment of the physical state (e.g., color, shape, size) of the drug subst
ance or product. [Source: Adapted from ICH Q6A]</td></tr><tr><td style="white-space:nowra
p">C138993<a name="testCat-C138993"> </a></td><td>Identification</td><td>Tests that estab
lishes the characteristic and uniqueness  of the substance of interest and should be able
 to discriminate between compounds of closely related structures which are likely to be p
resent. [Source: ICH Q6A]</td></tr><tr><td style="white-space:nowrap">C158424<a name="tes
tCat-C158424"> </a></td><td>Physical Properties</td><td>Assessments of the characteristic
s of a material that are not associated with a change in its composition and basic nature
, including but not limited to its texture, smell, freezing point, boiling point, melting
 point, opacity, viscosity and density.</td></tr><tr><td style="white-space:nowrap">C1584
25<a name="testCat-C158425"> </a></td><td>Biological Properties</td><td>Any effect a give
n material has on a living organism (e.g., microbial limits, endotoxin).</td></tr><tr><td
 style="white-space:nowrap">C17771<a name="testCat-C17771"> </a></td><td>Chemical Propert
ies</td><td>A characteristic of a material that is observed during a reaction in which th
e chemical composition or identity of the material is changed (e.g., combustibility, solu
bility, acidity/basicity).</td></tr><tr><td style="white-space:nowrap">C158423<a name="te
stCat-C158423"> </a></td><td>Impurities</td><td>Analytical procedures that determine the
presence of a component of the material that is not the chemical entity defined as the ma
terial.</td></tr></table></div>
  </text>
  <url value="http://fda.gov/cder/fhir/pqcmc/CodeSystem/testCat"/>
  <version value="current"/>
  <name value="TestCategory"/>
  <status value="draft"/>
  <experimental value="false"/>
  <date value="2019-04-18T17:50:12-04:00"/>
  <contact>
```

```xml
    <telecom>
      <system value="url"/>
    </telecom>
    <telecom>
      <system value="email"/>
    </telecom>
  </contact>
  <description
              value="List of test categories allowable values for the Test Category data
 element"/>
  <caseSensitive value="true"/>
  <valueSet value="http://fda.gov/cder/fhir/pqcmc/ValueSet/testCat"/>
  <content value="complete"/>
  <concept>
    <code value="C60819"/>
    <display value="Assay"/>
    <definition
              value="Tests which measure the content of the active ingredient in the dr
ug substance or drug product. Synonymous with strength or purity which is commonly used o
f define the content of the active ingredient in a drug product. [Source: Adapted from IC
H Q6A and Q6B]  Note:  chiral purity, preservative content, Anti-Oxidant Concentration, C
helate Concentration, isomeric ratio."/>
  </concept>
  <concept>
    <code value="C138990"/>
    <display value="Description"/>
    <definition
              value="An assessment of the physical state (e.g., color, shape, size) of
the drug substance or product. [Source: Adapted from ICH Q6A]"/>
  </concept>
  <concept>
    <code value="C138993"/>
    <display value="Identification"/>
    <definition
              value="Tests that establishes the characteristic and uniqueness  of the s
ubstance of interest and should be able to discriminate between compounds of closely rela
ted structures which are likely to be present. [Source: ICH Q6A]"/>
  </concept>
  <concept>
    <code value="C158424"/>
    <display value="Physical Properties"/>
    <definition
              value="Assessments of the characteristics of a material that are not asso
ciated with a change in its composition and basic nature, including but not limited to it
s texture, smell, freezing point, boiling point, melting point, opacity, viscosity and de
nsity."/>
  </concept>
  <concept>
    <code value="C158425"/>
    <display value="Biological Properties"/>
    <definition
              value="Any effect a given material has on a living organism (e.g., microb
ial limits, endotoxin)."/>
  </concept>
  <concept>
    <code value="C17771"/>
    <display value="Chemical Properties"/>
```

```
        <definition
                    value="A characteristic of a material that is observed during a reaction
in which the chemical composition or identity of the material is changed (e.g., combustib
ility, solubility, acidity/basicity)."/>
    </concept>
    <concept>
        <code value="C158423"/>
        <display value="Impurities"/>
        <definition
                    value="Analytical procedures that determine the presence of a component o
f the material that is not the chemical entity defined as the material."/>
    </concept>
</CodeSystem>
```

```xml
<?xml version="1.0" encoding="UTF-8"?>

<ValueSet xmlns="http://hl7.org/fhir">
  <id value="pqcmcUsage"/>
  <meta>
    <profile value="http://hl7.org/fhir/StructureDefinition/shareablevalueset"/>
  </meta>
  <text>
    <status value="generated"/><div xmlns="http://www.w3.org/1999/xhtml"><h2>TestUsage</h2><div><p>List of
codes specifying the time point during the manufacturing process of a substance or product when a particular analytical
procedure or measurement is being performed</p>
</div><p>This value set includes codes from the following code systems:</p><ul><li>Include all codes defined in <a
href="pqcmcUsage.html"><code>http://fda.gov/cder/fhir/pqcmc/CodeSystem/pqcmcUsage</code></a></li></ul>
</div>
  </text>
  <url value="http://fda.gov/cder/fhir/pqcmc/ValueSet/pqcmcUsage"/>
  <version value="current"/>
  <name value="TestUsage"/>
  <status value="draft"/>
  <experimental value="false"/>
  <date value="2019-04-18T17:50:12-04:00"/>
  <contact>
    <telecom>
      <system value="url"/>
    </telecom>
    <telecom>
      <system value="email"/>
    </telecom>
  </contact>
  <description value="List of codes specifying the time point during the manufacturing process of a substance or product
when a particular analytical procedure or measurement is being performed"/>
  <immutable value="true"/>
  <compose>
    <include>
      <system value="http://fda.gov/cder/fhir/pqcmc/CodeSystem/pqcmcUsage"/>
    </include>
  </compose>
</ValueSet>
```

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Raw xml

```
<CodeSystem xmlns="http://hl7.org/fhir">
  <id value="pqcmcUsage"/>
  <text>
    <status value="generated"/>
    <div xmlns="http://www.w3.org/1999/xhtml"><h2>TestUsage</h2><div><p>List of codes spe
cifying the time point during the manufacturing process of a substance or product when a
particular analytical procedure or measurement is being performed</p>
</div><p>This code system http://fda.gov/cder/fhir/pqcmc/CodeSystem/pqcmcUsage defines th
e following codes:</p><table class="codes"><tr><td style="white-space:nowrap"><b>Code</b>
</td><td><b>Display</b></td><td><b>Definition</b></td></tr><tr><td style="white-space:now
rap">C134029<a name="pqcmcUsage-C134029"> </a></td><td>Release</td><td>For determination
of acceptability for use of a material, drug or a drug substance. NOTE: The &quot;use&quo
t; could be for distribution, marketing, further manufacturing stages, etc.</td></tr><tr>
<td style="white-space:nowrap">C134030<a name="pqcmcUsage-C134030"> </a></td><td>Stabilit
y</td><td>For determination of maintained performance parameters on storage over time, of
 a material, drug or a drug substance.</td></tr><tr><td style="white-space:nowrap">C13403
1<a name="pqcmcUsage-C134031"> </a></td><td>Release and Stability</td><td>For determinati
on at release and on stability when test and acceptance criteria are the same in both cas
es.</td></tr></table></div>
  </text>
  <url value="http://fda.gov/cder/fhir/pqcmc/CodeSystem/pqcmcUsage"/>
  <version value="current"/>
  <name value="TestUsage"/>
  <status value="draft"/>
  <experimental value="false"/>
  <date value="2019-04-18T17:50:12-04:00"/>
  <contact>
    <telecom>
      <system value="url"/>
    </telecom>
    <telecom>
      <system value="email"/>
    </telecom>
  </contact>
  <description
              value="List of codes specifying the time point during the manufacturing pr
ocess of a substance or product when a particular analytical procedure or measurement is
being performed"/>
  <caseSensitive value="true"/>
  <valueSet value="http://fda.gov/cder/fhir/pqcmc/ValueSet/pqcmcUsage"/>
  <content value="complete"/>
  <concept>
```

```
        <code value="C134029"/>
        <display value="Release"/>
        <definition
                value="For determination of acceptability for use of a material, drug or
a drug substance. NOTE: The &quot;use&quot; could be for distribution, marketing, further
 manufacturing stages, etc."/>
    </concept>
    <concept>
        <code value="C134030"/>
        <display value="Stability"/>
        <definition
                value="For determination of maintained performance parameters on storage
over time, of a material, drug or a drug substance."/>
    </concept>
    <concept>
        <code value="C134031"/>
        <display value="Release and Stability"/>
        <definition
                value="For determination at release and on stability when test and accept
ance criteria are the same in both cases."/>
    </concept>
</CodeSystem>
```

Content | Detailed Descriptions | **Mappings** | Examples | XML

StructureDefinition: Quality Specification - Mappings

Mappings for the Profile.

Mappings for Workflow Pattern (http://hl7.org/fhir/workflow)

Quality Specification	
PlanDefinition	Definition
url	Definition.url
identifier	Definition.identifier
version	Definition.version
title	Definition.title
status	Definition.status {different ValueSet}
experimental	Definition.experimental
subjectReference	Definition.subject
date	Definition.date
publisher	Definition.publisher
contact	Definition.contact
description	Definition.description
useContext	Definition.useContext
jurisdiction	Definition.jurisdiction
purpose	Definition.purpose
copyright	Definition.copyright
approvalDate	Definition.approvalDate
lastReviewDate	Definition.lastReviewDate
effectivePeriod	Definition.effectivePeriod
topic	Definition.subject[x]
action	{Is a contained Definition}
title	Definition.title
description	Definition.description
textEquivalent	Definition.description
subject[x]	Definition.subject
definition[x]	Definition.derivedFrom
action	{InverseRelationship of Definition.partOf}

title	Definition.title
description	Definition.description
textEquivalent	Definition.description
subject[x]	Definition.subject
definition[x]	Definition.derivedFrom
action	{InverseRelationship of Definition.partOf}

Mappings for FiveWs Pattern Mapping (http://hl7.org/fhir/fivews)

Quality Specification	
PlanDefinition	
url	FiveWs.identifier
identifier	FiveWs.identifier
version	FiveWs.version
status	FiveWs.status
experimental	FiveWs.class
date	FiveWs.recorded
publisher	FiveWs.witness
purpose	FiveWs.why[x]

Mappings for Object Implementation Information (http://hl7.org/fhir/object-implementation)

Quality Specification	
PlanDefinition	
identifier	no-gen-base
purpose	no-gen-base
copyright	no-gen-base
approvalDate	no-gen-base
lastReviewDate	no-gen-base
effectivePeriod	no-gen-base

Mappings for RIM Mapping (http://hl7.org/v3)

Quality Specification	
PlanDefinition	Entity. Role, or Act
text	Act.text?
contained	N/A
extension	
extension (approvalStatus)	
id	n/a
extension	n/a
extension (type)	
id	n/a
extension	n/a
url	N/A

valueCode	N/A
extension (date)	
id	n/a
extension	n/a
url	N/A
valueDate	N/A
url	N/A
modifierExtension	N/A
author	.participation[typeCode=AUT]
reviewer	.participation[typeCode=VRF] {not clear whether VRF best corresponds to reviewer or endorser}
endorser	.participation[typeCode=VRF] {not clear whether VRF best corresponds to reviewer or endorser}
goal	
id	n/a
modifierExtension	N/A
description	
id	n/a
extension	n/a
coding	union(., ./translation)
text	./originalText[mediaType/code="text/plain"]/data
target	
id	n/a
extension	
extension (noTarget)	ANY.nullFlavor
id	n/a
url	N/A
valueCode	N/A
modifierExtension	N/A
detailQuantity (Quantity)	
id	n/a
extension	n/a
value	PQ.value, CO.value, MO.value, IVL.high or IVL.low depending on the value
comparator	IVL properties
unit	PQ.unit
system	CO.codeSystem, PQ.translation.codeSystem
code	PQ.code, MO.currency, PQ.translation.code
detailRange (Range)	
id	n/a
extension	n/a
extension (lowExclusive)	
id	n/a
extension	n/a

url	N/A
value[x]	N/A
id	n/a
extension	n/a
value	PQ.value, CO.value, MO.value, IVL.high or IVL.low depending on the value
comparator	IVL properties
unit	PQ.unit
system	CO.codeSystem, PQ.translation.codeSystem
code	PQ.code, MO.currency, PQ.translation.code
extension (highExclusive)	
id	n/a
extension	n/a
url	N/A
value[x]	N/A
id	n/a
extension	n/a
value	PQ.value, CO.value, MO.value, IVL.high or IVL.low depending on the value
comparator	IVL properties
unit	PQ.unit
system	CO.codeSystem, PQ.translation.codeSystem
code	PQ.code, MO.currency, PQ.translation.code
low	./low
id	n/a
extension	n/a
value	PQ.value, CO.value, MO.value, IVL.high or IVL.low depending on the value
unit	PQ.unit
system	CO.codeSystem, PQ.translation.codeSystem
code	PQ.code, MO.currency, PQ.translation.code
high	./high
id	n/a
extension	n/a
value	PQ.value, CO.value, MO.value, IVL.high or IVL.low depending on the value
unit	PQ.unit
system	CO.codeSystem, PQ.translation.codeSystem
code	PQ.code, MO.currency, PQ.translation.code
detailCodeableConcept (CodeableConcept)	
id	n/a
extension	n/a
coding	union(., ./translation)
text	./originalText[mediaType/code="text/plain"]/data
action	

id	n/a
modifierExtension	N/A
code	
id	n/a
extension	n/a
coding	union(., ./translation)
text	./originalText[mediaType/code="text/plain"]/data
condition	
id	n/a
extension	n/a
modifierExtension	N/A
relatedAction	
id	n/a
extension	n/a
modifierExtension	N/A
participant	
id	n/a
extension	n/a
modifierExtension	N/A
dynamicValue	
id	n/a
extension	n/a
modifierExtension	N/A
action	
id	n/a
extension	n/a
modifierExtension	N/A
condition	
id	n/a
extension	n/a
modifierExtension	N/A
relatedAction	
id	n/a
extension	n/a
modifierExtension	N/A
participant	
id	n/a
extension	n/a
modifierExtension	N/A
dynamicValue	
id	n/a
extension	n/a

modifierExtension	N/A

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StructureDefinition: Quality Specification - Examples

**No examples are currently available for the Profile. Refer to the examples of Drug Product
and Drug Substance for the the Structure Defintion of Quality Specification.**

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StructureDefinition: Quality Specification - XML Profile

XML representation of the qualityspecification Profile.

Narrative view of the profile

```
<StructureDefinition xmlns="http://hl7.org/fhir">
  <id value="qualityspecification"/>
  <text>
    <status value="generated"/>
    <div xmlns="http://www.w3.org/1999/xhtml"><table border="0" cellpadding="0" cellspaci
ng="0" style="border: 0px #F0F0F0 solid; font-size: 11px; font-family: verdana; vertical-
align: top;"><tr style="border: 1px #F0F0F0 solid; font-size: 11px; font-family: verdana;
 vertical-align: top;"><th style="vertical-align: top; text-align : left; background-colo
r: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><a href="
http://build.fhir.org/formats.html#table" title="The logical name of the element">Name</a
></th><th style="vertical-align: top; text-align : left; background-color: white; border:
 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><a href="http://build.fhir
.org/formats.html#table" title="Information about the use of the element">Flags</a></th><
th style="vertical-align: top; text-align : left; background-color: white; border: 0px #F
0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><a href="http://build.fhir.org/fo
rmats.html#table" title="Minimum and Maximum # of times the the element can appear in the
 instance">Card.</a></th><th style="width: 100px" class="hierarchy"><a href="http://build
.fhir.org/formats.html#table" title="Reference to the type of the element">Type</a></th><
th style="vertical-align: top; text-align : left; background-color: white; border: 0px #F
0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><a href="http://build.fhir.org/fo
rmats.html#table" title="Additional information about the element">Description &amp; Cons
traints</a><span style="float: right"><a href="http://build.fhir.org/formats.html#table"
title="Legend for this format"><img src="http://build.fhir.org/help16.png" alt="doco" sty
le="background-color: inherit"/></a></span></th></tr><tr style="border: 0px #F0F0F0 solid
; padding:0px; vertical-align: top; background-color: white;"><td style="vertical-align:
top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4
px 0px 4px; white-space: nowrap; background-image: url(tbl_bck1.png)" class="hierarchy"><
img src="tbl_spacer.png" alt="." style="background-color: inherit" class="hierarchy"/><im
g src="icon_element.gif" alt="." style="background-color: white; background-color: inheri
t" title="Element" class="hierarchy"/> <a href="qualityspecification-definitions.html#Pla
nDefinition" title="Specification means the quality standard (i.e. , tests, analytical pr
ocedures, and acceptance criteria) provided in an approved application to confirm the qua
lity of drug substances, drug products, intermediates, raw materials, reagents, component
s, in-process materials, container closure systems, and other materials used in the produ
ction of a drug substance or drug product. For the purpose of this definition, acceptance
 criteria means numerical limits, ranges, or other criteria for the tests described.">Pla
nDefinition</a><a name="PlanDefinition"> </a></td><td style="vertical-align: top; text-al
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hite; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"/><td style="v
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; padding:0px 4px 0px 4px" class="hierarchy"/><td style="vertical-align: top; text-align
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s="hierarchy">Quality Specification</td></tr>
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olor: inherit" class="hierarchy"/><img src="tbl_vjoin.png" alt="." style="background-colo
r: inherit" class="hierarchy"/><img src="icon_extension_complex.png" alt="." style="backg
round-color: white; background-color: inherit" title="Complex Extension" class="hierarchy
"/> <a href="qualityspecification-definitions.html#PlanDefinition.extension:approvalStatu
s" title="Extension URL = http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-approval
Status">ext-approvalStatus</a><a name="PlanDefinition.extension"> </a></td><td style="ver
tical-align: top; text-align : left; background-color: white; border: 0px #F0F0F0 solid;
padding:0px 4px 0px 4px" class="hierarchy"><span style="padding-left: 3px; padding-right:
 3px; color: white; background-color: red" title="This element must be supported">S</span
></td><td style="vertical-align: top; text-align : left; background-color: white; border:
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ding:0px 4px 0px 4px" class="hierarchy">(Complex)</td><td style="vertical-align: top; tex
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px" class="hierarchy">Approval Status<br/><span style="font-weight:bold">URL: </span><a h
ref="http://build.fhir.org/extension-ext-approvalStatus.html">http://fda.gov/cder/fhir/pq
cmc/StructureDefinition/ext-approvalStatus</a><br/><span style="font-weight:bold">Binding
: </span><a href="valueset-SpecStat.html">SpecStatus</a> (<a href="http://build.fhir.org/
terminologies.html#required" title="To be conformant, the concept in this element SHALL b
e from the specified value set.">required</a>)</td></tr>
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color: inherit" class="hierarchy"/><img src="icon_extension_simple.png" alt="." style="ba
ckground-color: white; background-color: inherit" title="Simple Extension" class="hierarc
hy"/> <a href="qualityspecification-definitions.html#PlanDefinition.extension:approvalSta
tus.extension:type" title="Slice type: A classification of specification related to the k
ind of the entity it is referencing. [Source: SME Defined].">extension</a><a name="PlanDe
finition.extension.extension"> </a></td><td style="vertical-align: top; text-align : left
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="background-color: white; background-color: inherit" title="Simple Extension" class="hie
rarchy"/> <a href="qualityspecification-definitions.html#PlanDefinition.extension:approva
lStatus.extension:date" title="Slice date: The date on which the FDA approval status for
a specification became effective. [Source: SME Defined] Note: If the application is not y
et approved, then this is the date of the current submission OR the date of the complete
response (CR).">extension</a><a name="PlanDefinition.extension.extension"> </a></td><td s
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r: white; background-color: inherit" title="Element" class="hierarchy"/> <a href="quality
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r the specification. [Source: SME Defined] Example: &lt;drug name&gt; 75 mg chewable tabl
ets Note: This may include the name of the drug substance, product or the raw material/ex
cipients.">title</a><a name="PlanDefinition.title"> </a></td><td style="vertical-align: t
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x 0px 4px" class="hierarchy"><span style="padding-left: 3px; padding-right: 3px; color: w
hite; background-color: red" title="This element must be supported">S</span></td><td styl
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olid; padding:0px 4px 0px 4px" class="hierarchy">1..1</td><td style="vertical-align: top;
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r: inherit" class="hierarchy"/><img src="icon_element.gif" alt="." style="background-colo
r: white; background-color: inherit" title="Element" class="hierarchy"/> <a href="quality
specification-definitions.html#PlanDefinition.version" title="The alphanumeric text assig
ned by the sponsor to a particular edition of a specification. [Source: SME Defined] Exam
ples: 2.1, 13.2, ST1, 00001, 00002, &lt;companyname&gt;001, etc.">version</a><a name="Pla
nDefinition.version"> </a></td><td style="vertical-align: top; text-align : left; backgro
und-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><
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itle="This element must be supported">S</span></td><td style="vertical-align: top; text-a
lign : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px"
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r: inherit" class="hierarchy"/><img src="icon_reference.png" alt="." style="background-co
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rchy"/> <a href="qualityspecification-definitions.html#PlanDefinition.subjectReference" t
itle="A classification of specification related to the kind of the entity it is referenci
ng. [Source: SME Defined].">subjectReference</a><a name="PlanDefinition.subjectReference"
> </a></td><td style="vertical-align: top; text-align : left; background-color: white; bo
rder: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><span style="padding-
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ust be supported">S</span></td><td style="vertical-align: top; text-align : left; backgro
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..1</td><td style="vertical-align: top; text-align : left; background-color: white; borde
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ir.org/references.html">Reference</a>(<a href="http://build.fhir.org/medicationknowledge.
html">MedicationKnowledge</a> | <a href="http://build.fhir.org/substance.html">Substance<
/a>)</td><td style="vertical-align: top; text-align : left; background-color: white; bord
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l(tbl_bck10.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="background-c
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r: inherit" class="hierarchy"/><img src="icon_element.gif" alt="." style="background-colo
r: white; background-color: inherit" title="Element" class="hierarchy"/> <a href="quality
specification-definitions.html#PlanDefinition.date" title="The date when the sponsor assi
gned a date to a specific version. [Source: SME Defined].">date</a><a name="PlanDefinitio
n.date"> </a></td><td style="vertical-align: top; text-align : left; background-color: wh
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adding-left: 3px; padding-right: 3px; color: white; background-color: red" title="This el
ement must be supported">S</span></td><td style="vertical-align: top; text-align : left;
background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hiera
rchy">1..1</td><td style="vertical-align: top; text-align : left; background-color: white
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 href="qualityspecification-definitions.html#PlanDefinition.status">status</a><a name="Pl
anDefinition.status"> </a></td><td style="vertical-align: top; text-align : left; backgro
und-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><
span style="padding-left: 3px; padding-right: 3px; color: white; background-color: red" t
itle="This element must be supported">S</span></td><td style="vertical-align: top; text-a
lign : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px"
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specification-definitions.html#PlanDefinition.usage" title="Placeholder for providing any
 comments that are relevant to the specification. [Source: SME Defined] Examples: replace
s method ABC, using the XYZ facility, etc.">usage</a><a name="PlanDefinition.usage"> </a>
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d><td style="vertical-align: top; text-align : left; background-color: white; border: 0px
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r: white; background-color: inherit" title="Element" class="hierarchy"/> <a href="quality
specification-definitions.html#PlanDefinition.goal" title="Numerical limits, ranges, or o
ther criteria for the tests described. [Source: 21 CFR 314.3, 514.3 and 600.3].">goal</a>
<a name="PlanDefinition.goal"> </a></td><td style="vertical-align: top; text-align : left
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r: red" title="This element must be supported">S</span></td><td style="vertical-align: to
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chy"/><td style="vertical-align: top; text-align : left; background-color: white; border:
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omment</a><a name="PlanDefinition.goal.extension"> </a></td><td style="vertical-align: to
p; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px
 0px 4px" class="hierarchy"><span style="padding-left: 3px; padding-right: 3px; color: wh
ite; background-color: red" title="This element must be supported">S</span></td><td style
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x 4px" class="hierarchy"><a href="http://build.fhir.org/datatypes.html#string">string</a>
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nDefinition.goal.description"> </a></td><td style="vertical-align: top; text-align : left
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lor: inherit" class="hierarchy"/><img src="tbl_vline.png" alt="." style="background-color
: inherit" class="hierarchy"/><img src="tbl_vjoin_end.png" alt="." style="background-colo
r: inherit" class="hierarchy"/><img src="icon_element.gif" alt="." style="background-colo
r: white; background-color: inherit" title="Element" class="hierarchy"/> <a href="quality
specification-definitions.html#PlanDefinition.goal.description.text" title="The text of t
he acceptance criteria as provided in the specification. [Source: SME Defined]  Examples:
 White to off-white cake; 22.5 -27.5 mg/ml Note: This is the text as it appears in the Sp
ecification.">text</a><a name="PlanDefinition.goal.description.text"> </a></td><td style=
"vertical-align: top; text-align : left; background-color: white; border: 0px #F0F0F0 sol
id; padding:0px 4px 0px 4px" class="hierarchy"><span style="padding-left: 3px; padding-ri
ght: 3px; color: white; background-color: red" title="This element must be supported">S</
span></td><td style="vertical-align: top; text-align : left; background-color: white; bor
der: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy">1..1</td><td style="ve
rtical-align: top; text-align : left; background-color: white; border: 0px #F0F0F0 solid;
 padding:0px 4px 0px 4px" class="hierarchy"/><td style="vertical-align: top; text-align :
 left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class
="hierarchy">Literal text</td></tr>
<tr style="border: 0px #F0F0F0 solid; padding:0px; vertical-align: top; background-color:
 white;"><td style="vertical-align: top; text-align : left; background-color: white; bord
er: 0px #F0F0F0 solid; padding:0px 4px 0px 4px; white-space: nowrap; background-image: ur
l(tbl_bck101.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="background-
color: inherit" class="hierarchy"/><img src="tbl_vline.png" alt="." style="background-col
or: inherit" class="hierarchy"/><img src="tbl_vjoin_end.png" alt="." style="background-co
lor: inherit" class="hierarchy"/><img src="icon_element.gif" alt="." style="background-co
lor: white; background-color: inherit" title="Element" class="hierarchy"/> <a href="quali
tyspecification-definitions.html#PlanDefinition.goal.target">target</a><a name="PlanDefin
ition.goal.target"> </a></td><td style="vertical-align: top; text-align : left; backgroun
d-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><sp
an style="padding-left: 3px; padding-right: 3px; color: white; background-color: red" tit
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le="This element must be supported">S</span></td><td style="vertical-align: top; text-ali
gn : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" c
lass="hierarchy">1..1</td><td style="vertical-align: top; text-align : left; background-c
olor: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"/><td s
tyle="vertical-align: top; text-align : left; background-color: white; border: 0px #F0F0F
0 solid; padding:0px 4px 0px 4px" class="hierarchy"/></tr>
<tr style="border: 0px #F0F0F0 solid; padding:0px; vertical-align: top; background-color:
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er: 0px #F0F0F0 solid; padding:0px 4px 0px 4px; white-space: nowrap; background-image: ur
l(tbl_bck1015.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="background
-color: inherit" class="hierarchy"/><img src="tbl_vline.png" alt="." style="background-co
lor: inherit" class="hierarchy"/><img src="tbl_blank.png" alt="." style="background-color
: inherit" class="hierarchy"/><img src="tbl_vjoin.png" alt="." style="background-color: i
nherit" class="hierarchy"/><img src="icon_extension_simple.png" alt="." style="background
-color: white; background-color: inherit" title="Simple Extension" class="hierarchy"/> <a
 href="qualityspecification-definitions.html#PlanDefinition.goal.target.extension:noTarge
t" title="Extension URL = http://hl7.org/fhir/StructureDefinition/data-absent-reason">dat
a-absent-reason</a><a name="PlanDefinition.goal.target.extension"> </a></td><td style="ve
rtical-align: top; text-align : left; background-color: white; border: 0px #F0F0F0 solid;
 padding:0px 4px 0px 4px" class="hierarchy"><span style="padding-left: 3px; padding-right
: 3px; color: white; background-color: red" title="This element must be supported">S</spa
n></td><td style="vertical-align: top; text-align : left; background-color: white; border
: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy">0..1</td><td style="verti
cal-align: top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; pa
dding:0px 4px 0px 4px" class="hierarchy"><a href="http://build.fhir.org/datatypes.html#co
de">code</a></td><td style="vertical-align: top; text-align : left; background-color: whi
te; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy">unknown | asked
 | temp | notasked | masked | unsupported | astext | error<br/><span style="font-weight:b
old">URL: </span><a href="http://build.fhir.org/extension-data-absent-reason.html">http:/
/hl7.org/fhir/StructureDefinition/data-absent-reason</a><br/><span style="font-weight:bol
d">Binding: </span><a href="http://build.fhir.org/valueset-data-absent-reason.html">DataA
bsentReason</a> (<a href="http://build.fhir.org/terminologies.html#required" title="To be
 conformant, the concept in this element SHALL be from the specified value set.">required
</a>)</td></tr>
<tr style="border: 0px #F0F0F0 solid; padding:0px; vertical-align: top; background-color:
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er: 0px #F0F0F0 solid; padding:0px 4px 0px 4px; white-space: nowrap; background-image: ur
l(tbl_bck10140.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="backgroun
d-color: inherit" class="hierarchy"/><img src="tbl_vline.png" alt="." style="background-c
olor: inherit" class="hierarchy"/><img src="tbl_blank.png" alt="." style="background-colo
r: inherit" class="hierarchy"/><img src="tbl_vline.png" alt="." style="background-color:
inherit" class="hierarchy"/><img src="tbl_vjoin_end_slice.png" alt="." style="background-
color: inherit" class="hierarchy"/><img src="icon_primitive.png" alt="." style="backgroun
d-color: white; background-color: inherit" title="Primitive Data Type" class="hierarchy"/
> <a href="qualityspecification-definitions.html#PlanDefinition.goal.target.extension:noT
arget.valueCode">valueCode</a><a name="PlanDefinition.goal.target.extension.valueCode"> <
/a></td><td style="vertical-align: top; text-align : left; background-color: white; borde
r: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><span style="padding-lef
t: 3px; padding-right: 3px; color: white; background-color: red" title="This element must
 be supported">S</span></td><td style="vertical-align: top; text-align : left; background
-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy">1..1
</td><td style="vertical-align: top; text-align : left; background-color: white; border:
0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><a href="http://build.fhir.
org/datatypes.html#code">code</a></td><td style="vertical-align: top; text-align : left;
background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hiera
rchy"><span style="font-weight:bold">Fixed Value: </span><span style="color: darkgreen">n
ot-applicable</span></td></tr>
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<tr style="border: 0px #F0F0F0 solid; padding:0px; vertical-align: top; background-color:
 white;"><td style="vertical-align: top; text-align : left; background-color: white; bord
er: 0px #F0F0F0 solid; padding:0px 4px 0px 4px; white-space: nowrap; background-image: ur
l(tbl_bck1012.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="background
-color: inherit" class="hierarchy"/><img src="tbl_vline.png" alt="." style="background-co
lor: inherit" class="hierarchy"/><img src="tbl_blank.png" alt="." style="background-color
: inherit" class="hierarchy"/><img src="tbl_vjoin.png" alt="." style="background-color: i
nherit" class="hierarchy"/><img src="icon_slice.png" alt="." style="background-color: whi
te; background-color: inherit" title="Slice Definition" class="hierarchy"/> <a style="fon
t-style: italic" href="qualityspecification-definitions.html#PlanDefinition.goal.target.d
etail[x]">detail[x]</a><a name="PlanDefinition.goal.target.detail_x_"> </a></td><td style
="vertical-align: top; text-align : left; background-color: white; border: 0px #F0F0F0 so
lid; padding:0px 4px 0px 4px" class="hierarchy"><span style="padding-left: 3px; padding-r
ight: 3px; color: white; background-color: red; font-style: italic" title="This element m
ust be supported">S</span></td><td style="vertical-align: top; text-align : left; backgro
und-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"/>
<td style="vertical-align: top; text-align : left; background-color: white; border: 0px #
F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><a style="font-style: italic" hr
ef="http://build.fhir.org/datatypes.html#Quantity">Quantity</a><span style="font-style: i
talic">, </span><a style="font-style: italic" href="http://build.fhir.org/datatypes.html#
Range">Range</a><span style="font-style: italic">, </span><a style="font-style: italic" h
ref="http://build.fhir.org/datatypes.html#CodeableConcept">CodeableConcept</a></td><td st
yle="vertical-align: top; text-align : left; background-color: white; border: 0px #F0F0F0
 solid; padding:0px 4px 0px 4px" class="hierarchy"><span style="font-weight:bold; font-st
yle: italic">Slice: </span><span style="font-style: italic">Unordered, Open by value:@Typ
e</span></td></tr>
<tr style="border: 0px #F0F0F0 solid; padding:0px; vertical-align: top; background-color:
 white;"><td style="vertical-align: top; text-align : left; background-color: white; bord
er: 0px #F0F0F0 solid; padding:0px 4px 0px 4px; white-space: nowrap; background-image: ur
l(tbl_bck1015.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="background
-color: inherit" class="hierarchy"/><img src="tbl_vline.png" alt="." style="background-co
lor: inherit" class="hierarchy"/><img src="tbl_blank.png" alt="." style="background-color
: inherit" class="hierarchy"/><img src="tbl_vjoin.png" alt="." style="background-color: i
nherit" class="hierarchy"/><img src="icon_datatype.gif" alt="." style="background-color:
white; background-color: inherit" title="Data Type" class="hierarchy"/> <a href="qualitys
pecification-definitions.html#PlanDefinition.goal.target.detailQuantity:Quantity" title="
Slice Quantity: ">detailQuantity</a><a name="PlanDefinition.goal.target.detailQuantity">
</a></td><td style="vertical-align: top; text-align : left; background-color: white; bord
er: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><span style="padding-le
ft: 3px; padding-right: 3px; color: white; background-color: red" title="This element mus
t be supported">S</span></td><td style="vertical-align: top; text-align : left; backgroun
d-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy">0..
1</td><td style="vertical-align: top; text-align : left; background-color: white; border:
 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><a href="http://build.fhir
.org/datatypes.html#Quantity">Quantity</a></td><td style="vertical-align: top; text-align
 : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" cla
ss="hierarchy"/></tr>
<tr style="border: 0px #F0F0F0 solid; padding:0px; vertical-align: top; background-color:
 white;"><td style="vertical-align: top; text-align : left; background-color: white; bord
er: 0px #F0F0F0 solid; padding:0px 4px 0px 4px; white-space: nowrap; background-image: ur
l(tbl_bck10150.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="backgroun
d-color: inherit" class="hierarchy"/><img src="tbl_vline.png" alt="." style="background-c
olor: inherit" class="hierarchy"/><img src="tbl_blank.png" alt="." style="background-colo
r: inherit" class="hierarchy"/><img src="tbl_vline.png" alt="." style="background-color:
inherit" class="hierarchy"/><img src="tbl_vjoin_slice.png" alt="." style="background-colo
r: inherit" class="hierarchy"/><img src="icon_element.gif" alt="." style="background-colo
r: white; background-color: inherit" title="Element" class="hierarchy"/> <a href="quality
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specification-definitions.html#PlanDefinition.goal.target.detailQuantity:Quantity.value">
value</a><a name="PlanDefinition.goal.target.detailQuantity.value"> </a></td><td style="v
ertical-align: top; text-align : left; background-color: white; border: 0px #F0F0F0 solid
; padding:0px 4px 0px 4px" class="hierarchy"><span style="padding-left: 3px; padding-righ
t: 3px; color: white; background-color: red" title="This element must be supported">S</sp
an></td><td style="vertical-align: top; text-align : left; background-color: white; borde
r: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy">1..1</td><td style="vert
ical-align: top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; p
adding:0px 4px 0px 4px" class="hierarchy"/><td style="vertical-align: top; text-align : l
eft; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="
hierarchy"/></tr>
<tr style="border: 0px #F0F0F0 solid; padding:0px; vertical-align: top; background-color:
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er: 0px #F0F0F0 solid; padding:0px 4px 0px 4px; white-space: nowrap; background-image: ur
l(tbl_bck10150.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="backgroun
d-color: inherit" class="hierarchy"/><img src="tbl_vline.png" alt="." style="background-c
olor: inherit" class="hierarchy"/><img src="tbl_blank.png" alt="." style="background-colo
r: inherit" class="hierarchy"/><img src="tbl_vline.png" alt="." style="background-color:
inherit" class="hierarchy"/><img src="tbl_vjoin_slice.png" alt="." style="background-colo
r: inherit" class="hierarchy"/><img src="icon_primitive.png" alt="." style="background-co
lor: white; background-color: inherit" title="Primitive Data Type" class="hierarchy"/> <a
 href="qualityspecification-definitions.html#PlanDefinition.goal.target.detailQuantity:Qu
antity.system">system</a><a name="PlanDefinition.goal.target.detailQuantity.system"> </a>
</td><td style="vertical-align: top; text-align : left; background-color: white; border:
0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><span style="padding-left:
3px; padding-right: 3px; color: white; background-color: red" title="This element must be
 supported">S</span></td><td style="vertical-align: top; text-align : left; background-co
lor: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy">1..1</t
d><td style="vertical-align: top; text-align : left; background-color: white; border: 0px
 #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><a href="http://build.fhir.org
/datatypes.html#uri">uri</a></td><td style="vertical-align: top; text-align : left; backg
round-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"
><span style="font-weight:bold">Fixed Value: </span><span style="color: darkgreen">http:/
/unitsofmeasure.org</span></td></tr>
<tr style="border: 0px #F0F0F0 solid; padding:0px; vertical-align: top; background-color:
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er: 0px #F0F0F0 solid; padding:0px 4px 0px 4px; white-space: nowrap; background-image: ur
l(tbl_bck10140.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="backgroun
d-color: inherit" class="hierarchy"/><img src="tbl_vline.png" alt="." style="background-c
olor: inherit" class="hierarchy"/><img src="tbl_blank.png" alt="." style="background-colo
r: inherit" class="hierarchy"/><img src="tbl_vline.png" alt="." style="background-color:
inherit" class="hierarchy"/><img src="tbl_vjoin_end_slice.png" alt="." style="background-
color: inherit" class="hierarchy"/><img src="icon_element.gif" alt="." style="background-
color: white; background-color: inherit" title="Element" class="hierarchy"/> <a href="qua
lityspecification-definitions.html#PlanDefinition.goal.target.detailQuantity:Quantity.cod
e">code</a><a name="PlanDefinition.goal.target.detailQuantity.code"> </a></td><td style="
vertical-align: top; text-align : left; background-color: white; border: 0px #F0F0F0 soli
d; padding:0px 4px 0px 4px" class="hierarchy"><span style="padding-left: 3px; padding-rig
ht: 3px; color: white; background-color: red" title="This element must be supported">S</s
pan></td><td style="vertical-align: top; text-align : left; background-color: white; bord
er: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy">1..1</td><td style="ver
tical-align: top; text-align : left; background-color: white; border: 0px #F0F0F0 solid;
padding:0px 4px 0px 4px" class="hierarchy"/><td style="vertical-align: top; text-align :
left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class=
"hierarchy"/></tr>
<tr style="border: 0px #F0F0F0 solid; padding:0px; vertical-align: top; background-color:
 white;"><td style="vertical-align: top; text-align : left; background-color: white; bord
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er: 0px #F0F0F0 solid; padding:0px 4px 0px 4px; white-space: nowrap; background-image: ur
l(tbl_bck1015.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="background
-color: inherit" class="hierarchy"/><img src="tbl_vline.png" alt="." style="background-co
lor: inherit" class="hierarchy"/><img src="tbl_blank.png" alt="." style="background-color
: inherit" class="hierarchy"/><img src="tbl_vjoin.png" alt="." style="background-color: i
nherit" class="hierarchy"/><img src="icon_datatype.gif" alt="." style="background-color:
white; background-color: inherit" title="Data Type" class="hierarchy"/> <a href="qualitys
pecification-definitions.html#PlanDefinition.goal.target.detailRange:Range" title="Slice
Range: ">detailRange</a><a name="PlanDefinition.goal.target.detailRange"> </a></td><td st
yle="vertical-align: top; text-align : left; background-color: white; border: 0px #F0F0F0
 solid; padding:0px 4px 0px 4px" class="hierarchy"><span style="padding-left: 3px; paddin
g-right: 3px; color: white; background-color: red" title="This element must be supported"
>S</span></td><td style="vertical-align: top; text-align : left; background-color: white;
 border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy">0..1</td><td style
="vertical-align: top; text-align : left; background-color: white; border: 0px #F0F0F0 so
lid; padding:0px 4px 0px 4px" class="hierarchy"><a href="http://build.fhir.org/datatypes.
html#Range">Range</a></td><td style="vertical-align: top; text-align : left; background-c
olor: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"/></tr>
<tr style="border: 0px #F0F0F0 solid; padding:0px; vertical-align: top; background-color:
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er: 0px #F0F0F0 solid; padding:0px 4px 0px 4px; white-space: nowrap; background-image: ur
l(tbl_bck10151.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="backgroun
d-color: inherit" class="hierarchy"/><img src="tbl_vline.png" alt="." style="background-c
olor: inherit" class="hierarchy"/><img src="tbl_blank.png" alt="." style="background-colo
r: inherit" class="hierarchy"/><img src="tbl_vline.png" alt="." style="background-color:
inherit" class="hierarchy"/><img src="tbl_vjoin_slice.png" alt="." style="background-colo
r: inherit" class="hierarchy"/><img src="icon_element.gif" alt="." style="background-colo
r: white; background-color: inherit" title="Element" class="hierarchy"/> <a href="quality
specification-definitions.html#PlanDefinition.goal.target.detailRange:Range.low" title="A
 code that describes how to relate the given value to an acceptance value. [Source: SME D
efined] Note: When result value is numeric there is a controlled vocabulary; when result
value is textual the vocabulary is Pass/Fail.">low</a><a name="PlanDefinition.goal.target
.detailRange.low"> </a></td><td style="vertical-align: top; text-align : left; background
-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><spa
n style="padding-left: 3px; padding-right: 3px; color: white; background-color: red" titl
e="This element must be supported">S</span></td><td style="vertical-align: top; text-alig
n : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" cl
ass="hierarchy">0..1</td><td style="vertical-align: top; text-align : left; background-co
lor: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"/><td st
yle="vertical-align: top; text-align : left; background-color: white; border: 0px #F0F0F0
 solid; padding:0px 4px 0px 4px" class="hierarchy">interpretationCode=NLT</td></tr>
<tr style="border: 0px #F0F0F0 solid; padding:0px; vertical-align: top; background-color:
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l(tbl_bck101510.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="backgrou
nd-color: inherit" class="hierarchy"/><img src="tbl_vline.png" alt="." style="background-
color: inherit" class="hierarchy"/><img src="tbl_blank.png" alt="." style="background-col
or: inherit" class="hierarchy"/><img src="tbl_vline.png" alt="." style="background-color:
 inherit" class="hierarchy"/><img src="tbl_vline_slice.png" alt="." style="background-col
or: inherit" class="hierarchy"/><img src="tbl_vjoin.png" alt="." style="background-color:
 inherit" class="hierarchy"/><img src="icon_element.gif" alt="." style="background-color:
 white; background-color: inherit" title="Element" class="hierarchy"/> <a href="qualitysp
ecification-definitions.html#PlanDefinition.goal.target.detailRange:Range.low.value" titl
e="A text or numeric value of the result of the test. [Source: SME Defined].">value</a><a
 name="PlanDefinition.goal.target.detailRange.low.value"> </a></td><td style="vertical-al
ign: top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:
0px 4px 0px 4px" class="hierarchy"><span style="padding-left: 3px; padding-right: 3px; co
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lor: white; background-color: red" title="This element must be supported">S</span></td><t
d style="vertical-align: top; text-align : left; background-color: white; border: 0px #F0
F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy">1..1</td><td style="vertical-align
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color: inherit" class="hierarchy"/><img src="tbl_blank.png" alt="." style="background-col
or: inherit" class="hierarchy"/><img src="tbl_vline.png" alt="." style="background-color:
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or: inherit" class="hierarchy"/><img src="tbl_vjoin.png" alt="." style="background-color:
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ow.system">system</a><a name="PlanDefinition.goal.target.detailRange.low.system"> </a></t
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itle="A named quantity in terms of which other quantities are measured or specified, used
 as a standard measurement of like kinds. [Source: NCI EVS -C25709] Examples: mg, L, etc.
">code</a><a name="PlanDefinition.goal.target.detailRange.low.code"> </a></td><td style="
vertical-align: top; text-align : left; background-color: white; border: 0px #F0F0F0 soli
d; padding:0px 4px 0px 4px" class="hierarchy"><span style="padding-left: 3px; padding-rig
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pan></td><td style="vertical-align: top; text-align : left; background-color: white; bord
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left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class=
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px; padding-right: 3px; color: white; background-color: red" title="This element must be
supported">S</span></td><td style="vertical-align: top; text-align : left; background-col
or: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy">1..1</td
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or: inherit" class="hierarchy"/><img src="tbl_vjoin_end.png" alt="." style="background-co
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d as a standard measurement of like kinds. [Source: NCI EVS -C25709] Examples: mg, L, etc
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/span></td><td style="vertical-align: top; text-align : left; background-color: white; bo
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inherit" class="hierarchy"/><img src="tbl_vjoin_slice.png" alt="." style="background-colo
r: inherit" class="hierarchy"/><img src="icon_extension_simple.png" alt="." style="backgr
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ange.extension:lowExclusive" title="Slice lowExclusive: A code that describes how to rela
te the given value to an acceptance value. [Source: SME Defined] Note: When result value
is numeric there is a controlled vocabulary; when result value is textual the vocabulary
is Pass/Fail.">extension</a><a name="PlanDefinition.goal.target.detailRange.extension"> <
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 be supported">S</span></td><td style="vertical-align: top; text-align : left; background
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</td><td style="vertical-align: top; text-align : left; background-color: white; border:
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a.gov/cder/fhir/pqcmc/StructureDefinition/ext-range-lowExclusive]]</td><td style="vertica
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or: inherit" class="hierarchy"/><img src="tbl_vline.png" alt="." style="background-color:
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or: inherit" class="hierarchy"/><img src="tbl_vjoin_end_slice.png" alt="." style="backgro
und-color: inherit" class="hierarchy"/><img src="icon_element.gif" alt="." style="backgro
und-color: white; background-color: inherit" title="Element" class="hierarchy"/> <a href=
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hite; background-color: inherit" title="Element" class="hierarchy"/> <a href="qualityspec
ification-definitions.html#PlanDefinition.goal.target.detailRange:Range.extension:lowExcl
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rce: SME Defined].">value</a><a name="PlanDefinition.goal.target.detailRange.extension.va
lueQuantity.value"> </a></td><td style="vertical-align: top; text-align : left; backgroun
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an style="padding-left: 3px; padding-right: 3px; color: white; background-color: red" tit
le="This element must be supported">S</span></td><td style="vertical-align: top; text-ali
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lass="hierarchy">1..1</td><td style="vertical-align: top; text-align : left; background-c
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[Source: NCI EVS -C25709] Examples: mg, L, etc.">system</a><a name="PlanDefinition.goal.t
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lid; padding:0px 4px 0px 4px" class="hierarchy">1..1</td><td style="vertical-align: top;
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x 4px" class="hierarchy"><a href="http://build.fhir.org/datatypes.html#uri">uri</a></td><
td style="vertical-align: top; text-align : left; background-color: white; border: 0px #F
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hy"/> <a href="qualityspecification-definitions.html#PlanDefinition.goal.target.detailRan
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o relate the given value to an acceptance value. [Source: SME Defined] Note: When result
value is numeric there is a controlled vocabulary; when result value is textual the vocab
ulary is Pass/Fail.">extension</a><a name="PlanDefinition.goal.target.detailRange.extensi
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t must be supported">S</span></td><td style="vertical-align: top; text-align : left; back
ground-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy
">0..1</td><td style="vertical-align: top; text-align : left; background-color: white; bo
rder: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy">?? [CanonicalType[htt
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ighExclusive</td></tr>
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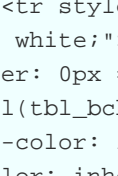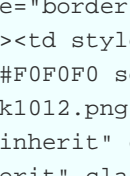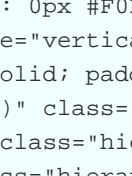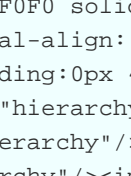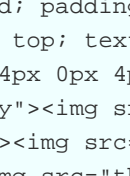
```
lor: inherit" class="hierarchy"/><img src="icon_element.gif" alt="." style="background-co
lor: white; background-color: inherit" title="Element" class="hierarchy"/> <a href="quali
tyspecification-definitions.html#PlanDefinition.goal.target.detailRange:Range.extension:h
ighExclusive.valueQuantity">valueQuantity</a><a name="PlanDefinition.goal.target.detailRa
nge.extension.valueQuantity"> </a></td><td style="vertical-align: top; text-align : left;
 background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hier
archy"/><td style="vertical-align: top; text-align : left; background-color: white; borde
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px 4px 0px 4px" class="hierarchy"/><td style="vertical-align: top; text-align : left; bac
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lor: inherit" class="hierarchy"/><img src="tbl_vline.png" alt="." style="background-color
: inherit" class="hierarchy"/><img src="tbl_blank.png" alt="." style="background-color: i
nherit" class="hierarchy"/><img src="tbl_blank.png" alt="." style="background-color: inhe
rit" class="hierarchy"/><img src="tbl_vjoin.png" alt="." style="background-color: inherit
" class="hierarchy"/><img src="icon_element.gif" alt="." style="background-color: white;
background-color: inherit" title="Element" class="hierarchy"/> <a href="qualityspecificat
ion-definitions.html#PlanDefinition.goal.target.detailRange:Range.extension:highExclusive
.valueQuantity.value" title="A text or numeric value of the result of the test. [Source:
SME Defined].">value</a><a name="PlanDefinition.goal.target.detailRange.extension.valueQu
antity.value"> </a></td><td style="vertical-align: top; text-align : left; background-col
or: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><span st
yle="padding-left: 3px; padding-right: 3px; color: white; background-color: red" title="T
his element must be supported">S</span></td><td style="vertical-align: top; text-align :
left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class=
"hierarchy">1..1</td><td style="vertical-align: top; text-align : left; background-color:
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"vertical-align: top; text-align : left; background-color: white; border: 0px #F0F0F0 sol
id; padding:0px 4px 0px 4px" class="hierarchy">valueNumeric</td></tr>
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l(tbl_bck1014400.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="backgro
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: inherit" class="hierarchy"/><img src="tbl_blank.png" alt="." style="background-color: i
nherit" class="hierarchy"/><img src="tbl_blank.png" alt="." style="background-color: inhe
rit" class="hierarchy"/><img src="tbl_vjoin_end.png" alt="." style="background-color: inh
erit" class="hierarchy"/><img src="icon_primitive.png" alt="." style="background-color: w
hite; background-color: inherit" title="Primitive Data Type" class="hierarchy"/> <a href=
"qualityspecification-definitions.html#PlanDefinition.goal.target.detailRange:Range.exten
sion:highExclusive.valueQuantity.system" title="A named quantity in terms of which other
quantities are measured or specified, used as a standard measurement of like kinds. [Sour
ce: NCI EVS -C25709] Examples: mg, L, etc.">system</a><a name="PlanDefinition.goal.target
.detailRange.extension.valueQuantity.system"> </a></td><td style="vertical-align: top; te
xt-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px
4px" class="hierarchy"><span style="padding-left: 3px; padding-right: 3px; color: white;
background-color: red" title="This element must be supported">S</span></td><td style="ver
tical-align: top; text-align : left; background-color: white; border: 0px #F0F0F0 solid;
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 solid; padding:0px 4px 0px 4px" class="hierarchy">Unit<br/><span style="font-weight:bold
">Fixed Value: </span><span style="color: darkgreen">http://unitsofmeasure.org</span></td
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: inherit" class="hierarchy"/><img src="tbl_vjoin_end.png" alt="." style="background-colo
r: inherit" class="hierarchy"/><img src="icon_datatype.gif" alt="." style="background-col
or: white; background-color: inherit" title="Data Type" class="hierarchy"/> <a href="qual
ityspecification-definitions.html#PlanDefinition.goal.target.detailCodeableConcept:Codeab
leConcept" title="Slice CodeableConcept: ">detailCodeableConcept</a><a name="PlanDefiniti
on.goal.target.detailCodeableConcept"> </a></td><td style="vertical-align: top; text-alig
n : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" cl
ass="hierarchy"><span style="padding-left: 3px; padding-right: 3px; color: white; backgro
und-color: red" title="This element must be supported">S</span></td><td style="vertical-a
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:0px 4px 0px 4px" class="hierarchy">0..1</td><td style="vertical-align: top; text-align :
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pt</a></td><td style="vertical-align: top; text-align : left; background-color: white; bo
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l(tbl_bck10040.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="backgroun
d-color: inherit" class="hierarchy"/><img src="tbl_vline.png" alt="." style="background-c
olor: inherit" class="hierarchy"/><img src="tbl_blank.png" alt="." style="background-colo
r: inherit" class="hierarchy"/><img src="tbl_blank.png" alt="." style="background-color:
inherit" class="hierarchy"/><img src="tbl_vjoin_end_slice.png" alt="." style="background-
color: inherit" class="hierarchy"/><img src="icon_element.gif" alt="." style="background-
color: white; background-color: inherit" title="Element" class="hierarchy"/> <a href="qua
lityspecification-definitions.html#PlanDefinition.goal.target.detailCodeableConcept:Codea
bleConcept.text" title="A text or numeric value of the result of the test. [Source: SME D
efined].">text</a><a name="PlanDefinition.goal.target.detailCodeableConcept.text"> </a></
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x #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><span style="padding-left: 3p
x; padding-right: 3px; color: white; background-color: red" title="This element must be s
upported">S</span></td><td style="vertical-align: top; text-align : left; background-colo
r: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy">1..1</td>
<td style="vertical-align: top; text-align : left; background-color: white; border: 0px #
F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"/><td style="vertical-align: top;
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l(tbl_bck01.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="background-c
olor: inherit" class="hierarchy"/><img src="tbl_vjoin_end.png" alt="." style="background-
color: inherit" class="hierarchy"/><img src="icon_element.gif" alt="." style="background-
color: white; background-color: inherit" title="Element" class="hierarchy"/> <a href="qua
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lityspecification-definitions.html#PlanDefinition.action" title="A determination of a phy
sical, chemical or biological property. [Source: SME Defined].">action</a><a name="PlanDe
finition.action"> </a></td><td style="vertical-align: top; text-align : left; background-
color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><span
 style="padding-left: 3px; padding-right: 3px; color: white; background-color: red" title
="This element must be supported">S</span></td><td style="vertical-align: top; text-align
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ss="hierarchy">1..*</td><td style="vertical-align: top; text-align : left; background-col
or: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"/><td sty
le="vertical-align: top; text-align : left; background-color: white; border: 0px #F0F0F0
solid; padding:0px 4px 0px 4px" class="hierarchy">Test<br/></td></tr>
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l(tbl_bck014.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="background-
color: inherit" class="hierarchy"/><img src="tbl_blank.png" alt="." style="background-col
or: inherit" class="hierarchy"/><img src="tbl_vjoin.png" alt="." style="background-color:
 inherit" class="hierarchy"/><img src="icon_extension_simple.png" alt="." style="backgrou
nd-color: white; background-color: inherit" title="Simple Extension" class="hierarchy"/>
<a href="qualityspecification-definitions.html#PlanDefinition.action.extension:methodOrig
in" title="Extension URL = http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-methodO
rigin">ext-methodOrigin</a><a name="PlanDefinition.action.extension"> </a></td><td style=
"vertical-align: top; text-align : left; background-color: white; border: 0px #F0F0F0 sol
id; padding:0px 4px 0px 4px" class="hierarchy"><span style="padding-left: 3px; padding-ri
ght: 3px; color: white; background-color: red" title="This element must be supported">S</
span></td><td style="vertical-align: top; text-align : left; background-color: white; bor
der: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy">0..1</td><td style="ve
rtical-align: top; text-align : left; background-color: white; border: 0px #F0F0F0 solid;
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#code">code</a></td><td style="vertical-align: top; text-align : left; background-color:
white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy">Test method
origin<br/><span style="font-weight:bold">URL: </span><a href="http://build.fhir.org/exte
nsion-ext-methodOrigin.html">http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-metho
dOrigin</a></td></tr>
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l(tbl_bck014.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="background-
color: inherit" class="hierarchy"/><img src="tbl_blank.png" alt="." style="background-col
or: inherit" class="hierarchy"/><img src="tbl_vjoin.png" alt="." style="background-color:
 inherit" class="hierarchy"/><img src="icon_extension_simple.png" alt="." style="backgrou
nd-color: white; background-color: inherit" title="Simple Extension" class="hierarchy"/>
<a href="qualityspecification-definitions.html#PlanDefinition.action.extension:referenceT
oProcedure" title="Extension URL = http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext
-definitionUri">ext-definitionUri</a><a name="PlanDefinition.action.extension"> </a></td>
<td style="vertical-align: top; text-align : left; background-color: white; border: 0px #
F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><span style="padding-left: 3px;
padding-right: 3px; color: white; background-color: red" title="This element must be supp
orted">S</span></td><td style="vertical-align: top; text-align : left; background-color:
white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy">0..1</td><td
 style="vertical-align: top; text-align : left; background-color: white; border: 0px #F0F
0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><a href="http://build.fhir.org/data
types.html#string">string</a></td><td style="vertical-align: top; text-align : left; back
ground-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy
">Reference to procedure (url)<br/><span style="font-weight:bold">URL: </span><a href="ht
tp://build.fhir.org/extension-ext-definitionUri.html">http://fda.gov/cder/fhir/pqcmc/Stru
ctureDefinition/ext-definitionUri</a></td></tr>
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l(tbl_bck014.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="background-
color: inherit" class="hierarchy"/><img src="tbl_blank.png" alt="." style="background-col
or: inherit" class="hierarchy"/><img src="tbl_vjoin.png" alt="." style="background-color:
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<a href="qualityspecification-definitions.html#PlanDefinition.action.extension:focus" tit
le="Extension URL = http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-focus">ext-foc
us</a><a name="PlanDefinition.action.extension"> </a></td><td style="vertical-align: top;
 text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0
px 4px" class="hierarchy"><span style="padding-left: 3px; padding-right: 3px; color: whit
e; background-color: red" title="This element must be supported">S</span></td><td style="
vertical-align: top; text-align : left; background-color: white; border: 0px #F0F0F0 soli
d; padding:0px 4px 0px 4px" class="hierarchy">0..1</td><td style="vertical-align: top; te
xt-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px
4px" class="hierarchy"><a href="http://build.fhir.org/datatypes.html#CodeableConcept">Cod
eableConcept</a></td><td style="vertical-align: top; text-align : left; background-color:
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tention time<br/><span style="font-weight:bold">URL: </span><a href="http://build.fhir.or
g/extension-ext-focus.html">http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-focus<
/a></td></tr>
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l(tbl_bck010.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="background-
color: inherit" class="hierarchy"/><img src="tbl_blank.png" alt="." style="background-col
or: inherit" class="hierarchy"/><img src="tbl_vjoin.png" alt="." style="background-color:
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ecification-definitions.html#PlanDefinition.action.title" title="The textual description
of a procedure or analytical method. [Source: SME Defined].">title</a><a name="PlanDefini
tion.action.title"> </a></td><td style="vertical-align: top; text-align : left; backgroun
d-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><sp
an style="padding-left: 3px; padding-right: 3px; color: white; background-color: red" tit
le="This element must be supported">S</span></td><td style="vertical-align: top; text-ali
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lass="hierarchy">1..1</td><td style="vertical-align: top; text-align : left; background-c
olor: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"/><td s
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color: inherit" class="hierarchy"/><img src="tbl_blank.png" alt="." style="background-col
or: inherit" class="hierarchy"/><img src="tbl_vjoin.png" alt="." style="background-color:
 inherit" class="hierarchy"/><img src="icon_datatype.gif" alt="." style="background-color
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yspecification-definitions.html#PlanDefinition.action.code">code</a><a name="PlanDefiniti
on.action.code"> </a></td><td style="vertical-align: top; text-align : left; background-c
olor: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><span
style="padding-left: 3px; padding-right: 3px; color: white; background-color: red" title=
"This element must be supported">S</span></td><td style="vertical-align: top; text-align
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s="hierarchy">1..1</td><td style="vertical-align: top; text-align : left; background-colo
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r: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><a href="
http://build.fhir.org/datatypes.html#CodeableConcept">CodeableConcept</a></td><td style="
vertical-align: top; text-align : left; background-color: white; border: 0px #F0F0F0 soli
d; padding:0px 4px 0px 4px" class="hierarchy">QualitySpecification Test category</td></tr
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: inherit" class="hierarchy"/><img src="tbl_vjoin.png" alt="." style="background-color: i
nherit" class="hierarchy"/><img src="icon_element.gif" alt="." style="background-color: w
hite; background-color: inherit" title="Element" class="hierarchy"/> <a href="qualityspec
ification-definitions.html#PlanDefinition.action.code.coding" title="A high level groupin
g of product quality attributes. [Source: SME Defined] Examples: Appearance, Physical Pro
perties, etc.">coding</a><a name="PlanDefinition.action.code.coding"> </a></td><td style=
"vertical-align: top; text-align : left; background-color: white; border: 0px #F0F0F0 sol
id; padding:0px 4px 0px 4px" class="hierarchy"><span style="padding-left: 3px; padding-ri
ght: 3px; color: white; background-color: red" title="This element must be supported">S</
span></td><td style="vertical-align: top; text-align : left; background-color: white; bor
der: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy">1..1</td><td style="ve
rtical-align: top; text-align : left; background-color: white; border: 0px #F0F0F0 solid;
 padding:0px 4px 0px 4px" class="hierarchy"/><td style="vertical-align: top; text-align :
 left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class
="hierarchy">Test category</td></tr>
<tr style="border: 0px #F0F0F0 solid; padding:0px; vertical-align: top; background-color:
 white;"><td style="vertical-align: top; text-align : left; background-color: white; bord
er: 0px #F0F0F0 solid; padding:0px 4px 0px 4px; white-space: nowrap; background-image: ur
l(tbl_bck0100.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="background
-color: inherit" class="hierarchy"/><img src="tbl_blank.png" alt="." style="background-co
lor: inherit" class="hierarchy"/><img src="tbl_vline.png" alt="." style="background-color
: inherit" class="hierarchy"/><img src="tbl_vjoin_end.png" alt="." style="background-colo
r: inherit" class="hierarchy"/><img src="icon_element.gif" alt="." style="background-colo
r: white; background-color: inherit" title="Element" class="hierarchy"/> <a href="quality
specification-definitions.html#PlanDefinition.action.code.text" title="A technique used t
o determine the nature of a characteristic. [Source: SME Defined] Examples: HPLC, Capilla
ry Electrophoresis, etc.">text</a><a name="PlanDefinition.action.code.text"> </a></td><td
 style="vertical-align: top; text-align : left; background-color: white; border: 0px #F0F
0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><span style="padding-left: 3px; pad
ding-right: 3px; color: white; background-color: red" title="This element must be support
ed">S</span></td><td style="vertical-align: top; text-align : left; background-color: whi
te; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy">1..1</td><td st
yle="vertical-align: top; text-align : left; background-color: white; border: 0px #F0F0F0
 solid; padding:0px 4px 0px 4px" class="hierarchy"/><td style="vertical-align: top; text-
align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px
" class="hierarchy">Analytical Procedure</td></tr>
<tr style="border: 0px #F0F0F0 solid; padding:0px; vertical-align: top; background-color:
 white;"><td style="vertical-align: top; text-align : left; background-color: white; bord
er: 0px #F0F0F0 solid; padding:0px 4px 0px 4px; white-space: nowrap; background-image: ur
l(tbl_bck010.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="background-
color: inherit" class="hierarchy"/><img src="tbl_blank.png" alt="." style="background-col
or: inherit" class="hierarchy"/><img src="tbl_vjoin.png" alt="." style="background-color:
 inherit" class="hierarchy"/><img src="icon_element.gif" alt="." style="background-color:
 white; background-color: inherit" title="Element" class="hierarchy"/> <a href="qualitysp
ecification-definitions.html#PlanDefinition.action.reason" title="A coded value specifyin
g the time point during the manufacturing process of a substance or product when a partic
```

ular analytical procedure or measurement is being performed. [Source: SME Defined].">reason </td><td style="vertical-align: top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy">S</td><td style="vertical-align: top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy">1..1</td><td style="vertical-align: top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"/><td style="vertical-align: top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy">Usage</td></tr>
<tr style="border: 0px #F0F0F0 solid; padding:0px; vertical-align: top; background-color: white;"><td style="vertical-align: top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px; white-space: nowrap; background-image: url(tbl_bck010.png)" class="hierarchy"> definitionUri </td><td style="vertical-align: top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy">S</td><td style="vertical-align: top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy">0..1</td><td style="vertical-align: top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"/><td style="vertical-align: top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy">referenceToProcedure (FHIR)</td></tr>
<tr style="border: 0px #F0F0F0 solid; padding:0px; vertical-align: top; background-color: white;"><td style="vertical-align: top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px; white-space: nowrap; background-image: url(tbl_bck001.png)" class="hierarchy"> action </td><td style="vertical-align: top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy">S</td><td style="vertical-align: top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy">1..*</td><td style="vertical-align: top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"/><td style="vertical-align: top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy">Stage
</td></tr>
<tr style="border: 0px #F0F0F0 solid; padding:0px; vertical-align: top; background-color: white;"><td style="vertical-align: top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px; white-space: nowrap; background-image: url(tbl_bck0010.png)" class="hierarchy"><img src="tbl_vjoin.png" alt="." style="background-color: i

```
nherit" class="hierarchy"/><img src="icon_element.gif" alt="." style="background-color: w
hite; background-color: inherit" title="Element" class="hierarchy"/> <a href="qualityspec
ification-definitions.html#PlanDefinition.action.action.title" title="A textual descripti
on and/or a number that identifies a level within a sequential test. [Source: SME Defined
] Examples – Single Stage, Stage 1, Stage 2 (sometimes referred to as L1, L2 L3 or A1, A2
 as in USP &lt;711&gt;) Note: A Stage may or may not provide a conditional sequence with
associated acceptance criteria. [Source: SME Defined] (e.g., dissolution test, pyrogen te
st -USP &lt;151&gt;; 21 CFR 610.13(b) Test for pyrogenic substances).">title</a><a name="
PlanDefinition.action.action.title"> </a></td><td style="vertical-align: top; text-align
: left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" clas
s="hierarchy"><span style="padding-left: 3px; padding-right: 3px; color: white; backgroun
d-color: red" title="This element must be supported">S</span></td><td style="vertical-ali
gn: top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0
px 4px 0px 4px" class="hierarchy">1..1</td><td style="vertical-align: top; text-align : l
eft; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="
hierarchy"/><td style="vertical-align: top; text-align : left; background-color: white; b
order: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy">Stage name</td></tr>
<tr style="border: 0px #F0F0F0 solid; padding:0px; vertical-align: top; background-color:
 white;"><td style="vertical-align: top; text-align : left; background-color: white; bord
er: 0px #F0F0F0 solid; padding:0px 4px 0px 4px; white-space: nowrap; background-image: ur
l(tbl_bck0010.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="background
-color: inherit" class="hierarchy"/><img src="tbl_blank.png" alt="." style="background-co
lor: inherit" class="hierarchy"/><img src="tbl_blank.png" alt="." style="background-color
: inherit" class="hierarchy"/><img src="tbl_vjoin.png" alt="." style="background-color: i
nherit" class="hierarchy"/><img src="icon_element.gif" alt="." style="background-color: w
hite; background-color: inherit" title="Element" class="hierarchy"/> <a href="qualityspec
ification-definitions.html#PlanDefinition.action.action.goalId">goalId</a><a name="PlanDe
finition.action.action.goalId"> </a></td><td style="vertical-align: top; text-align : lef
t; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hi
erarchy"><span style="padding-left: 3px; padding-right: 3px; color: white; background-col
or: red" title="This element must be supported">S</span></td><td style="vertical-align: t
op; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4p
x 0px 4px" class="hierarchy">1..*</td><td style="vertical-align: top; text-align : left;
background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hiera
rchy"/><td style="vertical-align: top; text-align : left; background-color: white; border
: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy">Acceptance criteria<br/><
/td></tr>
<tr style="border: 0px #F0F0F0 solid; padding:0px; vertical-align: top; background-color:
 white;"><td style="vertical-align: top; text-align : left; background-color: white; bord
er: 0px #F0F0F0 solid; padding:0px 4px 0px 4px; white-space: nowrap; background-image: ur
l(tbl_bck0001.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="background
-color: inherit" class="hierarchy"/><img src="tbl_blank.png" alt="." style="background-co
lor: inherit" class="hierarchy"/><img src="tbl_blank.png" alt="." style="background-color
: inherit" class="hierarchy"/><img src="tbl_vjoin_end.png" alt="." style="background-colo
r: inherit" class="hierarchy"/><img src="icon_element.gif" alt="." style="background-colo
r: white; background-color: inherit" title="Element" class="hierarchy"/> <a href="quality
specification-definitions.html#PlanDefinition.action.action.relatedAction" title="The ord
er of the stages in regular succession. [Source: SME Defined] Examples: 1, 2, 3, etc.  Th
is is not a direct mapping in FHIR.">relatedAction</a><a name="PlanDefinition.action.acti
on.relatedAction"> </a></td><td style="vertical-align: top; text-align : left; background
-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><spa
n style="padding-left: 3px; padding-right: 3px; color: white; background-color: red" titl
e="This element must be supported">S</span></td><td style="vertical-align: top; text-alig
n : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" cl
ass="hierarchy">0..1</td><td style="vertical-align: top; text-align : left; background-co
lor: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"/><td st
yle="vertical-align: top; text-align : left; background-color: white; border: 0px #F0F0F0
```

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solid; padding:0px 4px 0px 4px" class="hierarchy">Indicates relative sequence</td></tr>
<tr style="border: 0px #F0F0F0 solid; padding:0px; vertical-align: top; background-color:
 white;"><td style="vertical-align: top; text-align : left; background-color: white; bord
er: 0px #F0F0F0 solid; padding:0px 4px 0px 4px; white-space: nowrap; background-image: ur
l(tbl_bck00010.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="backgroun
d-color: inherit" class="hierarchy"/><img src="tbl_blank.png" alt="." style="background-c
olor: inherit" class="hierarchy"/><img src="tbl_blank.png" alt="." style="background-colo
r: inherit" class="hierarchy"/><img src="tbl_blank.png" alt="." style="background-color:
inherit" class="hierarchy"/><img src="tbl_vjoin.png" alt="." style="background-color: inh
erit" class="hierarchy"/><img src="icon_element.gif" alt="." style="background-color: whi
te; background-color: inherit" title="Element" class="hierarchy"/> <a href="qualityspecif
ication-definitions.html#PlanDefinition.action.action.relatedAction.actionId" title="The
identifier of the previous stage.">actionId</a><a name="PlanDefinition.action.action.rela
tedAction.actionId"> </a></td><td style="vertical-align: top; text-align : left; backgrou
nd-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><s
pan style="padding-left: 3px; padding-right: 3px; color: white; background-color: red" ti
tle="This element must be supported">S</span></td><td style="vertical-align: top; text-al
ign : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px"
class="hierarchy">1..1</td><td style="vertical-align: top; text-align : left; background-
color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"/><td
style="vertical-align: top; text-align : left; background-color: white; border: 0px #F0F0
F0 solid; padding:0px 4px 0px 4px" class="hierarchy">GUID identifer for related stage</td
></tr>
<tr style="border: 0px #F0F0F0 solid; padding:0px; vertical-align: top; background-color:
 white;"><td style="vertical-align: top; text-align : left; background-color: white; bord
er: 0px #F0F0F0 solid; padding:0px 4px 0px 4px; white-space: nowrap; background-image: ur
l(tbl_bck00000.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="backgroun
d-color: inherit" class="hierarchy"/><img src="tbl_blank.png" alt="." style="background-c
olor: inherit" class="hierarchy"/><img src="tbl_blank.png" alt="." style="background-colo
r: inherit" class="hierarchy"/><img src="tbl_blank.png" alt="." style="background-color:
inherit" class="hierarchy"/><img src="tbl_vjoin_end.png" alt="." style="background-color:
 inherit" class="hierarchy"/><img src="icon_element.gif" alt="." style="background-color:
 white; background-color: inherit" title="Element" class="hierarchy"/> <a href="qualitysp
ecification-definitions.html#PlanDefinition.action.action.relatedAction.relationship">rel
ationship</a><a name="PlanDefinition.action.action.relatedAction.relationship"> </a></td>
<td style="vertical-align: top; text-align : left; background-color: white; border: 0px #
F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><span style="padding-left: 3px;
padding-right: 3px; color: white; background-color: red" title="This element must be supp
orted">S</span></td><td style="vertical-align: top; text-align : left; background-color:
white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy">1..1</td><td
 style="vertical-align: top; text-align : left; background-color: white; border: 0px #F0F
0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"/><td style="vertical-align: top; te
xt-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px
4px" class="hierarchy">Sequence reference</td></tr>
<tr><td colspan="5" class="hierarchy"><br/><a href="http://build.fhir.org/formats.html#ta
ble" title="Legend for this format"><img src="http://build.fhir.org/help16.png" alt="doco
" style="background-color: inherit"/> Documentation for this format</a></td></tr></table>
</div>
  </text>
  <url
      value="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/qualityspecification"/>
  <version value="current"/>
  <name value="Quality Specification"/>
  <title value="Quality Specification"/>
  <status value="draft"/>
  <experimental value="false"/>
  <date value="2018-10-05T00:00:00-04:00"/>
```

```xml
  <publisher value="U.S. FDA - CDER division"/>
  <contact>
    <telecom>
      <system value="url"/>
      <value
            value="https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsan
dtobacco/cder"/>
    </telecom>
  </contact>
  <description
              value="Describes the protocol for checking the chemical, manufacturing and
 controls associated with a particular drug product."/>
  <fhirVersion value="4.0.0"/>
  <mapping>
    <identity value="workflow"/>
    <uri value="http://hl7.org/fhir/workflow"/>
    <name value="Workflow Pattern"/>
  </mapping>
  <mapping>
    <identity value="w5"/>
    <uri value="http://hl7.org/fhir/fivews"/>
    <name value="FiveWs Pattern Mapping"/>
  </mapping>
  <mapping>
    <identity value="objimpl"/>
    <uri value="http://hl7.org/fhir/object-implementation"/>
    <name value="Object Implementation Information"/>
  </mapping>
  <mapping>
    <identity value="rim"/>
    <uri value="http://hl7.org/v3"/>
    <name value="RIM Mapping"/>
  </mapping>
  <kind value="resource"/>
  <abstract value="false"/>
  <type value="PlanDefinition"/>
  <baseDefinition value="http://hl7.org/fhir/StructureDefinition/PlanDefinition"/>
  <derivation value="constraint"/>
  <snapshot>
    <element id="PlanDefinition">
      <path value="PlanDefinition"/>
      <short value="Quality Specification"/>
      <definition
                  value="Specification means the quality standard (i.e. , tests, analytic
al procedures, and acceptance criteria) provided in an approved application to confirm th
e quality of drug substances, drug products, intermediates, raw materials, reagents, comp
onents, in-process materials, container closure systems, and other materials used in the
production of a drug substance or drug product. For the purpose of this definition, accep
tance criteria means numerical limits, ranges, or other criteria for the tests described.
"/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="PlanDefinition"/>
        <min value="0"/>
        <max value="*"/>
      </base>
```

```xml
      <constraint>
        <key value="dom-2"/>
        <severity value="error"/>
        <human
                value="If the resource is contained in another resource, it SHALL NOT cont
ain nested Resources"/>
        <expression value="contained.contained.empty()"/>
        <xpath value="not(parent::f:contained and f:contained)"/>
        <source value="DomainResource"/>
      </constraint>
      <constraint>
        <key value="dom-4"/>
        <severity value="error"/>
        <human
                value="If a resource is contained in another resource, it SHALL NOT have a
 meta.versionId or a meta.lastUpdated"/>
        <expression
                    value="contained.meta.versionId.empty() and contained.meta.lastUpdate
d.empty()"/>
        <xpath
                value="not(exists(f:contained/*/f:meta/f:versionId)) and not(exists(f:cont
ained/*/f:meta/f:lastUpdated))"/>
        <source value="DomainResource"/>
      </constraint>
      <constraint>
        <key value="dom-3"/>
        <severity value="error"/>
        <human
                value="If the resource is contained in another resource, it SHALL be refer
red to from elsewhere in the resource or SHALL refer to the containing resource"/>
        <expression
                    value="contained.where((((&#39;#&#39;+id in (%resource.descendants().r
eference | %resource.descendants().as(canonical) | %resource.descendants().as(uri) | %res
ource.descendants().as(url))) or descendants().where(reference = &#39;#&#39;).exists() or
 descendants().where(as(canonical) = &#39;#&#39;).exists() or descendants().where(as(cano
nical) = &#39;#&#39;).exists()).not()).trace(&#39;unmatched&#39;, id).empty()"/>
        <xpath
                value="not(exists(for $contained in f:contained return $contained[not(pare
nt::*/descendant::f:reference/@value=concat(&#39;#&#39;, $contained/*/id/@value) or desce
ndant::f:reference[@value=&#39;#&#39;])]))"/>
        <source value="DomainResource"/>
      </constraint>
      <constraint>
        <extension
                   url="http://hl7.org/fhir/StructureDefinition/elementdefinition-bestpra
ctice">
          <valueBoolean value="true"/>
        </extension>
        <extension
                   url="http://hl7.org/fhir/StructureDefinition/elementdefinition-bestpra
ctice-explanation">
          <valueMarkdown
                         value="When a resource has no narrative, only systems that fully
 understand the data can display the resource to a human safely. Including a human readab
le representation in the resource makes for a much more robust eco-system and cheaper han
dling of resources by intermediary systems. Some ecosystems restrict distribution of reso
urces to only those systems that do fully understand the resources, and as a consequence
```

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implementers may believe that the narrative is superfluous. However experience shows that
 such eco-systems often open up to new participants over time."/>
          </extension>
          <key value="dom-6"/>
          <severity value="warning"/>
          <human value="A resource should have narrative for robust management"/>
          <expression value="text.div.exists()"/>
          <xpath value="exists(f:text/h:div)"/>
          <source value="DomainResource"/>
        </constraint>
        <constraint>
          <key value="dom-5"/>
          <severity value="error"/>
          <human
                value="If a resource is contained in another resource, it SHALL NOT have a
 security label"/>
          <expression value="contained.meta.security.empty()"/>
          <xpath value="not(exists(f:contained/*/f:meta/f:security))"/>
          <source value="DomainResource"/>
        </constraint>
        <constraint>
          <key value="pdf-0"/>
          <severity value="warning"/>
          <human
                value="Name should be usable as an identifier for the module by machine pr
ocessing applications such as code generation"/>
          <expression value="name.matches(&#39;[A-Z]([A-Za-z0-9_]){0,254}&#39;)"/>
          <xpath
                value="not(exists(f:name/@value)) or matches(f:name/@value, &#39;[A-Z]([A-
Za-z0-9_]){0,254}&#39;)"/>
          <source value="PlanDefinition"/>
        </constraint>
        <mustSupport value="false"/>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="Entity. Role, or Act"/>
        </mapping>
        <mapping>
          <identity value="workflow"/>
          <map value="Definition"/>
        </mapping>
      </element>
      <element id="PlanDefinition.id">
        <path value="PlanDefinition.id"/>
        <short value="Logical id of this artifact"/>
        <definition
                    value="The logical id of the resource, as used in the URL for the resou
rce. Once assigned, this value never changes."/>
        <comment
                value="The only time that a resource does not have an id is when it is bei
ng submitted to the server using a create operation."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Resource.id"/>
```

```xml
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="id"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="true"/>
      </element>
      <element id="PlanDefinition.meta">
        <path value="PlanDefinition.meta"/>
        <short value="Metadata about the resource"/>
        <definition
                  value="The metadata about the resource. This is content that is maintai
ned by the infrastructure. Changes to the content might not always be associated with ver
sion changes to the resource."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Resource.meta"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="Meta"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="true"/>
      </element>
      <element id="PlanDefinition.implicitRules">
        <path value="PlanDefinition.implicitRules"/>
        <short value="A set of rules under which this content was created"/>
        <definition
                  value="A reference to a set of rules that were followed when the resour
ce was constructed, and which must be understood when processing the content. Often, this
 is a reference to an implementation guide that defines the special rules along with othe
r profiles etc."/>
        <comment
                value="Asserting this rule set restricts the content to be only understood
 by a limited set of trading partners. This inherently limits the usefulness of the data
in the long term. However, the existing health eco-system is highly fractured, and not ye
t ready to define, collect, and exchange data in a generally computable sense. Wherever p
ossible, implementers and/or specification writers should avoid using this element. Often
, when used, the URL is a reference to an implementation guide that defines these special
 rules as part of it&#39;s narrative along with other profiles, value sets, etc."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Resource.implicitRules"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="uri"/>
        </type>
        <isModifier value="true"/>
        <isModifierReason
```

```
                               value="This element is labeled as a modifier because the implicit
 rules may provide additional knowledge about the resource that modifies it&#39;s meaning
 or interpretation"/>
        <isSummary value="true"/>
      </element>
      <element id="PlanDefinition.language">
        <path value="PlanDefinition.language"/>
        <short value="Language of the resource content"/>
        <definition value="The base language in which the resource is written."/>
        <comment
                  value="Language is provided to support indexing and accessibility (typical
ly, services such as text to speech use the language tag). The html language tag in the n
arrative applies  to the narrative. The language tag on the resource may be used to speci
fy the language of other presentations generated from the data in the resource. Not all t
he content has to be in the base language. The Resource.language should not be assumed to
 apply to the narrative automatically. If a language is specified, it should it also be s
pecified on the div element in the html (see rules in HTML5 for information about the rel
ationship between xml:lang and the html lang attribute)."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Resource.language"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="code"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <binding>
          <extension
                    url="http://hl7.org/fhir/StructureDefinition/elementdefinition-maxValu
eSet">
            <valueCanonical value="http://hl7.org/fhir/ValueSet/all-languages"/>
          </extension>
          <extension
                    url="http://hl7.org/fhir/StructureDefinition/elementdefinition-binding
Name">
            <valueString value="Language"/>
          </extension>
          <extension
                    url="http://hl7.org/fhir/StructureDefinition/elementdefinition-isCommo
nBinding">
            <valueBoolean value="true"/>
          </extension>
          <strength value="preferred"/>
          <description value="A human language."/>
          <valueSet value="http://hl7.org/fhir/ValueSet/languages"/>
        </binding>
      </element>
      <element id="PlanDefinition.text">
        <path value="PlanDefinition.text"/>
        <short value="Text summary of the resource, for human interpretation"/>
        <definition
                    value="A human-readable narrative that contains a summary of the resour
ce and can be used to represent the content of the resource to a human. The narrative nee
```

```
d not encode all the structured data, but is required to contain sufficient detail to mak
e it &quot;clinically safe&quot; for a human to just read the narrative. Resource definit
ions may define what content should be represented in the narrative to ensure clinical sa
fety."/>
        <comment
                value="Contained resources do not have narrative. Resources that are not c
ontained SHOULD have a narrative. In some cases, a resource may only have text with littl
e or no additional discrete data (as long as all minOccurs=1 elements are satisfied).  Th
is may be necessary for data from legacy systems where information is captured as a &quot
;text blob&quot; or where text is additionally entered raw or narrated and encoded inform
ation is added later."/>
        <alias value="narrative"/>
        <alias value="html"/>
        <alias value="xhtml"/>
        <alias value="display"/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="DomainResource.text"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="Narrative"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="Act.text?"/>
        </mapping>
      </element>
      <element id="PlanDefinition.contained">
        <path value="PlanDefinition.contained"/>
        <short value="Contained, inline Resources"/>
        <definition
                value="These resources do not have an independent existence apart from
the resource that contains them - they cannot be identified independently, and nor can th
ey have their own independent transaction scope."/>
        <comment
                value="This should never be done when the content can be identified proper
ly, as once identification is lost, it is extremely difficult (and context dependent) to
restore it again. Contained resources may have profiles and tags In their meta elements,
but SHALL NOT have security labels."/>
        <alias value="inline resources"/>
        <alias value="anonymous resources"/>
        <alias value="contained resources"/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="DomainResource.contained"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Resource"/>
        </type>
```

```
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="N/A"/>
      </mapping>
    </element>
    <element id="PlanDefinition.extension">
      <path value="PlanDefinition.extension"/>
      <slicing id="4">
        <discriminator>
          <type value="value"/>
          <path value="url"/>
        </discriminator>
        <ordered value="false"/>
        <rules value="open"/>
      </slicing>
      <short value="Extension"/>
      <definition value="An Extension"/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="DomainResource.extension"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Extension"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="PlanDefinition.extension:approvalStatus">
      <extension
                url="http://hl7.org/fhir/StructureDefinition/structuredefinition-standar
ds-status">
        <valueCode value="normative"/>
      </extension>
      <extension
                url="http://hl7.org/fhir/StructureDefinition/structuredefinition-normati
ve-version">
        <valueCode value="4.0.0"/>
      </extension>
      <path value="PlanDefinition.extension"/>
      <sliceName value="approvalStatus"/>
      <short value="Approval Status"/>
      <definition
                  value="The current FDA regulatory status of the specification. [Source:
 SME Defined] Examples: Approved, Not Approved, etc."/>
      <comment
              value="Indicates that the form has been designed with an expectation that
it will be submitted to the specified URI.  If multiple endpoints are specified, expectat
ion is that answers are submitted to all endpoints.

If no end-point is specified, then the form is not exclusively designed to be submitted t
o a specific site.  If and where the form needs to be submitted or how the form should be
 internally processed must be inferred from external context or system business rules."/>
```

```xml
          <min value="0"/>
          <max value="1"/>
          <base>
            <path value="DomainResource.extension"/>
            <min value="0"/>
            <max value="*"/>
          </base>
          <type>
            <code value="Extension"/>
            <profile
                    value="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-approvalSt
atus"/>
          </type>
          <condition value="ele-1"/>
          <constraint>
            <key value="ele-1"/>
            <severity value="error"/>
            <human value="All FHIR elements must have a @value or children"/>
            <expression value="hasValue() or (children().count() &gt; id.count())"/>
            <xpath value="@value|f:*|h:div"/>
            <source value="Element"/>
          </constraint>
          <constraint>
            <key value="ext-1"/>
            <severity value="error"/>
            <human value="Must have either extensions or value[x], not both"/>
            <expression value="extension.exists() != value.exists()"/>
            <xpath
                  value="exists(f:extension)!=exists(f:*[starts-with(local-name(.), &#39;val
ue&#39;)])"/>
            <source value="Extension"/>
          </constraint>
          <mustSupport value="true"/>
          <isModifier value="false"/>
        </element>
        <element id="PlanDefinition.extension:approvalStatus.id">
          <path value="PlanDefinition.extension.id"/>
          <representation value="xmlAttr"/>
          <short value="Unique id for inter-element referencing"/>
          <definition
                      value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
          <min value="0"/>
          <max value="1"/>
          <base>
            <path value="Element.id"/>
            <min value="0"/>
            <max value="1"/>
          </base>
          <type>
            <code value="string"/>
          </type>
          <isModifier value="false"/>
          <isSummary value="false"/>
          <mapping>
            <identity value="rim"/>
            <map value="n/a"/>
```

```xml
        </mapping>
      </element>
      <element id="PlanDefinition.extension:approvalStatus.extension">
        <path value="PlanDefinition.extension.extension"/>
        <slicing>
          <discriminator>
            <type value="value"/>
            <path value="url"/>
          </discriminator>
          <description value="Extensions are always sliced by (at least) url"/>
          <rules value="open"/>
        </slicing>
        <short value="Additional content defined by implementations"/>
        <definition
                  value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
        <comment
                value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
        <alias value="extensions"/>
        <alias value="user content"/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="Element.extension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="PlanDefinition.extension:approvalStatus.extension:type">
        <path value="PlanDefinition.extension.extension"/>
        <sliceName value="type"/>
        <short value="Specification Type"/>
        <definition
                  value="A classification of specification related to the kind of the ent
ity it is referencing. [Source: SME Defined]."/>
        <min value="1"/>
        <max value="1"/>
        <base>
          <path value="Element.extension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
```

```xml
      <type>
        <code value="Extension"/>
      </type>
      <mustSupport value="true"/>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="PlanDefinition.extension:approvalStatus.extension:type.id">
      <path value="PlanDefinition.extension.extension.id"/>
      <representation value="xmlAttr"/>
      <short value="Unique id for inter-element referencing"/>
      <definition
                value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="Element.id"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="string"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="n/a"/>
      </mapping>
    </element>
    <element
            id="PlanDefinition.extension:approvalStatus.extension:type.extension">
      <path value="PlanDefinition.extension.extension.extension"/>
      <slicing>
        <discriminator>
          <type value="value"/>
          <path value="url"/>
        </discriminator>
        <description value="Extensions are always sliced by (at least) url"/>
        <rules value="open"/>
      </slicing>
      <short value="Additional content defined by implementations"/>
      <definition
                value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
      <comment
              value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
      <alias value="extensions"/>
      <alias value="user content"/>
      <min value="0"/>
```

```
          <max value="*"/>
          <base>
            <path value="Element.extension"/>
            <min value="0"/>
            <max value="*"/>
          </base>
          <type>
            <code value="Extension"/>
          </type>
          <isModifier value="false"/>
          <isSummary value="false"/>
          <mapping>
            <identity value="rim"/>
            <map value="n/a"/>
          </mapping>
        </element>
        <element id="PlanDefinition.extension:approvalStatus.extension:type.url">
          <path value="PlanDefinition.extension.extension.url"/>
          <representation value="xmlAttr"/>
          <short value="identifies the meaning of the extension"/>
          <definition
                    value="Source of the definition for the extension code - a logical name
 or a URL."/>
          <comment
                  value="The definition may point directly to a computable or human-readable
 definition of the extensibility codes, or it may be a logical URI as declared in some ot
her specification. The definition SHALL be a URI for the Structure Definition defining th
e extension."/>
          <min value="1"/>
          <max value="1"/>
          <base>
            <path value="Extension.url"/>
            <min value="1"/>
            <max value="1"/>
          </base>
          <type>
            <code>
              <extension
                        url="http://hl7.org/fhir/StructureDefinition/structuredefinition-jso
n-type">
                <valueString value="string"/>
              </extension>
              <extension
                        url="http://hl7.org/fhir/StructureDefinition/structuredefinition-xml
-type">
                <valueString value="xsd:string"/>
              </extension>
              <extension
                        url="http://hl7.org/fhir/StructureDefinition/structuredefinition-rdf
-type">
                <valueString value="xsd:string"/>
              </extension>
              <extension url="http://hl7.org/fhir/StructureDefinition/regex">
                <valueString
                            value="((http|https)://([A-Za-z0-9\\\.\:\%\$]*\/)*)?(Account|Act
ivityDefinition|AdverseEvent|AllergyIntolerance|Appointment|AppointmentResponse|AuditEven
t|Basic|Binary|BiologicallyDerivedProduct|BodyStructure|Bundle|CapabilityStatement|CarePl
```

```
an|CareTeam|CatalogEntry|ChargeItem|ChargeItemDefinition|Claim|ClaimResponse|ClinicalImpr
ession|CodeSystem|Communication|CommunicationRequest|CompartmentDefinition|Composition|Co
nceptMap|Condition|Consent|Contract|Coverage|CoverageEligibilityRequest|CoverageEligibili
tyResponse|DetectedIssue|Device|DeviceDefinition|DeviceMetric|DeviceRequest|DeviceUseStat
ement|DiagnosticReport|DocumentManifest|DocumentReference|EffectEvidenceSynthesis|Encount
er|Endpoint|EnrollmentRequest|EnrollmentResponse|EpisodeOfCare|EventDefinition|Evidence|E
videnceVariable|ExampleScenario|ExplanationOfBenefit|FamilyMemberHistory|Flag|Goal|GraphD
efinition|Group|GuidanceResponse|HealthcareService|ImagingStudy|Immunization|Immunization
Evaluation|ImmunizationRecommendation|ImplementationGuide|InsurancePlan|Invoice|Library|L
inkage|List|Location|Measure|MeasureReport|Media|Medication|MedicationAdministration|Medi
cationDispense|MedicationKnowledge|MedicationRequest|MedicationStatement|MedicinalProduct
|MedicinalProductAuthorization|MedicinalProductContraindication|MedicinalProductIndicatio
n|MedicinalProductIngredient|MedicinalProductInteraction|MedicinalProductManufactured|Med
icinalProductPackaged|MedicinalProductPharmaceutical|MedicinalProductUndesirableEffect|Me
ssageDefinition|MessageHeader|MolecularSequence|NamingSystem|NutritionOrder|Observation|O
bservationDefinition|OperationDefinition|OperationOutcome|Organization|OrganizationAffili
ation|Patient|PaymentNotice|PaymentReconciliation|Person|PlanDefinition|Practitioner|Prac
titionerRole|Procedure|Provenance|Questionnaire|QuestionnaireResponse|RelatedPerson|Reque
stGroup|ResearchDefinition|ResearchElementDefinition|ResearchStudy|ResearchSubject|RiskAs
sessment|RiskEvidenceSynthesis|Schedule|SearchParameter|ServiceRequest|Slot|Specimen|Spec
imenDefinition|StructureDefinition|StructureMap|Subscription|Substance|SubstanceNucleicAc
id|SubstancePolymer|SubstanceProtein|SubstanceReferenceInformation|SubstanceSourceMateria
l|SubstanceSpecification|SupplyDelivery|SupplyRequest|Task|TerminologyCapabilities|TestRe
port|TestScript|ValueSet|VerificationResult|VisionPrescription)\/[A-Za-z0-9\-\.]{1,64}(\/
_history\/[A-Za-z0-9\-\.]{1,64})?"/>
            </extension>
          </code>
        </type>
        <fixedUri value="type"/>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="N/A"/>
        </mapping>
      </element>
      <element
              id="PlanDefinition.extension:approvalStatus.extension:type.valueCode">
        <path value="PlanDefinition.extension.extension.valueCode"/>
        <short value="Value of extension"/>
        <definition
                value="Value of extension - must be one of a constrained set of the dat
a types (see [Extensibility](http://build.fhir.org/extensibility.html) for a list)."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Extension.value[x]"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="code"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
```

```xml
          <map value="N/A"/>
        </mapping>
      </element>
      <element id="PlanDefinition.extension:approvalStatus.extension:date">
        <path value="PlanDefinition.extension.extension"/>
        <sliceName value="date"/>
        <short value="Approval Status Date"/>
        <definition
                    value="The date on which the FDA approval status for a specification be
came effective. [Source: SME Defined] Note: If the application is not yet approved, then
this is the date of the current submission OR the date of the complete response (CR)."/>
        <min value="1"/>
        <max value="1"/>
        <base>
          <path value="Element.extension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
        </type>
        <mustSupport value="true"/>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="PlanDefinition.extension:approvalStatus.extension:date.id">
        <path value="PlanDefinition.extension.extension.id"/>
        <representation value="xmlAttr"/>
        <short value="Unique id for inter-element referencing"/>
        <definition
                    value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Element.id"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="string"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element
              id="PlanDefinition.extension:approvalStatus.extension:date.extension">
        <path value="PlanDefinition.extension.extension.extension"/>
        <slicing>
          <discriminator>
            <type value="value"/>
            <path value="url"/>
          </discriminator>
```

```
            <description value="Extensions are always sliced by (at least) url"/>
            <rules value="open"/>
        </slicing>
        <short value="Additional content defined by implementations"/>
        <definition
                    value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
        <comment
                 value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
        <alias value="extensions"/>
        <alias value="user content"/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="Element.extension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="PlanDefinition.extension:approvalStatus.extension:date.url">
        <path value="PlanDefinition.extension.extension.url"/>
        <representation value="xmlAttr"/>
        <short value="identifies the meaning of the extension"/>
        <definition
                    value="Source of the definition for the extension code - a logical name
 or a URL."/>
        <comment
                 value="The definition may point directly to a computable or human-readable
 definition of the extensibility codes, or it may be a logical URI as declared in some ot
her specification. The definition SHALL be a URI for the Structure Definition defining th
e extension."/>
        <min value="1"/>
        <max value="1"/>
        <base>
          <path value="Extension.url"/>
          <min value="1"/>
          <max value="1"/>
        </base>
        <type>
          <code>
            <extension
                       url="http://hl7.org/fhir/StructureDefinition/structuredefinition-jso
```

```xml
n-type">
                <valueString value="string"/>
            </extension>
            <extension
                    url="http://hl7.org/fhir/StructureDefinition/structuredefinition-xml
-type">
                <valueString value="xsd:string"/>
            </extension>
            <extension
                    url="http://hl7.org/fhir/StructureDefinition/structuredefinition-rdf
-type">
                <valueString value="xsd:string"/>
            </extension>
            <extension url="http://hl7.org/fhir/StructureDefinition/regex">
              <valueString
                        value="((http|https)://([A-Za-z0-9\\\.\:\%\$]*\/)*)?(Account|Act
ivityDefinition|AdverseEvent|AllergyIntolerance|Appointment|AppointmentResponse|AuditEven
t|Basic|Binary|BiologicallyDerivedProduct|BodyStructure|Bundle|CapabilityStatement|CarePl
an|CareTeam|CatalogEntry|ChargeItem|ChargeItemDefinition|Claim|ClaimResponse|ClinicalImpr
ession|CodeSystem|Communication|CommunicationRequest|CompartmentDefinition|Composition|Co
nceptMap|Condition|Consent|Contract|Coverage|CoverageEligibilityRequest|CoverageEligibili
tyResponse|DetectedIssue|Device|DeviceDefinition|DeviceMetric|DeviceRequest|DeviceUseStat
ement|DiagnosticReport|DocumentManifest|DocumentReference|EffectEvidenceSynthesis|Encount
er|Endpoint|EnrollmentRequest|EnrollmentResponse|EpisodeOfCare|EventDefinition|Evidence|E
videnceVariable|ExampleScenario|ExplanationOfBenefit|FamilyMemberHistory|Flag|Goal|GraphD
efinition|Group|GuidanceResponse|HealthcareService|ImagingStudy|Immunization|Immunization
Evaluation|ImmunizationRecommendation|ImplementationGuide|InsurancePlan|Invoice|Library|L
inkage|List|Location|Measure|MeasureReport|Media|Medication|MedicationAdministration|Medi
cationDispense|MedicationKnowledge|MedicationRequest|MedicationStatement|MedicinalProduct
|MedicinalProductAuthorization|MedicinalProductContraindication|MedicinalProductIndicatio
n|MedicinalProductIngredient|MedicinalProductInteraction|MedicinalProductManufactured|Med
icinalProductPackaged|MedicinalProductPharmaceutical|MedicinalProductUndesirableEffect|Me
ssageDefinition|MessageHeader|MolecularSequence|NamingSystem|NutritionOrder|Observation|O
bservationDefinition|OperationDefinition|OperationOutcome|Organization|OrganizationAffili
ation|Patient|PaymentNotice|PaymentReconciliation|Person|PlanDefinition|Practitioner|Prac
titionerRole|Procedure|Provenance|Questionnaire|QuestionnaireResponse|RelatedPerson|Reque
stGroup|ResearchDefinition|ResearchElementDefinition|ResearchStudy|ResearchSubject|RiskAs
sessment|RiskEvidenceSynthesis|Schedule|SearchParameter|ServiceRequest|Slot|Specimen|Spec
imenDefinition|StructureDefinition|StructureMap|Subscription|Substance|SubstanceNucleicAc
id|SubstancePolymer|SubstanceProtein|SubstanceReferenceInformation|SubstanceSourceMateria
l|SubstanceSpecification|SupplyDelivery|SupplyRequest|Task|TerminologyCapabilities|TestRe
port|TestScript|ValueSet|VerificationResult|VisionPrescription)\/[A-Za-z0-9\-\.]{1,64}(\/
_history\/[A-Za-z0-9\-\.]{1,64})?"/>
            </extension>
          </code>
      </type>
      <fixedUri value="date"/>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="N/A"/>
      </mapping>
    </element>
    <element
            id="PlanDefinition.extension:approvalStatus.extension:date.valueDate">
      <path value="PlanDefinition.extension.extension.valueDate"/>
```

```
        <short value="Value of extension"/>
        <definition
                    value="Value of extension - must be one of a constrained set of the dat
a types (see [Extensibility](http://build.fhir.org/extensibility.html) for a list)."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Extension.value[x]"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="date"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="N/A"/>
        </mapping>
      </element>
      <element id="PlanDefinition.extension:approvalStatus.url">
        <path value="PlanDefinition.extension.url"/>
        <representation value="xmlAttr"/>
        <short value="identifies the meaning of the extension"/>
        <definition
                    value="Source of the definition for the extension code - a logical name
 or a URL."/>
        <comment
                value="The definition may point directly to a computable or human-readable
 definition of the extensibility codes, or it may be a logical URI as declared in some ot
her specification. The definition SHALL be a URI for the Structure Definition defining th
e extension."/>
        <min value="1"/>
        <max value="1"/>
        <base>
          <path value="Extension.url"/>
          <min value="1"/>
          <max value="1"/>
        </base>
        <type>
          <code value="uri"/>
        </type>
        <fixedUri
                value="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-approvalSta
tus"/>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="N/A"/>
        </mapping>
      </element>
      <element id="PlanDefinition.extension:approvalStatus.value[x]">
        <path value="PlanDefinition.extension.value[x]"/>
        <short value="Value of extension"/>
        <definition
```

```xml
                    value="Value of extension - must be one of a constrained set of the dat
a types (see [Extensibility](http://build.fhir.org/extensibility.html) for a list)."/>
        <min value="0"/>
        <max value="0"/>
        <base>
          <path value="Extension.value[x]"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="base64Binary"/>
        </type>
        <type>
          <code value="boolean"/>
        </type>
        <type>
          <code value="canonical"/>
        </type>
        <type>
          <code value="code"/>
        </type>
        <type>
          <code value="date"/>
        </type>
        <type>
          <code value="dateTime"/>
        </type>
        <type>
          <code value="decimal"/>
        </type>
        <type>
          <code value="id"/>
        </type>
        <type>
          <code value="instant"/>
        </type>
        <type>
          <code value="integer"/>
        </type>
        <type>
          <code value="markdown"/>
        </type>
        <type>
          <code value="oid"/>
        </type>
        <type>
          <code value="positiveInt"/>
        </type>
        <type>
          <code value="string"/>
        </type>
        <type>
          <code value="time"/>
        </type>
        <type>
          <code value="unsignedInt"/>
        </type>
```

```xml
      <type>
        <code value="uri"/>
      </type>
      <type>
        <code value="url"/>
      </type>
      <type>
        <code value="uuid"/>
      </type>
      <type>
        <code value="Address"/>
      </type>
      <type>
        <code value="Age"/>
      </type>
      <type>
        <code value="Annotation"/>
      </type>
      <type>
        <code value="Attachment"/>
      </type>
      <type>
        <code value="CodeableConcept"/>
      </type>
      <type>
        <code value="Coding"/>
      </type>
      <type>
        <code value="ContactPoint"/>
      </type>
      <type>
        <code value="Count"/>
      </type>
      <type>
        <code value="Distance"/>
      </type>
      <type>
        <code value="Duration"/>
      </type>
      <type>
        <code value="HumanName"/>
      </type>
      <type>
        <code value="Identifier"/>
      </type>
      <type>
        <code value="Money"/>
      </type>
      <type>
        <code value="Period"/>
      </type>
      <type>
        <code value="Quantity"/>
      </type>
      <type>
        <code value="Range"/>
      </type>
```

```xml
      <type>
        <code value="Ratio"/>
      </type>
      <type>
        <code value="Reference"/>
      </type>
      <type>
        <code value="SampledData"/>
      </type>
      <type>
        <code value="Signature"/>
      </type>
      <type>
        <code value="Timing"/>
      </type>
      <type>
        <code value="ContactDetail"/>
      </type>
      <type>
        <code value="Contributor"/>
      </type>
      <type>
        <code value="DataRequirement"/>
      </type>
      <type>
        <code value="Expression"/>
      </type>
      <type>
        <code value="ParameterDefinition"/>
      </type>
      <type>
        <code value="RelatedArtifact"/>
      </type>
      <type>
        <code value="TriggerDefinition"/>
      </type>
      <type>
        <code value="UsageContext"/>
      </type>
      <type>
        <code value="Dosage"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="N/A"/>
      </mapping>
    </element>
    <element id="PlanDefinition.modifierExtension">
      <path value="PlanDefinition.modifierExtension"/>
      <short value="Extensions that cannot be ignored"/>
      <definition
                  value="May be used to represent additional information that is not part
 of the basic definition of the resource and that modifies the understanding of the eleme
nt that contains it and/or the understanding of the containing element&#39;s descendants.
 Usually modifier elements provide negation or qualification. To make the use of extensio
```

```
ns safe and manageable, there is a strict set of governance applied to the definition and
 use of extensions. Though any implementer is allowed to define an extension, there is a
set of requirements that SHALL be met as part of the definition of the extension. Applica
tions processing a resource are required to check for modifier extensions.

Modifier extensions SHALL NOT change the meaning of any elements on Resource or DomainRes
ource (including cannot change the meaning of modifierExtension itself)."/>
      <comment
             value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
      <requirements
                    value="Modifier extensions allow for extensions that *cannot* be safe
ly ignored to be clearly distinguished from the vast majority of extensions which can be
safely ignored.  This promotes interoperability by eliminating the need for implementers
to prohibit the presence of extensions. For further information, see the [definition of m
odifier extensions](http://build.fhir.org/extensibility.html#modifierExtension)."/>
      <alias value="extensions"/>
      <alias value="user content"/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="DomainResource.modifierExtension"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Extension"/>
      </type>
      <isModifier value="true"/>
      <isModifierReason
                        value="Modifier extensions are expected to modify the meaning or
interpretation of the resource that contains them"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="N/A"/>
      </mapping>
    </element>
    <element id="PlanDefinition.url">
      <path value="PlanDefinition.url"/>
      <short
            value="Canonical identifier for this plan definition, represented as a URI (
globally unique)"/>
      <definition
                  value="An absolute URI that is used to identify this plan definition wh
en it is referenced in a specification, model, design or an instance; also called its can
onical identifier. This SHOULD be globally unique and SHOULD be a literal address at whic
h at which an authoritative instance of this plan definition is (or will be) published. T
his URL can be the target of a canonical reference. It SHALL remain the same when the pla
n definition is stored on different servers."/>
      <comment
             value="Can be a urn:uuid: or a urn:oid: but real http: addresses are prefe
rred.  Multiple instances may share the same URL if they have a distinct version.

The determination of when to create a new version of a resource (same url, new version) v
```

```
s. defining a new artifact is up to the author.  Considerations for making this decision
are found in [Technical and Business Versions](http://build.fhir.org/resource.html#versio
ns).

In some cases, the resource can no longer be found at the stated url, but the url itself
cannot change. Implementations can use the [meta.source](http://build.fhir.org/resource.h
tml#meta) element to indicate where the current master source of the resource can be foun
d."/>
      <requirements
                    value="Allows the plan definition to be referenced by a single global
ly unique identifier."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="PlanDefinition.url"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="uri"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="true"/>
      <mapping>
        <identity value="workflow"/>
        <map value="Definition.url"/>
      </mapping>
      <mapping>
        <identity value="w5"/>
        <map value="FiveWs.identifier"/>
      </mapping>
    </element>
    <element id="PlanDefinition.identifier">
      <path value="PlanDefinition.identifier"/>
      <short value="Additional identifier for the plan definition"/>
      <definition
                  value="A formal identifier that is used to identify this plan definitio
n when it is represented in other formats, or referenced in a specification, model, desig
n or an instance."/>
      <comment
              value="Typically, this is used for identifiers that can go in an HL7 V3 II
 (instance identifier) data type, and can then identify this plan definition outside of F
HIR, where it is not possible to use the logical URI."/>
      <requirements
                    value="Allows externally provided and/or usable business identifiers
to be easily associated with the module."/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="PlanDefinition.identifier"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Identifier"/>
      </type>
      <isModifier value="false"/>
```

```xml
        <isSummary value="true"/>
        <mapping>
          <identity value="workflow"/>
          <map value="Definition.identifier"/>
        </mapping>
        <mapping>
          <identity value="w5"/>
          <map value="FiveWs.identifier"/>
        </mapping>
        <mapping>
          <identity value="objimpl"/>
          <map value="no-gen-base"/>
        </mapping>
      </element>
      <element id="PlanDefinition.version">
        <path value="PlanDefinition.version"/>
        <short value="Quality Specification Version"/>
        <definition
                  value="The alphanumeric text assigned by the sponsor to a particular ed
ition of a specification. [Source: SME Defined] Examples: 2.1, 13.2, ST1, 00001, 00002, &
lt;companyname&gt;001, etc."/>
        <comment
                value="There may be different plan definition instances that have the same
 identifier but different versions.  The version can be appended to the url in a referenc
e to allow a reference to a particular business version of the plan definition with the f
ormat [url]|[version]."/>
        <min value="1"/>
        <max value="1"/>
        <base>
          <path value="PlanDefinition.version"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="string"/>
        </type>
        <mustSupport value="true"/>
        <isModifier value="false"/>
        <isSummary value="true"/>
        <mapping>
          <identity value="workflow"/>
          <map value="Definition.version"/>
        </mapping>
        <mapping>
          <identity value="w5"/>
          <map value="FiveWs.version"/>
        </mapping>
      </element>
      <element id="PlanDefinition.name">
        <path value="PlanDefinition.name"/>
        <short value="Name for this plan definition (computer friendly)"/>
        <definition
                  value="A natural language name identifying the plan definition. This na
me should be usable as an identifier for the module by machine processing applications su
ch as code generation."/>
        <comment
                value="The name is not expected to be globally unique. The name should be
```

```xml
a simple alphanumeric type name to ensure that it is machine-processing friendly."/>
      <requirements value="Support human navigation and code generation."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="PlanDefinition.name"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="string"/>
      </type>
      <condition value="inv-0"/>
      <isModifier value="false"/>
      <isSummary value="true"/>
    </element>
    <element id="PlanDefinition.title">
      <path value="PlanDefinition.title"/>
      <short value="Quality Specification Title"/>
      <definition
                value="The textual identification for the specification. [Source: SME D
efined] Example: &lt;drug name&gt; 75 mg chewable tablets Note: This may include the name
 of the drug substance, product or the raw material/excipients."/>
      <comment
              value="This name does not need to be machine-processing friendly and may c
ontain punctuation, white-space, etc."/>
      <min value="1"/>
      <max value="1"/>
      <base>
        <path value="PlanDefinition.title"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="string"/>
      </type>
      <mustSupport value="true"/>
      <isModifier value="false"/>
      <isSummary value="true"/>
      <mapping>
        <identity value="workflow"/>
        <map value="Definition.title"/>
      </mapping>
    </element>
    <element id="PlanDefinition.subtitle">
      <path value="PlanDefinition.subtitle"/>
      <short value="Subordinate title of the plan definition"/>
      <definition
                value="An explanatory or alternate title for the plan definition giving
 additional information about its content."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="PlanDefinition.subtitle"/>
        <min value="0"/>
        <max value="1"/>
      </base>
```

```xml
      <type>
        <code value="string"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="PlanDefinition.type">
      <path value="PlanDefinition.type"/>
      <short
             value="order-set | clinical-protocol | eca-rule | workflow-definition"/>
      <definition
                  value="A high-level category for the plan definition that distinguishes
 the kinds of systems that would be interested in the plan definition."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="PlanDefinition.type"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="CodeableConcept"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="true"/>
      <binding>
        <extension
                   url="http://hl7.org/fhir/StructureDefinition/elementdefinition-binding
Name">
          <valueString value="PlanDefinitionType"/>
        </extension>
        <strength value="extensible"/>
        <description value="The type of PlanDefinition."/>
        <valueSet value="http://hl7.org/fhir/ValueSet/plan-definition-type"/>
      </binding>
    </element>
    <element id="PlanDefinition.status">
      <path value="PlanDefinition.status"/>
      <short value="draft | active | retired | unknown"/>
      <definition
                  value="The status of this plan definition. Enables tracking the life-cy
cle of the content."/>
      <comment
               value="Allows filtering of plan definitions that are appropriate for use v
ersus not."/>
      <min value="1"/>
      <max value="1"/>
      <base>
        <path value="PlanDefinition.status"/>
        <min value="1"/>
        <max value="1"/>
      </base>
      <type>
        <code value="code"/>
      </type>
      <fixedCode value="active"/>
      <mustSupport value="true"/>
```

```xml
        <isModifier value="true"/>
        <isModifierReason
                          value="This is labeled as &quot;Is Modifier&quot; because applica
tions should not use a retired  without due consideration"/>
        <isSummary value="true"/>
        <binding>
          <extension
                    url="http://hl7.org/fhir/StructureDefinition/elementdefinition-binding
Name">
            <valueString value="PublicationStatus"/>
          </extension>
          <extension
                    url="http://hl7.org/fhir/StructureDefinition/elementdefinition-isCommo
nBinding">
            <valueBoolean value="true"/>
          </extension>
          <strength value="required"/>
          <description value="The lifecycle status of an artifact."/>
          <valueSet value="http://hl7.org/fhir/ValueSet/publication-status|4.0.0"/>
        </binding>
        <mapping>
          <identity value="workflow"/>
          <map value="Definition.status {different ValueSet}"/>
        </mapping>
        <mapping>
          <identity value="w5"/>
          <map value="FiveWs.status"/>
        </mapping>
      </element>
      <element id="PlanDefinition.experimental">
        <path value="PlanDefinition.experimental"/>
        <short value="For testing purposes, not real usage"/>
        <definition
                   value="A Boolean value to indicate that this plan definition is authore
d for testing purposes (or education/evaluation/marketing) and is not intended to be used
 for genuine usage."/>
        <comment
                value="Allows filtering of plan definitions that are appropriate for use v
ersus not."/>
        <requirements
                     value="Enables experimental content to be developed following the sam
e lifecycle that would be used for a production-level plan definition."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="PlanDefinition.experimental"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="boolean"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="true"/>
        <mapping>
          <identity value="workflow"/>
          <map value="Definition.experimental"/>
```

```xml
          </mapping>
          <mapping>
            <identity value="w5"/>
            <map value="FiveWs.class"/>
          </mapping>
        </element>
        <element id="PlanDefinition.subjectReference">
          <path value="PlanDefinition.subjectReference"/>
          <short value="Tested Product or Substance"/>
          <definition
                   value="A classification of specification related to the kind of the ent
ity it is referencing. [Source: SME Defined]."/>
          <min value="1"/>
          <max value="1"/>
          <base>
            <path value="PlanDefinition.subject[x]"/>
            <min value="0"/>
            <max value="1"/>
          </base>
          <type>
            <code value="Reference"/>
            <targetProfile
                         value="http://hl7.org/fhir/StructureDefinition/MedicationKnowledge
"/>
            <targetProfile value="http://hl7.org/fhir/StructureDefinition/Substance"/>
          </type>
          <meaningWhenMissing value="Patient"/>
          <mustSupport value="true"/>
          <isModifier value="false"/>
          <isSummary value="false"/>
          <mapping>
            <identity value="workflow"/>
            <map value="Definition.subject"/>
          </mapping>
        </element>
        <element id="PlanDefinition.date">
          <path value="PlanDefinition.date"/>
          <short value="Version Date"/>
          <definition
                   value="The date when the sponsor assigned a date to a specific version.
 [Source: SME Defined]."/>
          <comment
                 value="Note that this is not the same as the resource last-modified-date,
since the resource may be a secondary representation of the plan definition. Additional s
pecific dates may be added as extensions or be found by consulting Provenances associated
 with past versions of the resource."/>
          <alias value="Revision Date"/>
          <min value="1"/>
          <max value="1"/>
          <base>
            <path value="PlanDefinition.date"/>
            <min value="0"/>
            <max value="1"/>
          </base>
          <type>
            <code value="dateTime"/>
          </type>
```

```xml
        <mustSupport value="true"/>
        <isModifier value="false"/>
        <isSummary value="true"/>
        <mapping>
          <identity value="workflow"/>
          <map value="Definition.date"/>
        </mapping>
        <mapping>
          <identity value="w5"/>
          <map value="FiveWs.recorded"/>
        </mapping>
      </element>
      <element id="PlanDefinition.publisher">
        <path value="PlanDefinition.publisher"/>
        <short value="Name of the publisher (organization or individual)"/>
        <definition
                   value="The name of the organization or individual that published the pl
an definition."/>
        <comment
                 value="Usually an organization but may be an individual. The publisher (or
 steward) of the plan definition is the organization or individual primarily responsible
for the maintenance and upkeep of the plan definition. This is not necessarily the same i
ndividual or organization that developed and initially authored the content. The publishe
r is the primary point of contact for questions or issues with the plan definition. This
item SHOULD be populated unless the information is available from context."/>
        <requirements
                      value="Helps establish the &quot;authority/credibility&quot; of the p
lan definition.  May also allow for contact."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="PlanDefinition.publisher"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="string"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="true"/>
        <mapping>
          <identity value="workflow"/>
          <map value="Definition.publisher"/>
        </mapping>
        <mapping>
          <identity value="w5"/>
          <map value="FiveWs.witness"/>
        </mapping>
      </element>
      <element id="PlanDefinition.contact">
        <path value="PlanDefinition.contact"/>
        <short value="Contact details for the publisher"/>
        <definition
                   value="Contact details to assist a user in finding and communicating wi
th the publisher."/>
        <comment
                 value="May be a web site, an email address, a telephone number, etc."/>
```

```xml
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="PlanDefinition.contact"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="ContactDetail"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="true"/>
        <mapping>
          <identity value="workflow"/>
          <map value="Definition.contact"/>
        </mapping>
      </element>
      <element id="PlanDefinition.description">
        <path value="PlanDefinition.description"/>
        <short value="Natural language description of the plan definition"/>
        <definition
                  value="A free text natural language description of the plan definition
from a consumer&#39;s perspective."/>
        <comment
                value="This description can be used to capture details such as why the pla
n definition was built, comments about misuse, instructions for clinical use and interpre
tation, literature references, examples from the paper world, etc. It is not a rendering
of the plan definition as conveyed in the &#39;text&#39; field of the resource itself. Th
is item SHOULD be populated unless the information is available from context (e.g. the la
nguage of the plan definition is presumed to be the predominant language in the place the
 plan definition was created)."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="PlanDefinition.description"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="markdown"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="true"/>
        <mapping>
          <identity value="workflow"/>
          <map value="Definition.description"/>
        </mapping>
      </element>
      <element id="PlanDefinition.useContext">
        <path value="PlanDefinition.useContext"/>
        <short value="The context that the content is intended to support"/>
        <definition
                  value="The content was developed with a focus and intent of supporting
the contexts that are listed. These contexts may be general categories (gender, age, ...)
 or may be references to specific programs (insurance plans, studies, ...) and may be use
d to assist with indexing and searching for appropriate plan definition instances."/>
        <comment
```

```
                    value="When multiple useContexts are specified, there is no expectation th
at all or any of the contexts apply."/>
        <requirements value="Assist in searching for appropriate content."/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="PlanDefinition.useContext"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="UsageContext"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="true"/>
        <mapping>
          <identity value="workflow"/>
          <map value="Definition.useContext"/>
        </mapping>
      </element>
      <element id="PlanDefinition.jurisdiction">
        <path value="PlanDefinition.jurisdiction"/>
        <short value="Intended jurisdiction for plan definition (if applicable)"/>
        <definition
                    value="A legal or geographic region in which the plan definition is int
ended to be used."/>
        <comment
                value="It may be possible for the plan definition to be used in jurisdicti
ons other than those for which it was originally designed or intended."/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="PlanDefinition.jurisdiction"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="CodeableConcept"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="true"/>
        <binding>
          <extension
                    url="http://hl7.org/fhir/StructureDefinition/elementdefinition-binding
Name">
            <valueString value="Jurisdiction"/>
          </extension>
          <extension
                    url="http://hl7.org/fhir/StructureDefinition/elementdefinition-isCommo
nBinding">
            <valueBoolean value="true"/>
          </extension>
          <strength value="extensible"/>
          <description
                        value="Countries and regions within which this artifact is targeted
for use."/>
          <valueSet value="http://hl7.org/fhir/ValueSet/jurisdiction"/>
```

```xml
      </binding>
      <mapping>
        <identity value="workflow"/>
        <map value="Definition.jurisdiction"/>
      </mapping>
    </element>
    <element id="PlanDefinition.purpose">
      <path value="PlanDefinition.purpose"/>
      <short value="Why this plan definition is defined"/>
      <definition
                  value="Explanation of why this plan definition is needed and why it has
 been designed as it has."/>
      <comment
                value="This element does not describe the usage of the plan definition. In
stead, it provides traceability of &#39;&#39;why&#39;&#39; the resource is either needed
 or &#39;&#39;why&#39;&#39; it is defined as it is.  This may be used to point to source m
aterials or specifications that drove the structure of this plan definition."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="PlanDefinition.purpose"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="markdown"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="workflow"/>
        <map value="Definition.purpose"/>
      </mapping>
      <mapping>
        <identity value="w5"/>
        <map value="FiveWs.why[x]"/>
      </mapping>
      <mapping>
        <identity value="objimpl"/>
        <map value="no-gen-base"/>
      </mapping>
    </element>
    <element id="PlanDefinition.usage">
      <path value="PlanDefinition.usage"/>
      <short value="Additional Information"/>
      <definition
                  value="Placeholder for providing any comments that are relevant to the
specification. [Source: SME Defined] Examples: replaces method ABC, using the XYZ facilit
y, etc."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="PlanDefinition.usage"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
```

```
        <code value="string"/>
      </type>
      <mustSupport value="true"/>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="PlanDefinition.copyright">
      <path value="PlanDefinition.copyright"/>
      <short value="Use and/or publishing restrictions"/>
      <definition
                  value="A copyright statement relating to the plan definition and/or its
 contents. Copyright statements are generally legal restrictions on the use and publishin
g of the plan definition."/>
      <requirements
                    value="Consumers must be able to determine any legal restrictions on
the use of the plan definition and/or its content."/>
      <alias value="License"/>
      <alias value="Restrictions"/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="PlanDefinition.copyright"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="markdown"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="workflow"/>
        <map value="Definition.copyright"/>
      </mapping>
      <mapping>
        <identity value="objimpl"/>
        <map value="no-gen-base"/>
      </mapping>
    </element>
    <element id="PlanDefinition.approvalDate">
      <path value="PlanDefinition.approvalDate"/>
      <short value="When the plan definition was approved by publisher"/>
      <definition
                  value="The date on which the resource content was approved by the publi
sher. Approval happens once when the content is officially approved for usage."/>
      <comment
                value="The &#39;date&#39; element may be more recent than the approval dat
e because of minor changes or editorial corrections."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="PlanDefinition.approvalDate"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="date"/>
```

```
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="workflow"/>
          <map value="Definition.approvalDate"/>
        </mapping>
        <mapping>
          <identity value="objimpl"/>
          <map value="no-gen-base"/>
        </mapping>
      </element>
      <element id="PlanDefinition.lastReviewDate">
        <path value="PlanDefinition.lastReviewDate"/>
        <short value="When the plan definition was last reviewed"/>
        <definition
                   value="The date on which the resource content was last reviewed. Review
 happens periodically after approval but does not change the original approval date."/>
        <comment
                 value="If specified, this date follows the original approval date."/>
        <requirements
                     value="Gives a sense of how &quot;current&quot; the content is.  Reso
urces that have not been reviewed in a long time may have a risk of being less appropriat
e/relevant."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="PlanDefinition.lastReviewDate"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="date"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="workflow"/>
          <map value="Definition.lastReviewDate"/>
        </mapping>
        <mapping>
          <identity value="objimpl"/>
          <map value="no-gen-base"/>
        </mapping>
      </element>
      <element id="PlanDefinition.effectivePeriod">
        <path value="PlanDefinition.effectivePeriod"/>
        <short value="When the plan definition is expected to be used"/>
        <definition
                   value="The period during which the plan definition content was or is pl
anned to be in active use."/>
        <comment
                 value="The effective period for a plan definition  determines when the con
tent is applicable for usage and is independent of publication and review dates. For exam
ple, a measure intended to be used for the year 2016 might be published in 2015."/>
        <requirements
                     value="Allows establishing a transition before a resource comes into
```

```
effect and also allows for a sunsetting  process when new versions of the plan definition
 are or are expected to be used instead."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="PlanDefinition.effectivePeriod"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="Period"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="true"/>
      <mapping>
        <identity value="workflow"/>
        <map value="Definition.effectivePeriod"/>
      </mapping>
      <mapping>
        <identity value="objimpl"/>
        <map value="no-gen-base"/>
      </mapping>
    </element>
    <element id="PlanDefinition.topic">
      <path value="PlanDefinition.topic"/>
      <short value="E.g. Education, Treatment, Assessment"/>
      <definition
                value="Descriptive topics related to the content of the plan definition
. Topics provide a high-level categorization of the definition that can be useful for fil
tering and searching."/>
      <requirements
                  value="Repositories must be able to determine how to categorize the p
lan definition so that it can be found by topical searches."/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="PlanDefinition.topic"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="CodeableConcept"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <binding>
        <extension
                  url="http://hl7.org/fhir/StructureDefinition/elementdefinition-binding
Name">
          <valueString value="DefinitionTopic"/>
        </extension>
        <strength value="example"/>
        <description
                    value="High-level categorization of the definition, used for searchi
ng, sorting, and filtering."/>
        <valueSet value="http://hl7.org/fhir/ValueSet/definition-topic"/>
      </binding>
```

```xml
      <mapping>
        <identity value="workflow"/>
        <map value="Definition.subject[x]"/>
      </mapping>
    </element>
    <element id="PlanDefinition.author">
      <path value="PlanDefinition.author"/>
      <short value="Who authored the content"/>
      <definition
                  value="An individiual or organization primarily involved in the creatio
n and maintenance of the content."/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="PlanDefinition.author"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="ContactDetail"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value=".participation[typeCode=AUT]"/>
      </mapping>
    </element>
    <element id="PlanDefinition.editor">
      <path value="PlanDefinition.editor"/>
      <short value="Who edited the content"/>
      <definition
                  value="An individual or organization primarily responsible for internal
 coherence of the content."/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="PlanDefinition.editor"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="ContactDetail"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="PlanDefinition.reviewer">
      <path value="PlanDefinition.reviewer"/>
      <short value="Who reviewed the content"/>
      <definition
                  value="An individual or organization primarily responsible for review o
f some aspect of the content."/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="PlanDefinition.reviewer"/>
```

```
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="ContactDetail"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map
              value=".participation[typeCode=VRF] {not clear whether VRF best corresponds
to reviewer or endorser}"/>
        </mapping>
      </element>
      <element id="PlanDefinition.endorser">
        <path value="PlanDefinition.endorser"/>
        <short value="Who endorsed the content"/>
        <definition
                  value="An individual or organization responsible for officially endorsi
ng the content for use in some setting."/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="PlanDefinition.endorser"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="ContactDetail"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map
              value=".participation[typeCode=VRF] {not clear whether VRF best corresponds
to reviewer or endorser}"/>
        </mapping>
      </element>
      <element id="PlanDefinition.relatedArtifact">
        <path value="PlanDefinition.relatedArtifact"/>
        <short value="Additional documentation, citations"/>
        <definition
                  value="Related artifacts such as additional documentation, justificatio
n, or bibliographic references."/>
        <comment
                value="Each related artifact is either an attachment, or a reference to an
other resource, but not both."/>
        <requirements
                    value="Plan definitions must be able to provide enough information fo
r consumers of the content (and/or interventions or results produced by the content) to b
e able to determine and understand the justification for and evidence in support of the c
ontent."/>
        <min value="0"/>
        <max value="*"/>
        <base>
```

```xml
        <path value="PlanDefinition.relatedArtifact"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="RelatedArtifact"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="PlanDefinition.library">
      <path value="PlanDefinition.library"/>
      <short value="Logic used by the plan definition"/>
      <definition
                value="A reference to a Library resource containing any formal logic us
ed by the plan definition."/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="PlanDefinition.library"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="canonical"/>
        <targetProfile value="http://hl7.org/fhir/StructureDefinition/Library"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="PlanDefinition.goal">
      <path value="PlanDefinition.goal"/>
      <short value="Acceptance criteria"/>
      <definition
                value="Numerical limits, ranges, or other criteria for the tests descri
bed. [Source: 21 CFR 314.3, 514.3 and 600.3]."/>
      <requirements
                value="Goal information needs to be captured for order sets, protocol
s, and care plan definitions to better describe the objectives of the protocol activities
 and to guide the creation of specific goals within the derived care plans and orders."/>
      <min value="1"/>
      <max value="*"/>
      <base>
        <path value="PlanDefinition.goal"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="BackboneElement"/>
      </type>
      <constraint>
        <key value="ele-1"/>
        <severity value="error"/>
        <human value="All FHIR elements must have a @value or children"/>
        <expression value="hasValue() or (children().count() &gt; id.count())"/>
        <xpath value="@value|f:*|h:div"/>
        <source value="Element"/>
```

```xml
        </constraint>
        <mustSupport value="true"/>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="PlanDefinition.goal.id">
        <path value="PlanDefinition.goal.id"/>
        <representation value="xmlAttr"/>
        <short value="Unique id for inter-element referencing"/>
        <definition
                   value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Element.id"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="string"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="PlanDefinition.goal.extension">
        <path value="PlanDefinition.goal.extension"/>
        <slicing id="5">
          <discriminator>
            <type value="value"/>
            <path value="url"/>
          </discriminator>
          <ordered value="false"/>
          <rules value="open"/>
        </slicing>
        <short value="Extension"/>
        <definition value="An Extension"/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="Element.extension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="PlanDefinition.goal.extension:comment">
        <extension
                   url="http://hl7.org/fhir/StructureDefinition/structuredefinition-standar
```

```
ds-status">
        <valueCode value="normative"/>
      </extension>
      <extension
                url="http://hl7.org/fhir/StructureDefinition/structuredefinition-normati
ve-version">
        <valueCode value="4.0.0"/>
      </extension>
      <path value="PlanDefinition.goal.extension"/>
      <sliceName value="comment"/>
      <short value="Additional Information"/>
      <definition
                value="acceptance criteria. [Source: SME Defined] Example: value change
d from 4% to 5% on 01/01/2010."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="Element.extension"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Extension"/>
        <profile
                value="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-comment"/>
      </type>
      <condition value="ele-1"/>
      <constraint>
        <key value="ele-1"/>
        <severity value="error"/>
        <human value="All FHIR elements must have a @value or children"/>
        <expression value="hasValue() or (children().count() &gt; id.count())"/>
        <xpath value="@value|f:*|h:div"/>
        <source value="Element"/>
      </constraint>
      <constraint>
        <key value="ext-1"/>
        <severity value="error"/>
        <human value="Must have either extensions or value[x], not both"/>
        <expression value="extension.exists() != value.exists()"/>
        <xpath
              value="exists(f:extension)!=exists(f:*[starts-with(local-name(.), &#39;val
ue&#39;)])"/>
        <source value="Extension"/>
      </constraint>
      <mustSupport value="true"/>
      <isModifier value="false"/>
    </element>
    <element id="PlanDefinition.goal.modifierExtension">
      <path value="PlanDefinition.goal.modifierExtension"/>
      <short value="Extensions that cannot be ignored even if unrecognized"/>
      <definition
                value="May be used to represent additional information that is not part
 of the basic definition of the element and that modifies the understanding of the elemen
t in which it is contained and/or the understanding of the containing element&#39;s desce
ndants. Usually modifier elements provide negation or qualification. To make the use of e
xtensions safe and manageable, there is a strict set of governance applied to the definit
```

ion and use of extensions. Though any implementer can define an extension, there is a set of requirements that SHALL be met as part of the definition of the extension. Applicatio ns processing a resource are required to check for modifier extensions.

Modifier extensions SHALL NOT change the meaning of any elements on Resource or DomainRes ource (including cannot change the meaning of modifierExtension itself)."/>
      `<comment`
             `value="There can be no stigma associated with the use of extensions by any`
application, project, or standard - regardless of the institution or jurisdiction that u ses or defines the extensions. The use of extensions is what allows the FHIR specificati on to retain a core level of simplicity for everyone."/>
      `<requirements`
               `value="Modifier extensions allow for extensions that *cannot* be safe`
ly ignored to be clearly distinguished from the vast majority of extensions which can be safely ignored. This promotes interoperability by eliminating the need for implementers to prohibit the presence of extensions. For further information, see the [definition of m odifier extensions](http://build.fhir.org/extensibility.html#modifierExtension)."/>
      `<alias value="extensions"/>`
      `<alias value="user content"/>`
      `<alias value="modifiers"/>`
      `<min value="0"/>`
      `<max value="*"/>`
      `<base>`
        `<path value="BackboneElement.modifierExtension"/>`
        `<min value="0"/>`
        `<max value="*"/>`
      `</base>`
      `<type>`
        `<code value="Extension"/>`
      `</type>`
      `<isModifier value="true"/>`
      `<isModifierReason`
               `value="Modifier extensions are expected to modify the meaning or`
interpretation of the element that contains them"/>
      `<isSummary value="true"/>`
      `<mapping>`
        `<identity value="rim"/>`
        `<map value="N/A"/>`
      `</mapping>`
    `</element>`
    `<element id="PlanDefinition.goal.category">`
      `<path value="PlanDefinition.goal.category"/>`
      `<short value="E.g. Treatment, dietary, behavioral"/>`
      `<definition value="Indicates a category the goal falls within."/>`
      `<min value="0"/>`
      `<max value="1"/>`
      `<base>`
        `<path value="PlanDefinition.goal.category"/>`
        `<min value="0"/>`
        `<max value="1"/>`
      `</base>`
      `<type>`
        `<code value="CodeableConcept"/>`
      `</type>`
      `<isModifier value="false"/>`
      `<isSummary value="false"/>`
      `<binding>`

```xml
        <extension
                  url="http://hl7.org/fhir/StructureDefinition/elementdefinition-binding
Name">
          <valueString value="GoalCategory"/>
        </extension>
        <strength value="example"/>
        <description
                  value="Example codes for grouping goals for filtering or presentatio
n."/>
        <valueSet value="http://hl7.org/fhir/ValueSet/goal-category"/>
      </binding>
    </element>
    <element id="PlanDefinition.goal.description">
      <path value="PlanDefinition.goal.description"/>
      <short value="Code or text describing the goal"/>
      <definition
                  value="Human-readable and/or coded description of a specific desired ob
jective of care, such as &quot;control blood pressure&quot; or &quot;negotiate an obstacl
e course&quot; or &quot;dance with child at wedding&quot;."/>
      <comment value="If no code is available, use CodeableConcept.text."/>
      <min value="1"/>
      <max value="1"/>
      <base>
        <path value="PlanDefinition.goal.description"/>
        <min value="1"/>
        <max value="1"/>
      </base>
      <type>
        <code value="CodeableConcept"/>
      </type>
      <mustSupport value="true"/>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <binding>
        <extension
                  url="http://hl7.org/fhir/StructureDefinition/elementdefinition-binding
Name">
          <valueString value="GoalDescription"/>
        </extension>
        <strength value="example"/>
        <description value="Describes goals that can be achieved."/>
        <valueSet value="http://hl7.org/fhir/ValueSet/clinical-findings"/>
      </binding>
    </element>
    <element id="PlanDefinition.goal.description.id">
      <path value="PlanDefinition.goal.description.id"/>
      <representation value="xmlAttr"/>
      <short value="Unique id for inter-element referencing"/>
      <definition
                  value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="Element.id"/>
        <min value="0"/>
        <max value="1"/>
```

```
        </base>
        <type>
          <code value="string"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="PlanDefinition.goal.description.extension">
        <path value="PlanDefinition.goal.description.extension"/>
        <slicing>
          <discriminator>
            <type value="value"/>
            <path value="url"/>
          </discriminator>
          <description value="Extensions are always sliced by (at least) url"/>
          <rules value="open"/>
        </slicing>
        <short value="Additional content defined by implementations"/>
        <definition
                  value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
        <comment
                value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
        <alias value="extensions"/>
        <alias value="user content"/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="Element.extension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="PlanDefinition.goal.description.coding">
        <path value="PlanDefinition.goal.description.coding"/>
        <short value="Code defined by a terminology system"/>
        <definition value="A reference to a code defined by a terminology system."/>
        <comment
```

```xml
              value="Codes may be defined very casually in enumerations, or code lists,
up to very formal definitions such as SNOMED CT - see the HL7 v3 Core Principles for more
 information.  Ordering of codings is undefined and SHALL NOT be used to infer meaning. G
enerally, at most only one of the coding values will be labeled as UserSelected = true."/
>
      <requirements
                 value="Allows for alternative encodings within a code system, and tra
nslations to other code systems."/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="CodeableConcept.coding"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Coding"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="true"/>
      <mapping>
        <identity value="v2"/>
        <map value="C*E.1-8, C*E.10-22"/>
      </mapping>
      <mapping>
        <identity value="rim"/>
        <map value="union(., ./translation)"/>
      </mapping>
      <mapping>
        <identity value="orim"/>
        <map value="fhir:CodeableConcept.coding rdfs:subPropertyOf dt:CD.coding"/>
      </mapping>
    </element>
    <element id="PlanDefinition.goal.description.text">
      <extension
                url="http://hl7.org/fhir/StructureDefinition/elementdefinition-translata
ble">
        <valueBoolean value="true"/>
      </extension>
      <path value="PlanDefinition.goal.description.text"/>
      <short value="Literal text"/>
      <definition
                value="The text of the acceptance criteria as provided in the specifica
tion. [Source: SME Defined]  Examples: White to off-white cake; 22.5 -27.5 mg/ml Note: Th
is is the text as it appears in the Specification."/>
      <comment
              value="Very often the text is the same as a displayName of one of the codi
ngs."/>
      <requirements
                 value="The codes from the terminologies do not always capture the cor
rect meaning with all the nuances of the human using them, or sometimes there is no appro
priate code at all. In these cases, the text is used to capture the full meaning of the s
ource."/>
      <min value="1"/>
      <max value="1"/>
      <base>
        <path value="CodeableConcept.text"/>
```

```
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="string"/>
        </type>
        <mustSupport value="true"/>
        <isModifier value="false"/>
        <isSummary value="true"/>
        <mapping>
          <identity value="v2"/>
          <map value="C*E.9. But note many systems use C*E.2 for this"/>
        </mapping>
        <mapping>
          <identity value="rim"/>
          <map value="./originalText[mediaType/code=&quot;text/plain&quot;]/data"/>
        </mapping>
        <mapping>
          <identity value="orim"/>
          <map
              value="fhir:CodeableConcept.text rdfs:subPropertyOf dt:CD.originalText"/>
        </mapping>
      </element>
      <element id="PlanDefinition.goal.priority">
        <path value="PlanDefinition.goal.priority"/>
        <short value="high-priority | medium-priority | low-priority"/>
        <definition
                value="Identifies the expected level of importance associated with reac
hing/sustaining the defined goal."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="PlanDefinition.goal.priority"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="CodeableConcept"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <binding>
          <extension
                  url="http://hl7.org/fhir/StructureDefinition/elementdefinition-binding
Name">
            <valueString value="GoalPriority"/>
          </extension>
          <strength value="preferred"/>
          <description
                    value="Indicates the level of importance associated with reaching or
 sustaining a goal."/>
          <valueSet value="http://hl7.org/fhir/ValueSet/goal-priority"/>
        </binding>
      </element>
      <element id="PlanDefinition.goal.start">
        <path value="PlanDefinition.goal.start"/>
        <short value="When goal pursuit begins"/>
```

```xml
        <definition
                    value="The event after which the goal should begin being pursued."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="PlanDefinition.goal.start"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="CodeableConcept"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <binding>
          <extension
                    url="http://hl7.org/fhir/StructureDefinition/elementdefinition-binding
Name">
            <valueString value="GoalStartEvent"/>
          </extension>
          <strength value="example"/>
          <description
                      value="Identifies the types of events that might trigger the start o
f a goal."/>
          <valueSet value="http://hl7.org/fhir/ValueSet/goal-start-event"/>
        </binding>
      </element>
      <element id="PlanDefinition.goal.addresses">
        <path value="PlanDefinition.goal.addresses"/>
        <short value="What does the goal address"/>
        <definition
                    value="Identifies problems, conditions, issues, or concerns the goal is
 intended to address."/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="PlanDefinition.goal.addresses"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="CodeableConcept"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <binding>
          <extension
                      url="http://hl7.org/fhir/StructureDefinition/elementdefinition-binding
Name">
            <valueString value="GoalAddresses"/>
          </extension>
          <strength value="example"/>
          <description
                      value="Identifies problems, conditions, issues, or concerns that goa
ls may address."/>
          <valueSet value="http://hl7.org/fhir/ValueSet/condition-code"/>
        </binding>
```

```
      </element>
      <element id="PlanDefinition.goal.documentation">
        <path value="PlanDefinition.goal.documentation"/>
        <short value="Supporting documentation for the goal"/>
        <definition
                    value="Didactic or other informational resources associated with the go
al that provide further supporting information about the goal. Information resources can
include inline text commentary and links to web resources."/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="PlanDefinition.goal.documentation"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="RelatedArtifact"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="PlanDefinition.goal.target">
        <path value="PlanDefinition.goal.target"/>
        <short value="Target outcome for the goal"/>
        <definition
                    value="Indicates what should be done and within what timeframe."/>
        <min value="1"/>
        <max value="1"/>
        <base>
          <path value="PlanDefinition.goal.target"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="BackboneElement"/>
        </type>
        <constraint>
          <key value="ele-1"/>
          <severity value="error"/>
          <human value="All FHIR elements must have a @value or children"/>
          <expression value="hasValue() or (children().count() &gt; id.count())"/>
          <xpath value="@value|f:*|h:div"/>
          <source value="Element"/>
        </constraint>
        <mustSupport value="true"/>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="PlanDefinition.goal.target.id">
        <path value="PlanDefinition.goal.target.id"/>
        <representation value="xmlAttr"/>
        <short value="Unique id for inter-element referencing"/>
        <definition
                    value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
        <min value="0"/>
        <max value="1"/>
```

```xml
      <base>
        <path value="Element.id"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="string"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="n/a"/>
      </mapping>
    </element>
    <element id="PlanDefinition.goal.target.extension">
      <path value="PlanDefinition.goal.target.extension"/>
      <slicing id="6">
        <discriminator>
          <type value="value"/>
          <path value="url"/>
        </discriminator>
        <ordered value="false"/>
        <rules value="open"/>
      </slicing>
      <short value="Extension"/>
      <definition value="An Extension"/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="Element.extension"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Extension"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="PlanDefinition.goal.target.extension:noTarget">
      <extension
                url="http://hl7.org/fhir/StructureDefinition/structuredefinition-standar
ds-status">
        <valueCode value="normative"/>
      </extension>
      <extension
                url="http://hl7.org/fhir/StructureDefinition/structuredefinition-normati
ve-version">
        <valueCode value="4.0.0"/>
      </extension>
      <path value="PlanDefinition.goal.target.extension"/>
      <sliceName value="noTarget"/>
      <short
            value="unknown | asked | temp | notasked | masked | unsupported | astext | e
rror"/>
      <definition
```

```xml
                    value="Provides a reason why the expected value or elements in the elem
ent that is extended are missing."/>
        <requirements
                    value="This extension is included to explicitly indicate that there i
s no target for the specific test and to disambiguate from a situation where a target may
 have been accidentally omitted."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Element.extension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
          <profile
                  value="http://hl7.org/fhir/StructureDefinition/data-absent-reason"/>
        </type>
        <condition value="ele-1"/>
        <constraint>
          <key value="ele-1"/>
          <severity value="error"/>
          <human value="All FHIR elements must have a @value or children"/>
          <expression value="hasValue() or (children().count() &gt; id.count())"/>
          <xpath value="@value|f:*|h:div"/>
          <source value="Element"/>
        </constraint>
        <constraint>
          <key value="ext-1"/>
          <severity value="error"/>
          <human value="Must have either extensions or value[x], not both"/>
          <expression value="extension.exists() != value.exists()"/>
          <xpath
                  value="exists(f:extension)!=exists(f:*[starts-with(local-name(.), &#39;val
ue&#39;)])"/>
          <source value="Extension"/>
        </constraint>
        <mustSupport value="true"/>
        <isModifier value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="ANY.nullFlavor"/>
        </mapping>
      </element>
      <element id="PlanDefinition.goal.target.extension:noTarget.id">
        <path value="PlanDefinition.goal.target.extension.id"/>
        <representation value="xmlAttr"/>
        <short value="Unique id for inter-element referencing"/>
        <definition
                    value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Element.id"/>
          <min value="0"/>
          <max value="1"/>
```

```
      </base>
      <type>
        <code value="string"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="n/a"/>
      </mapping>
    </element>
    <element id="PlanDefinition.goal.target.extension:noTarget.extension">
      <path value="PlanDefinition.goal.target.extension.extension"/>
      <slicing>
        <discriminator>
          <type value="value"/>
          <path value="url"/>
        </discriminator>
        <description value="Extensions are always sliced by (at least) url"/>
        <rules value="open"/>
      </slicing>
      <short value="Extension"/>
      <definition value="An Extension"/>
      <min value="0"/>
      <max value="0"/>
      <base>
        <path value="Element.extension"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Extension"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="PlanDefinition.goal.target.extension:noTarget.url">
      <path value="PlanDefinition.goal.target.extension.url"/>
      <representation value="xmlAttr"/>
      <short value="identifies the meaning of the extension"/>
      <definition
                  value="Source of the definition for the extension code - a logical name
 or a URL."/>
      <comment
              value="The definition may point directly to a computable or human-readable
 definition of the extensibility codes, or it may be a logical URI as declared in some ot
her specification. The definition SHALL be a URI for the Structure Definition defining th
e extension."/>
      <min value="1"/>
      <max value="1"/>
      <base>
        <path value="Extension.url"/>
        <min value="1"/>
        <max value="1"/>
      </base>
      <type>
        <code value="uri"/>
```

```
        </type>
        <fixedUri
                  value="http://hl7.org/fhir/StructureDefinition/data-absent-reason"/>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="N/A"/>
        </mapping>
      </element>
      <element id="PlanDefinition.goal.target.extension:noTarget.valueCode">
        <path value="PlanDefinition.goal.target.extension.valueCode"/>
        <short value="Value of extension"/>
        <definition
                    value="Value of extension - must be one of a constrained set of the dat
a types (see [Extensibility](http://build.fhir.org/extensibility.html) for a list)."/>
        <min value="1"/>
        <max value="1"/>
        <base>
          <path value="Extension.value[x]"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="code"/>
        </type>
        <fixedCode value="not-applicable"/>
        <mustSupport value="true"/>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <binding>
          <extension
                      url="http://hl7.org/fhir/StructureDefinition/elementdefinition-binding
Name">
            <valueString value="DataAbsentReason"/>
          </extension>
          <extension
                      url="http://hl7.org/fhir/StructureDefinition/elementdefinition-isCommo
nBinding">
            <valueBoolean value="true"/>
          </extension>
          <strength value="required"/>
          <description
                        value="Used to specify why the normally expected content of the data
 element is missing."/>
          <valueSet value="http://hl7.org/fhir/ValueSet/data-absent-reason|4.0.0"/>
        </binding>
        <mapping>
          <identity value="rim"/>
          <map value="N/A"/>
        </mapping>
      </element>
      <element id="PlanDefinition.goal.target.modifierExtension">
        <path value="PlanDefinition.goal.target.modifierExtension"/>
        <short value="Extensions that cannot be ignored even if unrecognized"/>
        <definition
                    value="May be used to represent additional information that is not part
```

 of the basic definition of the element and that modifies the understanding of the elemen
t in which it is contained and/or the understanding of the containing element's desce
ndants. Usually modifier elements provide negation or qualification. To make the use of e
xtensions safe and manageable, there is a strict set of governance applied to the definit
ion and use of extensions. Though any implementer can define an extension, there is a set
 of requirements that SHALL be met as part of the definition of the extension. Applicatio
ns processing a resource are required to check for modifier extensions.

Modifier extensions SHALL NOT change the meaning of any elements on Resource or DomainRes
ource (including cannot change the meaning of modifierExtension itself)."/>
      <comment
              value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions. The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
      <requirements
                   value="Modifier extensions allow for extensions that *cannot* be safe
ly ignored to be clearly distinguished from the vast majority of extensions which can be
safely ignored. This promotes interoperability by eliminating the need for implementers
to prohibit the presence of extensions. For further information, see the [definition of m
odifier extensions](http://build.fhir.org/extensibility.html#modifierExtension)."/>
      <alias value="extensions"/>
      <alias value="user content"/>
      <alias value="modifiers"/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="BackboneElement.modifierExtension"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Extension"/>
      </type>
      <isModifier value="true"/>
      <isModifierReason
                        value="Modifier extensions are expected to modify the meaning or
interpretation of the element that contains them"/>
      <isSummary value="true"/>
      <mapping>
        <identity value="rim"/>
        <map value="N/A"/>
      </mapping>
    </element>
    <element id="PlanDefinition.goal.target.measure">
      <path value="PlanDefinition.goal.target.measure"/>
      <short value="The parameter whose value is to be tracked"/>
      <definition
                 value="The parameter whose value is to be tracked, e.g. body weight, bl
ood pressure, or hemoglobin A1c level."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="PlanDefinition.goal.target.measure"/>
        <min value="0"/>
        <max value="1"/>
      </base>

```xml
      <type>
        <code value="CodeableConcept"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <binding>
        <extension
                  url="http://hl7.org/fhir/StructureDefinition/elementdefinition-binding
Name">
          <valueString value="GoalTargetMeasure"/>
        </extension>
        <strength value="example"/>
        <description
                    value="Identifies types of parameters that can be tracked to determi
ne goal achievement."/>
        <valueSet value="http://hl7.org/fhir/ValueSet/observation-codes"/>
      </binding>
    </element>
    <element id="PlanDefinition.goal.target.detail[x]">
      <path value="PlanDefinition.goal.target.detail[x]"/>
      <short value="The target value to be achieved"/>
      <definition
                  value="The target value of the measure to be achieved to signify fulfil
lment of the goal, e.g. 150 pounds or 7.0%. Either the high or low or both values of the
range can be specified. When a low value is missing, it indicates that the goal is achiev
ed at any value at or below the high value. Similarly, if the high value is missing, it i
ndicates that the goal is achieved at any value at or above the low value."/>
      <alias value="Quantity"/>
      <alias value="Range"/>
      <alias value="CodeableConcept"/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="PlanDefinition.goal.target.detail[x]"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="Quantity"/>
      </type>
      <type>
        <code value="Range"/>
      </type>
      <type>
        <code value="CodeableConcept"/>
      </type>
      <mustSupport value="true"/>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="PlanDefinition.goal.target.detailQuantity:Quantity">
      <path value="PlanDefinition.goal.target.detailQuantity"/>
      <sliceName value="Quantity"/>
      <short value="The target value to be achieved"/>
      <definition
                  value="The target value of the measure to be achieved to signify fulfil
lment of the goal, e.g. 150 pounds or 7.0%. Either the high or low or both values of the
```

```
range can be specified. When a low value is missing, it indicates that the goal is achiev
ed at any value at or below the high value. Similarly, if the high value is missing, it i
ndicates that the goal is achieved at any value at or above the low value."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="PlanDefinition.goal.target.detail[x]"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="Quantity"/>
      </type>
      <mustSupport value="true"/>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="PlanDefinition.goal.target.detailQuantity:Quantity.id">
      <path value="PlanDefinition.goal.target.detailQuantity.id"/>
      <representation value="xmlAttr"/>
      <short value="Unique id for inter-element referencing"/>
      <definition
                value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="Element.id"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="string"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="n/a"/>
      </mapping>
    </element>
    <element id="PlanDefinition.goal.target.detailQuantity:Quantity.extension">
      <path value="PlanDefinition.goal.target.detailQuantity.extension"/>
      <slicing>
        <discriminator>
          <type value="value"/>
          <path value="url"/>
        </discriminator>
        <description value="Extensions are always sliced by (at least) url"/>
        <rules value="open"/>
      </slicing>
      <short value="Additional content defined by implementations"/>
      <definition
                value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
```

```
 be met as part of the definition of the extension."/>
      <comment
               value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
      <alias value="extensions"/>
      <alias value="user content"/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="Element.extension"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Extension"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="n/a"/>
      </mapping>
    </element>
    <element id="PlanDefinition.goal.target.detailQuantity:Quantity.value">
      <path value="PlanDefinition.goal.target.detailQuantity.value"/>
      <short value="Numerical value (with implicit precision)"/>
      <definition
               value="The value of the measured amount. The value includes an implicit
 precision in the presentation of the value."/>
      <comment
              value="The implicit precision in the value should always be honored. Monet
ary values have their own rules for handling precision (refer to standard accounting text
 books)."/>
      <requirements
                 value="Precision is handled implicitly in almost all cases of measure
ment."/>
      <min value="1"/>
      <max value="1"/>
      <base>
        <path value="Quantity.value"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="decimal"/>
      </type>
      <mustSupport value="true"/>
      <isModifier value="false"/>
      <isSummary value="true"/>
      <mapping>
        <identity value="v2"/>
        <map value="SN.2  / CQ - N/A"/>
      </mapping>
      <mapping>
        <identity value="rim"/>
```

```
        <map
            value="PQ.value, CO.value, MO.value, IVL.high or IVL.low depending on the va
lue"/>
      </mapping>
    </element>
    <element id="PlanDefinition.goal.target.detailQuantity:Quantity.comparator">
      <path value="PlanDefinition.goal.target.detailQuantity.comparator"/>
      <short value="&lt; | &lt;= | &gt;= | &gt; - how to understand the value"/>
      <definition
                value="How the value should be understood and represented - whether the
 actual value is greater or less than the stated value due to measurement issues; e.g. if
 the comparator is &quot;&lt;&quot; , then the real value is &lt; stated value."/>
      <requirements
                  value="Need a framework for handling measures where the value is &lt;
5ug/L or &gt;400mg/L due to the limitations of measuring methodology."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="Quantity.comparator"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="code"/>
      </type>
      <meaningWhenMissing
                          value="If there is no comparator, then there is no modification
 of the value"/>
      <isModifier value="true"/>
      <isModifierReason
                         value="This is labeled as &quot;Is Modifier&quot; because the com
parator modifies the interpretation of the value significantly. If there is no comparator
, then there is no modification of the value"/>
      <isSummary value="true"/>
      <binding>
        <extension
                  url="http://hl7.org/fhir/StructureDefinition/elementdefinition-binding
Name">
          <valueString value="QuantityComparator"/>
        </extension>
        <strength value="required"/>
        <description
                    value="How the Quantity should be understood and represented."/>
        <valueSet value="http://hl7.org/fhir/ValueSet/quantity-comparator|4.0.0"/>
      </binding>
      <mapping>
        <identity value="v2"/>
        <map value="SN.1  / CQ.1"/>
      </mapping>
      <mapping>
        <identity value="rim"/>
        <map value="IVL properties"/>
      </mapping>
    </element>
    <element id="PlanDefinition.goal.target.detailQuantity:Quantity.unit">
      <extension
                url="http://hl7.org/fhir/StructureDefinition/elementdefinition-translata
```

```
ble">
          <valueBoolean value="true"/>
        </extension>
        <path value="PlanDefinition.goal.target.detailQuantity.unit"/>
        <short value="Unit representation"/>
        <definition value="A human-readable form of the unit."/>
        <requirements
                    value="There are many representations for units of measure and in man
y contexts, particular representations are fixed and required. I.e. mcg for micrograms."/
>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Quantity.unit"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="string"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="true"/>
        <mapping>
          <identity value="v2"/>
          <map value="(see OBX.6 etc.) / CQ.2"/>
        </mapping>
        <mapping>
          <identity value="rim"/>
          <map value="PQ.unit"/>
        </mapping>
      </element>
      <element id="PlanDefinition.goal.target.detailQuantity:Quantity.system">
        <path value="PlanDefinition.goal.target.detailQuantity.system"/>
        <short value="System that defines coded unit form"/>
        <definition
                    value="The identification of the system that provides the coded form of
 the unit."/>
        <requirements
                    value="Need to know the system that defines the coded form of the uni
t."/>
        <min value="1"/>
        <max value="1"/>
        <base>
          <path value="Quantity.system"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="uri"/>
        </type>
        <fixedUri value="http://unitsofmeasure.org"/>
        <condition value="qty-3"/>
        <mustSupport value="true"/>
        <isModifier value="false"/>
        <isSummary value="true"/>
        <mapping>
          <identity value="v2"/>
```

```xml
          <map value="(see OBX.6 etc.) / CQ.2"/>
        </mapping>
        <mapping>
          <identity value="rim"/>
          <map value="CO.codeSystem, PQ.translation.codeSystem"/>
        </mapping>
      </element>
      <element id="PlanDefinition.goal.target.detailQuantity:Quantity.code">
        <path value="PlanDefinition.goal.target.detailQuantity.code"/>
        <short value="Coded form of the unit"/>
        <definition
                value="A computer processable form of the unit in some unit representat
ion system."/>
        <comment
              value="The preferred system is UCUM, but SNOMED CT can also be used (for c
ustomary units) or ISO 4217 for currency.  The context of use may additionally require a
code from a particular system."/>
        <requirements
                  value="Need a computable form of the unit that is fixed across all fo
rms. UCUM provides this for quantities, but SNOMED CT provides many units of interest."/>
        <min value="1"/>
        <max value="1"/>
        <base>
          <path value="Quantity.code"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="code"/>
        </type>
        <mustSupport value="true"/>
        <isModifier value="false"/>
        <isSummary value="true"/>
        <mapping>
          <identity value="v2"/>
          <map value="(see OBX.6 etc.) / CQ.2"/>
        </mapping>
        <mapping>
          <identity value="rim"/>
          <map value="PQ.code, MO.currency, PQ.translation.code"/>
        </mapping>
      </element>
      <element id="PlanDefinition.goal.target.detailRange:Range">
        <path value="PlanDefinition.goal.target.detailRange"/>
        <sliceName value="Range"/>
        <short value="The target value to be achieved"/>
        <definition
                value="The target value of the measure to be achieved to signify fulfil
lment of the goal, e.g. 150 pounds or 7.0%. Either the high or low or both values of the
range can be specified. When a low value is missing, it indicates that the goal is achiev
ed at any value at or below the high value. Similarly, if the high value is missing, it i
ndicates that the goal is achieved at any value at or above the low value."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="PlanDefinition.goal.target.detail[x]"/>
          <min value="0"/>
```

```
          <max value="1"/>
        </base>
        <type>
          <code value="Range"/>
        </type>
        <mustSupport value="true"/>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="PlanDefinition.goal.target.detailRange:Range.id">
        <path value="PlanDefinition.goal.target.detailRange.id"/>
        <representation value="xmlAttr"/>
        <short value="Unique id for inter-element referencing"/>
        <definition
                  value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Element.id"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="string"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="PlanDefinition.goal.target.detailRange:Range.extension">
        <path value="PlanDefinition.goal.target.detailRange.extension"/>
        <slicing>
          <discriminator>
            <type value="value"/>
            <path value="url"/>
          </discriminator>
          <description value="Extensions are always sliced by (at least) url"/>
          <rules value="open"/>
        </slicing>
        <short value="Additional content defined by implementations"/>
        <definition
                  value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
        <comment
                value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
        <alias value="extensions"/>
        <alias value="user content"/>
```

```xml
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="Element.extension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element
              id="PlanDefinition.goal.target.detailRange:Range.extension:lowExclusive">
        <path value="PlanDefinition.goal.target.detailRange.extension"/>
        <sliceName value="lowExclusive"/>
        <short value="interpretationCode= GT"/>
        <definition
                  value="A code that describes how to relate the given value to an accept
ance value. [Source: SME Defined] Note: When result value is numeric there is a controlle
d vocabulary; when result value is textual the vocabulary is Pass/Fail."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Element.extension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
          <profile
                  value="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-range-lowE
xclusive"/>
        </type>
        <mustSupport value="true"/>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element
              id="PlanDefinition.goal.target.detailRange:Range.extension:lowExclusive.id">
        <path value="PlanDefinition.goal.target.detailRange.extension.id"/>
        <representation value="xmlAttr"/>
        <short value="Unique id for inter-element referencing"/>
        <definition
                  value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Element.id"/>
          <min value="0"/>
          <max value="1"/>
```

```
          </base>
          <type>
            <code value="string"/>
          </type>
          <isModifier value="false"/>
          <isSummary value="false"/>
          <mapping>
            <identity value="rim"/>
            <map value="n/a"/>
          </mapping>
        </element>
        <element
                id="PlanDefinition.goal.target.detailRange:Range.extension:lowExclusive.exte
nsion">
          <path value="PlanDefinition.goal.target.detailRange.extension.extension"/>
          <slicing>
            <discriminator>
              <type value="value"/>
              <path value="url"/>
            </discriminator>
            <description value="Extensions are always sliced by (at least) url"/>
            <rules value="open"/>
          </slicing>
          <short value="Additional content defined by implementations"/>
          <definition
                    value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
          <comment
                  value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
          <alias value="extensions"/>
          <alias value="user content"/>
          <min value="0"/>
          <max value="*"/>
          <base>
            <path value="Element.extension"/>
            <min value="0"/>
            <max value="*"/>
          </base>
          <type>
            <code value="Extension"/>
          </type>
          <isModifier value="false"/>
          <isSummary value="false"/>
          <mapping>
            <identity value="rim"/>
            <map value="n/a"/>
          </mapping>
        </element>
        <element
                id="PlanDefinition.goal.target.detailRange:Range.extension:lowExclusive.url"
>
```

```xml
        <path value="PlanDefinition.goal.target.detailRange.extension.url"/>
        <representation value="xmlAttr"/>
        <short value="identifies the meaning of the extension"/>
        <definition
                  value="Source of the definition for the extension code - a logical name
 or a URL."/>
        <comment
                value="The definition may point directly to a computable or human-readable
 definition of the extensibility codes, or it may be a logical URI as declared in some ot
her specification. The definition SHALL be a URI for the Structure Definition defining th
e extension."/>
        <min value="1"/>
        <max value="1"/>
        <base>
          <path value="Extension.url"/>
          <min value="1"/>
          <max value="1"/>
        </base>
        <type>
          <code>
            <extension
                      url="http://hl7.org/fhir/StructureDefinition/structuredefinition-jso
n-type">
              <valueString value="string"/>
            </extension>
            <extension
                      url="http://hl7.org/fhir/StructureDefinition/structuredefinition-xml
-type">
              <valueString value="xsd:string"/>
            </extension>
            <extension
                      url="http://hl7.org/fhir/StructureDefinition/structuredefinition-rdf
-type">
              <valueString value="xsd:string"/>
            </extension>
            <extension url="http://hl7.org/fhir/StructureDefinition/regex">
              <valueString
                          value="((http|https)://([A-Za-z0-9\\\.\:\%\$]*\/)*)?(Account|Act
ivityDefinition|AdverseEvent|AllergyIntolerance|Appointment|AppointmentResponse|AuditEven
t|Basic|Binary|BiologicallyDerivedProduct|BodyStructure|Bundle|CapabilityStatement|CarePl
an|CareTeam|CatalogEntry|ChargeItem|ChargeItemDefinition|Claim|ClaimResponse|ClinicalImpr
ession|CodeSystem|Communication|CommunicationRequest|CompartmentDefinition|Composition|Co
nceptMap|Condition|Consent|Contract|Coverage|CoverageEligibilityRequest|CoverageEligibili
tyResponse|DetectedIssue|Device|DeviceDefinition|DeviceMetric|DeviceRequest|DeviceUseStat
ement|DiagnosticReport|DocumentManifest|DocumentReference|EffectEvidenceSynthesis|Encount
er|Endpoint|EnrollmentRequest|EnrollmentResponse|EpisodeOfCare|EventDefinition|Evidence|E
videnceVariable|ExampleScenario|ExplanationOfBenefit|FamilyMemberHistory|Flag|Goal|GraphD
efinition|Group|GuidanceResponse|HealthcareService|ImagingStudy|Immunization|Immunization
Evaluation|ImmunizationRecommendation|ImplementationGuide|InsurancePlan|Invoice|Library|L
inkage|List|Location|Measure|MeasureReport|Media|Medication|MedicationAdministration|Medi
cationDispense|MedicationKnowledge|MedicationRequest|MedicationStatement|MedicinalProduct
|MedicinalProductAuthorization|MedicinalProductContraindication|MedicinalProductIndicatio
n|MedicinalProductIngredient|MedicinalProductInteraction|MedicinalProductManufactured|Med
icinalProductPackaged|MedicinalProductPharmaceutical|MedicinalProductUndesirableEffect|Me
ssageDefinition|MessageHeader|MolecularSequence|NamingSystem|NutritionOrder|Observation|O
bservationDefinition|OperationDefinition|OperationOutcome|Organization|OrganizationAffili
ation|Patient|PaymentNotice|PaymentReconciliation|Person|PlanDefinition|Practitioner|Prac
```

```
titionerRole|Procedure|Provenance|Questionnaire|QuestionnaireResponse|RelatedPerson|Reque
stGroup|ResearchDefinition|ResearchElementDefinition|ResearchStudy|ResearchSubject|RiskAs
sessment|RiskEvidenceSynthesis|Schedule|SearchParameter|ServiceRequest|Slot|Specimen|Spec
imenDefinition|StructureDefinition|StructureMap|Subscription|Substance|SubstanceNucleicAc
id|SubstancePolymer|SubstanceProtein|SubstanceReferenceInformation|SubstanceSourceMateria
l|SubstanceSpecification|SupplyDelivery|SupplyRequest|Task|TerminologyCapabilities|TestRe
port|TestScript|ValueSet|VerificationResult|VisionPrescription)\/[A-Za-z0-9\-\.]{1,64}(\/
_history\/[A-Za-z0-9\-\.]{1,64})?"/>
            </extension>
          </code>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="N/A"/>
        </mapping>
      </element>
      <element
              id="PlanDefinition.goal.target.detailRange:Range.extension:lowExclusive.valu
e[x]">
        <path value="PlanDefinition.goal.target.detailRange.extension.value[x]"/>
        <short value="Value of extension"/>
        <definition
                  value="Value of extension - must be one of a constrained set of the dat
a types (see [Extensibility](http://build.fhir.org/extensibility.html) for a list)."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Extension.value[x]"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="Quantity"/>
        </type>
        <mustSupport value="false"/>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="N/A"/>
        </mapping>
      </element>
      <element
              id="PlanDefinition.goal.target.detailRange:Range.extension:lowExclusive.valu
e[x].id">
        <path value="PlanDefinition.goal.target.detailRange.extension.value[x].id"/>
        <representation value="xmlAttr"/>
        <short value="Unique id for inter-element referencing"/>
        <definition
                  value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Element.id"/>
```

```xml
              <min value="0"/>
              <max value="1"/>
            </base>
            <type>
              <code value="string"/>
            </type>
            <isModifier value="false"/>
            <isSummary value="false"/>
            <mapping>
              <identity value="rim"/>
              <map value="n/a"/>
            </mapping>
          </element>
          <element
                    id="PlanDefinition.goal.target.detailRange:Range.extension:lowExclusive.valu
e[x].extension">
            <path
                 value="PlanDefinition.goal.target.detailRange.extension.value[x].extension"/>
            <slicing>
              <discriminator>
                <type value="value"/>
                <path value="url"/>
              </discriminator>
              <description value="Extensions are always sliced by (at least) url"/>
              <rules value="open"/>
            </slicing>
            <short value="Additional content defined by implementations"/>
            <definition
                        value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
            <comment
                     value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
            <alias value="extensions"/>
            <alias value="user content"/>
            <min value="0"/>
            <max value="*"/>
            <base>
              <path value="Element.extension"/>
              <min value="0"/>
              <max value="*"/>
            </base>
            <type>
              <code value="Extension"/>
            </type>
            <isModifier value="false"/>
            <isSummary value="false"/>
            <mapping>
              <identity value="rim"/>
              <map value="n/a"/>
            </mapping>
          </element>
```

```xml
    <element
            id="PlanDefinition.goal.target.detailRange:Range.extension:lowExclusive.valu
e[x].value">
        <path
            value="PlanDefinition.goal.target.detailRange.extension.value[x].value"/>
        <short value="valueNumeric"/>
        <definition
                value="A text or numeric value of the result of the test. [Source: SME
Defined]."/>
        <comment
                value="The implicit precision in the value should always be honored. Monet
ary values have their own rules for handling precision (refer to standard accounting text
 books)."/>
        <requirements
                    value="Precision is handled implicitly in almost all cases of measure
ment."/>
        <min value="1"/>
        <max value="1"/>
        <base>
          <path value="Quantity.value"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="decimal"/>
        </type>
        <mustSupport value="true"/>
        <isModifier value="false"/>
        <isSummary value="true"/>
        <mapping>
          <identity value="v2"/>
          <map value="SN.2  / CQ - N/A"/>
        </mapping>
        <mapping>
          <identity value="rim"/>
          <map
              value="PQ.value, CO.value, MO.value, IVL.high or IVL.low depending on the va
lue"/>
        </mapping>
    </element>
    <element
            id="PlanDefinition.goal.target.detailRange:Range.extension:lowExclusive.valu
e[x].comparator">
        <path
            value="PlanDefinition.goal.target.detailRange.extension.value[x].comparator"/
>
        <short value="&lt; | &lt;= | &gt;= | &gt; - how to understand the value"/>
        <definition
                value="How the value should be understood and represented - whether the
 actual value is greater or less than the stated value due to measurement issues; e.g. if
 the comparator is &quot;&lt;&quot; , then the real value is &lt; stated value."/>
        <requirements
                    value="Need a framework for handling measures where the value is &lt;
5ug/L or &gt;400mg/L due to the limitations of measuring methodology."/>
        <min value="0"/>
        <max value="1"/>
        <base>
```

```xml
        <path value="Quantity.comparator"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="code"/>
      </type>
      <meaningWhenMissing
                          value="If there is no comparator, then there is no modification
 of the value"/>
      <isModifier value="true"/>
      <isModifierReason
                          value="This is labeled as &quot;Is Modifier&quot; because the com
parator modifies the interpretation of the value significantly. If there is no comparator
, then there is no modification of the value"/>
      <isSummary value="true"/>
      <binding>
        <extension
                    url="http://hl7.org/fhir/StructureDefinition/elementdefinition-binding
Name">
          <valueString value="QuantityComparator"/>
        </extension>
        <strength value="required"/>
        <description
                      value="How the Quantity should be understood and represented."/>
        <valueSet value="http://hl7.org/fhir/ValueSet/quantity-comparator|4.0.0"/>
      </binding>
      <mapping>
        <identity value="v2"/>
        <map value="SN.1  / CQ.1"/>
      </mapping>
      <mapping>
        <identity value="rim"/>
        <map value="IVL properties"/>
      </mapping>
    </element>
    <element
            id="PlanDefinition.goal.target.detailRange:Range.extension:lowExclusive.valu
e[x].unit">
      <extension
                  url="http://hl7.org/fhir/StructureDefinition/elementdefinition-translata
ble">
        <valueBoolean value="true"/>
      </extension>
      <path
          value="PlanDefinition.goal.target.detailRange.extension.value[x].unit"/>
      <short value="Unit representation"/>
      <definition value="A human-readable form of the unit."/>
      <requirements
                    value="There are many representations for units of measure and in man
y contexts, particular representations are fixed and required. I.e. mcg for micrograms."/
>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="Quantity.unit"/>
        <min value="0"/>
```

```xml
            <max value="1"/>
          </base>
          <type>
            <code value="string"/>
          </type>
          <isModifier value="false"/>
          <isSummary value="true"/>
          <mapping>
            <identity value="v2"/>
            <map value="(see OBX.6 etc.) / CQ.2"/>
          </mapping>
          <mapping>
            <identity value="rim"/>
            <map value="PQ.unit"/>
          </mapping>
        </element>
        <element
                id="PlanDefinition.goal.target.detailRange:Range.extension:lowExclusive.valu
e[x].system">
          <path
                value="PlanDefinition.goal.target.detailRange.extension.value[x].system"/>
          <short value="Unit"/>
          <definition
                    value="A named quantity in terms of which other quantities are measured
 or specified, used as a standard measurement of like kinds. [Source: NCI EVS -C25709] Ex
amples: mg, L, etc."/>
          <requirements
                      value="Need to know the system that defines the coded form of the uni
t."/>
          <min value="1"/>
          <max value="1"/>
          <base>
            <path value="Quantity.system"/>
            <min value="0"/>
            <max value="1"/>
          </base>
          <type>
            <code value="uri"/>
          </type>
          <fixedUri value="http://unitsofmeasure.org"/>
          <condition value="qty-3"/>
          <mustSupport value="true"/>
          <isModifier value="false"/>
          <isSummary value="true"/>
          <mapping>
            <identity value="v2"/>
            <map value="(see OBX.6 etc.) / CQ.2"/>
          </mapping>
          <mapping>
            <identity value="rim"/>
            <map value="CO.codeSystem, PQ.translation.codeSystem"/>
          </mapping>
        </element>
        <element
                id="PlanDefinition.goal.target.detailRange:Range.extension:lowExclusive.valu
e[x].code">
          <path
```

```
                     value="PlanDefinition.goal.target.detailRange.extension.value[x].code"/>
        <short value="Coded form of the unit"/>
        <definition
                     value="A computer processable form of the unit in some unit representat
ion system."/>
        <comment
                  value="The preferred system is UCUM, but SNOMED CT can also be used (for c
ustomary units) or ISO 4217 for currency.  The context of use may additionally require a
code from a particular system."/>
        <requirements
                       value="Need a computable form of the unit that is fixed across all fo
rms. UCUM provides this for quantities, but SNOMED CT provides many units of interest."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Quantity.code"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="code"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="true"/>
        <mapping>
          <identity value="v2"/>
          <map value="(see OBX.6 etc.) / CQ.2"/>
        </mapping>
        <mapping>
          <identity value="rim"/>
          <map value="PQ.code, MO.currency, PQ.translation.code"/>
        </mapping>
      </element>
      <element
               id="PlanDefinition.goal.target.detailRange:Range.extension:highExclusive">
        <path value="PlanDefinition.goal.target.detailRange.extension"/>
        <sliceName value="highExclusive"/>
        <short value="interpretationCode= LT"/>
        <definition
                     value="A code that describes how to relate the given value to an accept
ance value. [Source: SME Defined] Note: When result value is numeric there is a controlle
d vocabulary; when result value is textual the vocabulary is Pass/Fail."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Element.extension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
          <profile
                    value="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-range-high
Exclusive"/>
        </type>
        <mustSupport value="true"/>
        <isModifier value="false"/>
```

```xml
          <isSummary value="false"/>
      </element>
      <element
              id="PlanDefinition.goal.target.detailRange:Range.extension:highExclusive.id"
>
        <path value="PlanDefinition.goal.target.detailRange.extension.id"/>
        <representation value="xmlAttr"/>
        <short value="Unique id for inter-element referencing"/>
        <definition
                    value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Element.id"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="string"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element
              id="PlanDefinition.goal.target.detailRange:Range.extension:highExclusive.ext
ension">
        <path value="PlanDefinition.goal.target.detailRange.extension.extension"/>
        <slicing>
          <discriminator>
            <type value="value"/>
            <path value="url"/>
          </discriminator>
          <description value="Extensions are always sliced by (at least) url"/>
          <rules value="open"/>
        </slicing>
        <short value="Additional content defined by implementations"/>
        <definition
                    value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
        <comment
                  value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
        <alias value="extensions"/>
        <alias value="user content"/>
        <min value="0"/>
        <max value="*"/>
        <base>
```

```xml
          <path value="Element.extension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element
              id="PlanDefinition.goal.target.detailRange:Range.extension:highExclusive.url
">
        <path value="PlanDefinition.goal.target.detailRange.extension.url"/>
        <representation value="xmlAttr"/>
        <short value="identifies the meaning of the extension"/>
        <definition
                    value="Source of the definition for the extension code - a logical name
 or a URL."/>
        <comment
                value="The definition may point directly to a computable or human-readable
 definition of the extensibility codes, or it may be a logical URI as declared in some ot
her specification. The definition SHALL be a URI for the Structure Definition defining th
e extension."/>
        <min value="1"/>
        <max value="1"/>
        <base>
          <path value="Extension.url"/>
          <min value="1"/>
          <max value="1"/>
        </base>
        <type>
          <code>
            <extension
                      url="http://hl7.org/fhir/StructureDefinition/structuredefinition-jso
n-type">
              <valueString value="string"/>
            </extension>
            <extension
                      url="http://hl7.org/fhir/StructureDefinition/structuredefinition-xml
-type">
              <valueString value="xsd:string"/>
            </extension>
            <extension
                      url="http://hl7.org/fhir/StructureDefinition/structuredefinition-rdf
-type">
              <valueString value="xsd:string"/>
            </extension>
            <extension url="http://hl7.org/fhir/StructureDefinition/regex">
              <valueString
                          value="((http|https)://([A-Za-z0-9\\\.\:\%\$]*\/)*)?(Account|Act
ivityDefinition|AdverseEvent|AllergyIntolerance|Appointment|AppointmentResponse|AuditEven
t|Basic|Binary|BiologicallyDerivedProduct|BodyStructure|Bundle|CapabilityStatement|CarePl
```

```
an|CareTeam|CatalogEntry|ChargeItem|ChargeItemDefinition|Claim|ClaimResponse|ClinicalImpr
ession|CodeSystem|Communication|CommunicationRequest|CompartmentDefinition|Composition|Co
nceptMap|Condition|Consent|Contract|Coverage|CoverageEligibilityRequest|CoverageEligibili
tyResponse|DetectedIssue|Device|DeviceDefinition|DeviceMetric|DeviceRequest|DeviceUseStat
ement|DiagnosticReport|DocumentManifest|DocumentReference|EffectEvidenceSynthesis|Encount
er|Endpoint|EnrollmentRequest|EnrollmentResponse|EpisodeOfCare|EventDefinition|Evidence|E
videnceVariable|ExampleScenario|ExplanationOfBenefit|FamilyMemberHistory|Flag|Goal|GraphD
efinition|Group|GuidanceResponse|HealthcareService|ImagingStudy|Immunization|Immunization
Evaluation|ImmunizationRecommendation|ImplementationGuide|InsurancePlan|Invoice|Library|L
inkage|List|Location|Measure|MeasureReport|Media|Medication|MedicationAdministration|Medi
cationDispense|MedicationKnowledge|MedicationRequest|MedicationStatement|MedicinalProduct
|MedicinalProductAuthorization|MedicinalProductContraindication|MedicinalProductIndicatio
n|MedicinalProductIngredient|MedicinalProductInteraction|MedicinalProductManufactured|Med
icinalProductPackaged|MedicinalProductPharmaceutical|MedicinalProductUndesirableEffect|Me
ssageDefinition|MessageHeader|MolecularSequence|NamingSystem|NutritionOrder|Observation|O
bservationDefinition|OperationDefinition|OperationOutcome|Organization|OrganizationAffili
ation|Patient|PaymentNotice|PaymentReconciliation|Person|PlanDefinition|Practitioner|Prac
titionerRole|Procedure|Provenance|Questionnaire|QuestionnaireResponse|RelatedPerson|Reque
stGroup|ResearchDefinition|ResearchElementDefinition|ResearchStudy|ResearchSubject|RiskAs
sessment|RiskEvidenceSynthesis|Schedule|SearchParameter|ServiceRequest|Slot|Specimen|Spec
imenDefinition|StructureDefinition|StructureMap|Subscription|Substance|SubstanceNucleicAc
id|SubstancePolymer|SubstanceProtein|SubstanceReferenceInformation|SubstanceSourceMateria
l|SubstanceSpecification|SupplyDelivery|SupplyRequest|Task|TerminologyCapabilities|TestRe
port|TestScript|ValueSet|VerificationResult|VisionPrescription)\/[A-Za-z0-9\-\.]{1,64}(\/
_history\/[A-Za-z0-9\-\.]{1,64})?"/>
            </extension>
          </code>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="N/A"/>
        </mapping>
      </element>
      <element
              id="PlanDefinition.goal.target.detailRange:Range.extension:highExclusive.val
ue[x]">
        <path value="PlanDefinition.goal.target.detailRange.extension.value[x]"/>
        <short value="Value of extension"/>
        <definition
                 value="Value of extension - must be one of a constrained set of the dat
a types (see [Extensibility](http://build.fhir.org/extensibility.html) for a list)."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Extension.value[x]"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="Quantity"/>
        </type>
        <mustSupport value="false"/>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
```

```xml
          <identity value="rim"/>
          <map value="N/A"/>
        </mapping>
      </element>
      <element
              id="PlanDefinition.goal.target.detailRange:Range.extension:highExclusive.val
ue[x].id">
        <path value="PlanDefinition.goal.target.detailRange.extension.value[x].id"/>
        <representation value="xmlAttr"/>
        <short value="Unique id for inter-element referencing"/>
        <definition
                  value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Element.id"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="string"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element
              id="PlanDefinition.goal.target.detailRange:Range.extension:highExclusive.val
ue[x].extension">
        <path
              value="PlanDefinition.goal.target.detailRange.extension.value[x].extension"/>
        <slicing>
          <discriminator>
            <type value="value"/>
            <path value="url"/>
          </discriminator>
          <description value="Extensions are always sliced by (at least) url"/>
          <rules value="open"/>
        </slicing>
        <short value="Additional content defined by implementations"/>
        <definition
                  value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
        <comment
                value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
        <alias value="extensions"/>
        <alias value="user content"/>
```

```xml
          <min value="0"/>
          <max value="*"/>
          <base>
            <path value="Element.extension"/>
            <min value="0"/>
            <max value="*"/>
          </base>
          <type>
            <code value="Extension"/>
          </type>
          <isModifier value="false"/>
          <isSummary value="false"/>
          <mapping>
            <identity value="rim"/>
            <map value="n/a"/>
          </mapping>
        </element>
        <element
                id="PlanDefinition.goal.target.detailRange:Range.extension:highExclusive.val
ue[x].value">
          <path
                value="PlanDefinition.goal.target.detailRange.extension.value[x].value"/>
          <short value="valueNumeric"/>
          <definition
                   value="A text or numeric value of the result of the test. [Source: SME
Defined]."/>
          <comment
                 value="The implicit precision in the value should always be honored. Monet
ary values have their own rules for handling precision (refer to standard accounting text
 books)."/>
          <requirements
                      value="Precision is handled implicitly in almost all cases of measure
ment."/>
          <min value="1"/>
          <max value="1"/>
          <base>
            <path value="Quantity.value"/>
            <min value="0"/>
            <max value="1"/>
          </base>
          <type>
            <code value="decimal"/>
          </type>
          <mustSupport value="true"/>
          <isModifier value="false"/>
          <isSummary value="true"/>
          <mapping>
            <identity value="v2"/>
            <map value="SN.2   / CQ - N/A"/>
          </mapping>
          <mapping>
            <identity value="rim"/>
            <map
                value="PQ.value, CO.value, MO.value, IVL.high or IVL.low depending on the va
lue"/>
          </mapping>
        </element>
```

```xml
    <element
              id="PlanDefinition.goal.target.detailRange:Range.extension:highExclusive.val
ue[x].comparator">
      <path
            value="PlanDefinition.goal.target.detailRange.extension.value[x].comparator"/
>
      <short value="&lt; | &lt;= | &gt;= | &gt; - how to understand the value"/>
      <definition
                   value="How the value should be understood and represented - whether the
 actual value is greater or less than the stated value due to measurement issues; e.g. if
 the comparator is &quot;&lt;&quot; , then the real value is &lt; stated value."/>
      <requirements
                     value="Need a framework for handling measures where the value is &lt;
5ug/L or &gt;400mg/L due to the limitations of measuring methodology."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="Quantity.comparator"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="code"/>
      </type>
      <meaningWhenMissing
                            value="If there is no comparator, then there is no modification
 of the value"/>
      <isModifier value="true"/>
      <isModifierReason
                          value="This is labeled as &quot;Is Modifier&quot; because the com
parator modifies the interpretation of the value significantly. If there is no comparator
, then there is no modification of the value"/>
      <isSummary value="true"/>
      <binding>
        <extension
                   url="http://hl7.org/fhir/StructureDefinition/elementdefinition-binding
Name">
          <valueString value="QuantityComparator"/>
        </extension>
        <strength value="required"/>
        <description
                     value="How the Quantity should be understood and represented."/>
        <valueSet value="http://hl7.org/fhir/ValueSet/quantity-comparator|4.0.0"/>
      </binding>
      <mapping>
        <identity value="v2"/>
        <map value="SN.1  / CQ.1"/>
      </mapping>
      <mapping>
        <identity value="rim"/>
        <map value="IVL properties"/>
      </mapping>
    </element>
    <element
              id="PlanDefinition.goal.target.detailRange:Range.extension:highExclusive.val
ue[x].unit">
      <extension
```

```
                      url="http://hl7.org/fhir/StructureDefinition/elementdefinition-translata
ble">
            <valueBoolean value="true"/>
        </extension>
        <path
              value="PlanDefinition.goal.target.detailRange.extension.value[x].unit"/>
        <short value="Unit representation"/>
        <definition value="A human-readable form of the unit."/>
        <requirements
                        value="There are many representations for units of measure and in man
y contexts, particular representations are fixed and required. I.e. mcg for micrograms."/
>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Quantity.unit"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="string"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="true"/>
        <mapping>
          <identity value="v2"/>
          <map value="(see OBX.6 etc.) / CQ.2"/>
        </mapping>
        <mapping>
          <identity value="rim"/>
          <map value="PQ.unit"/>
        </mapping>
      </element>
      <element
              id="PlanDefinition.goal.target.detailRange:Range.extension:highExclusive.val
ue[x].system">
        <path
              value="PlanDefinition.goal.target.detailRange.extension.value[x].system"/>
        <short value="Unit"/>
        <definition
                    value="A named quantity in terms of which other quantities are measured
 or specified, used as a standard measurement of like kinds. [Source: NCI EVS -C25709] Ex
amples: mg, L, etc."/>
        <requirements
                        value="Need to know the system that defines the coded form of the uni
t."/>
        <min value="1"/>
        <max value="1"/>
        <base>
          <path value="Quantity.system"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="uri"/>
        </type>
        <fixedUri value="http://unitsofmeasure.org"/>
```

```xml
        <condition value="qty-3"/>
        <mustSupport value="true"/>
        <isModifier value="false"/>
        <isSummary value="true"/>
        <mapping>
          <identity value="v2"/>
          <map value="(see OBX.6 etc.) / CQ.2"/>
        </mapping>
        <mapping>
          <identity value="rim"/>
          <map value="CO.codeSystem, PQ.translation.codeSystem"/>
        </mapping>
      </element>
      <element
              id="PlanDefinition.goal.target.detailRange:Range.extension:highExclusive.val
ue[x].code">
        <path
             value="PlanDefinition.goal.target.detailRange.extension.value[x].code"/>
        <short value="Coded form of the unit"/>
        <definition
                   value="A computer processable form of the unit in some unit representat
ion system."/>
        <comment
                 value="The preferred system is UCUM, but SNOMED CT can also be used (for c
ustomary units) or ISO 4217 for currency.  The context of use may additionally require a
code from a particular system."/>
        <requirements
                      value="Need a computable form of the unit that is fixed across all fo
rms. UCUM provides this for quantities, but SNOMED CT provides many units of interest."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Quantity.code"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="code"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="true"/>
        <mapping>
          <identity value="v2"/>
          <map value="(see OBX.6 etc.) / CQ.2"/>
        </mapping>
        <mapping>
          <identity value="rim"/>
          <map value="PQ.code, MO.currency, PQ.translation.code"/>
        </mapping>
      </element>
      <element id="PlanDefinition.goal.target.detailRange:Range.low">
        <path value="PlanDefinition.goal.target.detailRange.low"/>
        <short value="interpretationCode=NLT"/>
        <definition
                   value="A code that describes how to relate the given value to an accept
ance value. [Source: SME Defined] Note: When result value is numeric there is a controlle
d vocabulary; when result value is textual the vocabulary is Pass/Fail."/>
```

```xml
        <comment
                  value="If the low element is missing, the low boundary is not known."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Range.low"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="Quantity"/>
          <profile value="http://hl7.org/fhir/StructureDefinition/SimpleQuantity"/>
        </type>
        <mustSupport value="true"/>
        <isModifier value="false"/>
        <isSummary value="true"/>
        <mapping>
          <identity value="v2"/>
          <map value="NR.1"/>
        </mapping>
        <mapping>
          <identity value="rim"/>
          <map value="./low"/>
        </mapping>
      </element>
      <element id="PlanDefinition.goal.target.detailRange:Range.low.id">
        <path value="PlanDefinition.goal.target.detailRange.low.id"/>
        <representation value="xmlAttr"/>
        <short value="Unique id for inter-element referencing"/>
        <definition
                   value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Element.id"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="string"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="PlanDefinition.goal.target.detailRange:Range.low.extension">
        <path value="PlanDefinition.goal.target.detailRange.low.extension"/>
        <slicing>
          <discriminator>
            <type value="value"/>
            <path value="url"/>
          </discriminator>
          <description value="Extensions are always sliced by (at least) url"/>
```

```xml
            <rules value="open"/>
        </slicing>
        <short value="Additional content defined by implementations"/>
        <definition
                    value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
        <comment
                value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
        <alias value="extensions"/>
        <alias value="user content"/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="Element.extension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="PlanDefinition.goal.target.detailRange:Range.low.value">
        <path value="PlanDefinition.goal.target.detailRange.low.value"/>
        <short value="valueNumeric"/>
        <definition
                    value="A text or numeric value of the result of the test. [Source: SME
Defined]."/>
        <comment
                value="The implicit precision in the value should always be honored. Monet
ary values have their own rules for handling precision (refer to standard accounting text
 books)."/>
        <requirements
                      value="Precision is handled implicitly in almost all cases of measure
ment."/>
        <min value="1"/>
        <max value="1"/>
        <base>
          <path value="Quantity.value"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="decimal"/>
        </type>
        <mustSupport value="true"/>
```

```xml
        <isModifier value="false"/>
        <isSummary value="true"/>
        <mapping>
          <identity value="v2"/>
          <map value="SN.2  / CQ - N/A"/>
        </mapping>
        <mapping>
          <identity value="rim"/>
          <map
              value="PQ.value, CO.value, MO.value, IVL.high or IVL.low depending on the va
lue"/>
        </mapping>
      </element>
      <element id="PlanDefinition.goal.target.detailRange:Range.low.comparator">
        <path value="PlanDefinition.goal.target.detailRange.low.comparator"/>
        <short value="&lt; | &lt;= | &gt;= | &gt; - how to understand the value"/>
        <definition value="Not allowed to be used in this context"/>
        <requirements
                    value="Need a framework for handling measures where the value is &lt;
5ug/L or &gt;400mg/L due to the limitations of measuring methodology."/>
        <min value="0"/>
        <max value="0"/>
        <base>
          <path value="Quantity.comparator"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="code"/>
        </type>
        <meaningWhenMissing
                          value="If there is no comparator, then there is no modification
 of the value"/>
        <isModifier value="true"/>
        <isModifierReason
                          value="This is labeled as &quot;Is Modifier&quot; because the com
parator modifies the interpretation of the value significantly. If there is no comparator
, then there is no modification of the value"/>
        <isSummary value="true"/>
        <binding>
          <extension
                    url="http://hl7.org/fhir/StructureDefinition/elementdefinition-binding
Name">
            <valueString value="QuantityComparator"/>
          </extension>
          <strength value="required"/>
          <description
                      value="How the Quantity should be understood and represented."/>
          <valueSet value="http://hl7.org/fhir/ValueSet/quantity-comparator|4.0.0"/>
        </binding>
        <mapping>
          <identity value="v2"/>
          <map value="SN.1  / CQ.1"/>
        </mapping>
        <mapping>
          <identity value="rim"/>
          <map value="IVL properties"/>
```

```xml
        </mapping>
      </element>
      <element id="PlanDefinition.goal.target.detailRange:Range.low.unit">
        <extension
                  url="http://hl7.org/fhir/StructureDefinition/elementdefinition-translata
ble">
          <valueBoolean value="true"/>
        </extension>
        <path value="PlanDefinition.goal.target.detailRange.low.unit"/>
        <short value="Unit representation"/>
        <definition value="A human-readable form of the unit."/>
        <requirements
                      value="There are many representations for units of measure and in man
y contexts, particular representations are fixed and required. I.e. mcg for micrograms."/
>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Quantity.unit"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="string"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="true"/>
        <mapping>
          <identity value="v2"/>
          <map value="(see OBX.6 etc.) / CQ.2"/>
        </mapping>
        <mapping>
          <identity value="rim"/>
          <map value="PQ.unit"/>
        </mapping>
      </element>
      <element id="PlanDefinition.goal.target.detailRange:Range.low.system">
        <path value="PlanDefinition.goal.target.detailRange.low.system"/>
        <short value="System that defines coded unit form"/>
        <definition
                  value="The identification of the system that provides the coded form of
 the unit."/>
        <requirements
                      value="Need to know the system that defines the coded form of the uni
t."/>
        <min value="1"/>
        <max value="1"/>
        <base>
          <path value="Quantity.system"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="uri"/>
        </type>
        <fixedUri value="http://unitsofmeasure.org"/>
        <condition value="qty-3"/>
```

```xml
      <mustSupport value="true"/>
      <isModifier value="false"/>
      <isSummary value="true"/>
      <mapping>
        <identity value="v2"/>
        <map value="(see OBX.6 etc.) / CQ.2"/>
      </mapping>
      <mapping>
        <identity value="rim"/>
        <map value="CO.codeSystem, PQ.translation.codeSystem"/>
      </mapping>
    </element>
    <element id="PlanDefinition.goal.target.detailRange:Range.low.code">
      <path value="PlanDefinition.goal.target.detailRange.low.code"/>
      <short value="Unit"/>
      <definition
                  value="A named quantity in terms of which other quantities are measured
 or specified, used as a standard measurement of like kinds. [Source: NCI EVS -C25709] Ex
amples: mg, L, etc."/>
      <comment
              value="The preferred system is UCUM, but SNOMED CT can also be used (for c
ustomary units) or ISO 4217 for currency.  The context of use may additionally require a
code from a particular system."/>
      <requirements
                    value="Need a computable form of the unit that is fixed across all fo
rms. UCUM provides this for quantities, but SNOMED CT provides many units of interest."/>
      <min value="1"/>
      <max value="1"/>
      <base>
        <path value="Quantity.code"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="code"/>
      </type>
      <mustSupport value="true"/>
      <isModifier value="false"/>
      <isSummary value="true"/>
      <mapping>
        <identity value="v2"/>
        <map value="(see OBX.6 etc.) / CQ.2"/>
      </mapping>
      <mapping>
        <identity value="rim"/>
        <map value="PQ.code, MO.currency, PQ.translation.code"/>
      </mapping>
    </element>
    <element id="PlanDefinition.goal.target.detailRange:Range.high">
      <path value="PlanDefinition.goal.target.detailRange.high"/>
      <short value="interpretationCode=NMT"/>
      <definition
                  value="A code that describes how to relate the given value to an accept
ance value. [Source: SME Defined] Note: When result value is numeric there is a controlle
d vocabulary; when result value is textual the vocabulary is Pass/Fail."/>
      <comment
              value="If the high element is missing, the high boundary is not known."/>
```

```xml
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Range.high"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="Quantity"/>
          <profile value="http://hl7.org/fhir/StructureDefinition/SimpleQuantity"/>
        </type>
        <mustSupport value="true"/>
        <isModifier value="false"/>
        <isSummary value="true"/>
        <mapping>
          <identity value="v2"/>
          <map value="NR.2"/>
        </mapping>
        <mapping>
          <identity value="rim"/>
          <map value="./high"/>
        </mapping>
      </element>
      <element id="PlanDefinition.goal.target.detailRange:Range.high.id">
        <path value="PlanDefinition.goal.target.detailRange.high.id"/>
        <representation value="xmlAttr"/>
        <short value="Unique id for inter-element referencing"/>
        <definition
                   value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Element.id"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="string"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="PlanDefinition.goal.target.detailRange:Range.high.extension">
        <path value="PlanDefinition.goal.target.detailRange.high.extension"/>
        <slicing>
          <discriminator>
            <type value="value"/>
            <path value="url"/>
          </discriminator>
          <description value="Extensions are always sliced by (at least) url"/>
          <rules value="open"/>
        </slicing>
```

```xml
        <short value="Additional content defined by implementations"/>
        <definition
                    value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
        <comment
                value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
        <alias value="extensions"/>
        <alias value="user content"/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="Element.extension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="PlanDefinition.goal.target.detailRange:Range.high.value">
        <path value="PlanDefinition.goal.target.detailRange.high.value"/>
        <short value="valueNumeric"/>
        <definition
                    value="A text or numeric value of the result of the test. [Source: SME
Defined]."/>
        <comment
                value="The implicit precision in the value should always be honored. Monet
ary values have their own rules for handling precision (refer to standard accounting text
 books)."/>
        <requirements
                      value="Precision is handled implicitly in almost all cases of measure
ment."/>
        <min value="1"/>
        <max value="1"/>
        <base>
          <path value="Quantity.value"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="decimal"/>
        </type>
        <mustSupport value="true"/>
        <isModifier value="false"/>
        <isSummary value="true"/>
```

```xml
      <mapping>
        <identity value="v2"/>
        <map value="SN.2  / CQ - N/A"/>
      </mapping>
      <mapping>
        <identity value="rim"/>
        <map
              value="PQ.value, CO.value, MO.value, IVL.high or IVL.low depending on the va
lue"/>
      </mapping>
    </element>
    <element id="PlanDefinition.goal.target.detailRange:Range.high.comparator">
      <path value="PlanDefinition.goal.target.detailRange.high.comparator"/>
      <short value="&lt; | &lt;= | &gt;= | &gt; - how to understand the value"/>
      <definition value="Not allowed to be used in this context"/>
      <requirements
                   value="Need a framework for handling measures where the value is &lt;
5ug/L or &gt;400mg/L due to the limitations of measuring methodology."/>
      <min value="0"/>
      <max value="0"/>
      <base>
        <path value="Quantity.comparator"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="code"/>
      </type>
      <meaningWhenMissing
                          value="If there is no comparator, then there is no modification
 of the value"/>
      <isModifier value="true"/>
      <isModifierReason
                       value="This is labeled as &quot;Is Modifier&quot; because the com
parator modifies the interpretation of the value significantly. If there is no comparator
, then there is no modification of the value"/>
      <isSummary value="true"/>
      <binding>
        <extension
                 url="http://hl7.org/fhir/StructureDefinition/elementdefinition-binding
Name">
          <valueString value="QuantityComparator"/>
        </extension>
        <strength value="required"/>
        <description
                    value="How the Quantity should be understood and represented."/>
        <valueSet value="http://hl7.org/fhir/ValueSet/quantity-comparator|4.0.0"/>
      </binding>
      <mapping>
        <identity value="v2"/>
        <map value="SN.1  / CQ.1"/>
      </mapping>
      <mapping>
        <identity value="rim"/>
        <map value="IVL properties"/>
      </mapping>
    </element>
```

```
  <element id="PlanDefinition.goal.target.detailRange:Range.high.unit">
    <extension
              url="http://hl7.org/fhir/StructureDefinition/elementdefinition-translata
ble">
      <valueBoolean value="true"/>
    </extension>
    <path value="PlanDefinition.goal.target.detailRange.high.unit"/>
    <short value="Unit representation"/>
    <definition value="A human-readable form of the unit."/>
    <requirements
                 value="There are many representations for units of measure and in man
y contexts, particular representations are fixed and required. I.e. mcg for micrograms."/
>
    <min value="0"/>
    <max value="1"/>
    <base>
      <path value="Quantity.unit"/>
      <min value="0"/>
      <max value="1"/>
    </base>
    <type>
      <code value="string"/>
    </type>
    <isModifier value="false"/>
    <isSummary value="true"/>
    <mapping>
      <identity value="v2"/>
      <map value="(see OBX.6 etc.) / CQ.2"/>
    </mapping>
    <mapping>
      <identity value="rim"/>
      <map value="PQ.unit"/>
    </mapping>
  </element>
  <element id="PlanDefinition.goal.target.detailRange:Range.high.system">
    <path value="PlanDefinition.goal.target.detailRange.high.system"/>
    <short value="System that defines coded unit form"/>
    <definition
                 value="The identification of the system that provides the coded form of
 the unit."/>
    <requirements
                 value="Need to know the system that defines the coded form of the uni
t."/>
    <min value="1"/>
    <max value="1"/>
    <base>
      <path value="Quantity.system"/>
      <min value="0"/>
      <max value="1"/>
    </base>
    <type>
      <code value="uri"/>
    </type>
    <fixedUri value="http://unitsofmeasure.org"/>
    <condition value="qty-3"/>
    <mustSupport value="true"/>
    <isModifier value="false"/>
```

```xml
      <isSummary value="true"/>
      <mapping>
        <identity value="v2"/>
        <map value="(see OBX.6 etc.) / CQ.2"/>
      </mapping>
      <mapping>
        <identity value="rim"/>
        <map value="CO.codeSystem, PQ.translation.codeSystem"/>
      </mapping>
    </element>
    <element id="PlanDefinition.goal.target.detailRange:Range.high.code">
      <path value="PlanDefinition.goal.target.detailRange.high.code"/>
      <short value="Unit"/>
      <definition
                 value="A named quantity in terms of which other quantities are measured
 or specified, used as a standard measurement of like kinds. [Source: NCI EVS -C25709] Ex
amples: mg, L, etc."/>
      <comment
                value="The preferred system is UCUM, but SNOMED CT can also be used (for c
ustomary units) or ISO 4217 for currency.  The context of use may additionally require a
code from a particular system."/>
      <requirements
                   value="Need a computable form of the unit that is fixed across all fo
rms. UCUM provides this for quantities, but SNOMED CT provides many units of interest."/>
      <min value="1"/>
      <max value="1"/>
      <base>
        <path value="Quantity.code"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="code"/>
      </type>
      <mustSupport value="true"/>
      <isModifier value="false"/>
      <isSummary value="true"/>
      <mapping>
        <identity value="v2"/>
        <map value="(see OBX.6 etc.) / CQ.2"/>
      </mapping>
      <mapping>
        <identity value="rim"/>
        <map value="PQ.code, MO.currency, PQ.translation.code"/>
      </mapping>
    </element>
    <element
             id="PlanDefinition.goal.target.detailCodeableConcept:CodeableConcept">
      <path value="PlanDefinition.goal.target.detailCodeableConcept"/>
      <sliceName value="CodeableConcept"/>
      <short value="The target value to be achieved"/>
      <definition
                 value="The target value of the measure to be achieved to signify fulfil
lment of the goal, e.g. 150 pounds or 7.0%. Either the high or low or both values of the
range can be specified. When a low value is missing, it indicates that the goal is achiev
ed at any value at or below the high value. Similarly, if the high value is missing, it i
ndicates that the goal is achieved at any value at or above the low value."/>
```

```xml
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="PlanDefinition.goal.target.detail[x]"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="CodeableConcept"/>
        </type>
        <mustSupport value="true"/>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element
              id="PlanDefinition.goal.target.detailCodeableConcept:CodeableConcept.id">
        <path value="PlanDefinition.goal.target.detailCodeableConcept.id"/>
        <representation value="xmlAttr"/>
        <short value="Unique id for inter-element referencing"/>
        <definition
                    value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Element.id"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="string"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element
              id="PlanDefinition.goal.target.detailCodeableConcept:CodeableConcept.extensi
on">
        <path value="PlanDefinition.goal.target.detailCodeableConcept.extension"/>
        <slicing>
          <discriminator>
            <type value="value"/>
            <path value="url"/>
          </discriminator>
          <description value="Extensions are always sliced by (at least) url"/>
          <rules value="open"/>
        </slicing>
        <short value="Additional content defined by implementations"/>
        <definition
                    value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
```

```xml
 be met as part of the definition of the extension."/>
      <comment
               value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
      <alias value="extensions"/>
      <alias value="user content"/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="Element.extension"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Extension"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="n/a"/>
      </mapping>
    </element>
    <element
            id="PlanDefinition.goal.target.detailCodeableConcept:CodeableConcept.coding"
>
      <path value="PlanDefinition.goal.target.detailCodeableConcept.coding"/>
      <short value="Code defined by a terminology system"/>
      <definition value="A reference to a code defined by a terminology system."/>
      <comment
               value="Codes may be defined very casually in enumerations, or code lists,
up to very formal definitions such as SNOMED CT - see the HL7 v3 Core Principles for more
 information.  Ordering of codings is undefined and SHALL NOT be used to infer meaning. G
enerally, at most only one of the coding values will be labeled as UserSelected = true."/
>
      <requirements
                   value="Allows for alternative encodings within a code system, and tra
nslations to other code systems."/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="CodeableConcept.coding"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Coding"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="true"/>
      <mapping>
        <identity value="v2"/>
        <map value="C*E.1-8, C*E.10-22"/>
      </mapping>
      <mapping>
```

```xml
          <identity value="rim"/>
          <map value="union(., ./translation)"/>
        </mapping>
        <mapping>
          <identity value="orim"/>
          <map value="fhir:CodeableConcept.coding rdfs:subPropertyOf dt:CD.coding"/>
        </mapping>
      </element>
      <element
              id="PlanDefinition.goal.target.detailCodeableConcept:CodeableConcept.text">
        <extension
                url="http://hl7.org/fhir/StructureDefinition/elementdefinition-translatable">
          <valueBoolean value="true"/>
        </extension>
        <path value="PlanDefinition.goal.target.detailCodeableConcept.text"/>
        <short value="value"/>
        <definition
                value="A text or numeric value of the result of the test. [Source: SME Defined]."/>
        <comment
              value="Very often the text is the same as a displayName of one of the codings."/>
        <requirements
                    value="The codes from the terminologies do not always capture the correct meaning with all the nuances of the human using them, or sometimes there is no appropriate code at all. In these cases, the text is used to capture the full meaning of the source."/>
        <min value="1"/>
        <max value="1"/>
        <base>
          <path value="CodeableConcept.text"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="string"/>
        </type>
        <mustSupport value="true"/>
        <isModifier value="false"/>
        <isSummary value="true"/>
        <mapping>
          <identity value="v2"/>
          <map value="C*E.9. But note many systems use C*E.2 for this"/>
        </mapping>
        <mapping>
          <identity value="rim"/>
          <map value="./originalText[mediaType/code=&quot;text/plain&quot;]/data"/>
        </mapping>
        <mapping>
          <identity value="orim"/>
          <map
              value="fhir:CodeableConcept.text rdfs:subPropertyOf dt:CD.originalText"/>
        </mapping>
      </element>
      <element id="PlanDefinition.goal.target.due">
        <path value="PlanDefinition.goal.target.due"/>
```

```xml
      <short value="Reach goal within"/>
      <definition
                  value="Indicates the timeframe after the start of the goal in which the
 goal should be met."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="PlanDefinition.goal.target.due"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="Duration"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="PlanDefinition.action">
      <path value="PlanDefinition.action"/>
      <short value="Test"/>
      <definition
                  value="A determination of a physical, chemical or biological property.
[Source: SME Defined]."/>
      <comment
                value="Note that there is overlap between many of the elements defined her
e and the ActivityDefinition resource. When an ActivityDefinition is referenced (using th
e definition element), the overlapping elements in the plan override the content of the r
eferenced ActivityDefinition unless otherwise documented in the specific elements. See th
e PlanDefinition resource for more detailed information."/>
      <min value="1"/>
      <max value="*"/>
      <base>
        <path value="PlanDefinition.action"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="BackboneElement"/>
      </type>
      <constraint>
        <key value="ele-1"/>
        <severity value="error"/>
        <human value="All FHIR elements must have a @value or children"/>
        <expression value="hasValue() or (children().count() &gt; id.count())"/>
        <xpath value="@value|f:*|h:div"/>
        <source value="Element"/>
      </constraint>
      <mustSupport value="true"/>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="workflow"/>
        <map value="{Is a contained Definition}"/>
      </mapping>
    </element>
    <element id="PlanDefinition.action.id">
      <path value="PlanDefinition.action.id"/>
```

```xml
        <representation value="xmlAttr"/>
        <short value="Unique id for inter-element referencing"/>
        <definition
                  value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Element.id"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="string"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="PlanDefinition.action.extension">
        <path value="PlanDefinition.action.extension"/>
        <slicing id="7">
          <discriminator>
            <type value="value"/>
            <path value="url"/>
          </discriminator>
          <ordered value="false"/>
          <rules value="open"/>
        </slicing>
        <short value="Extension"/>
        <definition value="An Extension"/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="Element.extension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="PlanDefinition.action.extension:methodOrigin">
        <extension
                  url="http://hl7.org/fhir/StructureDefinition/structuredefinition-standar
ds-status">
          <valueCode value="normative"/>
        </extension>
        <extension
                  url="http://hl7.org/fhir/StructureDefinition/structuredefinition-normati
ve-version">
          <valueCode value="4.0.0"/>
```

```xml
        </extension>
        <path value="PlanDefinition.action.extension"/>
        <sliceName value="methodOrigin"/>
        <short value="Test method origin"/>
        <definition
                  value="A coded value specifying the source of the method. [Source: SME
Defined] Example: Compendial."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Element.extension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
          <profile
                  value="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-methodOrig
in"/>
        </type>
        <condition value="ele-1"/>
        <constraint>
          <key value="ele-1"/>
          <severity value="error"/>
          <human value="All FHIR elements must have a @value or children"/>
          <expression value="hasValue() or (children().count() &gt; id.count())"/>
          <xpath value="@value|f:*|h:div"/>
          <source value="Element"/>
        </constraint>
        <constraint>
          <key value="ext-1"/>
          <severity value="error"/>
          <human value="Must have either extensions or value[x], not both"/>
          <expression value="extension.exists() != value.exists()"/>
          <xpath
                  value="exists(f:extension)!=exists(f:*[starts-with(local-name(.), &#39;val
ue&#39;)])"/>
          <source value="Extension"/>
        </constraint>
        <mustSupport value="true"/>
        <isModifier value="false"/>
      </element>
      <element id="PlanDefinition.action.extension:referenceToProcedure">
        <extension
                  url="http://hl7.org/fhir/StructureDefinition/structuredefinition-standar
ds-status">
          <valueCode value="normative"/>
        </extension>
        <extension
                  url="http://hl7.org/fhir/StructureDefinition/structuredefinition-normati
ve-version">
          <valueCode value="4.0.0"/>
        </extension>
        <path value="PlanDefinition.action.extension"/>
        <sliceName value="referenceToProcedure"/>
        <short value="Reference to procedure (url)"/>
        <definition value="An Extension"/>
```

```xml
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Element.extension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
          <profile
                    value="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-definition
Uri"/>
        </type>
        <condition value="ele-1"/>
        <constraint>
          <key value="ele-1"/>
          <severity value="error"/>
          <human value="All FHIR elements must have a @value or children"/>
          <expression value="hasValue() or (children().count() &gt; id.count())"/>
          <xpath value="@value|f:*|h:div"/>
          <source value="Element"/>
        </constraint>
        <constraint>
          <key value="ext-1"/>
          <severity value="error"/>
          <human value="Must have either extensions or value[x], not both"/>
          <expression value="extension.exists() != value.exists()"/>
          <xpath
                  value="exists(f:extension)!=exists(f:*[starts-with(local-name(.), &#39;val
ue&#39;)])"/>
          <source value="Extension"/>
        </constraint>
        <mustSupport value="true"/>
        <isModifier value="false"/>
      </element>
      <element id="PlanDefinition.action.extension:focus">
        <extension
                    url="http://hl7.org/fhir/StructureDefinition/structuredefinition-standar
ds-status">
          <valueCode value="normative"/>
        </extension>
        <extension
                    url="http://hl7.org/fhir/StructureDefinition/structuredefinition-normati
ve-version">
          <valueCode value="4.0.0"/>
        </extension>
        <path value="PlanDefinition.action.extension"/>
        <sliceName value="focus"/>
        <short value="Relative retention time"/>
        <definition
                    value="The ratio of the retention time of a component relative to that
of another used as a reference obtained under identical conditions. It is used as an alia
s for the name of the unidentified impurities. [Source: Adapted from USP] Example: 1:23 (
a ratio)."/>
        <min value="0"/>
        <max value="1"/>
        <base>
```

```
          <path value="Element.extension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
          <profile
                  value="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-focus"/>
        </type>
        <condition value="ele-1"/>
        <constraint>
          <key value="ele-1"/>
          <severity value="error"/>
          <human value="All FHIR elements must have a @value or children"/>
          <expression value="hasValue() or (children().count() &gt; id.count())"/>
          <xpath value="@value|f:*|h:div"/>
          <source value="Element"/>
        </constraint>
        <constraint>
          <key value="ext-1"/>
          <severity value="error"/>
          <human value="Must have either extensions or value[x], not both"/>
          <expression value="extension.exists() != value.exists()"/>
          <xpath
                value="exists(f:extension)!=exists(f:*[starts-with(local-name(.), &#39;val
ue&#39;)])"/>
          <source value="Extension"/>
        </constraint>
        <mustSupport value="true"/>
        <isModifier value="false"/>
      </element>
      <element id="PlanDefinition.action.modifierExtension">
        <path value="PlanDefinition.action.modifierExtension"/>
        <short value="Extensions that cannot be ignored even if unrecognized"/>
        <definition
                    value="May be used to represent additional information that is not part
 of the basic definition of the element and that modifies the understanding of the elemen
t in which it is contained and/or the understanding of the containing element&#39;s desce
ndants. Usually modifier elements provide negation or qualification. To make the use of e
xtensions safe and manageable, there is a strict set of governance applied to the definit
ion and use of extensions. Though any implementer can define an extension, there is a set
 of requirements that SHALL be met as part of the definition of the extension. Applicatio
ns processing a resource are required to check for modifier extensions.

Modifier extensions SHALL NOT change the meaning of any elements on Resource or DomainRes
ource (including cannot change the meaning of modifierExtension itself)."/>
        <comment
                value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
        <requirements
                    value="Modifier extensions allow for extensions that *cannot* be safe
ly ignored to be clearly distinguished from the vast majority of extensions which can be
safely ignored.  This promotes interoperability by eliminating the need for implementers
to prohibit the presence of extensions. For further information, see the [definition of m
odifier extensions](http://build.fhir.org/extensibility.html#modifierExtension)."/>
```

```xml
      <alias value="extensions"/>
      <alias value="user content"/>
      <alias value="modifiers"/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="BackboneElement.modifierExtension"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Extension"/>
      </type>
      <isModifier value="true"/>
      <isModifierReason
                        value="Modifier extensions are expected to modify the meaning or
interpretation of the element that contains them"/>
      <isSummary value="true"/>
      <mapping>
        <identity value="rim"/>
        <map value="N/A"/>
      </mapping>
    </element>
    <element id="PlanDefinition.action.prefix">
      <path value="PlanDefinition.action.prefix"/>
      <short value="User-visible prefix for the action (e.g. 1. or A.)"/>
      <definition value="A user-visible prefix for the action."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="PlanDefinition.action.prefix"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="string"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="PlanDefinition.action.title">
      <path value="PlanDefinition.action.title"/>
      <short value="Test Name"/>
      <definition
                  value="The textual description of a procedure or analytical method. [So
urce: SME Defined]."/>
      <min value="1"/>
      <max value="1"/>
      <base>
        <path value="PlanDefinition.action.title"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="string"/>
      </type>
      <mustSupport value="true"/>
```

```xml
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="workflow"/>
          <map value="Definition.title"/>
        </mapping>
      </element>
      <element id="PlanDefinition.action.description">
        <path value="PlanDefinition.action.description"/>
        <short value="Brief description of the action"/>
        <definition
                    value="A brief description of the action used to provide a summary to d
isplay to the user."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="PlanDefinition.action.description"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="string"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="workflow"/>
          <map value="Definition.description"/>
        </mapping>
      </element>
      <element id="PlanDefinition.action.textEquivalent">
        <path value="PlanDefinition.action.textEquivalent"/>
        <short
              value="Static text equivalent of the action, used if the dynamic aspects can
not be interpreted by the receiving system"/>
        <definition
                    value="A text equivalent of the action to be performed. This provides a
 human-interpretable description of the action when the definition is consumed by a syste
m that might not be capable of interpreting it dynamically."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="PlanDefinition.action.textEquivalent"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="string"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="workflow"/>
          <map value="Definition.description"/>
        </mapping>
      </element>
      <element id="PlanDefinition.action.priority">
```

```
          <path value="PlanDefinition.action.priority"/>
          <short value="routine | urgent | asap | stat"/>
          <definition
                    value="Indicates how quickly the action should be addressed with respec
t to other actions."/>
          <min value="0"/>
          <max value="1"/>
          <base>
            <path value="PlanDefinition.action.priority"/>
            <min value="0"/>
            <max value="1"/>
          </base>
          <type>
            <code value="code"/>
          </type>
          <isModifier value="false"/>
          <isSummary value="false"/>
          <binding>
            <extension
                    url="http://hl7.org/fhir/StructureDefinition/elementdefinition-binding
Name">
              <valueString value="RequestPriority"/>
            </extension>
            <strength value="required"/>
            <description
                      value="Identifies the level of importance to be assigned to actionin
g the request."/>
            <valueSet value="http://hl7.org/fhir/ValueSet/request-priority|4.0.0"/>
          </binding>
        </element>
        <element id="PlanDefinition.action.code">
          <path value="PlanDefinition.action.code"/>
          <short value="QualitySpecification Test category"/>
          <definition
                    value="A code that provides meaning for the action or action group. For
 example, a section may have a LOINC code for the section of a documentation template."/>
          <min value="1"/>
          <max value="1"/>
          <base>
            <path value="PlanDefinition.action.code"/>
            <min value="0"/>
            <max value="*"/>
          </base>
          <type>
            <code value="CodeableConcept"/>
          </type>
          <mustSupport value="true"/>
          <isModifier value="false"/>
          <isSummary value="false"/>
        </element>
        <element id="PlanDefinition.action.code.id">
          <path value="PlanDefinition.action.code.id"/>
          <representation value="xmlAttr"/>
          <short value="Unique id for inter-element referencing"/>
          <definition
                    value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
```

```xml
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Element.id"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="string"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="PlanDefinition.action.code.extension">
        <path value="PlanDefinition.action.code.extension"/>
        <slicing>
          <discriminator>
            <type value="value"/>
            <path value="url"/>
          </discriminator>
          <description value="Extensions are always sliced by (at least) url"/>
          <rules value="open"/>
        </slicing>
        <short value="Additional content defined by implementations"/>
        <definition
                   value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
        <comment
                value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
        <alias value="extensions"/>
        <alias value="user content"/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="Element.extension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
```

```xml
          </element>
        <element id="PlanDefinition.action.code.coding">
            <path value="PlanDefinition.action.code.coding"/>
            <short value="Test category"/>
            <definition
                      value="A high level grouping of product quality attributes. [Source: SM
E Defined] Examples: Appearance, Physical Properties, etc."/>
            <comment
                    value="Codes may be defined very casually in enumerations, or code lists,
up to very formal definitions such as SNOMED CT - see the HL7 v3 Core Principles for more
 information.  Ordering of codings is undefined and SHALL NOT be used to infer meaning. G
enerally, at most only one of the coding values will be labeled as UserSelected = true."/
>
            <requirements
                        value="Allows for alternative encodings within a code system, and tra
nslations to other code systems."/>
            <min value="1"/>
            <max value="1"/>
            <base>
              <path value="CodeableConcept.coding"/>
              <min value="0"/>
              <max value="*"/>
            </base>
            <type>
              <code value="Coding"/>
            </type>
            <mustSupport value="true"/>
            <isModifier value="false"/>
            <isSummary value="true"/>
            <mapping>
              <identity value="v2"/>
              <map value="C*E.1-8, C*E.10-22"/>
            </mapping>
            <mapping>
              <identity value="rim"/>
              <map value="union(., ./translation)"/>
            </mapping>
            <mapping>
              <identity value="orim"/>
              <map value="fhir:CodeableConcept.coding rdfs:subPropertyOf dt:CD.coding"/>
            </mapping>
          </element>
        <element id="PlanDefinition.action.code.text">
            <extension
                      url="http://hl7.org/fhir/StructureDefinition/elementdefinition-translata
ble">
              <valueBoolean value="true"/>
            </extension>
            <path value="PlanDefinition.action.code.text"/>
            <short value="Analytical Procedure"/>
            <definition
                        value="A technique used to determine the nature of a characteristic. [S
ource: SME Defined] Examples: HPLC, Capillary Electrophoresis, etc."/>
            <comment
                    value="Very often the text is the same as a displayName of one of the codi
ngs."/>
            <requirements
```

```
                  value="The codes from the terminologies do not always capture the cor
rect meaning with all the nuances of the human using them, or sometimes there is no appro
priate code at all. In these cases, the text is used to capture the full meaning of the s
ource."/>
        <min value="1"/>
        <max value="1"/>
        <base>
          <path value="CodeableConcept.text"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="string"/>
        </type>
        <mustSupport value="true"/>
        <isModifier value="false"/>
        <isSummary value="true"/>
        <mapping>
          <identity value="v2"/>
          <map value="C*E.9. But note many systems use C*E.2 for this"/>
        </mapping>
        <mapping>
          <identity value="rim"/>
          <map value="./originalText[mediaType/code=&quot;text/plain&quot;]/data"/>
        </mapping>
        <mapping>
          <identity value="orim"/>
          <map
              value="fhir:CodeableConcept.text rdfs:subPropertyOf dt:CD.originalText"/>
        </mapping>
      </element>
      <element id="PlanDefinition.action.reason">
        <path value="PlanDefinition.action.reason"/>
        <short value="Usage"/>
        <definition
                  value="A coded value specifying the time point during the manufacturing
 process of a substance or product when a particular analytical procedure or measurement
is being performed. [Source: SME Defined]."/>
        <comment
              value="This is different than the clinical evidence documentation, it&#39;
s an actual business description of the reason for performing the action."/>
        <min value="1"/>
        <max value="1"/>
        <base>
          <path value="PlanDefinition.action.reason"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="CodeableConcept"/>
        </type>
        <mustSupport value="true"/>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="PlanDefinition.action.documentation">
        <path value="PlanDefinition.action.documentation"/>
```

```xml
      <short
            value="Supporting documentation for the intended performer of the action"/>
      <definition
                value="Didactic or other informational resources associated with the ac
tion that can be provided to the CDS recipient. Information resources can include inline
text commentary and links to web resources."/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="PlanDefinition.action.documentation"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="RelatedArtifact"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="PlanDefinition.action.goalId">
      <path value="PlanDefinition.action.goalId"/>
      <short value="What goals this action supports"/>
      <definition
                value="Identifies goals that this action supports. The reference must b
e to a goal element defined within this plan definition."/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="PlanDefinition.action.goalId"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="id"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="PlanDefinition.action.subject[x]">
      <path value="PlanDefinition.action.subject[x]"/>
      <short value="Type of individual the action is focused on"/>
      <definition
                value="A code or group definition that describes the intended subject o
f the action and its children, if any."/>
      <comment
              value="The subject of an action overrides the subject at a parent action o
r on the root of the PlanDefinition if specified.

In addition, because the subject needs to be resolved during realization, use of subjects
 in actions (or in the ActivityDefinition referenced by the action) resolves based on the
 set of subjects supplied in context and by type (i.e. the patient subject would resolve
to a resource of type Patient)."/>
      <requirements
                    value="Multiple steps in a protocol often have different groups of st
eps that are focused on testing different things. The subject of an action specifies the
focus of the action and any child actions."/>
      <min value="0"/>
```

```xml
        <max value="1"/>
        <base>
          <path value="PlanDefinition.action.subject[x]"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="CodeableConcept"/>
        </type>
        <type>
          <code value="Reference"/>
          <targetProfile value="http://hl7.org/fhir/StructureDefinition/Group"/>
        </type>
        <meaningWhenMissing value="Patient"/>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <binding>
          <extension
                     url="http://hl7.org/fhir/StructureDefinition/elementdefinition-binding
Name">
            <valueString value="SubjectType"/>
          </extension>
          <strength value="extensible"/>
          <description
                     value="The possible types of subjects for a plan definition (E.g. Pa
tient, Practitioner, Organization, Location, etc.)."/>
          <valueSet value="http://hl7.org/fhir/ValueSet/subject-type"/>
        </binding>
        <mapping>
          <identity value="workflow"/>
          <map value="Definition.subject"/>
        </mapping>
      </element>
      <element id="PlanDefinition.action.trigger">
        <path value="PlanDefinition.action.trigger"/>
        <short value="When the action should be triggered"/>
        <definition value="A description of when the action should be triggered."/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="PlanDefinition.action.trigger"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="TriggerDefinition"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="PlanDefinition.action.condition">
        <path value="PlanDefinition.action.condition"/>
        <short value="Whether or not the action is applicable"/>
        <definition
                     value="An expression that describes applicability criteria or start/sto
p conditions for the action."/>
        <comment
```

```
                  value="When multiple conditions of the same kind are present, the effects
are combined using AND semantics, so the overall condition is true only if all the condit
ions are true."/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="PlanDefinition.action.condition"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="BackboneElement"/>
        </type>
        <constraint>
          <key value="ele-1"/>
          <severity value="error"/>
          <human value="All FHIR elements must have a @value or children"/>
          <expression value="hasValue() or (children().count() &gt; id.count())"/>
          <xpath value="@value|f:*|h:div"/>
          <source value="Element"/>
        </constraint>
        <isModifier value="false"/>
        <isSummary value="false"/>
    </element>
    <element id="PlanDefinition.action.condition.id">
        <path value="PlanDefinition.action.condition.id"/>
        <representation value="xmlAttr"/>
        <short value="Unique id for inter-element referencing"/>
        <definition
                  value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Element.id"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="string"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
    </element>
    <element id="PlanDefinition.action.condition.extension">
        <path value="PlanDefinition.action.condition.extension"/>
        <short value="Additional content defined by implementations"/>
        <definition
                  value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
```

```xml
      <comment
              value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
      <alias value="extensions"/>
      <alias value="user content"/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="Element.extension"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Extension"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="n/a"/>
      </mapping>
    </element>
    <element id="PlanDefinition.action.condition.modifierExtension">
      <path value="PlanDefinition.action.condition.modifierExtension"/>
      <short value="Extensions that cannot be ignored even if unrecognized"/>
      <definition
              value="May be used to represent additional information that is not part
 of the basic definition of the element and that modifies the understanding of the elemen
t in which it is contained and/or the understanding of the containing element&#39;s desce
ndants. Usually modifier elements provide negation or qualification. To make the use of e
xtensions safe and manageable, there is a strict set of governance applied to the definit
ion and use of extensions. Though any implementer can define an extension, there is a set
 of requirements that SHALL be met as part of the definition of the extension. Applicatio
ns processing a resource are required to check for modifier extensions.

Modifier extensions SHALL NOT change the meaning of any elements on Resource or DomainRes
ource (including cannot change the meaning of modifierExtension itself)."/>
      <comment
              value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
      <requirements
                value="Modifier extensions allow for extensions that *cannot* be safe
ly ignored to be clearly distinguished from the vast majority of extensions which can be
safely ignored.  This promotes interoperability by eliminating the need for implementers
to prohibit the presence of extensions. For further information, see the [definition of m
odifier extensions](http://build.fhir.org/extensibility.html#modifierExtension)."/>
      <alias value="extensions"/>
      <alias value="user content"/>
      <alias value="modifiers"/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="BackboneElement.modifierExtension"/>
```

```xml
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
        </type>
        <isModifier value="true"/>
        <isModifierReason
                          value="Modifier extensions are expected to modify the meaning or
interpretation of the element that contains them"/>
        <isSummary value="true"/>
        <mapping>
          <identity value="rim"/>
          <map value="N/A"/>
        </mapping>
      </element>
      <element id="PlanDefinition.action.condition.kind">
        <path value="PlanDefinition.action.condition.kind"/>
        <short value="applicability | start | stop"/>
        <definition value="The kind of condition."/>
        <comment
                  value="Applicability criteria are used to determine immediate applicabilit
y when a plan definition is applied to a given context. Start and stop criteria are carri
ed through application and used to describe enter/exit criteria for an action."/>
        <min value="1"/>
        <max value="1"/>
        <base>
          <path value="PlanDefinition.action.condition.kind"/>
          <min value="1"/>
          <max value="1"/>
        </base>
        <type>
          <code value="code"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <binding>
          <extension
                    url="http://hl7.org/fhir/StructureDefinition/elementdefinition-binding
Name">
            <valueString value="ActionConditionKind"/>
          </extension>
          <strength value="required"/>
          <description
                      value="Defines the kinds of conditions that can appear on actions."/
>
          <valueSet
                    value="http://hl7.org/fhir/ValueSet/action-condition-kind|4.0.0"/>
        </binding>
      </element>
      <element id="PlanDefinition.action.condition.expression">
        <path value="PlanDefinition.action.condition.expression"/>
        <short value="Boolean-valued expression"/>
        <definition
                    value="An expression that returns true or false, indicating whether the
 condition is satisfied."/>
        <comment
```

```xml
                   value="The expression may be inlined or may be a reference to a named expr
ession within a logic library referenced by the library element."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="PlanDefinition.action.condition.expression"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="Expression"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="PlanDefinition.action.input">
        <path value="PlanDefinition.action.input"/>
        <short value="Input data requirements"/>
        <definition value="Defines input data requirements for the action."/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="PlanDefinition.action.input"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="DataRequirement"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="PlanDefinition.action.output">
        <path value="PlanDefinition.action.output"/>
        <short value="Output data definition"/>
        <definition value="Defines the outputs of the action, if any."/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="PlanDefinition.action.output"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="DataRequirement"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="PlanDefinition.action.relatedAction">
        <path value="PlanDefinition.action.relatedAction"/>
        <short value="Relationship to another action"/>
        <definition
                  value="A relationship to another action such as &quot;before&quot; or &
quot;30-60 minutes after start of&quot;."/>
        <comment
                  value="When an action depends on multiple actions, the meaning is that all
```

```
 actions are dependencies, rather than that any of the actions are a dependency."/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="PlanDefinition.action.relatedAction"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="BackboneElement"/>
      </type>
      <constraint>
        <key value="ele-1"/>
        <severity value="error"/>
        <human value="All FHIR elements must have a @value or children"/>
        <expression value="hasValue() or (children().count() &gt; id.count())"/>
        <xpath value="@value|f:*|h:div"/>
        <source value="Element"/>
      </constraint>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="PlanDefinition.action.relatedAction.id">
      <path value="PlanDefinition.action.relatedAction.id"/>
      <representation value="xmlAttr"/>
      <short value="Unique id for inter-element referencing"/>
      <definition
                  value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="Element.id"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="string"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="n/a"/>
      </mapping>
    </element>
    <element id="PlanDefinition.action.relatedAction.extension">
      <path value="PlanDefinition.action.relatedAction.extension"/>
      <short value="Additional content defined by implementations"/>
      <definition
                  value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
      <comment
               value="There can be no stigma associated with the use of extensions by any
```

```
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
      <alias value="extensions"/>
      <alias value="user content"/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="Element.extension"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Extension"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="n/a"/>
      </mapping>
    </element>
    <element id="PlanDefinition.action.relatedAction.modifierExtension">
      <path value="PlanDefinition.action.relatedAction.modifierExtension"/>
      <short value="Extensions that cannot be ignored even if unrecognized"/>
      <definition
                  value="May be used to represent additional information that is not part
 of the basic definition of the element and that modifies the understanding of the elemen
t in which it is contained and/or the understanding of the containing element&#39;s desce
ndants. Usually modifier elements provide negation or qualification. To make the use of e
xtensions safe and manageable, there is a strict set of governance applied to the definit
ion and use of extensions. Though any implementer can define an extension, there is a set
 of requirements that SHALL be met as part of the definition of the extension. Applicatio
ns processing a resource are required to check for modifier extensions.

Modifier extensions SHALL NOT change the meaning of any elements on Resource or DomainRes
ource (including cannot change the meaning of modifierExtension itself)."/>
      <comment
              value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
      <requirements
                    value="Modifier extensions allow for extensions that *cannot* be safe
ly ignored to be clearly distinguished from the vast majority of extensions which can be
safely ignored.  This promotes interoperability by eliminating the need for implementers
to prohibit the presence of extensions. For further information, see the [definition of m
odifier extensions](http://build.fhir.org/extensibility.html#modifierExtension)."/>
      <alias value="extensions"/>
      <alias value="user content"/>
      <alias value="modifiers"/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="BackboneElement.modifierExtension"/>
        <min value="0"/>
        <max value="*"/>
```

```xml
        </base>
        <type>
          <code value="Extension"/>
        </type>
        <isModifier value="true"/>
        <isModifierReason
                          value="Modifier extensions are expected to modify the meaning or
interpretation of the element that contains them"/>
        <isSummary value="true"/>
        <mapping>
          <identity value="rim"/>
          <map value="N/A"/>
        </mapping>
      </element>
      <element id="PlanDefinition.action.relatedAction.actionId">
        <path value="PlanDefinition.action.relatedAction.actionId"/>
        <short value="What action is this related to"/>
        <definition value="The element id of the related action."/>
        <min value="1"/>
        <max value="1"/>
        <base>
          <path value="PlanDefinition.action.relatedAction.actionId"/>
          <min value="1"/>
          <max value="1"/>
        </base>
        <type>
          <code value="id"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="PlanDefinition.action.relatedAction.relationship">
        <path value="PlanDefinition.action.relatedAction.relationship"/>
        <short
               value="before-start | before | before-end | concurrent-with-start | concurre
nt | concurrent-with-end | after-start | after | after-end"/>
        <definition value="The relationship of this action to the related action."/>
        <min value="1"/>
        <max value="1"/>
        <base>
          <path value="PlanDefinition.action.relatedAction.relationship"/>
          <min value="1"/>
          <max value="1"/>
        </base>
        <type>
          <code value="code"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <binding>
          <extension
                     url="http://hl7.org/fhir/StructureDefinition/elementdefinition-binding
Name">
            <valueString value="ActionRelationshipType"/>
          </extension>
          <strength value="required"/>
          <description value="Defines the types of relationships between actions."/>
```

```
            <valueSet
                    value="http://hl7.org/fhir/ValueSet/action-relationship-type|4.0.0"/>
        </binding>
    </element>
    <element id="PlanDefinition.action.relatedAction.offset[x]">
        <path value="PlanDefinition.action.relatedAction.offset[x]"/>
        <short value="Time offset for the relationship"/>
        <definition
                    value="A duration or range of durations to apply to the relationship. F
or example, 30-60 minutes before."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="PlanDefinition.action.relatedAction.offset[x]"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="Duration"/>
        </type>
        <type>
          <code value="Range"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
    </element>
    <element id="PlanDefinition.action.timing[x]">
        <path value="PlanDefinition.action.timing[x]"/>
        <short value="When the action should take place"/>
        <definition
                    value="An optional value describing when the action should be performed
."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="PlanDefinition.action.timing[x]"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="dateTime"/>
        </type>
        <type>
          <code value="Age"/>
        </type>
        <type>
          <code value="Period"/>
        </type>
        <type>
          <code value="Duration"/>
        </type>
        <type>
          <code value="Range"/>
        </type>
        <type>
          <code value="Timing"/>
        </type>
```

```xml
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="PlanDefinition.action.participant">
        <path value="PlanDefinition.action.participant"/>
        <short value="Who should participate in the action"/>
        <definition
                value="Indicates who should participate in performing the action descri
bed."/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="PlanDefinition.action.participant"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="BackboneElement"/>
        </type>
        <constraint>
          <key value="ele-1"/>
          <severity value="error"/>
          <human value="All FHIR elements must have a @value or children"/>
          <expression value="hasValue() or (children().count() &gt; id.count())"/>
          <xpath value="@value|f:*|h:div"/>
          <source value="Element"/>
        </constraint>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="PlanDefinition.action.participant.id">
        <path value="PlanDefinition.action.participant.id"/>
        <representation value="xmlAttr"/>
        <short value="Unique id for inter-element referencing"/>
        <definition
                value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Element.id"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="string"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="PlanDefinition.action.participant.extension">
        <path value="PlanDefinition.action.participant.extension"/>
        <short value="Additional content defined by implementations"/>
```

```xml
      <definition
                  value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
      <comment
                value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
      <alias value="extensions"/>
      <alias value="user content"/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="Element.extension"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Extension"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="n/a"/>
      </mapping>
    </element>
    <element id="PlanDefinition.action.participant.modifierExtension">
      <path value="PlanDefinition.action.participant.modifierExtension"/>
      <short value="Extensions that cannot be ignored even if unrecognized"/>
      <definition
                  value="May be used to represent additional information that is not part
 of the basic definition of the element and that modifies the understanding of the elemen
t in which it is contained and/or the understanding of the containing element&#39;s desce
ndants. Usually modifier elements provide negation or qualification. To make the use of e
xtensions safe and manageable, there is a strict set of governance applied to the definit
ion and use of extensions. Though any implementer can define an extension, there is a set
 of requirements that SHALL be met as part of the definition of the extension. Applicatio
ns processing a resource are required to check for modifier extensions.

Modifier extensions SHALL NOT change the meaning of any elements on Resource or DomainRes
ource (including cannot change the meaning of modifierExtension itself)."/>
      <comment
                value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
      <requirements
                     value="Modifier extensions allow for extensions that *cannot* be safe
ly ignored to be clearly distinguished from the vast majority of extensions which can be
safely ignored.  This promotes interoperability by eliminating the need for implementers
to prohibit the presence of extensions. For further information, see the [definition of m
odifier extensions](http://build.fhir.org/extensibility.html#modifierExtension)."/>
      <alias value="extensions"/>
```

```
        <alias value="user content"/>
        <alias value="modifiers"/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="BackboneElement.modifierExtension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
        </type>
        <isModifier value="true"/>
        <isModifierReason
                        value="Modifier extensions are expected to modify the meaning or
interpretation of the element that contains them"/>
        <isSummary value="true"/>
        <mapping>
          <identity value="rim"/>
          <map value="N/A"/>
        </mapping>
      </element>
      <element id="PlanDefinition.action.participant.type">
        <path value="PlanDefinition.action.participant.type"/>
        <short value="patient | practitioner | related-person | device"/>
        <definition value="The type of participant in the action."/>
        <min value="1"/>
        <max value="1"/>
        <base>
          <path value="PlanDefinition.action.participant.type"/>
          <min value="1"/>
          <max value="1"/>
        </base>
        <type>
          <code value="code"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <binding>
          <extension
                    url="http://hl7.org/fhir/StructureDefinition/elementdefinition-binding
Name">
            <valueString value="ActionParticipantType"/>
          </extension>
          <strength value="required"/>
          <description value="The type of participant for the action."/>
          <valueSet
                    value="http://hl7.org/fhir/ValueSet/action-participant-type|4.0.0"/>
        </binding>
      </element>
      <element id="PlanDefinition.action.participant.role">
        <path value="PlanDefinition.action.participant.role"/>
        <short value="E.g. Nurse, Surgeon, Parent"/>
        <definition
                    value="The role the participant should play in performing the described
 action."/>
        <min value="0"/>
```

```xml
        <max value="1"/>
        <base>
          <path value="PlanDefinition.action.participant.role"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="CodeableConcept"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <binding>
          <extension
                    url="http://hl7.org/fhir/StructureDefinition/elementdefinition-binding
Name">
            <valueString value="ActionParticipantRole"/>
          </extension>
          <strength value="example"/>
          <description
                      value="Defines roles played by participants for the action."/>
          <valueSet value="http://hl7.org/fhir/ValueSet/action-participant-role"/>
        </binding>
      </element>
      <element id="PlanDefinition.action.type">
        <path value="PlanDefinition.action.type"/>
        <short value="create | update | remove | fire-event"/>
        <definition
                    value="The type of action to perform (create, update, remove)."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="PlanDefinition.action.type"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="CodeableConcept"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <binding>
          <extension
                    url="http://hl7.org/fhir/StructureDefinition/elementdefinition-binding
Name">
            <valueString value="ActionType"/>
          </extension>
          <strength value="extensible"/>
          <description value="The type of action to be performed."/>
          <valueSet value="http://hl7.org/fhir/ValueSet/action-type"/>
        </binding>
      </element>
      <element id="PlanDefinition.action.groupingBehavior">
        <path value="PlanDefinition.action.groupingBehavior"/>
        <short value="visual-group | logical-group | sentence-group"/>
        <definition
                    value="Defines the grouping behavior for the action and its children."/
>
```

```xml
            <min value="0"/>
            <max value="1"/>
            <base>
              <path value="PlanDefinition.action.groupingBehavior"/>
              <min value="0"/>
              <max value="1"/>
            </base>
            <type>
              <code value="code"/>
            </type>
            <isModifier value="false"/>
            <isSummary value="false"/>
            <binding>
              <extension
                        url="http://hl7.org/fhir/StructureDefinition/elementdefinition-binding
Name">
                <valueString value="ActionGroupingBehavior"/>
              </extension>
              <strength value="required"/>
              <description value="Defines organization behavior of a group."/>
              <valueSet
                        value="http://hl7.org/fhir/ValueSet/action-grouping-behavior|4.0.0"/>
            </binding>
          </element>
          <element id="PlanDefinition.action.selectionBehavior">
            <path value="PlanDefinition.action.selectionBehavior"/>
            <short
                    value="any | all | all-or-none | exactly-one | at-most-one | one-or-more"/>
            <definition
                        value="Defines the selection behavior for the action and its children."
/>
            <min value="0"/>
            <max value="1"/>
            <base>
              <path value="PlanDefinition.action.selectionBehavior"/>
              <min value="0"/>
              <max value="1"/>
            </base>
            <type>
              <code value="code"/>
            </type>
            <isModifier value="false"/>
            <isSummary value="false"/>
            <binding>
              <extension
                        url="http://hl7.org/fhir/StructureDefinition/elementdefinition-binding
Name">
                <valueString value="ActionSelectionBehavior"/>
              </extension>
              <strength value="required"/>
              <description value="Defines selection behavior of a group."/>
              <valueSet
                        value="http://hl7.org/fhir/ValueSet/action-selection-behavior|4.0.0"/>
            </binding>
          </element>
          <element id="PlanDefinition.action.requiredBehavior">
            <path value="PlanDefinition.action.requiredBehavior"/>
```

```
      <short value="must | could | must-unless-documented"/>
      <definition value="Defines the required behavior for the action."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="PlanDefinition.action.requiredBehavior"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="code"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <binding>
        <extension
                   url="http://hl7.org/fhir/StructureDefinition/elementdefinition-binding
Name">
          <valueString value="ActionRequiredBehavior"/>
        </extension>
        <strength value="required"/>
        <description
                     value="Defines expectations around whether an action or action group
 is required."/>
        <valueSet
                   value="http://hl7.org/fhir/ValueSet/action-required-behavior|4.0.0"/>
      </binding>
    </element>
    <element id="PlanDefinition.action.precheckBehavior">
      <path value="PlanDefinition.action.precheckBehavior"/>
      <short value="yes | no"/>
      <definition
                   value="Defines whether the action should usually be preselected."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="PlanDefinition.action.precheckBehavior"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="code"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <binding>
        <extension
                   url="http://hl7.org/fhir/StructureDefinition/elementdefinition-binding
Name">
          <valueString value="ActionPrecheckBehavior"/>
        </extension>
        <strength value="required"/>
        <description
                     value="Defines selection frequency behavior for an action or group."
/>
        <valueSet
                   value="http://hl7.org/fhir/ValueSet/action-precheck-behavior|4.0.0"/>
```

```xml
        </binding>
      </element>
      <element id="PlanDefinition.action.cardinalityBehavior">
        <path value="PlanDefinition.action.cardinalityBehavior"/>
        <short value="single | multiple"/>
        <definition
                   value="Defines whether the action can be selected multiple times."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="PlanDefinition.action.cardinalityBehavior"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="code"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <binding>
          <extension
                   url="http://hl7.org/fhir/StructureDefinition/elementdefinition-binding
Name">
            <valueString value="ActionCardinalityBehavior"/>
          </extension>
          <strength value="required"/>
          <description
                      value="Defines behavior for an action or a group for how many times
that item may be repeated."/>
          <valueSet
                   value="http://hl7.org/fhir/ValueSet/action-cardinality-behavior|4.0.0"/
>
        </binding>
      </element>
      <element id="PlanDefinition.action.definition[x]">
        <path value="PlanDefinition.action.definition[x]"/>
        <short value="referenceToProcedure (FHIR)"/>
        <definition value="Location of procedure in eCTD."/>
        <comment
                 value="Note that the definition is optional, and if no definition is speci
fied, a dynamicValue with a root ($this) path can be used to define the entire resource d
ynamically."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="PlanDefinition.action.definition[x]"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="canonical"/>
          <targetProfile
                        value="http://hl7.org/fhir/StructureDefinition/ActivityDefinition"
/>
          <targetProfile
                        value="http://hl7.org/fhir/StructureDefinition/PlanDefinition"/>
          <targetProfile
```

```xml
                        value="http://hl7.org/fhir/StructureDefinition/Questionnaire"/>
      </type>
      <type>
        <code value="uri"/>
      </type>
      <mustSupport value="true"/>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="workflow"/>
        <map value="Definition.derivedFrom"/>
      </mapping>
    </element>
    <element id="PlanDefinition.action.transform">
      <path value="PlanDefinition.action.transform"/>
      <short value="Transform to apply the template"/>
      <definition
                value="A reference to a StructureMap resource that defines a transform
that can be executed to produce the intent resource using the ActivityDefinition instance
 as the input."/>
      <comment
              value="Note that when a referenced ActivityDefinition also defines a trans
form, the transform specified here generally takes precedence. In addition, if both a tra
nsform and dynamic values are specific, the dynamic values are applied to the result of t
he transform."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="PlanDefinition.action.transform"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="canonical"/>
        <targetProfile
                    value="http://hl7.org/fhir/StructureDefinition/StructureMap"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="PlanDefinition.action.dynamicValue">
      <path value="PlanDefinition.action.dynamicValue"/>
      <short value="Dynamic aspects of the definition"/>
      <definition
                value="Customizations that should be applied to the statically defined
resource. For example, if the dosage of a medication must be computed based on the patien
t&#39;s weight, a customization would be used to specify an expression that calculated th
e weight, and the path on the resource that would contain the result."/>
      <comment
              value="Dynamic values are applied in the order in which they are defined i
n the PlanDefinition resource. Note that when dynamic values are also specified by a refe
renced ActivityDefinition, the dynamicValues from the ActivityDefinition are applied firs
t, followed by the dynamicValues specified here. In addition, if both a transform and dyn
amic values are specific, the dynamic values are applied to the result of the transform."
/>
      <min value="0"/>
      <max value="*"/>
```

```xml
      <base>
        <path value="PlanDefinition.action.dynamicValue"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="BackboneElement"/>
      </type>
      <constraint>
        <key value="ele-1"/>
        <severity value="error"/>
        <human value="All FHIR elements must have a @value or children"/>
        <expression value="hasValue() or (children().count() &gt; id.count())"/>
        <xpath value="@value|f:*|h:div"/>
        <source value="Element"/>
      </constraint>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="PlanDefinition.action.dynamicValue.id">
      <path value="PlanDefinition.action.dynamicValue.id"/>
      <representation value="xmlAttr"/>
      <short value="Unique id for inter-element referencing"/>
      <definition
                   value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="Element.id"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="string"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="n/a"/>
      </mapping>
    </element>
    <element id="PlanDefinition.action.dynamicValue.extension">
      <path value="PlanDefinition.action.dynamicValue.extension"/>
      <short value="Additional content defined by implementations"/>
      <definition
                   value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
      <comment
               value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
```

```xml
        <alias value="extensions"/>
        <alias value="user content"/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="Element.extension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="PlanDefinition.action.dynamicValue.modifierExtension">
        <path value="PlanDefinition.action.dynamicValue.modifierExtension"/>
        <short value="Extensions that cannot be ignored even if unrecognized"/>
        <definition
                   value="May be used to represent additional information that is not part
 of the basic definition of the element and that modifies the understanding of the elemen
t in which it is contained and/or the understanding of the containing element&#39;s desce
ndants. Usually modifier elements provide negation or qualification. To make the use of e
xtensions safe and manageable, there is a strict set of governance applied to the definit
ion and use of extensions. Though any implementer can define an extension, there is a set
 of requirements that SHALL be met as part of the definition of the extension. Applicatio
ns processing a resource are required to check for modifier extensions.

Modifier extensions SHALL NOT change the meaning of any elements on Resource or DomainRes
ource (including cannot change the meaning of modifierExtension itself)."/>
        <comment
                value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
        <requirements
                     value="Modifier extensions allow for extensions that *cannot* be safe
ly ignored to be clearly distinguished from the vast majority of extensions which can be
safely ignored.  This promotes interoperability by eliminating the need for implementers
to prohibit the presence of extensions. For further information, see the [definition of m
odifier extensions](http://build.fhir.org/extensibility.html#modifierExtension)."/>
        <alias value="extensions"/>
        <alias value="user content"/>
        <alias value="modifiers"/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="BackboneElement.modifierExtension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
```

```
      </type>
      <isModifier value="true"/>
      <isModifierReason
                       value="Modifier extensions are expected to modify the meaning or
interpretation of the element that contains them"/>
      <isSummary value="true"/>
      <mapping>
        <identity value="rim"/>
        <map value="N/A"/>
      </mapping>
    </element>
    <element id="PlanDefinition.action.dynamicValue.path">
      <path value="PlanDefinition.action.dynamicValue.path"/>
      <short value="The path to the element to be set dynamically"/>
      <definition
                   value="The path to the element to be customized. This is the path on th
e resource that will hold the result of the calculation defined by the expression. The sp
ecified path SHALL be a FHIRPath resolveable on the specified target type of the Activity
Definition, and SHALL consist only of identifiers, constant indexers, and a restricted su
bset of functions. The path is allowed to contain qualifiers (.) to traverse sub-elements
, as well as indexers ([x]) to traverse multiple-cardinality sub-elements (see the [Simpl
e FHIRPath Profile](http://build.fhir.org/fhirpath.html#simple) for full details)."/>
      <comment
                 value="To specify the path to the current action being realized, the %acti
on environment variable is available in this path. For example, to specify the descriptio
n element of the target action, the path would be %action.description. The path attribute
 contains a [Simple FHIRPath Subset](http://build.fhir.org/fhirpath.html#simple) that all
ows path traversal, but not calculation."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="PlanDefinition.action.dynamicValue.path"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="string"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="PlanDefinition.action.dynamicValue.expression">
      <path value="PlanDefinition.action.dynamicValue.expression"/>
      <short
              value="An expression that provides the dynamic value for the customization"/
>
      <definition
                   value="An expression specifying the value of the customized element."/>
      <comment
                 value="The expression may be inlined or may be a reference to a named expr
ession within a logic library referenced by the library element."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="PlanDefinition.action.dynamicValue.expression"/>
        <min value="0"/>
        <max value="1"/>
```

```xml
        </base>
        <type>
          <code value="Expression"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="PlanDefinition.action.action">
        <path value="PlanDefinition.action.action"/>
        <short value="Stage"/>
        <definition
                    value="A set of discrete sequential steps performed on a given test. [S
ource: SME Defined] Note: Level and Tier could be synonyms for Stage. A Test can have man
y stages."/>
        <min value="1"/>
        <max value="*"/>
        <base>
          <path value="PlanDefinition.action.action"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="BackboneElement"/>
        </type>
        <mustSupport value="true"/>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="workflow"/>
          <map value="{InverseRelationship of Definition.partOf}"/>
        </mapping>
      </element>
      <element id="PlanDefinition.action.action.id">
        <path value="PlanDefinition.action.action.id"/>
        <representation value="xmlAttr"/>
        <short value="Unique id for inter-element referencing"/>
        <definition
                    value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Element.id"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="string"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="PlanDefinition.action.action.extension">
```

```
          <path value="PlanDefinition.action.action.extension"/>
          <short value="Additional content defined by implementations"/>
          <definition
                    value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
          <comment
                   value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
          <alias value="extensions"/>
          <alias value="user content"/>
          <min value="0"/>
          <max value="*"/>
          <base>
            <path value="Element.extension"/>
            <min value="0"/>
            <max value="*"/>
          </base>
          <type>
            <code value="Extension"/>
          </type>
          <isModifier value="false"/>
          <isSummary value="false"/>
          <mapping>
            <identity value="rim"/>
            <map value="n/a"/>
          </mapping>
        </element>
        <element id="PlanDefinition.action.action.modifierExtension">
          <path value="PlanDefinition.action.action.modifierExtension"/>
          <short value="Extensions that cannot be ignored even if unrecognized"/>
          <definition
                    value="May be used to represent additional information that is not part
 of the basic definition of the element and that modifies the understanding of the elemen
t in which it is contained and/or the understanding of the containing element&#39;s desce
ndants. Usually modifier elements provide negation or qualification. To make the use of e
xtensions safe and manageable, there is a strict set of governance applied to the definit
ion and use of extensions. Though any implementer can define an extension, there is a set
 of requirements that SHALL be met as part of the definition of the extension. Applicatio
ns processing a resource are required to check for modifier extensions.

Modifier extensions SHALL NOT change the meaning of any elements on Resource or DomainRes
ource (including cannot change the meaning of modifierExtension itself)."/>
          <comment
                   value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
          <requirements
                       value="Modifier extensions allow for extensions that *cannot* be safe
ly ignored to be clearly distinguished from the vast majority of extensions which can be
safely ignored.  This promotes interoperability by eliminating the need for implementers
to prohibit the presence of extensions. For further information, see the [definition of m
```

```
odifier extensions](http://build.fhir.org/extensibility.html#modifierExtension)."/>
      <alias value="extensions"/>
      <alias value="user content"/>
      <alias value="modifiers"/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="BackboneElement.modifierExtension"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Extension"/>
      </type>
      <isModifier value="true"/>
      <isModifierReason
                        value="Modifier extensions are expected to modify the meaning or
interpretation of the element that contains them"/>
      <isSummary value="true"/>
      <mapping>
        <identity value="rim"/>
        <map value="N/A"/>
      </mapping>
    </element>
    <element id="PlanDefinition.action.action.prefix">
      <path value="PlanDefinition.action.action.prefix"/>
      <short value="User-visible prefix for the action (e.g. 1. or A.)"/>
      <definition value="A user-visible prefix for the action."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="PlanDefinition.action.prefix"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="string"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="PlanDefinition.action.action.title">
      <path value="PlanDefinition.action.action.title"/>
      <short value="Stage name"/>
      <definition
                value="A textual description and/or a number that identifies a level wi
thin a sequential test. [Source: SME Defined] Examples – Single Stage, Stage 1, Stage 2 (
sometimes referred to as L1, L2 L3 or A1, A2 as in USP &lt;711&gt;) Note: A Stage may or
may not provide a conditional sequence with associated acceptance criteria. [Source: SME
Defined] (e.g., dissolution test, pyrogen test -USP &lt;151&gt;; 21 CFR 610.13(b) Test fo
r pyrogenic substances)."/>
      <min value="1"/>
      <max value="1"/>
      <base>
        <path value="PlanDefinition.action.title"/>
        <min value="0"/>
        <max value="1"/>
```

```xml
        </base>
        <type>
          <code value="string"/>
        </type>
        <mustSupport value="true"/>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="workflow"/>
          <map value="Definition.title"/>
        </mapping>
      </element>
      <element id="PlanDefinition.action.action.description">
        <path value="PlanDefinition.action.action.description"/>
        <short value="Brief description of the action"/>
        <definition
                   value="A brief description of the action used to provide a summary to d
isplay to the user."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="PlanDefinition.action.description"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="string"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="workflow"/>
          <map value="Definition.description"/>
        </mapping>
      </element>
      <element id="PlanDefinition.action.action.textEquivalent">
        <path value="PlanDefinition.action.action.textEquivalent"/>
        <short
              value="Static text equivalent of the action, used if the dynamic aspects can
not be interpreted by the receiving system"/>
        <definition
                   value="A text equivalent of the action to be performed. This provides a
 human-interpretable description of the action when the definition is consumed by a syste
m that might not be capable of interpreting it dynamically."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="PlanDefinition.action.textEquivalent"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="string"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
```

```
          <identity value="workflow"/>
          <map value="Definition.description"/>
        </mapping>
      </element>
      <element id="PlanDefinition.action.action.priority">
        <path value="PlanDefinition.action.action.priority"/>
        <short value="routine | urgent | asap | stat"/>
        <definition
                    value="Indicates how quickly the action should be addressed with respec
t to other actions."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="PlanDefinition.action.priority"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="code"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <binding>
          <extension
                      url="http://hl7.org/fhir/StructureDefinition/elementdefinition-binding
Name">
            <valueString value="RequestPriority"/>
          </extension>
          <strength value="required"/>
          <description
                        value="Identifies the level of importance to be assigned to actionin
g the request."/>
          <valueSet value="http://hl7.org/fhir/ValueSet/request-priority|4.0.0"/>
        </binding>
      </element>
      <element id="PlanDefinition.action.action.code">
        <path value="PlanDefinition.action.action.code"/>
        <short value="Code representing the meaning of the action or sub-actions"/>
        <definition
                    value="A code that provides meaning for the action or action group. For
 example, a section may have a LOINC code for the section of a documentation template."/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="PlanDefinition.action.code"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="CodeableConcept"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="PlanDefinition.action.action.reason">
        <path value="PlanDefinition.action.action.reason"/>
        <short value="Why the action should be performed"/>
```

```xml
      <definition
                value="A description of why this action is necessary or appropriate."/>
      <comment
              value="This is different than the clinical evidence documentation, it&#39;
s an actual business description of the reason for performing the action."/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="PlanDefinition.action.reason"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="CodeableConcept"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="PlanDefinition.action.action.documentation">
      <path value="PlanDefinition.action.action.documentation"/>
      <short
            value="Supporting documentation for the intended performer of the action"/>
      <definition
                value="Didactic or other informational resources associated with the ac
tion that can be provided to the CDS recipient. Information resources can include inline
text commentary and links to web resources."/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="PlanDefinition.action.documentation"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="RelatedArtifact"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="PlanDefinition.action.action.goalId">
      <path value="PlanDefinition.action.action.goalId"/>
      <short value="Acceptance criteria"/>
      <definition
                value="Identifies goals that this action supports. The reference must b
e to a goal element defined within this plan definition."/>
      <min value="1"/>
      <max value="*"/>
      <base>
        <path value="PlanDefinition.action.goalId"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="id"/>
      </type>
      <mustSupport value="true"/>
      <isModifier value="false"/>
```

```xml
      <isSummary value="false"/>
    </element>
    <element id="PlanDefinition.action.action.subject[x]">
      <path value="PlanDefinition.action.action.subject[x]"/>
      <short value="Type of individual the action is focused on"/>
      <definition
                 value="A code or group definition that describes the intended subject o
f the action and its children, if any."/>
      <comment
              value="The subject of an action overrides the subject at a parent action o
r on the root of the PlanDefinition if specified.

In addition, because the subject needs to be resolved during realization, use of subjects
 in actions (or in the ActivityDefinition referenced by the action) resolves based on the
 set of subjects supplied in context and by type (i.e. the patient subject would resolve
to a resource of type Patient)."/>
      <requirements
                   value="Multiple steps in a protocol often have different groups of st
eps that are focused on testing different things. The subject of an action specifies the
focus of the action and any child actions."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="PlanDefinition.action.subject[x]"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="CodeableConcept"/>
      </type>
      <type>
        <code value="Reference"/>
        <targetProfile value="http://hl7.org/fhir/StructureDefinition/Group"/>
      </type>
      <meaningWhenMissing value="Patient"/>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <binding>
        <extension
                  url="http://hl7.org/fhir/StructureDefinition/elementdefinition-binding
Name">
          <valueString value="SubjectType"/>
        </extension>
        <strength value="extensible"/>
        <description
                    value="The possible types of subjects for a plan definition (E.g. Pa
tient, Practitioner, Organization, Location, etc.)."/>
        <valueSet value="http://hl7.org/fhir/ValueSet/subject-type"/>
      </binding>
      <mapping>
        <identity value="workflow"/>
        <map value="Definition.subject"/>
      </mapping>
    </element>
    <element id="PlanDefinition.action.action.trigger">
      <path value="PlanDefinition.action.action.trigger"/>
      <short value="When the action should be triggered"/>
```

```
        <definition value="A description of when the action should be triggered."/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="PlanDefinition.action.trigger"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="TriggerDefinition"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="PlanDefinition.action.action.condition">
        <path value="PlanDefinition.action.action.condition"/>
        <short value="Whether or not the action is applicable"/>
        <definition
                   value="An expression that describes applicability criteria or start/sto
p conditions for the action."/>
        <comment
                  value="When multiple conditions of the same kind are present, the effects
are combined using AND semantics, so the overall condition is true only if all the condit
ions are true."/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="PlanDefinition.action.condition"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="BackboneElement"/>
        </type>
        <constraint>
          <key value="ele-1"/>
          <severity value="error"/>
          <human value="All FHIR elements must have a @value or children"/>
          <expression value="hasValue() or (children().count() &gt; id.count())"/>
          <xpath value="@value|f:*|h:div"/>
          <source value="Element"/>
        </constraint>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="PlanDefinition.action.action.condition.id">
        <path value="PlanDefinition.action.action.condition.id"/>
        <representation value="xmlAttr"/>
        <short value="Unique id for inter-element referencing"/>
        <definition
                   value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Element.id"/>
          <min value="0"/>
```

```xml
          <max value="1"/>
        </base>
        <type>
          <code value="string"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="PlanDefinition.action.action.condition.extension">
        <path value="PlanDefinition.action.action.condition.extension"/>
        <short value="Additional content defined by implementations"/>
        <definition
                   value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
        <comment
                 value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
        <alias value="extensions"/>
        <alias value="user content"/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="Element.extension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="PlanDefinition.action.action.condition.modifierExtension">
        <path value="PlanDefinition.action.action.condition.modifierExtension"/>
        <short value="Extensions that cannot be ignored even if unrecognized"/>
        <definition
                   value="May be used to represent additional information that is not part
 of the basic definition of the element and that modifies the understanding of the elemen
t in which it is contained and/or the understanding of the containing element&#39;s desce
ndants. Usually modifier elements provide negation or qualification. To make the use of e
xtensions safe and manageable, there is a strict set of governance applied to the definit
ion and use of extensions. Though any implementer can define an extension, there is a set
 of requirements that SHALL be met as part of the definition of the extension. Applicatio
ns processing a resource are required to check for modifier extensions.
```

```
Modifier extensions SHALL NOT change the meaning of any elements on Resource or DomainRes
ource (including cannot change the meaning of modifierExtension itself)."/>
      <comment
              value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
      <requirements
                   value="Modifier extensions allow for extensions that *cannot* be safe
ly ignored to be clearly distinguished from the vast majority of extensions which can be
safely ignored.  This promotes interoperability by eliminating the need for implementers
to prohibit the presence of extensions. For further information, see the [definition of m
odifier extensions](http://build.fhir.org/extensibility.html#modifierExtension)."/>
      <alias value="extensions"/>
      <alias value="user content"/>
      <alias value="modifiers"/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="BackboneElement.modifierExtension"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Extension"/>
      </type>
      <isModifier value="true"/>
      <isModifierReason
                       value="Modifier extensions are expected to modify the meaning or
interpretation of the element that contains them"/>
      <isSummary value="true"/>
      <mapping>
        <identity value="rim"/>
        <map value="N/A"/>
      </mapping>
    </element>
    <element id="PlanDefinition.action.action.condition.kind">
      <path value="PlanDefinition.action.action.condition.kind"/>
      <short value="applicability | start | stop"/>
      <definition value="The kind of condition."/>
      <comment
              value="Applicability criteria are used to determine immediate applicabilit
y when a plan definition is applied to a given context. Start and stop criteria are carri
ed through application and used to describe enter/exit criteria for an action."/>
      <min value="1"/>
      <max value="1"/>
      <base>
        <path value="PlanDefinition.action.condition.kind"/>
        <min value="1"/>
        <max value="1"/>
      </base>
      <type>
        <code value="code"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
```

```xml
        <binding>
          <extension
                    url="http://hl7.org/fhir/StructureDefinition/elementdefinition-binding
Name">
            <valueString value="ActionConditionKind"/>
          </extension>
          <strength value="required"/>
          <description
                      value="Defines the kinds of conditions that can appear on actions."/
>
          <valueSet
                    value="http://hl7.org/fhir/ValueSet/action-condition-kind|4.0.0"/>
        </binding>
      </element>
      <element id="PlanDefinition.action.action.condition.expression">
        <path value="PlanDefinition.action.action.condition.expression"/>
        <short value="Boolean-valued expression"/>
        <definition
                    value="An expression that returns true or false, indicating whether the
 condition is satisfied."/>
        <comment
                  value="The expression may be inlined or may be a reference to a named expr
ession within a logic library referenced by the library element."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="PlanDefinition.action.condition.expression"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="Expression"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="PlanDefinition.action.action.input">
        <path value="PlanDefinition.action.action.input"/>
        <short value="Input data requirements"/>
        <definition value="Defines input data requirements for the action."/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="PlanDefinition.action.input"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="DataRequirement"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="PlanDefinition.action.action.output">
        <path value="PlanDefinition.action.action.output"/>
        <short value="Output data definition"/>
        <definition value="Defines the outputs of the action, if any."/>
```

```
            <min value="0"/>
            <max value="*"/>
            <base>
              <path value="PlanDefinition.action.output"/>
              <min value="0"/>
              <max value="*"/>
            </base>
            <type>
              <code value="DataRequirement"/>
            </type>
            <isModifier value="false"/>
            <isSummary value="false"/>
          </element>
          <element id="PlanDefinition.action.action.relatedAction">
            <path value="PlanDefinition.action.action.relatedAction"/>
            <short value="Indicates relative sequence"/>
            <definition
                    value="The order of the stages in regular succession. [Source: SME Defi
ned] Examples: 1, 2, 3, etc.  This is not a direct mapping in FHIR."/>
            <comment
                  value="When an action depends on multiple actions, the meaning is that all
 actions are dependencies, rather than that any of the actions are a dependency."/>
            <min value="0"/>
            <max value="1"/>
            <base>
              <path value="PlanDefinition.action.relatedAction"/>
              <min value="0"/>
              <max value="*"/>
            </base>
            <type>
              <code value="BackboneElement"/>
            </type>
            <constraint>
              <key value="ele-1"/>
              <severity value="error"/>
              <human value="All FHIR elements must have a @value or children"/>
              <expression value="hasValue() or (children().count() &gt; id.count())"/>
              <xpath value="@value|f:*|h:div"/>
              <source value="Element"/>
            </constraint>
            <mustSupport value="true"/>
            <isModifier value="false"/>
            <isSummary value="false"/>
          </element>
          <element id="PlanDefinition.action.action.relatedAction.id">
            <path value="PlanDefinition.action.action.relatedAction.id"/>
            <representation value="xmlAttr"/>
            <short value="Unique id for inter-element referencing"/>
            <definition
                    value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
            <min value="0"/>
            <max value="1"/>
            <base>
              <path value="Element.id"/>
              <min value="0"/>
              <max value="1"/>
```

```
        </base>
        <type>
          <code value="string"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="PlanDefinition.action.action.relatedAction.extension">
        <path value="PlanDefinition.action.action.relatedAction.extension"/>
        <short value="Additional content defined by implementations"/>
        <definition
                    value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
        <comment
                value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
        <alias value="extensions"/>
        <alias value="user content"/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="Element.extension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="PlanDefinition.action.action.relatedAction.modifierExtension">
        <path value="PlanDefinition.action.action.relatedAction.modifierExtension"/>
        <short value="Extensions that cannot be ignored even if unrecognized"/>
        <definition
                    value="May be used to represent additional information that is not part
 of the basic definition of the element and that modifies the understanding of the elemen
t in which it is contained and/or the understanding of the containing element&#39;s desce
ndants. Usually modifier elements provide negation or qualification. To make the use of e
xtensions safe and manageable, there is a strict set of governance applied to the definit
ion and use of extensions. Though any implementer can define an extension, there is a set
 of requirements that SHALL be met as part of the definition of the extension. Applicatio
ns processing a resource are required to check for modifier extensions.
```

```
Modifier extensions SHALL NOT change the meaning of any elements on Resource or DomainRes
ource (including cannot change the meaning of modifierExtension itself)."/>
      <comment
             value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
      <requirements
                    value="Modifier extensions allow for extensions that *cannot* be safe
ly ignored to be clearly distinguished from the vast majority of extensions which can be
safely ignored.  This promotes interoperability by eliminating the need for implementers
to prohibit the presence of extensions. For further information, see the [definition of m
odifier extensions](http://build.fhir.org/extensibility.html#modifierExtension)."/>
      <alias value="extensions"/>
      <alias value="user content"/>
      <alias value="modifiers"/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="BackboneElement.modifierExtension"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Extension"/>
      </type>
      <isModifier value="true"/>
      <isModifierReason
                         value="Modifier extensions are expected to modify the meaning or
interpretation of the element that contains them"/>
      <isSummary value="true"/>
      <mapping>
        <identity value="rim"/>
        <map value="N/A"/>
      </mapping>
    </element>
    <element id="PlanDefinition.action.action.relatedAction.actionId">
      <path value="PlanDefinition.action.action.relatedAction.actionId"/>
      <short value="GUID identifer for related stage"/>
      <definition value="The identifier of the previous stage."/>
      <min value="1"/>
      <max value="1"/>
      <base>
        <path value="PlanDefinition.action.relatedAction.actionId"/>
        <min value="1"/>
        <max value="1"/>
      </base>
      <type>
        <code value="id"/>
      </type>
      <mustSupport value="true"/>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="PlanDefinition.action.action.relatedAction.relationship">
      <path value="PlanDefinition.action.action.relatedAction.relationship"/>
      <short value="Sequence reference"/>
```

```
        <definition value="The relationship of this action to the related action."/>
        <min value="1"/>
        <max value="1"/>
        <base>
          <path value="PlanDefinition.action.relatedAction.relationship"/>
          <min value="1"/>
          <max value="1"/>
        </base>
        <type>
          <code value="code"/>
        </type>
        <mustSupport value="true"/>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <binding>
          <extension
                    url="http://hl7.org/fhir/StructureDefinition/elementdefinition-binding
Name">
            <valueString value="ActionRelationshipType"/>
          </extension>
          <strength value="required"/>
          <description value="Defines the types of relationships between actions."/>
          <valueSet
                    value="http://hl7.org/fhir/ValueSet/action-relationship-type|4.0.0"/>
        </binding>
      </element>
      <element id="PlanDefinition.action.action.relatedAction.offset[x]">
        <path value="PlanDefinition.action.action.relatedAction.offset[x]"/>
        <short value="Time offset for the relationship"/>
        <definition
                    value="A duration or range of durations to apply to the relationship. F
or example, 30-60 minutes before."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="PlanDefinition.action.relatedAction.offset[x]"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="Duration"/>
        </type>
        <type>
          <code value="Range"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="PlanDefinition.action.action.timing[x]">
        <path value="PlanDefinition.action.action.timing[x]"/>
        <short value="When the action should take place"/>
        <definition
                    value="An optional value describing when the action should be performed
."/>
        <min value="0"/>
        <max value="1"/>
        <base>
```

```xml
        <path value="PlanDefinition.action.timing[x]"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="dateTime"/>
      </type>
      <type>
        <code value="Age"/>
      </type>
      <type>
        <code value="Period"/>
      </type>
      <type>
        <code value="Duration"/>
      </type>
      <type>
        <code value="Range"/>
      </type>
      <type>
        <code value="Timing"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="PlanDefinition.action.action.participant">
      <path value="PlanDefinition.action.action.participant"/>
      <short value="Who should participate in the action"/>
      <definition
                value="Indicates who should participate in performing the action descri
bed."/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="PlanDefinition.action.participant"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="BackboneElement"/>
      </type>
      <constraint>
        <key value="ele-1"/>
        <severity value="error"/>
        <human value="All FHIR elements must have a @value or children"/>
        <expression value="hasValue() or (children().count() &gt; id.count())"/>
        <xpath value="@value|f:*|h:div"/>
        <source value="Element"/>
      </constraint>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="PlanDefinition.action.action.participant.id">
      <path value="PlanDefinition.action.action.participant.id"/>
      <representation value="xmlAttr"/>
      <short value="Unique id for inter-element referencing"/>
      <definition
```

```
                                  value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Element.id"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="string"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="PlanDefinition.action.action.participant.extension">
        <path value="PlanDefinition.action.action.participant.extension"/>
        <short value="Additional content defined by implementations"/>
        <definition
                    value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
        <comment
                value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
        <alias value="extensions"/>
        <alias value="user content"/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="Element.extension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="PlanDefinition.action.action.participant.modifierExtension">
        <path value="PlanDefinition.action.action.participant.modifierExtension"/>
        <short value="Extensions that cannot be ignored even if unrecognized"/>
        <definition
                    value="May be used to represent additional information that is not part
```

 of the basic definition of the element and that modifies the understanding of the elemen
t in which it is contained and/or the understanding of the containing element's desce
ndants. Usually modifier elements provide negation or qualification. To make the use of e
xtensions safe and manageable, there is a strict set of governance applied to the definit
ion and use of extensions. Though any implementer can define an extension, there is a set
 of requirements that SHALL be met as part of the definition of the extension. Applicatio
ns processing a resource are required to check for modifier extensions.

Modifier extensions SHALL NOT change the meaning of any elements on Resource or DomainRes
ource (including cannot change the meaning of modifierExtension itself)."/>
      <comment
               value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions. The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
      <requirements
                    value="Modifier extensions allow for extensions that *cannot* be safe
ly ignored to be clearly distinguished from the vast majority of extensions which can be
safely ignored. This promotes interoperability by eliminating the need for implementers
to prohibit the presence of extensions. For further information, see the [definition of m
odifier extensions](http://build.fhir.org/extensibility.html#modifierExtension)."/>
      <alias value="extensions"/>
      <alias value="user content"/>
      <alias value="modifiers"/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="BackboneElement.modifierExtension"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Extension"/>
      </type>
      <isModifier value="true"/>
      <isModifierReason
                       value="Modifier extensions are expected to modify the meaning or
interpretation of the element that contains them"/>
      <isSummary value="true"/>
      <mapping>
        <identity value="rim"/>
        <map value="N/A"/>
      </mapping>
    </element>
    <element id="PlanDefinition.action.action.participant.type">
      <path value="PlanDefinition.action.action.participant.type"/>
      <short value="patient | practitioner | related-person | device"/>
      <definition value="The type of participant in the action."/>
      <min value="1"/>
      <max value="1"/>
      <base>
        <path value="PlanDefinition.action.participant.type"/>
        <min value="1"/>
        <max value="1"/>
      </base>
      <type>
        <code value="code"/>

```xml
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <binding>
          <extension
                    url="http://hl7.org/fhir/StructureDefinition/elementdefinition-binding
Name">
            <valueString value="ActionParticipantType"/>
          </extension>
          <strength value="required"/>
          <description value="The type of participant for the action."/>
          <valueSet
                    value="http://hl7.org/fhir/ValueSet/action-participant-type|4.0.0"/>
        </binding>
      </element>
      <element id="PlanDefinition.action.action.participant.role">
        <path value="PlanDefinition.action.action.participant.role"/>
        <short value="E.g. Nurse, Surgeon, Parent"/>
        <definition
                    value="The role the participant should play in performing the described
 action."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="PlanDefinition.action.participant.role"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="CodeableConcept"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <binding>
          <extension
                    url="http://hl7.org/fhir/StructureDefinition/elementdefinition-binding
Name">
            <valueString value="ActionParticipantRole"/>
          </extension>
          <strength value="example"/>
          <description
                     value="Defines roles played by participants for the action."/>
          <valueSet value="http://hl7.org/fhir/ValueSet/action-participant-role"/>
        </binding>
      </element>
      <element id="PlanDefinition.action.action.type">
        <path value="PlanDefinition.action.action.type"/>
        <short value="create | update | remove | fire-event"/>
        <definition
                    value="The type of action to perform (create, update, remove)."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="PlanDefinition.action.type"/>
          <min value="0"/>
          <max value="1"/>
        </base>
```

```
        <type>
          <code value="CodeableConcept"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <binding>
          <extension
                   url="http://hl7.org/fhir/StructureDefinition/elementdefinition-binding
Name">
            <valueString value="ActionType"/>
          </extension>
          <strength value="extensible"/>
          <description value="The type of action to be performed."/>
          <valueSet value="http://hl7.org/fhir/ValueSet/action-type"/>
        </binding>
      </element>
      <element id="PlanDefinition.action.action.groupingBehavior">
        <path value="PlanDefinition.action.action.groupingBehavior"/>
        <short value="visual-group | logical-group | sentence-group"/>
        <definition
                   value="Defines the grouping behavior for the action and its children."/
>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="PlanDefinition.action.groupingBehavior"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="code"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <binding>
          <extension
                   url="http://hl7.org/fhir/StructureDefinition/elementdefinition-binding
Name">
            <valueString value="ActionGroupingBehavior"/>
          </extension>
          <strength value="required"/>
          <description value="Defines organization behavior of a group."/>
          <valueSet
                   value="http://hl7.org/fhir/ValueSet/action-grouping-behavior|4.0.0"/>
        </binding>
      </element>
      <element id="PlanDefinition.action.action.selectionBehavior">
        <path value="PlanDefinition.action.action.selectionBehavior"/>
        <short
              value="any | all | all-or-none | exactly-one | at-most-one | one-or-more"/>
        <definition
                   value="Defines the selection behavior for the action and its children."
/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="PlanDefinition.action.selectionBehavior"/>
```

```xml
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="code"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <binding>
          <extension
                    url="http://hl7.org/fhir/StructureDefinition/elementdefinition-binding
Name">
            <valueString value="ActionSelectionBehavior"/>
          </extension>
          <strength value="required"/>
          <description value="Defines selection behavior of a group."/>
          <valueSet
                    value="http://hl7.org/fhir/ValueSet/action-selection-behavior|4.0.0"/>
        </binding>
      </element>
      <element id="PlanDefinition.action.action.requiredBehavior">
        <path value="PlanDefinition.action.action.requiredBehavior"/>
        <short value="must | could | must-unless-documented"/>
        <definition value="Defines the required behavior for the action."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="PlanDefinition.action.requiredBehavior"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="code"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <binding>
          <extension
                    url="http://hl7.org/fhir/StructureDefinition/elementdefinition-binding
Name">
            <valueString value="ActionRequiredBehavior"/>
          </extension>
          <strength value="required"/>
          <description
                      value="Defines expectations around whether an action or action group
 is required."/>
          <valueSet
                    value="http://hl7.org/fhir/ValueSet/action-required-behavior|4.0.0"/>
        </binding>
      </element>
      <element id="PlanDefinition.action.action.precheckBehavior">
        <path value="PlanDefinition.action.action.precheckBehavior"/>
        <short value="yes | no"/>
        <definition
                    value="Defines whether the action should usually be preselected."/>
        <min value="0"/>
        <max value="1"/>
```

```xml
      <base>
        <path value="PlanDefinition.action.precheckBehavior"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="code"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <binding>
        <extension
                 url="http://hl7.org/fhir/StructureDefinition/elementdefinition-binding
Name">
           <valueString value="ActionPrecheckBehavior"/>
        </extension>
        <strength value="required"/>
        <description
                    value="Defines selection frequency behavior for an action or group."
/>
        <valueSet
                 value="http://hl7.org/fhir/ValueSet/action-precheck-behavior|4.0.0"/>
      </binding>
    </element>
    <element id="PlanDefinition.action.action.cardinalityBehavior">
      <path value="PlanDefinition.action.action.cardinalityBehavior"/>
      <short value="single | multiple"/>
      <definition
                 value="Defines whether the action can be selected multiple times."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="PlanDefinition.action.cardinalityBehavior"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="code"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <binding>
        <extension
                 url="http://hl7.org/fhir/StructureDefinition/elementdefinition-binding
Name">
           <valueString value="ActionCardinalityBehavior"/>
        </extension>
        <strength value="required"/>
        <description
                    value="Defines behavior for an action or a group for how many times
that item may be repeated."/>
        <valueSet
                 value="http://hl7.org/fhir/ValueSet/action-cardinality-behavior|4.0.0"/
>
      </binding>
    </element>
    <element id="PlanDefinition.action.action.definition[x]">
```

```
    <path value="PlanDefinition.action.action.definition[x]"/>
    <short value="Description of the activity to be performed"/>
    <definition
               value="A reference to an ActivityDefinition that describes the action t
o be taken in detail, or a PlanDefinition that describes a series of actions to be taken.
"/>
    <comment
             value="Note that the definition is optional, and if no definition is speci
fied, a dynamicValue with a root ($this) path can be used to define the entire resource d
ynamically."/>
    <min value="0"/>
    <max value="1"/>
    <base>
      <path value="PlanDefinition.action.definition[x]"/>
      <min value="0"/>
      <max value="1"/>
    </base>
    <type>
      <code value="canonical"/>
      <targetProfile
                     value="http://hl7.org/fhir/StructureDefinition/ActivityDefinition"
/>
      <targetProfile
                     value="http://hl7.org/fhir/StructureDefinition/PlanDefinition"/>
      <targetProfile
                     value="http://hl7.org/fhir/StructureDefinition/Questionnaire"/>
    </type>
    <type>
      <code value="uri"/>
    </type>
    <isModifier value="false"/>
    <isSummary value="false"/>
    <mapping>
      <identity value="workflow"/>
      <map value="Definition.derivedFrom"/>
    </mapping>
  </element>
  <element id="PlanDefinition.action.action.transform">
    <path value="PlanDefinition.action.action.transform"/>
    <short value="Transform to apply the template"/>
    <definition
               value="A reference to a StructureMap resource that defines a transform
that can be executed to produce the intent resource using the ActivityDefinition instance
 as the input."/>
    <comment
             value="Note that when a referenced ActivityDefinition also defines a trans
form, the transform specified here generally takes precedence. In addition, if both a tra
nsform and dynamic values are specific, the dynamic values are applied to the result of t
he transform."/>
    <min value="0"/>
    <max value="1"/>
    <base>
      <path value="PlanDefinition.action.transform"/>
      <min value="0"/>
      <max value="1"/>
    </base>
    <type>
```

```xml
            <code value="canonical"/>
            <targetProfile
                        value="http://hl7.org/fhir/StructureDefinition/StructureMap"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="PlanDefinition.action.action.dynamicValue">
        <path value="PlanDefinition.action.action.dynamicValue"/>
        <short value="Dynamic aspects of the definition"/>
        <definition
                    value="Customizations that should be applied to the statically defined
resource. For example, if the dosage of a medication must be computed based on the patien
t&#39;s weight, a customization would be used to specify an expression that calculated th
e weight, and the path on the resource that would contain the result."/>
        <comment
                value="Dynamic values are applied in the order in which they are defined i
n the PlanDefinition resource. Note that when dynamic values are also specified by a refe
renced ActivityDefinition, the dynamicValues from the ActivityDefinition are applied firs
t, followed by the dynamicValues specified here. In addition, if both a transform and dyn
amic values are specific, the dynamic values are applied to the result of the transform."
/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="PlanDefinition.action.dynamicValue"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="BackboneElement"/>
        </type>
        <constraint>
          <key value="ele-1"/>
          <severity value="error"/>
          <human value="All FHIR elements must have a @value or children"/>
          <expression value="hasValue() or (children().count() &gt; id.count())"/>
          <xpath value="@value|f:*|h:div"/>
          <source value="Element"/>
        </constraint>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="PlanDefinition.action.action.dynamicValue.id">
        <path value="PlanDefinition.action.action.dynamicValue.id"/>
        <representation value="xmlAttr"/>
        <short value="Unique id for inter-element referencing"/>
        <definition
                    value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Element.id"/>
          <min value="0"/>
          <max value="1"/>
        </base>
```

```xml
        <type>
          <code value="string"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="PlanDefinition.action.action.dynamicValue.extension">
        <path value="PlanDefinition.action.action.dynamicValue.extension"/>
        <short value="Additional content defined by implementations"/>
        <definition
                    value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
        <comment
                value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
        <alias value="extensions"/>
        <alias value="user content"/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="Element.extension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="PlanDefinition.action.action.dynamicValue.modifierExtension">
        <path value="PlanDefinition.action.action.dynamicValue.modifierExtension"/>
        <short value="Extensions that cannot be ignored even if unrecognized"/>
        <definition
                    value="May be used to represent additional information that is not part
 of the basic definition of the element and that modifies the understanding of the elemen
t in which it is contained and/or the understanding of the containing element&#39;s desce
ndants. Usually modifier elements provide negation or qualification. To make the use of e
xtensions safe and manageable, there is a strict set of governance applied to the definit
ion and use of extensions. Though any implementer can define an extension, there is a set
 of requirements that SHALL be met as part of the definition of the extension. Applicatio
ns processing a resource are required to check for modifier extensions.

Modifier extensions SHALL NOT change the meaning of any elements on Resource or DomainRes
```

```
ource (including cannot change the meaning of modifierExtension itself)."/>
        <comment
                value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
        <requirements
                    value="Modifier extensions allow for extensions that *cannot* be safe
ly ignored to be clearly distinguished from the vast majority of extensions which can be
safely ignored.  This promotes interoperability by eliminating the need for implementers
to prohibit the presence of extensions. For further information, see the [definition of m
odifier extensions](http://build.fhir.org/extensibility.html#modifierExtension)."/>
        <alias value="extensions"/>
        <alias value="user content"/>
        <alias value="modifiers"/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="BackboneElement.modifierExtension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
        </type>
        <isModifier value="true"/>
        <isModifierReason
                        value="Modifier extensions are expected to modify the meaning or
interpretation of the element that contains them"/>
        <isSummary value="true"/>
        <mapping>
          <identity value="rim"/>
          <map value="N/A"/>
        </mapping>
      </element>
      <element id="PlanDefinition.action.action.dynamicValue.path">
        <path value="PlanDefinition.action.action.dynamicValue.path"/>
        <short value="The path to the element to be set dynamically"/>
        <definition
                  value="The path to the element to be customized. This is the path on th
e resource that will hold the result of the calculation defined by the expression. The sp
ecified path SHALL be a FHIRPath resolveable on the specified target type of the Activity
Definition, and SHALL consist only of identifiers, constant indexers, and a restricted su
bset of functions. The path is allowed to contain qualifiers (.) to traverse sub-elements
, as well as indexers ([x]) to traverse multiple-cardinality sub-elements (see the [Simpl
e FHIRPath Profile](http://build.fhir.org/fhirpath.html#simple) for full details)."/>
        <comment
                value="To specify the path to the current action being realized, the %acti
on environment variable is available in this path. For example, to specify the descriptio
n element of the target action, the path would be %action.description. The path attribute
 contains a [Simple FHIRPath Subset](http://build.fhir.org/fhirpath.html#simple) that all
ows path traversal, but not calculation."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="PlanDefinition.action.dynamicValue.path"/>
          <min value="0"/>
```

```xml
          <max value="1"/>
        </base>
        <type>
          <code value="string"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="PlanDefinition.action.action.dynamicValue.expression">
        <path value="PlanDefinition.action.action.dynamicValue.expression"/>
        <short
              value="An expression that provides the dynamic value for the customization"/
>
        <definition
                    value="An expression specifying the value of the customized element."/>
        <comment
                  value="The expression may be inlined or may be a reference to a named expr
ession within a logic library referenced by the library element."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="PlanDefinition.action.dynamicValue.expression"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="Expression"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="PlanDefinition.action.action.action">
        <path value="PlanDefinition.action.action.action"/>
        <short value="A sub-action"/>
        <definition
                    value="Sub actions that are contained within the action. The behavior o
f this action determines the functionality of the sub-actions. For example, a selection b
ehavior of at-most-one indicates that of the sub-actions, at most one may be chosen as pa
rt of realizing the action definition."/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="PlanDefinition.action.action"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <contentReference value="#PlanDefinition.action"/>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="workflow"/>
          <map value="{InverseRelationship of Definition.partOf}"/>
        </mapping>
      </element>
    </snapshot>
    <differential>
      <element id="PlanDefinition">
```

```
      <path value="PlanDefinition"/>
      <short value="Quality Specification"/>
      <definition
                  value="Specification means the quality standard (i.e. , tests, analytic
al procedures, and acceptance criteria) provided in an approved application to confirm th
e quality of drug substances, drug products, intermediates, raw materials, reagents, comp
onents, in-process materials, container closure systems, and other materials used in the
production of a drug substance or drug product. For the purpose of this definition, accep
tance criteria means numerical limits, ranges, or other criteria for the tests described.
"/>
      <mustSupport value="false"/>
      <isModifier value="false"/>
    </element>
    <element id="PlanDefinition.extension:approvalStatus">
      <path value="PlanDefinition.extension"/>
      <sliceName value="approvalStatus"/>
      <short value="Approval Status"/>
      <definition
                  value="The current FDA regulatory status of the specification. [Source:
 SME Defined] Examples: Approved, Not Approved, etc."/>
      <min value="0"/>
      <max value="1"/>
      <type>
        <code value="Extension"/>
        <profile
                  value="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-approvalSt
atus"/>
      </type>
      <mustSupport value="true"/>
      <isModifier value="false"/>
      <binding>
        <strength value="required"/>
        <description
                      value="Code indicating the current FDA regulatory status of the spec
ification"/>
        <valueSet value="http://fda.gov/cder/fhir/pqcmc/ValueSet/SpecStat|"/>
      </binding>
    </element>
    <element id="PlanDefinition.extension:approvalStatus.extension:type">
      <path value="PlanDefinition.extension.extension"/>
      <sliceName value="type"/>
      <short value="Specification Type"/>
      <definition
                  value="A classification of specification related to the kind of the ent
ity it is referencing. [Source: SME Defined]."/>
      <min value="1"/>
      <max value="1"/>
      <mustSupport value="true"/>
      <isModifier value="false"/>
    </element>
    <element id="PlanDefinition.extension:approvalStatus.extension:date">
      <path value="PlanDefinition.extension.extension"/>
      <sliceName value="date"/>
      <short value="Approval Status Date"/>
      <definition
                  value="The date on which the FDA approval status for a specification be
came effective. [Source: SME Defined] Note: If the application is not yet approved, then
```

```
this is the date of the current submission OR the date of the complete response (CR)."/>
      <min value="1"/>
      <max value="1"/>
      <mustSupport value="true"/>
      <isModifier value="false"/>
    </element>
    <element id="PlanDefinition.version">
      <path value="PlanDefinition.version"/>
      <short value="Quality Specification Version"/>
      <definition
                  value="The alphanumeric text assigned by the sponsor to a particular ed
ition of a specification. [Source: SME Defined] Examples: 2.1, 13.2, ST1, 00001, 00002, &
lt;companyname&gt;001, etc."/>
      <min value="1"/>
      <max value="1"/>
      <mustSupport value="true"/>
      <isModifier value="false"/>
    </element>
    <element id="PlanDefinition.title">
      <path value="PlanDefinition.title"/>
      <short value="Quality Specification Title"/>
      <definition
                  value="The textual identification for the specification. [Source: SME D
efined] Example: &lt;drug name&gt; 75 mg chewable tablets Note: This may include the name
 of the drug substance, product or the raw material/excipients."/>
      <min value="1"/>
      <max value="1"/>
      <mustSupport value="true"/>
      <isModifier value="false"/>
    </element>
    <element id="PlanDefinition.status">
      <path value="PlanDefinition.status"/>
      <min value="1"/>
      <max value="1"/>
      <type>
        <code value="code"/>
      </type>
      <fixedCode value="active"/>
      <mustSupport value="true"/>
      <isModifier value="false"/>
    </element>
    <element id="PlanDefinition.subjectReference">
      <path value="PlanDefinition.subjectReference"/>
      <short value="Tested Product or Substance"/>
      <definition
                  value="A classification of specification related to the kind of the ent
ity it is referencing. [Source: SME Defined]."/>
      <min value="1"/>
      <max value="1"/>
      <type>
        <code value="Reference"/>
        <targetProfile
                       value="http://hl7.org/fhir/StructureDefinition/MedicationKnowledge
"/>
        <targetProfile value="http://hl7.org/fhir/StructureDefinition/Substance"/>
      </type>
      <mustSupport value="true"/>
```

```xml
          <isModifier value="false"/>
        </element>
        <element id="PlanDefinition.date">
          <path value="PlanDefinition.date"/>
          <short value="Version Date"/>
          <definition
                  value="The date when the sponsor assigned a date to a specific version.
 [Source: SME Defined]."/>
          <min value="1"/>
          <max value="1"/>
          <mustSupport value="true"/>
          <isModifier value="false"/>
        </element>
        <element id="PlanDefinition.usage">
          <path value="PlanDefinition.usage"/>
          <short value="Additional Information"/>
          <definition
                  value="Placeholder for providing any comments that are relevant to the
specification. [Source: SME Defined] Examples: replaces method ABC, using the XYZ facilit
y, etc."/>
          <min value="0"/>
          <max value="1"/>
          <mustSupport value="true"/>
          <isModifier value="false"/>
        </element>
        <element id="PlanDefinition.goal">
          <path value="PlanDefinition.goal"/>
          <short value="Acceptance criteria"/>
          <definition
                  value="Numerical limits, ranges, or other criteria for the tests descri
bed. [Source: 21 CFR 314.3, 514.3 and 600.3]."/>
          <min value="1"/>
          <max value="*"/>
          <mustSupport value="true"/>
          <isModifier value="false"/>
        </element>
        <element id="PlanDefinition.goal.extension:comment">
          <path value="PlanDefinition.goal.extension"/>
          <sliceName value="comment"/>
          <short value="Additional Information"/>
          <definition
                  value="acceptance criteria. [Source: SME Defined] Example: value change
d from 4% to 5% on 01/01/2010."/>
          <min value="0"/>
          <max value="1"/>
          <type>
            <code value="Extension"/>
            <profile
                  value="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-comment"/>
          </type>
          <mustSupport value="true"/>
          <isModifier value="false"/>
        </element>
        <element id="PlanDefinition.goal.description">
          <path value="PlanDefinition.goal.description"/>
          <min value="1"/>
          <max value="1"/>
```

```xml
            <mustSupport value="true"/>
            <isModifier value="false"/>
        </element>
        <element id="PlanDefinition.goal.description.text">
            <path value="PlanDefinition.goal.description.text"/>
            <short value="Literal text"/>
            <definition
                    value="The text of the acceptance criteria as provided in the specifica
tion. [Source: SME Defined]  Examples: White to off-white cake; 22.5 -27.5 mg/ml Note: Th
is is the text as it appears in the Specification."/>
            <min value="1"/>
            <max value="1"/>
            <mustSupport value="true"/>
            <isModifier value="false"/>
        </element>
        <element id="PlanDefinition.goal.target">
            <path value="PlanDefinition.goal.target"/>
            <min value="1"/>
            <max value="1"/>
            <mustSupport value="true"/>
            <isModifier value="false"/>
        </element>
        <element id="PlanDefinition.goal.target.extension:noTarget">
            <path value="PlanDefinition.goal.target.extension"/>
            <sliceName value="noTarget"/>
            <requirements
                    value="This extension is included to explicitly indicate that there i
s no target for the specific test and to disambiguate from a situation where a target may
 have been accidentally omitted."/>
            <min value="0"/>
            <max value="1"/>
            <type>
              <code value="Extension"/>
              <profile
                    value="http://hl7.org/fhir/StructureDefinition/data-absent-reason"/>
            </type>
            <mustSupport value="true"/>
            <isModifier value="false"/>
        </element>
        <element id="PlanDefinition.goal.target.extension:noTarget.valueCode">
            <path value="PlanDefinition.goal.target.extension.valueCode"/>
            <min value="1"/>
            <max value="1"/>
            <type>
              <code value="code"/>
            </type>
            <fixedCode value="not-applicable"/>
            <mustSupport value="true"/>
            <isModifier value="false"/>
        </element>
        <element id="PlanDefinition.goal.target.detail[x]">
            <path value="PlanDefinition.goal.target.detail[x]"/>
            <slicing>
              <discriminator>
                <type value="value"/>
                <path value="@Type"/>
              </discriminator>
```

```xml
          <rules value="open"/>
        </slicing>
        <alias value="Quantity"/>
        <alias value="Range"/>
        <alias value="CodeableConcept"/>
        <min value="0"/>
        <max value="1"/>
        <type>
          <code value="Quantity"/>
        </type>
        <type>
          <code value="Range"/>
        </type>
        <type>
          <code value="CodeableConcept"/>
        </type>
        <mustSupport value="true"/>
        <isModifier value="false"/>
      </element>
      <element id="PlanDefinition.goal.target.detailQuantity:Quantity">
        <path value="PlanDefinition.goal.target.detailQuantity"/>
        <sliceName value="Quantity"/>
        <min value="0"/>
        <max value="1"/>
        <type>
          <code value="Quantity"/>
        </type>
        <mustSupport value="true"/>
        <isModifier value="false"/>
      </element>
      <element id="PlanDefinition.goal.target.detailQuantity:Quantity.value">
        <path value="PlanDefinition.goal.target.detailQuantity.value"/>
        <min value="1"/>
        <max value="1"/>
        <mustSupport value="true"/>
        <isModifier value="false"/>
      </element>
      <element id="PlanDefinition.goal.target.detailQuantity:Quantity.system">
        <path value="PlanDefinition.goal.target.detailQuantity.system"/>
        <min value="1"/>
        <max value="1"/>
        <type>
          <code value="uri"/>
        </type>
        <fixedUri value="http://unitsofmeasure.org"/>
        <mustSupport value="true"/>
        <isModifier value="false"/>
      </element>
      <element id="PlanDefinition.goal.target.detailQuantity:Quantity.code">
        <path value="PlanDefinition.goal.target.detailQuantity.code"/>
        <min value="1"/>
        <max value="1"/>
        <mustSupport value="true"/>
        <isModifier value="false"/>
      </element>
      <element id="PlanDefinition.goal.target.detailRange:Range">
        <path value="PlanDefinition.goal.target.detailRange"/>
```

```xml
      <sliceName value="Range"/>
      <min value="0"/>
      <max value="1"/>
      <type>
        <code value="Range"/>
      </type>
      <mustSupport value="true"/>
      <isModifier value="false"/>
    </element>
    <element
            id="PlanDefinition.goal.target.detailRange:Range.extension:lowExclusive">
      <path value="PlanDefinition.goal.target.detailRange.extension"/>
      <sliceName value="lowExclusive"/>
      <short value="interpretationCode= GT"/>
      <definition
                  value="A code that describes how to relate the given value to an accept
ance value. [Source: SME Defined] Note: When result value is numeric there is a controlle
d vocabulary; when result value is textual the vocabulary is Pass/Fail."/>
      <min value="0"/>
      <max value="1"/>
      <type>
        <code value="Extension"/>
        <profile
                  value="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-range-lowE
xclusive"/>
      </type>
      <mustSupport value="true"/>
      <isModifier value="false"/>
    </element>
    <element
            id="PlanDefinition.goal.target.detailRange:Range.extension:lowExclusive.valu
eQuantity">
      <path
            value="PlanDefinition.goal.target.detailRange.extension.valueQuantity"/>
      <mustSupport value="false"/>
      <isModifier value="false"/>
    </element>
    <element
            id="PlanDefinition.goal.target.detailRange:Range.extension:lowExclusive.valu
eQuantity.value">
      <path
            value="PlanDefinition.goal.target.detailRange.extension.valueQuantity.value"/
>
      <short value="valueNumeric"/>
      <definition
                  value="A text or numeric value of the result of the test. [Source: SME
Defined]."/>
      <min value="1"/>
      <max value="1"/>
      <mustSupport value="true"/>
      <isModifier value="false"/>
    </element>
    <element
            id="PlanDefinition.goal.target.detailRange:Range.extension:lowExclusive.valu
eQuantity.system">
      <path
            value="PlanDefinition.goal.target.detailRange.extension.valueQuantity.system"
```

```
/>
      <short value="Unit"/>
      <definition
                  value="A named quantity in terms of which other quantities are measured
 or specified, used as a standard measurement of like kinds. [Source: NCI EVS -C25709] Ex
amples: mg, L, etc."/>
      <min value="1"/>
      <max value="1"/>
      <type>
        <code value="uri"/>
      </type>
      <fixedUri value="http://unitsofmeasure.org"/>
      <mustSupport value="true"/>
      <isModifier value="false"/>
    </element>
    <element
            id="PlanDefinition.goal.target.detailRange:Range.extension:highExclusive">
      <path value="PlanDefinition.goal.target.detailRange.extension"/>
      <sliceName value="highExclusive"/>
      <short value="interpretationCode= LT"/>
      <definition
                  value="A code that describes how to relate the given value to an accept
ance value. [Source: SME Defined] Note: When result value is numeric there is a controlle
d vocabulary; when result value is textual the vocabulary is Pass/Fail."/>
      <min value="0"/>
      <max value="1"/>
      <type>
        <code value="Extension"/>
        <profile
                value="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-range-high
Exclusive"/>
      </type>
      <mustSupport value="true"/>
      <isModifier value="false"/>
    </element>
    <element
            id="PlanDefinition.goal.target.detailRange:Range.extension:highExclusive.val
ueQuantity">
      <path
            value="PlanDefinition.goal.target.detailRange.extension.valueQuantity"/>
      <mustSupport value="false"/>
      <isModifier value="false"/>
    </element>
    <element
            id="PlanDefinition.goal.target.detailRange:Range.extension:highExclusive.val
ueQuantity.value">
      <path
            value="PlanDefinition.goal.target.detailRange.extension.valueQuantity.value"/
>
      <short value="valueNumeric"/>
      <definition
                  value="A text or numeric value of the result of the test. [Source: SME
Defined]."/>
      <min value="1"/>
      <max value="1"/>
      <mustSupport value="true"/>
      <isModifier value="false"/>
```

```xml
    </element>
    <element
            id="PlanDefinition.goal.target.detailRange:Range.extension:highExclusive.val
ueQuantity.system">
      <path
            value="PlanDefinition.goal.target.detailRange.extension.valueQuantity.system"
/>
      <short value="Unit"/>
      <definition
                value="A named quantity in terms of which other quantities are measured
 or specified, used as a standard measurement of like kinds. [Source: NCI EVS -C25709] Ex
amples: mg, L, etc."/>
      <min value="1"/>
      <max value="1"/>
      <type>
        <code value="uri"/>
      </type>
      <fixedUri value="http://unitsofmeasure.org"/>
      <mustSupport value="true"/>
      <isModifier value="false"/>
    </element>
    <element id="PlanDefinition.goal.target.detailRange:Range.low">
      <path value="PlanDefinition.goal.target.detailRange.low"/>
      <short value="interpretationCode=NLT"/>
      <definition
                value="A code that describes how to relate the given value to an accept
ance value. [Source: SME Defined] Note: When result value is numeric there is a controlle
d vocabulary; when result value is textual the vocabulary is Pass/Fail."/>
      <min value="0"/>
      <max value="1"/>
      <mustSupport value="true"/>
      <isModifier value="false"/>
    </element>
    <element id="PlanDefinition.goal.target.detailRange:Range.low.value">
      <path value="PlanDefinition.goal.target.detailRange.low.value"/>
      <short value="valueNumeric"/>
      <definition
                value="A text or numeric value of the result of the test. [Source: SME
Defined]."/>
      <min value="1"/>
      <max value="1"/>
      <mustSupport value="true"/>
      <isModifier value="false"/>
    </element>
    <element id="PlanDefinition.goal.target.detailRange:Range.low.system">
      <path value="PlanDefinition.goal.target.detailRange.low.system"/>
      <min value="1"/>
      <max value="1"/>
      <type>
        <code value="uri"/>
      </type>
      <fixedUri value="http://unitsofmeasure.org"/>
      <mustSupport value="true"/>
      <isModifier value="false"/>
    </element>
    <element id="PlanDefinition.goal.target.detailRange:Range.low.code">
      <path value="PlanDefinition.goal.target.detailRange.low.code"/>
```

```xml
      <short value="Unit"/>
      <definition
                  value="A named quantity in terms of which other quantities are measured
 or specified, used as a standard measurement of like kinds. [Source: NCI EVS -C25709] Ex
amples: mg, L, etc."/>
      <min value="1"/>
      <max value="1"/>
      <mustSupport value="true"/>
      <isModifier value="false"/>
    </element>
    <element id="PlanDefinition.goal.target.detailRange:Range.high">
      <path value="PlanDefinition.goal.target.detailRange.high"/>
      <short value="interpretationCode=NMT"/>
      <definition
                  value="A code that describes how to relate the given value to an accept
ance value. [Source: SME Defined] Note: When result value is numeric there is a controlle
d vocabulary; when result value is textual the vocabulary is Pass/Fail."/>
      <min value="0"/>
      <max value="1"/>
      <mustSupport value="true"/>
      <isModifier value="false"/>
    </element>
    <element id="PlanDefinition.goal.target.detailRange:Range.high.value">
      <path value="PlanDefinition.goal.target.detailRange.high.value"/>
      <short value="valueNumeric"/>
      <definition
                  value="A text or numeric value of the result of the test. [Source: SME
Defined]."/>
      <min value="1"/>
      <max value="1"/>
      <mustSupport value="true"/>
      <isModifier value="false"/>
    </element>
    <element id="PlanDefinition.goal.target.detailRange:Range.high.system">
      <path value="PlanDefinition.goal.target.detailRange.high.system"/>
      <min value="1"/>
      <max value="1"/>
      <type>
        <code value="uri"/>
      </type>
      <fixedUri value="http://unitsofmeasure.org"/>
      <mustSupport value="true"/>
      <isModifier value="false"/>
    </element>
    <element id="PlanDefinition.goal.target.detailRange:Range.high.code">
      <path value="PlanDefinition.goal.target.detailRange.high.code"/>
      <short value="Unit"/>
      <definition
                  value="A named quantity in terms of which other quantities are measured
 or specified, used as a standard measurement of like kinds. [Source: NCI EVS -C25709] Ex
amples: mg, L, etc."/>
      <min value="1"/>
      <max value="1"/>
      <mustSupport value="true"/>
      <isModifier value="false"/>
    </element>
    <element
```

```
                    id="PlanDefinition.goal.target.detailCodeableConcept:CodeableConcept">
      <path value="PlanDefinition.goal.target.detailCodeableConcept"/>
      <sliceName value="CodeableConcept"/>
      <min value="0"/>
      <max value="1"/>
      <type>
        <code value="CodeableConcept"/>
      </type>
      <mustSupport value="true"/>
      <isModifier value="false"/>
    </element>
    <element
              id="PlanDefinition.goal.target.detailCodeableConcept:CodeableConcept.text">
      <path value="PlanDefinition.goal.target.detailCodeableConcept.text"/>
      <short value="value"/>
      <definition
                  value="A text or numeric value of the result of the test. [Source: SME
Defined]."/>
      <min value="1"/>
      <max value="1"/>
      <mustSupport value="true"/>
      <isModifier value="false"/>
    </element>
    <element id="PlanDefinition.action">
      <path value="PlanDefinition.action"/>
      <short value="Test"/>
      <definition
                  value="A determination of a physical, chemical or biological property.
[Source: SME Defined]."/>
      <min value="1"/>
      <max value="*"/>
      <mustSupport value="true"/>
      <isModifier value="false"/>
    </element>
    <element id="PlanDefinition.action.extension:methodOrigin">
      <path value="PlanDefinition.action.extension"/>
      <sliceName value="methodOrigin"/>
      <short value="Test method origin"/>
      <definition
                  value="A coded value specifying the source of the method. [Source: SME
Defined] Example: Compendial."/>
      <min value="0"/>
      <max value="1"/>
      <type>
        <code value="Extension"/>
        <profile
                  value="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-methodOrig
in"/>
      </type>
      <mustSupport value="true"/>
      <isModifier value="false"/>
    </element>
    <element id="PlanDefinition.action.extension:referenceToProcedure">
      <path value="PlanDefinition.action.extension"/>
      <sliceName value="referenceToProcedure"/>
      <short value="Reference to procedure (url)"/>
      <min value="0"/>
```

```xml
      <max value="1"/>
      <type>
        <code value="Extension"/>
        <profile
                  value="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-definition
Uri"/>
      </type>
      <mustSupport value="true"/>
      <isModifier value="false"/>
    </element>
    <element id="PlanDefinition.action.extension:focus">
      <path value="PlanDefinition.action.extension"/>
      <sliceName value="focus"/>
      <short value="Relative retention time"/>
      <definition
                  value="The ratio of the retention time of a component relative to that
of another used as a reference obtained under identical conditions. It is used as an alia
s for the name of the unidentified impurities. [Source: Adapted from USP] Example: 1:23 (
a ratio)."/>
      <min value="0"/>
      <max value="1"/>
      <type>
        <code value="Extension"/>
        <profile
                  value="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-focus"/>
      </type>
      <mustSupport value="true"/>
      <isModifier value="false"/>
    </element>
    <element id="PlanDefinition.action.title">
      <path value="PlanDefinition.action.title"/>
      <short value="Test Name"/>
      <definition
                  value="The textual description of a procedure or analytical method. [So
urce: SME Defined]."/>
      <min value="1"/>
      <max value="1"/>
      <mustSupport value="true"/>
      <isModifier value="false"/>
    </element>
    <element id="PlanDefinition.action.code">
      <path value="PlanDefinition.action.code"/>
      <short value="QualitySpecification Test category"/>
      <min value="1"/>
      <max value="1"/>
      <type>
        <code value="CodeableConcept"/>
      </type>
      <mustSupport value="true"/>
      <isModifier value="false"/>
    </element>
    <element id="PlanDefinition.action.code.coding">
      <path value="PlanDefinition.action.code.coding"/>
      <short value="Test category"/>
      <definition
                  value="A high level grouping of product quality attributes. [Source: SM
E Defined] Examples: Appearance, Physical Properties, etc."/>
```

```
        <min value="1"/>
        <max value="1"/>
        <mustSupport value="true"/>
        <isModifier value="false"/>
      </element>
      <element id="PlanDefinition.action.code.text">
        <path value="PlanDefinition.action.code.text"/>
        <short value="Analytical Procedure"/>
        <definition
                   value="A technique used to determine the nature of a characteristic. [S
ource: SME Defined] Examples: HPLC, Capillary Electrophoresis, etc."/>
        <min value="1"/>
        <max value="1"/>
        <mustSupport value="true"/>
        <isModifier value="false"/>
      </element>
      <element id="PlanDefinition.action.reason">
        <path value="PlanDefinition.action.reason"/>
        <short value="Usage"/>
        <definition
                   value="A coded value specifying the time point during the manufacturing
 process of a substance or product when a particular analytical procedure or measurement
is being performed. [Source: SME Defined]."/>
        <min value="1"/>
        <max value="1"/>
        <mustSupport value="true"/>
        <isModifier value="false"/>
      </element>
      <element id="PlanDefinition.action.definitionUri">
        <path value="PlanDefinition.action.definitionUri"/>
        <short value="referenceToProcedure (FHIR)"/>
        <definition value="Location of procedure in eCTD."/>
        <min value="0"/>
        <max value="1"/>
        <mustSupport value="true"/>
        <isModifier value="false"/>
      </element>
      <element id="PlanDefinition.action.action">
        <path value="PlanDefinition.action.action"/>
        <short value="Stage"/>
        <definition
                   value="A set of discrete sequential steps performed on a given test. [S
ource: SME Defined] Note: Level and Tier could be synonyms for Stage. A Test can have man
y stages."/>
        <min value="1"/>
        <max value="*"/>
        <mustSupport value="true"/>
        <isModifier value="false"/>
      </element>
      <element id="PlanDefinition.action.action.title">
        <path value="PlanDefinition.action.action.title"/>
        <short value="Stage name"/>
        <definition
                   value="A textual description and/or a number that identifies a level wi
thin a sequential test. [Source: SME Defined] Examples – Single Stage, Stage 1, Stage 2 (
sometimes referred to as L1, L2 L3 or A1, A2 as in USP &lt;711&gt;) Note: A Stage may or
may not provide a conditional sequence with associated acceptance criteria. [Source: SME
```

```
Defined] (e.g., dissolution test, pyrogen test -USP &lt;151&gt;; 21 CFR 610.13(b) Test fo
r pyrogenic substances)."/>
        <min value="1"/>
        <max value="1"/>
        <mustSupport value="true"/>
        <isModifier value="false"/>
    </element>
    <element id="PlanDefinition.action.action.goalId">
        <path value="PlanDefinition.action.action.goalId"/>
        <short value="Acceptance criteria"/>
        <min value="1"/>
        <max value="*"/>
        <mustSupport value="true"/>
        <isModifier value="false"/>
    </element>
    <element id="PlanDefinition.action.action.relatedAction">
        <path value="PlanDefinition.action.action.relatedAction"/>
        <short value="Indicates relative sequence"/>
        <definition
                   value="The order of the stages in regular succession. [Source: SME Defi
ned] Examples: 1, 2, 3, etc.  This is not a direct mapping in FHIR."/>
        <min value="0"/>
        <max value="1"/>
        <mustSupport value="true"/>
        <isModifier value="false"/>
    </element>
    <element id="PlanDefinition.action.action.relatedAction.actionId">
        <path value="PlanDefinition.action.action.relatedAction.actionId"/>
        <short value="GUID identifer for related stage"/>
        <definition value="The identifier of the previous stage."/>
        <min value="1"/>
        <max value="1"/>
        <mustSupport value="true"/>
        <isModifier value="false"/>
    </element>
    <element id="PlanDefinition.action.action.relatedAction.relationship">
        <path value="PlanDefinition.action.action.relatedAction.relationship"/>
        <short value="Sequence reference"/>
        <min value="1"/>
        <max value="1"/>
        <mustSupport value="true"/>
        <isModifier value="false"/>
    </element>
  </differential>
</StructureDefinition>
```

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| Content | Detailed Descriptions | Mappings | Examples | XML |

StructureDefinition: PQCMC_MedicationKnowledge - Mappings

Mappings for the Profile.

Mappings for RIM Mapping (http://hl7.org/v3)

PQCMC_MedicationKnowledge	
MedicationKnowledge	Entity. Role, or Act
text	Act.text?
contained	N/A
extension	
extension (productType)	
id	n/a
extension	n/a
url	N/A
valueCode	N/A
modifierExtension	N/A
code	.code
id	n/a
extension	n/a
coding	union(., ./translation)
text	./originalText[mediaType/code="text/plain"]/data
status	.statusCode
manufacturer	.player.scopingRole[typeCode=MANU].scoper
doseForm	.formCode
amount	.quantity
relatedMedicationKnowledge	
id	n/a
extension	n/a
modifierExtension	N/A
monograph	
id	n/a
extension	n/a
modifierExtension	N/A

ingredient	
id	n/a
modifierExtension	N/A
item[x]	.player
isActive	NA
strength	.quantity
id	n/a
extension	n/a
numerator	.numerator
id	n/a
extension	n/a
value	PQ.value, CO.value, MO.value, IVL.high or IVL.low depending on the value
comparator	IVL properties
unit	PQ.unit
system	CO.codeSystem, PQ.translation.codeSystem
code	PQ.code, MO.currency, PQ.translation.code
denominator	.denominator
id	n/a
extension	n/a
value	PQ.value, CO.value, MO.value, IVL.high or IVL.low depending on the value
comparator	IVL properties
unit	PQ.unit
system	CO.codeSystem, PQ.translation.codeSystem
code	PQ.code, MO.currency, PQ.translation.code
cost	
id	n/a
extension	n/a
modifierExtension	N/A
monitoringProgram	
id	n/a
extension	n/a
modifierExtension	N/A
administrationGuidelines	
id	n/a
extension	n/a
modifierExtension	N/A
dosage	
id	n/a
extension	n/a
modifierExtension	N/A
patientCharacteristics	
id	n/a

extension	n/a
modifierExtension	N/A
medicineClassification	
id	n/a
extension	n/a
modifierExtension	N/A
packaging	
id	n/a
extension	n/a
modifierExtension	N/A
drugCharacteristic	
id	n/a
extension	n/a
modifierExtension	N/A
regulatory	
id	n/a
extension	n/a
modifierExtension	N/A
substitution	
id	n/a
extension	n/a
modifierExtension	N/A
schedule	
id	n/a
extension	n/a
modifierExtension	N/A
maxDispense	
id	n/a
extension	n/a
modifierExtension	N/A
kinetics	
id	n/a
extension	n/a
modifierExtension	N/A

Mappings for Mapping to NCPDP SCRIPT 10.6 (http://ncpdp.org/SCRIPT10_6)

PQCMC_MedicationKnowledge	
MedicationKnowledge	
code	coding.code = //element(*,MedicationType)/DrugCoded/ProductCode coding.system = //element(*,MedicationType)/DrugCoded/ProductCodeQualifier coding.display = //element(*,MedicationType)/DrugDescription
manufacturer	no mapping
doseForm	coding.code = //element(*,DrugCodedType)/FormCode coding.system =

	//element(*,DrugCodedType)/FormSourceCode
ingredient	
item[x]	coding.code = //element(*,MedicationType)/DrugCoded/ProductCode coding.system = //element(*,MedicationType)/DrugCoded/ProductCodeQualifier coding.display = //element(*,MedicationType)/DrugDescription
strength	//element(*,DrugCodedType)/Strength

Mappings for FiveWs Pattern Mapping (http://hl7.org/fhir/fivews)

PQCMC_MedicationKnowledge	
MedicationKnowledge	
code	FiveWs.class
manufacturer	FiveWs.actor

Mappings for HL7 v2 Mapping (http://hl7.org/v2)

PQCMC_MedicationKnowledge	
MedicationKnowledge	
code	RXO-1.1-Requested Give Code.code / RXE-2.1-Give Code.code / RXD-2.1-Dispense/Give Code.code / RXG-4.1-Give Code.code /RXA-5.1-Administered Code.code / RXC-2.1 Component Code
coding	C*E.1-8, C*E.10-22
text	C*E.9. But note many systems use C*E.2 for this
manufacturer	RXD-20-Substance Manufacturer Name / RXG-21-Substance Manufacturer Name / RXA-17-Substance Manufacturer Name
doseForm	RXO-5-Requested Dosage Form / RXE-6-Give Dosage Form / RXD-6-Actual Dosage Form / RXG-8-Give Dosage Form / RXA-8-Administered Dosage Form
ingredient	
item[x]	RXC-2-Component Code if medication: RXO-1-Requested Give Code / RXE-2-Give Code / RXD-2-Dispense/Give Code / RXG-4-Give Code / RXA-5-Administered Code
strength	RXC-3-Component Amount & RXC-4-Component Units if medication: RXO-2-Requested Give Amount - Minimum & RXO-4-Requested Give Units / RXO-3-Requested Give Amount - Maximum & RXO-4-Requested Give Units / RXO-11-Requested Dispense Amount & RXO-12-Requested Dispense Units / RXE-3-Give Amount - Minimum & RXE-5-Give Units / RXE-4-Give Amount - Maximum & RXE-5-Give Units / RXE-10-Dispense Amount & RXE-10-Dispense Units
numerator	
value	SN.2 / CQ - N/A
comparator	SN.1 / CQ.1
unit	(see OBX.6 etc.) / CQ.2
system	(see OBX.6 etc.) / CQ.2
code	(see OBX.6 etc.) / CQ.2
denominator	
value	SN.2 / CQ - N/A
comparator	SN.1 / CQ.1
unit	(see OBX.6 etc.) / CQ.2
system	(see OBX.6 etc.) / CQ.2
code	(see OBX.6 etc.) / CQ.2

Links: Table of Contents | QA Report | Version History | PUBLIC DOMAIN | Propose a change FDA

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StructureDefinition: PQCMC_MedicationKnowledge - Examples

No examples are currently available for the Profile.

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Links: Table of Contents | QA Report | Version History | PUBLIC DOMAIN | Propose a change FDA

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Table of Contents > Artifact index > **PQCMC Drug Product**

| Content | Detailed Descriptions | Mappings | Examples | XML |

StructureDefinition: PQCMC_MedicationKnowledge - XML Profile

XML representation of the drugproduct Profile.

Narrative view of the profile

```
<StructureDefinition xmlns="http://hl7.org/fhir">
  <id value="drugproduct"/>
  <text>
    <status value="generated"/>
    <div xmlns="http://www.w3.org/1999/xhtml"><table border="0" cellpadding="0" cellspaci
ng="0" style="border: 0px #F0F0F0 solid; font-size: 11px; font-family: verdana; vertical-
align: top;"><tr style="border: 1px #F0F0F0 solid; font-size: 11px; font-family: verdana;
 vertical-align: top;"><th style="vertical-align: top; text-align : left; background-colo
r: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><a href="
http://build.fhir.org/formats.html#table" title="The logical name of the element">Name</a
></th><th style="vertical-align: top; text-align : left; background-color: white; border:
 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><a href="http://build.fhir
.org/formats.html#table" title="Information about the use of the element">Flags</a></th><
th style="vertical-align: top; text-align : left; background-color: white; border: 0px #F
0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><a href="http://build.fhir.org/fo
rmats.html#table" title="Minimum and Maximum # of times the the element can appear in the
 instance">Card.</a></th><th style="width: 100px" class="hierarchy"><a href="http://build
.fhir.org/formats.html#table" title="Reference to the type of the element">Type</a></th><
th style="vertical-align: top; text-align : left; background-color: white; border: 0px #F
0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><a href="http://build.fhir.org/fo
rmats.html#table" title="Additional information about the element">Description &amp; Cons
traints</a><span style="float: right"><a href="http://build.fhir.org/formats.html#table"
title="Legend for this format"><img src="http://build.fhir.org/help16.png" alt="doco" sty
le="background-color: inherit"/></a></span></th></tr><tr style="border: 0px #F0F0F0 solid
; padding:0px; vertical-align: top; background-color: white;"><td style="vertical-align:
top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4
px 0px 4px; white-space: nowrap; background-image: url(tbl_bck1.png)" class="hierarchy"><
img src="tbl_spacer.png" alt="." style="background-color: inherit" class="hierarchy"/><im
g src="icon_element.gif" alt="." style="background-color: white; background-color: inheri
t" title="Element" class="hierarchy"/> <a href="drugproduct-definitions.html#MedicationKn
owledge">MedicationKnowledge</a><a name="MedicationKnowledge"> </a></td><td style="vertic
al-align: top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; pad
ding:0px 4px 0px 4px" class="hierarchy"/><td style="vertical-align: top; text-align : lef
t; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hi
erarchy"/><td style="vertical-align: top; text-align : left; background-color: white; bor
der: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"/><td style="vertical-a
lign: top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding
```

```
:0px 4px 0px 4px" class="hierarchy"/></tr>
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l(tbl_bck15.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="background-c
olor: inherit" class="hierarchy"/><img src="tbl_vjoin.png" alt="." style="background-colo
r: inherit" class="hierarchy"/><img src="icon_extension_simple.png" alt="." style="backgr
ound-color: white; background-color: inherit" title="Simple Extension" class="hierarchy"/
> <a href="drugproduct-definitions.html#MedicationKnowledge.extension:productType" title=
"Extension URL = http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-productType">ext-
productType</a><a name="MedicationKnowledge.extension"> </a></td><td style="vertical-alig
n: top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0p
x 4px 0px 4px" class="hierarchy"><span style="padding-left: 3px; padding-right: 3px; colo
r: white; background-color: red" title="This element must be supported">S</span></td><td
style="vertical-align: top; text-align : left; background-color: white; border: 0px #F0F0
F0 solid; padding:0px 4px 0px 4px" class="hierarchy">1..1</td><td style="vertical-align:
top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4
px 0px 4px" class="hierarchy"><a href="http://build.fhir.org/datatypes.html#code">code</a
></td><td style="vertical-align: top; text-align : left; background-color: white; border:
 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy">Specification Type<br/><sp
an style="font-weight:bold">URL: </span><a href="http://build.fhir.org/extension-ext-prod
uctType.html">http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-productType</a></td>
</tr>
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l(tbl_bck140.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="background-
color: inherit" class="hierarchy"/><img src="tbl_vline.png" alt="." style="background-col
or: inherit" class="hierarchy"/><img src="tbl_vjoin_end_slice.png" alt="." style="backgro
und-color: inherit" class="hierarchy"/><img src="icon_primitive.png" alt="." style="backg
round-color: white; background-color: inherit" title="Primitive Data Type" class="hierarc
hy"/> <a href="drugproduct-definitions.html#MedicationKnowledge.extension:productType.val
ueCode">valueCode</a><a name="MedicationKnowledge.extension.valueCode"> </a></td><td styl
e="vertical-align: top; text-align : left; background-color: white; border: 0px #F0F0F0 s
olid; padding:0px 4px 0px 4px" class="hierarchy"><span style="padding-left: 3px; padding-
right: 3px; color: white; background-color: red" title="This element must be supported">S
</span></td><td style="vertical-align: top; text-align : left; background-color: white; b
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vertical-align: top; text-align : left; background-color: white; border: 0px #F0F0F0 soli
d; padding:0px 4px 0px 4px" class="hierarchy"><a href="http://build.fhir.org/datatypes.ht
ml#code">code</a></td><td style="vertical-align: top; text-align : left; background-color
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ct<br/><span style="font-weight:bold">Fixed Value: </span><span style="color: darkgreen">
product</span></td></tr>
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l(tbl_bck11.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="background-c
olor: inherit" class="hierarchy"/><img src="tbl_vjoin.png" alt="." style="background-colo
r: inherit" class="hierarchy"/><img src="icon_element.gif" alt="." style="background-colo
r: white; background-color: inherit" title="Element" class="hierarchy"/> <a href="drugpro
duct-definitions.html#MedicationKnowledge.code">code</a><a name="MedicationKnowledge.code
"> </a></td><td style="vertical-align: top; text-align : left; background-color: white; b
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must be supported">S</span></td><td style="vertical-align: top; text-align : left; backgr
ound-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy">
```

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1..1</td><td style="vertical-align: top; text-align : left; background-color: white; bord
er: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"/><td style="vertical-al
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l(tbl_bck100.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="background-
color: inherit" class="hierarchy"/><img src="tbl_vline.png" alt="." style="background-col
or: inherit" class="hierarchy"/><img src="tbl_vjoin_end.png" alt="." style="background-co
lor: inherit" class="hierarchy"/><img src="icon_element.gif" alt="." style="background-co
lor: white; background-color: inherit" title="Element" class="hierarchy"/> <a href="drugp
roduct-definitions.html#MedicationKnowledge.code.text" title="A name unprotected by trade
mark rights that is entirely in the public domain. It may be used without restriction by
the public at large, both lay and professional. [Source: http://www.fda.gov/Drugs/Develop
mentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/DataStandardsManual
monographs/ucm071638.htm ].">text</a><a name="MedicationKnowledge.code.text"> </a></td><t
d style="vertical-align: top; text-align : left; background-color: white; border: 0px #F0
F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><span style="padding-left: 3px; pa
dding-right: 3px; color: white; background-color: red" title="This element must be suppor
ted">S</span></td><td style="vertical-align: top; text-align : left; background-color: wh
ite; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy">1..1</td><td s
tyle="vertical-align: top; text-align : left; background-color: white; border: 0px #F0F0F
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x" class="hierarchy">Non-proprietary Name</td></tr>
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r: inherit" class="hierarchy"/><img src="icon_slice.png" alt="." style="background-color:
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"font-style: italic" href="drugproduct-definitions.html#MedicationKnowledge.synonym">syno
nym</a><a name="MedicationKnowledge.synonym"> </a></td><td style="vertical-align: top; te
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4px" class="hierarchy"><span style="padding-left: 3px; padding-right: 3px; color: white;
background-color: red; font-style: italic" title="This element must be supported">S</span
></td><td style="vertical-align: top; text-align : left; background-color: white; border:
 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"/><td style="vertical-align
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 4px 0px 4px" class="hierarchy"/><td style="vertical-align: top; text-align : left; backg
round-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"
><span style="font-weight:bold; font-style: italic">Slice: </span><span style="font-style
: italic">Unordered, Open by value:extension('http://fda.gov/cder/fhir/pqcmc/StructureDef
inition/ext-nameType').valueCode</span><br style="font-style: italic"/></td></tr>
<tr style="border: 0px #F0F0F0 solid; padding:0px; vertical-align: top; background-color:
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er: 0px #F0F0F0 solid; padding:0px 4px 0px 4px; white-space: nowrap; background-image: ur
l(tbl_bck125.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="background-
color: inherit" class="hierarchy"/><img src="tbl_vline.png" alt="." style="background-col
or: inherit" class="hierarchy"/><img src="tbl_vjoin_end_slicer.png" alt="." style="backgr
ound-color: inherit" class="hierarchy"/><img src="icon_extension_simple.png" alt="." styl
e="background-color: white; background-color: inherit" title="Simple Extension" class="hi
erarchy"/> <a href="drugproduct-definitions.html#MedicationKnowledge.synonym.extension:pr
oprietaryNameType" title="Extension URL = http://fda.gov/cder/fhir/pqcmc/StructureDefinit
ion/ext-nameType">ext-nameType</a><a name="MedicationKnowledge.synonym.extension"> </a></
```

```
td><td style="vertical-align: top; text-align : left; background-color: white; border: 0p
x #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><span style="padding-left: 3p
x; padding-right: 3px; color: white; background-color: red" title="This element must be s
upported">S</span></td><td style="vertical-align: top; text-align : left; background-colo
r: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy">1..1</td>
<td style="vertical-align: top; text-align : left; background-color: white; border: 0px #
F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><a href="http://build.fhir.org/d
atatypes.html#base64Binary">base64Binary</a>, <a href="http://build.fhir.org/datatypes.ht
ml#boolean">boolean</a>, <a href="http://build.fhir.org/references.html">canonical</a>(),
 <a href="http://build.fhir.org/datatypes.html#code">code</a>, <a href="http://build.fhir
.org/datatypes.html#date">date</a>, <a href="http://build.fhir.org/datatypes.html#dateTim
e">dateTime</a>, <a href="http://build.fhir.org/datatypes.html#decimal">decimal</a>, <a h
ref="http://build.fhir.org/datatypes.html#id">id</a>, <a href="http://build.fhir.org/data
types.html#instant">instant</a>, <a href="http://build.fhir.org/datatypes.html#integer">i
nteger</a>, <a href="http://build.fhir.org/datatypes.html#markdown">markdown</a>, <a href
="http://build.fhir.org/datatypes.html#oid">oid</a>, <a href="http://build.fhir.org/datat
ypes.html#positiveInt">positiveInt</a>, <a href="http://build.fhir.org/datatypes.html#str
ing">string</a>, <a href="http://build.fhir.org/datatypes.html#time">time</a>, <a href="h
ttp://build.fhir.org/datatypes.html#unsignedInt">unsignedInt</a>, <a href="http://build.f
hir.org/datatypes.html#uri">uri</a>, <a href="http://build.fhir.org/datatypes.html#url">u
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ld.fhir.org/datatypes.html#Address">Address</a>, <a href="http://build.fhir.org/datatypes
.html#Age">Age</a>, <a href="http://build.fhir.org/datatypes.html#Annotation">Annotation<
/a>, <a href="http://build.fhir.org/datatypes.html#Attachment">Attachment</a>, <a href="h
ttp://build.fhir.org/datatypes.html#CodeableConcept">CodeableConcept</a>, <a href="http:/
/build.fhir.org/datatypes.html#Coding">Coding</a>, <a href="http://build.fhir.org/datatyp
es.html#ContactPoint">ContactPoint</a>, <a href="http://build.fhir.org/datatypes.html#Cou
nt">Count</a>, <a href="http://build.fhir.org/datatypes.html#Distance">Distance</a>, <a h
ref="http://build.fhir.org/datatypes.html#Duration">Duration</a>, <a href="http://build.f
hir.org/datatypes.html#HumanName">HumanName</a>, <a href="http://build.fhir.org/datatypes
.html#Identifier">Identifier</a>, <a href="http://build.fhir.org/datatypes.html#Money">Mo
ney</a>, <a href="http://build.fhir.org/datatypes.html#Period">Period</a>, <a href="http:
//build.fhir.org/datatypes.html#Quantity">Quantity</a>, <a href="http://build.fhir.org/da
tatypes.html#Range">Range</a>, <a href="http://build.fhir.org/datatypes.html#Ratio">Ratio
</a>, <a href="http://build.fhir.org/references.html">Reference</a>(), <a href="http://bu
ild.fhir.org/datatypes.html#SampledData">SampledData</a>, <a href="http://build.fhir.org/
datatypes.html#Signature">Signature</a>, <a href="http://build.fhir.org/datatypes.html#Ti
ming">Timing</a>, <a href="http://build.fhir.org/datatypes.html#ContactDetail">ContactDet
ail</a>, <a href="http://build.fhir.org/datatypes.html#Contributor">Contributor</a>, <a h
ref="http://build.fhir.org/datatypes.html#DataRequirement">DataRequirement</a>, <a href="
http://build.fhir.org/datatypes.html#Expression">Expression</a>, <a href="http://build.fh
ir.org/datatypes.html#ParameterDefinition">ParameterDefinition</a>, <a href="http://build
.fhir.org/datatypes.html#RelatedArtifact">RelatedArtifact</a>, <a href="http://build.fhir
.org/datatypes.html#TriggerDefinition">TriggerDefinition</a>, <a href="http://build.fhir.
org/datatypes.html#UsageContext">UsageContext</a>, <a href="http://build.fhir.org/datatyp
es.html#Dosage">Dosage</a></td><td style="vertical-align: top; text-align : left; backgro
und-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy">P
roprietary Name<br/><span style="font-weight:bold">URL: </span><a href="http://build.fhir
.org/extension-ext-nameType.html">http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-
nameType</a></td></tr>
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l(tbl_bck1240.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="background
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lor: inherit" class="hierarchy"/><img src="tbl_blank.png" alt="." style="background-color
: inherit" class="hierarchy"/><img src="tbl_vjoin_end_slice.png" alt="." style="backgroun
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d-color: inherit" class="hierarchy"/><img src="icon_primitive.png" alt="." style="backgro
und-color: white; background-color: inherit" title="Primitive Data Type" class="hierarchy
"/> <a href="drugproduct-definitions.html#MedicationKnowledge.synonym.extension:proprieta
ryNameType.valueCode" title="proprietary  or nonProprietary.">valueCode</a><a name="Medic
ationKnowledge.synonym.extension.valueCode"> </a></td><td style="vertical-align: top; tex
t-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4
px" class="hierarchy"><span style="padding-left: 3px; padding-right: 3px; color: white; b
ackground-color: red" title="This element must be supported">S</span></td><td style="vert
ical-align: top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; p
adding:0px 4px 0px 4px" class="hierarchy">1..1</td><td style="vertical-align: top; text-a
lign : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px"
 class="hierarchy"><a href="http://build.fhir.org/datatypes.html#code">code</a></td><td s
tyle="vertical-align: top; text-align : left; background-color: white; border: 0px #F0F0F
0 solid; padding:0px 4px 0px 4px" class="hierarchy"><span style="font-weight:bold">Fixed
Value: </span><span style="color: darkgreen">proprietary</span></td></tr>
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l(tbl_bck10.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="background-c
olor: inherit" class="hierarchy"/><img src="tbl_vjoin.png" alt="." style="background-colo
r: inherit" class="hierarchy"/><img src="icon_element.gif" alt="." style="background-colo
r: white; background-color: inherit" title="Element" class="hierarchy"/> <a href="drugpro
duct-definitions.html#MedicationKnowledge.doseForm" title="The form in which active and/o
r inert ingredient(s) are physically presented. [Source: NCI EVS - C42636]
Examples: tablet, capsule, solution, cream, etc. that contains a drug substance generally
, but not necessarily, in association with excipients. [Source: ICH Q1A(R2)]
Note: If there is a new dosage form that does not exist in the controlled terminology, th
en propose register this new dosage form during sponsor meetings with FDA.">doseForm</a><
a name="MedicationKnowledge.doseForm"> </a></td><td style="vertical-align: top; text-alig
n : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" cl
ass="hierarchy"><span style="padding-left: 3px; padding-right: 3px; color: white; backgro
und-color: red" title="This element must be supported">S</span></td><td style="vertical-a
lign: top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding
:0px 4px 0px 4px" class="hierarchy">1..1</td><td style="vertical-align: top; text-align :
 left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class
="hierarchy"/><td style="vertical-align: top; text-align : left; background-color: white;
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tr>
<tr style="border: 0px #F0F0F0 solid; padding:0px; vertical-align: top; background-color:
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l(tbl_bck01.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="background-c
olor: inherit" class="hierarchy"/><img src="tbl_vjoin_end.png" alt="." style="background-
color: inherit" class="hierarchy"/><img src="icon_element.gif" alt="." style="background-
color: white; background-color: inherit" title="Element" class="hierarchy"/> <a href="dru
gproduct-definitions.html#MedicationKnowledge.ingredient" title="Any ingredient intended
for use in the manufacture of a drug product, including those that may not appear in such
 drug product. [Source: (21 CFR 210.3(b)(3)) PAC-ATLS 1998].">ingredient</a><a name="Medi
cationKnowledge.ingredient"> </a></td><td style="vertical-align: top; text-align : left;
background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hiera
rchy"><span style="padding-left: 3px; padding-right: 3px; color: white; background-color:
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 text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0
px 4px" class="hierarchy">1..*</td><td style="vertical-align: top; text-align : left; bac
kground-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarch
y"/><td style="vertical-align: top; text-align : left; background-color: white; border: 0
px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy">Product Component Name<br/><
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/td></tr>
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l(tbl_bck014.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="background-
color: inherit" class="hierarchy"/><img src="tbl_blank.png" alt="." style="background-col
or: inherit" class="hierarchy"/><img src="tbl_vjoin.png" alt="." style="background-color:
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nd-color: white; background-color: inherit" title="Simple Extension" class="hierarchy"/>
<a href="drugproduct-definitions.html#MedicationKnowledge.ingredient.extension:contentPer
cent" title="Extension URL = http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-conte
ntPercent">ext-contentPercent</a><a name="MedicationKnowledge.ingredient.extension"> </a>
</td><td style="vertical-align: top; text-align : left; background-color: white; border:
0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><span style="padding-left:
3px; padding-right: 3px; color: white; background-color: red" title="This element must be
 supported">S</span></td><td style="vertical-align: top; text-align : left; background-co
lor: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy">0..1</t
d><td style="vertical-align: top; text-align : left; background-color: white; border: 0px
 #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><a href="http://build.fhir.org
/datatypes.html#decimal">decimal</a></td><td style="vertical-align: top; text-align : lef
t; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hi
erarchy">Content percent<br/><span style="font-weight:bold">URL: </span><a href="http://b
uild.fhir.org/extension-ext-contentPercent.html">http://fda.gov/cder/fhir/pqcmc/Structure
Definition/ext-contentPercent</a></td></tr>
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l(tbl_bck010.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="background-
color: inherit" class="hierarchy"/><img src="tbl_blank.png" alt="." style="background-col
or: inherit" class="hierarchy"/><img src="tbl_vjoin.png" alt="." style="background-color:
 inherit" class="hierarchy"/><img src="icon_element.gif" alt="." style="background-color:
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ct-definitions.html#MedicationKnowledge.ingredient.itemReference">itemReference</a><a nam
e="MedicationKnowledge.ingredient.itemReference"> </a></td><td style="vertical-align: top
; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px
0px 4px" class="hierarchy"><span style="padding-left: 3px; padding-right: 3px; color: whi
te; background-color: red" title="This element must be supported">S</span></td><td style=
"vertical-align: top; text-align : left; background-color: white; border: 0px #F0F0F0 sol
id; padding:0px 4px 0px 4px" class="hierarchy">1..1</td><td style="vertical-align: top; t
ext-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px
 4px" class="hierarchy"/><td style="vertical-align: top; text-align : left; background-co
lor: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"/></tr>
<tr style="border: 0px #F0F0F0 solid; padding:0px; vertical-align: top; background-color:
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l(tbl_bck001.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="background-
color: inherit" class="hierarchy"/><img src="tbl_blank.png" alt="." style="background-col
or: inherit" class="hierarchy"/><img src="tbl_vjoin_end.png" alt="." style="background-co
lor: inherit" class="hierarchy"/><img src="icon_element.gif" alt="." style="background-co
lor: white; background-color: inherit" title="Element" class="hierarchy"/> <a href="drugp
roduct-definitions.html#MedicationKnowledge.ingredient.strength" title="The content of an
 active ingredient expressed quantitatively per dosage unit, per unit of volume, or per u
nit of weight, according to the pharmaceutical dosage form. This should be the strength a
s listed on the label. [Source: Adapted from NCI EVS C53294]
Note: Strength can also be referred to as potency in biologics and other products.  This
information may be captured on the label.">strength</a><a name="MedicationKnowledge.ingre
dient.strength"> </a></td><td style="vertical-align: top; text-align : left; background-c
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olor: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><span
style="padding-left: 3px; padding-right: 3px; color: white; background-color: red" title=
"This element must be supported">S</span></td><td style="vertical-align: top; text-align
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s="hierarchy">1..*</td><td style="vertical-align: top; text-align : left; background-colo
r: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"/><td styl
e="vertical-align: top; text-align : left; background-color: white; border: 0px #F0F0F0 s
olid; padding:0px 4px 0px 4px" class="hierarchy">Strength<br/></td></tr>
<tr style="border: 0px #F0F0F0 solid; padding:0px; vertical-align: top; background-color:
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lor: inherit" class="hierarchy"/><img src="tbl_blank.png" alt="." style="background-color
: inherit" class="hierarchy"/><img src="tbl_vjoin.png" alt="." style="background-color: i
nherit" class="hierarchy"/><img src="icon_element.gif" alt="." style="background-color: w
hite; background-color: inherit" title="Element" class="hierarchy"/> <a href="drugproduct
-definitions.html#MedicationKnowledge.ingredient.strength.numerator" title="The labeled u
nit of measure for the content of an active ingredient, expressed quantitatively per dosa
ge unit. [Source: Adapted for NCI EVS C117055].">numerator</a><a name="MedicationKnowledg
e.ingredient.strength.numerator"> </a></td><td style="vertical-align: top; text-align : l
eft; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="
hierarchy"><span style="padding-left: 3px; padding-right: 3px; color: white; background-c
olor: red" title="This element must be supported">S</span></td><td style="vertical-align:
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4px 0px 4px" class="hierarchy">0..1</td><td style="vertical-align: top; text-align : left
; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hie
rarchy"/><td style="vertical-align: top; text-align : left; background-color: white; bord
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d-color: inherit" class="hierarchy"/><img src="tbl_blank.png" alt="." style="background-c
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r: inherit" class="hierarchy"/><img src="tbl_vline.png" alt="." style="background-color:
inherit" class="hierarchy"/><img src="tbl_vjoin.png" alt="." style="background-color: inh
erit" class="hierarchy"/><img src="icon_element.gif" alt="." style="background-color: whi
te; background-color: inherit" title="Element" class="hierarchy"/> <a href="drugproduct-d
efinitions.html#MedicationKnowledge.ingredient.strength.numerator.value">value</a><a name
="MedicationKnowledge.ingredient.strength.numerator.value"> </a></td><td style="vertical-
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g:0px 4px 0px 4px" class="hierarchy"><span style="padding-left: 3px; padding-right: 3px;
color: white; background-color: red" title="This element must be supported">S</span></td>
<td style="vertical-align: top; text-align : left; background-color: white; border: 0px #
F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy">1..1</td><td style="vertical-ali
gn: top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0
px 4px 0px 4px" class="hierarchy"/><td style="vertical-align: top; text-align : left; bac
kground-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarch
y"/></tr>
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l(tbl_bck00110.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="backgroun
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r: inherit" class="hierarchy"/><img src="tbl_vline.png" alt="." style="background-color:
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inherit" class="hierarchy"/><img src="tbl_vjoin.png" alt="." style="background-color: inh
erit" class="hierarchy"/><img src="icon_primitive.png" alt="." style="background-color: w
hite; background-color: inherit" title="Primitive Data Type" class="hierarchy"/> <a href=
"drugproduct-definitions.html#MedicationKnowledge.ingredient.strength.numerator.system" t
itle="UCUM.">system</a><a name="MedicationKnowledge.ingredient.strength.numerator.system"
> </a></td><td style="vertical-align: top; text-align : left; background-color: white; bo
rder: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><span style="padding-
left: 3px; padding-right: 3px; color: white; background-color: red" title="This element m
ust be supported">S</span></td><td style="vertical-align: top; text-align : left; backgro
und-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy">1
..1</td><td style="vertical-align: top; text-align : left; background-color: white; borde
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ir.org/datatypes.html#uri">uri</a></td><td style="vertical-align: top; text-align : left;
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http://unitsofmeasure.org</span></td></tr>
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r: inherit" class="hierarchy"/><img src="tbl_vline.png" alt="." style="background-color:
inherit" class="hierarchy"/><img src="tbl_vjoin_end.png" alt="." style="background-color:
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r: white; background-color: inherit" title="Primitive Data Type" class="hierarchy"/> <a h
ref="drugproduct-definitions.html#MedicationKnowledge.ingredient.strength.numerator.code"
 title="The labeled unit of measure for the content of an active ingredient, expressed qu
antitatively per dosage unit. [Source: Adapted for NCI EVS C117055] Examples: mg, g, mL,
etc.">code</a><a name="MedicationKnowledge.ingredient.strength.numerator.code"> </a></td>
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F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><span style="padding-left: 3px;
padding-right: 3px; color: white; background-color: red" title="This element must be supp
orted">S</span></td><td style="vertical-align: top; text-align : left; background-color:
white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy">1..1</td><td
 style="vertical-align: top; text-align : left; background-color: white; border: 0px #F0F
0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><a href="http://build.fhir.org/data
types.html#code">code</a></td><td style="vertical-align: top; text-align : left; backgrou
nd-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy">St
rength Unit of Measure</td></tr>
<tr style="border: 0px #F0F0F0 solid; padding:0px; vertical-align: top; background-color:
 white;"><td style="vertical-align: top; text-align : left; background-color: white; bord
er: 0px #F0F0F0 solid; padding:0px 4px 0px 4px; white-space: nowrap; background-image: ur
l(tbl_bck0001.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="background
-color: inherit" class="hierarchy"/><img src="tbl_blank.png" alt="." style="background-co
lor: inherit" class="hierarchy"/><img src="tbl_blank.png" alt="." style="background-color
: inherit" class="hierarchy"/><img src="tbl_vjoin_end.png" alt="." style="background-colo
r: inherit" class="hierarchy"/><img src="icon_element.gif" alt="." style="background-colo
r: white; background-color: inherit" title="Element" class="hierarchy"/> <a href="drugpro
duct-definitions.html#MedicationKnowledge.ingredient.strength.denominator">denominator</a
><a name="MedicationKnowledge.ingredient.strength.denominator"> </a></td><td style="verti
cal-align: top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; pa
dding:0px 4px 0px 4px" class="hierarchy"><span style="padding-left: 3px; padding-right: 3
px; color: white; background-color: red" title="This element must be supported">S</span><
/td><td style="vertical-align: top; text-align : left; background-color: white; border: 0
px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy">0..1</td><td style="vertical
-align: top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; paddi
```

```
ng:0px 4px 0px 4px" class="hierarchy"/><td style="vertical-align: top; text-align : left;
 background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hier
archy"/></tr>
<tr style="border: 0px #F0F0F0 solid; padding:0px; vertical-align: top; background-color:
 white;"><td style="vertical-align: top; text-align : left; background-color: white; bord
er: 0px #F0F0F0 solid; padding:0px 4px 0px 4px; white-space: nowrap; background-image: ur
l(tbl_bck00000.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="backgroun
d-color: inherit" class="hierarchy"/><img src="tbl_blank.png" alt="." style="background-c
olor: inherit" class="hierarchy"/><img src="tbl_blank.png" alt="." style="background-colo
r: inherit" class="hierarchy"/><img src="tbl_blank.png" alt="." style="background-color:
inherit" class="hierarchy"/><img src="tbl_vjoin_end.png" alt="." style="background-color:
 inherit" class="hierarchy"/><img src="icon_primitive.png" alt="." style="background-colo
r: white; background-color: inherit" title="Primitive Data Type" class="hierarchy"/> <a h
ref="drugproduct-definitions.html#MedicationKnowledge.ingredient.strength.denominator.val
ue">value</a><a name="MedicationKnowledge.ingredient.strength.denominator.value"> </a></t
d><td style="vertical-align: top; text-align : left; background-color: white; border: 0px
 #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"/><td style="vertical-align: to
p; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px
 0px 4px" class="hierarchy"/><td style="vertical-align: top; text-align : left; backgroun
d-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><a
href="http://build.fhir.org/datatypes.html#decimal">decimal</a></td><td style="vertical-a
lign: top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding
:0px 4px 0px 4px" class="hierarchy"><span style="font-weight:bold">Fixed Value: </span><s
pan style="color: darkgreen">1</span></td></tr>
<tr><td colspan="5" class="hierarchy"><br/><a href="http://build.fhir.org/formats.html#ta
ble" title="Legend for this format"><img src="http://build.fhir.org/help16.png" alt="doco
" style="background-color: inherit"/> Documentation for this format</a></td></tr></table>
</div>
  </text>
  <url value="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/drugproduct"/>
  <version value="current"/>
  <name value="PQCMC_MedicationKnowledge"/>
  <status value="draft"/>
  <experimental value="false"/>
  <date value="2018-10-05T00:00:00-04:00"/>
  <publisher value="U.S. FDA - CDER division"/>
  <contact>
    <telecom>
      <system value="url"/>
      <value value="https://www.fda.gov/Drugs/default.htm"/>
    </telecom>
  </contact>
  <description
             value="Describes the different levels of drug product whose chemical, manu
facturing and controls processes can be evaluated."/>
  <fhirVersion value="4.0.0"/>
  <mapping>
    <identity value="rim"/>
    <uri value="http://hl7.org/v3"/>
    <name value="RIM Mapping"/>
  </mapping>
  <mapping>
    <identity value="script10.6"/>
    <uri value="http://ncpdp.org/SCRIPT10_6"/>
    <name value="Mapping to NCPDP SCRIPT 10.6"/>
  </mapping>
  <mapping>
```

```
        <identity value="w5"/>
        <uri value="http://hl7.org/fhir/fivews"/>
        <name value="FiveWs Pattern Mapping"/>
    </mapping>
    <mapping>
        <identity value="v2"/>
        <uri value="http://hl7.org/v2"/>
        <name value="HL7 v2 Mapping"/>
    </mapping>
    <kind value="resource"/>
    <abstract value="false"/>
    <type value="MedicationKnowledge"/>
    <baseDefinition
                    value="http://hl7.org/fhir/StructureDefinition/MedicationKnowledge"/>
    <derivation value="constraint"/>
    <snapshot>
        <element id="MedicationKnowledge">
            <path value="MedicationKnowledge"/>
            <short value="Definition of Medication Knowledge"/>
            <definition
                    value="Information about a medication that is used to support knowledge
."/>
            <min value="0"/>
            <max value="*"/>
            <base>
                <path value="MedicationKnowledge"/>
                <min value="0"/>
                <max value="*"/>
            </base>
            <constraint>
                <key value="dom-2"/>
                <severity value="error"/>
                <human
                    value="If the resource is contained in another resource, it SHALL NOT cont
ain nested Resources"/>
                <expression value="contained.contained.empty()"/>
                <xpath value="not(parent::f:contained and f:contained)"/>
                <source value="DomainResource"/>
            </constraint>
            <constraint>
                <key value="dom-4"/>
                <severity value="error"/>
                <human
                    value="If a resource is contained in another resource, it SHALL NOT have a
 meta.versionId or a meta.lastUpdated"/>
                <expression
                        value="contained.meta.versionId.empty() and contained.meta.lastUpdate
d.empty()"/>
                <xpath
                    value="not(exists(f:contained/*/f:meta/f:versionId)) and not(exists(f:cont
ained/*/f:meta/f:lastUpdated))"/>
                <source value="DomainResource"/>
            </constraint>
            <constraint>
                <key value="dom-3"/>
                <severity value="error"/>
                <human
```

```
                        value="If the resource is contained in another resource, it SHALL be refer
red to from elsewhere in the resource or SHALL refer to the containing resource"/>
          <expression
                      value="contained.where(((&#39;#&#39;+id in (%resource.descendants().r
eference | %resource.descendants().as(canonical) | %resource.descendants().as(uri) | %res
ource.descendants().as(url))) or descendants().where(reference = &#39;#&#39;).exists() or
 descendants().where(as(canonical) = &#39;#&#39;).exists() or descendants().where(as(cano
nical) = &#39;#&#39;).exists())).not()).trace(&#39;unmatched&#39;, id).empty()"/>
          <xpath
                value="not(exists(for $contained in f:contained return $contained[not(pare
nt::*/descendant::f:reference/@value=concat(&#39;#&#39;, $contained/*/id/@value) or desce
ndant::f:reference[@value=&#39;#&#39;])]))"/>
          <source value="DomainResource"/>
      </constraint>
      <constraint>
        <extension
                  url="http://hl7.org/fhir/StructureDefinition/elementdefinition-bestpra
ctice">
            <valueBoolean value="true"/>
        </extension>
        <extension
                  url="http://hl7.org/fhir/StructureDefinition/elementdefinition-bestpra
ctice-explanation">
            <valueMarkdown
                          value="When a resource has no narrative, only systems that fully
 understand the data can display the resource to a human safely. Including a human readab
le representation in the resource makes for a much more robust eco-system and cheaper han
dling of resources by intermediary systems. Some ecosystems restrict distribution of reso
urces to only those systems that do fully understand the resources, and as a consequence
implementers may believe that the narrative is superfluous. However experience shows that
 such eco-systems often open up to new participants over time."/>
        </extension>
        <key value="dom-6"/>
        <severity value="warning"/>
        <human value="A resource should have narrative for robust management"/>
        <expression value="text.div.exists()"/>
        <xpath value="exists(f:text/h:div)"/>
        <source value="DomainResource"/>
      </constraint>
      <constraint>
        <key value="dom-5"/>
        <severity value="error"/>
        <human
                value="If a resource is contained in another resource, it SHALL NOT have a
 security label"/>
        <expression value="contained.meta.security.empty()"/>
        <xpath value="not(exists(f:contained/*/f:meta/f:security))"/>
        <source value="DomainResource"/>
      </constraint>
      <mustSupport value="false"/>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="Entity. Role, or Act"/>
      </mapping>
      <mapping>
```

```
                <identity value="rim"/>
                <map value="Todo"/>
            </mapping>
        </element>
        <element id="MedicationKnowledge.id">
            <path value="MedicationKnowledge.id"/>
            <short value="Logical id of this artifact"/>
            <definition
                    value="The logical id of the resource, as used in the URL for the resou
rce. Once assigned, this value never changes."/>
            <comment
                    value="The only time that a resource does not have an id is when it is bei
ng submitted to the server using a create operation."/>
            <min value="0"/>
            <max value="1"/>
            <base>
                <path value="Resource.id"/>
                <min value="0"/>
                <max value="1"/>
            </base>
            <type>
                <code value="id"/>
            </type>
            <isModifier value="false"/>
            <isSummary value="true"/>
        </element>
        <element id="MedicationKnowledge.meta">
            <path value="MedicationKnowledge.meta"/>
            <short value="Metadata about the resource"/>
            <definition
                    value="The metadata about the resource. This is content that is maintai
ned by the infrastructure. Changes to the content might not always be associated with ver
sion changes to the resource."/>
            <min value="0"/>
            <max value="1"/>
            <base>
                <path value="Resource.meta"/>
                <min value="0"/>
                <max value="1"/>
            </base>
            <type>
                <code value="Meta"/>
            </type>
            <isModifier value="false"/>
            <isSummary value="true"/>
        </element>
        <element id="MedicationKnowledge.implicitRules">
            <path value="MedicationKnowledge.implicitRules"/>
            <short value="A set of rules under which this content was created"/>
            <definition
                    value="A reference to a set of rules that were followed when the resour
ce was constructed, and which must be understood when processing the content. Often, this
 is a reference to an implementation guide that defines the special rules along with othe
r profiles etc."/>
            <comment
                    value="Asserting this rule set restricts the content to be only understood
 by a limited set of trading partners. This inherently limits the usefulness of the data
```

```
in the long term. However, the existing health eco-system is highly fractured, and not ye
t ready to define, collect, and exchange data in a generally computable sense. Wherever p
ossible, implementers and/or specification writers should avoid using this element. Often
, when used, the URL is a reference to an implementation guide that defines these special
 rules as part of it&#39;s narrative along with other profiles, value sets, etc."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Resource.implicitRules"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="uri"/>
        </type>
        <isModifier value="true"/>
        <isModifierReason
                        value="This element is labeled as a modifier because the implicit
 rules may provide additional knowledge about the resource that modifies it&#39;s meaning
 or interpretation"/>
        <isSummary value="true"/>
      </element>
      <element id="MedicationKnowledge.language">
        <path value="MedicationKnowledge.language"/>
        <short value="Language of the resource content"/>
        <definition value="The base language in which the resource is written."/>
        <comment
                value="Language is provided to support indexing and accessibility (typical
ly, services such as text to speech use the language tag). The html language tag in the n
arrative applies  to the narrative. The language tag on the resource may be used to speci
fy the language of other presentations generated from the data in the resource. Not all t
he content has to be in the base language. The Resource.language should not be assumed to
 apply to the narrative automatically. If a language is specified, it should it also be s
pecified on the div element in the html (see rules in HTML5 for information about the rel
ationship between xml:lang and the html lang attribute)."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Resource.language"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="code"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <binding>
          <extension
                    url="http://hl7.org/fhir/StructureDefinition/elementdefinition-maxValu
eSet">
            <valueCanonical value="http://hl7.org/fhir/ValueSet/all-languages"/>
          </extension>
          <extension
                    url="http://hl7.org/fhir/StructureDefinition/elementdefinition-binding
Name">
            <valueString value="Language"/>
```

```xml
            </extension>
            <extension
                    url="http://hl7.org/fhir/StructureDefinition/elementdefinition-isCommo
nBinding">
              <valueBoolean value="true"/>
            </extension>
            <strength value="preferred"/>
            <description value="A human language."/>
            <valueSet value="http://hl7.org/fhir/ValueSet/languages"/>
          </binding>
        </element>
        <element id="MedicationKnowledge.text">
          <path value="MedicationKnowledge.text"/>
          <short value="Text summary of the resource, for human interpretation"/>
          <definition
                    value="A human-readable narrative that contains a summary of the resour
ce and can be used to represent the content of the resource to a human. The narrative nee
d not encode all the structured data, but is required to contain sufficient detail to mak
e it &quot;clinically safe&quot; for a human to just read the narrative. Resource definit
ions may define what content should be represented in the narrative to ensure clinical sa
fety."/>
          <comment
                value="Contained resources do not have narrative. Resources that are not c
ontained SHOULD have a narrative. In some cases, a resource may only have text with littl
e or no additional discrete data (as long as all minOccurs=1 elements are satisfied).  Th
is may be necessary for data from legacy systems where information is captured as a &quot
;text blob&quot; or where text is additionally entered raw or narrated and encoded inform
ation is added later."/>
          <alias value="narrative"/>
          <alias value="html"/>
          <alias value="xhtml"/>
          <alias value="display"/>
          <min value="0"/>
          <max value="1"/>
          <base>
            <path value="DomainResource.text"/>
            <min value="0"/>
            <max value="1"/>
          </base>
          <type>
            <code value="Narrative"/>
          </type>
          <isModifier value="false"/>
          <isSummary value="false"/>
          <mapping>
            <identity value="rim"/>
            <map value="Act.text?"/>
          </mapping>
        </element>
        <element id="MedicationKnowledge.contained">
          <path value="MedicationKnowledge.contained"/>
          <short value="Contained, inline Resources"/>
          <definition
                    value="These resources do not have an independent existence apart from
the resource that contains them - they cannot be identified independently, and nor can th
ey have their own independent transaction scope."/>
          <comment
```

```
                    value="This should never be done when the content can be identified proper
ly, as once identification is lost, it is extremely difficult (and context dependent) to
restore it again. Contained resources may have profiles and tags In their meta elements,
but SHALL NOT have security labels."/>
        <alias value="inline resources"/>
        <alias value="anonymous resources"/>
        <alias value="contained resources"/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="DomainResource.contained"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Resource"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="N/A"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.extension">
        <path value="MedicationKnowledge.extension"/>
        <slicing id="1">
          <discriminator>
            <type value="value"/>
            <path value="url"/>
          </discriminator>
          <ordered value="false"/>
          <rules value="open"/>
        </slicing>
        <short value="Extension"/>
        <definition value="An Extension"/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="DomainResource.extension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="MedicationKnowledge.extension:productType">
        <extension
                  url="http://hl7.org/fhir/StructureDefinition/structuredefinition-standar
ds-status">
          <valueCode value="normative"/>
        </extension>
        <extension
                  url="http://hl7.org/fhir/StructureDefinition/structuredefinition-normati
```

```
ve-version">
          <valueCode value="4.0.0"/>
        </extension>
        <path value="MedicationKnowledge.extension"/>
        <sliceName value="productType"/>
        <short value="Specification Type"/>
        <definition
                    value="A classification of specification related to the kind of the ent
ity it is referencing. [Source: SME Defined]."/>
        <min value="1"/>
        <max value="1"/>
        <base>
          <path value="DomainResource.extension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
          <profile
                    value="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-productTyp
e"/>
        </type>
        <condition value="ele-1"/>
        <constraint>
          <key value="ele-1"/>
          <severity value="error"/>
          <human value="All FHIR elements must have a @value or children"/>
          <expression value="hasValue() or (children().count() &gt; id.count())"/>
          <xpath value="@value|f:*|h:div"/>
          <source value="Element"/>
        </constraint>
        <constraint>
          <key value="ext-1"/>
          <severity value="error"/>
          <human value="Must have either extensions or value[x], not both"/>
          <expression value="extension.exists() != value.exists()"/>
          <xpath
                  value="exists(f:extension)!=exists(f:*[starts-with(local-name(.), &#39;val
ue&#39;)])"/>
          <source value="Extension"/>
        </constraint>
        <mustSupport value="true"/>
        <isModifier value="false"/>
      </element>
      <element id="MedicationKnowledge.extension:productType.id">
        <path value="MedicationKnowledge.extension.id"/>
        <representation value="xmlAttr"/>
        <short value="Unique id for inter-element referencing"/>
        <definition
                    value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Element.id"/>
          <min value="0"/>
          <max value="1"/>
```

```xml
        </base>
        <type>
          <code value="string"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.extension:productType.extension">
        <path value="MedicationKnowledge.extension.extension"/>
        <slicing>
          <discriminator>
            <type value="value"/>
            <path value="url"/>
          </discriminator>
          <description value="Extensions are always sliced by (at least) url"/>
          <rules value="open"/>
        </slicing>
        <short value="Additional content defined by implementations"/>
        <definition
                  value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
        <comment
                value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
        <alias value="extensions"/>
        <alias value="user content"/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="Element.extension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.extension:productType.url">
        <path value="MedicationKnowledge.extension.url"/>
        <representation value="xmlAttr"/>
        <short value="identifies the meaning of the extension"/>
        <definition
```

```
                          value="Source of the definition for the extension code - a logical name
 or a URL."/>
        <comment
                  value="The definition may point directly to a computable or human-readable
 definition of the extensibility codes, or it may be a logical URI as declared in some ot
her specification. The definition SHALL be a URI for the Structure Definition defining th
e extension."/>
        <min value="1"/>
        <max value="1"/>
        <base>
          <path value="Extension.url"/>
          <min value="1"/>
          <max value="1"/>
        </base>
        <type>
          <code value="uri"/>
        </type>
        <fixedUri
                  value="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-productType
"/>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="N/A"/>
        </mapping>
    </element>
    <element id="MedicationKnowledge.extension:productType.valueCode">
        <path value="MedicationKnowledge.extension.valueCode"/>
        <short value="Drug Product"/>
        <definition
                  value="Value of extension - must be one of a constrained set of the dat
a types (see [Extensibility](http://build.fhir.org/extensibility.html) for a list)."/>
        <min value="1"/>
        <max value="1"/>
        <base>
          <path value="Extension.value[x]"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="code"/>
        </type>
        <fixedCode value="product"/>
        <mustSupport value="true"/>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="N/A"/>
        </mapping>
    </element>
    <element id="MedicationKnowledge.modifierExtension">
        <path value="MedicationKnowledge.modifierExtension"/>
        <short value="Extensions that cannot be ignored"/>
        <definition
                  value="May be used to represent additional information that is not part
```

 of the basic definition of the resource and that modifies the understanding of the eleme
nt that contains it and/or the understanding of the containing element's descendants.
 Usually modifier elements provide negation or qualification. To make the use of extensio
ns safe and manageable, there is a strict set of governance applied to the definition and
 use of extensions. Though any implementer is allowed to define an extension, there is a
set of requirements that SHALL be met as part of the definition of the extension. Applica
tions processing a resource are required to check for modifier extensions.

Modifier extensions SHALL NOT change the meaning of any elements on Resource or DomainRes
ource (including cannot change the meaning of modifierExtension itself)."/>
      <comment
                value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions. The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
      <requirements
                    value="Modifier extensions allow for extensions that *cannot* be safe
ly ignored to be clearly distinguished from the vast majority of extensions which can be
safely ignored. This promotes interoperability by eliminating the need for implementers
to prohibit the presence of extensions. For further information, see the [definition of m
odifier extensions](http://build.fhir.org/extensibility.html#modifierExtension)."/>
      <alias value="extensions"/>
      <alias value="user content"/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="DomainResource.modifierExtension"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Extension"/>
      </type>
      <isModifier value="true"/>
      <isModifierReason
                        value="Modifier extensions are expected to modify the meaning or
interpretation of the resource that contains them"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="N/A"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.code">
      <path value="MedicationKnowledge.code"/>
      <short value="Code that identifies this medication"/>
      <definition
                  value="A code that specifies this medication, or a textual description
if no code is available. Usage note: This could be a standard medication code such as a c
ode from RxNorm, SNOMED CT, IDMP etc. It could also be a national or local formulary code
, optionally with translations to other code systems."/>
      <comment
                value="Depending on the context of use, the code that was actually selecte
d by the user (prescriber, dispenser, etc.) will have the coding.userSelected set to true
. As described in the coding datatype: "A coding may be marked as a "userSelec
ted" if a user selected the particular coded value in a user interface (e.g. the use
r selects an item in a pick-list). If a user selected coding exists, it is the preferred

```
choice for performing translations etc. Other codes can only be literal translations to a
lternative code systems, or codes at a lower level of granularity (e.g. a generic code fo
r a vendor-specific primary one)."/>
      <min value="1"/>
      <max value="1"/>
      <base>
        <path value="MedicationKnowledge.code"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="CodeableConcept"/>
      </type>
      <mustSupport value="true"/>
      <isModifier value="false"/>
      <isSummary value="true"/>
      <binding>
        <extension
                   url="http://hl7.org/fhir/StructureDefinition/elementdefinition-binding
Name">
          <valueString value="MedicationFormalRepresentation"/>
        </extension>
        <strength value="example"/>
        <description
                     value="A coded concept that defines the type of a medication."/>
        <valueSet value="http://hl7.org/fhir/ValueSet/medication-codes"/>
      </binding>
      <mapping>
        <identity value="script10.6"/>
        <map
              value="coding.code = //element(*,MedicationType)/DrugCoded/ProductCode

coding.system = //element(*,MedicationType)/DrugCoded/ProductCodeQualifier

coding.display = //element(*,MedicationType)/DrugDescription"/>
      </mapping>
      <mapping>
        <identity value="w5"/>
        <map value="FiveWs.class"/>
      </mapping>
      <mapping>
        <identity value="v2"/>
        <map
              value="RXO-1.1-Requested Give Code.code / RXE-2.1-Give Code.code / RXD-2.1-D
ispense/Give Code.code / RXG-4.1-Give Code.code /RXA-5.1-Administered Code.code / RXC-2.1
 Component Code"/>
      </mapping>
      <mapping>
        <identity value="rim"/>
        <map value=".code"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.code.id">
      <path value="MedicationKnowledge.code.id"/>
      <representation value="xmlAttr"/>
      <short value="Unique id for inter-element referencing"/>
      <definition
```

```xml
                        value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Element.id"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="string"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.code.extension">
        <path value="MedicationKnowledge.code.extension"/>
        <slicing>
          <discriminator>
            <type value="value"/>
            <path value="url"/>
          </discriminator>
          <description value="Extensions are always sliced by (at least) url"/>
          <rules value="open"/>
        </slicing>
        <short value="Additional content defined by implementations"/>
        <definition
                    value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
        <comment
                value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
        <alias value="extensions"/>
        <alias value="user content"/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="Element.extension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
```

```xml
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.code.coding">
        <path value="MedicationKnowledge.code.coding"/>
        <short value="Code defined by a terminology system"/>
        <definition value="A reference to a code defined by a terminology system."/>
        <comment
                 value="Codes may be defined very casually in enumerations, or code lists,
up to very formal definitions such as SNOMED CT - see the HL7 v3 Core Principles for more
 information.  Ordering of codings is undefined and SHALL NOT be used to infer meaning. G
enerally, at most only one of the coding values will be labeled as UserSelected = true."/
>
        <requirements
                     value="Allows for alternative encodings within a code system, and tra
nslations to other code systems."/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="CodeableConcept.coding"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Coding"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="true"/>
        <mapping>
          <identity value="v2"/>
          <map value="C*E.1-8, C*E.10-22"/>
        </mapping>
        <mapping>
          <identity value="rim"/>
          <map value="union(., ./translation)"/>
        </mapping>
        <mapping>
          <identity value="orim"/>
          <map value="fhir:CodeableConcept.coding rdfs:subPropertyOf dt:CD.coding"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.code.text">
        <extension
                 url="http://hl7.org/fhir/StructureDefinition/elementdefinition-translata
ble">
          <valueBoolean value="true"/>
        </extension>
        <path value="MedicationKnowledge.code.text"/>
        <short value="Non-proprietary Name"/>
        <definition
                    value="A name unprotected by trademark rights that is entirely in the p
ublic domain. It may be used without restriction by the public at large, both lay and pro
fessional. [Source: http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRe
quirements/ElectronicSubmissions/DataStandardsManualmonographs/ucm071638.htm ]."/>
        <comment
                value="Very often the text is the same as a displayName of one of the codi
ngs."/>
```

```xml
      <requirements
                  value="The codes from the terminologies do not always capture the cor
rect meaning with all the nuances of the human using them, or sometimes there is no appro
priate code at all. In these cases, the text is used to capture the full meaning of the s
ource."/>
      <min value="1"/>
      <max value="1"/>
      <base>
        <path value="CodeableConcept.text"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="string"/>
      </type>
      <mustSupport value="true"/>
      <isModifier value="false"/>
      <isSummary value="true"/>
      <mapping>
        <identity value="v2"/>
        <map value="C*E.9. But note many systems use C*E.2 for this"/>
      </mapping>
      <mapping>
        <identity value="rim"/>
        <map value="./originalText[mediaType/code=&quot;text/plain&quot;]/data"/>
      </mapping>
      <mapping>
        <identity value="orim"/>
        <map
            value="fhir:CodeableConcept.text rdfs:subPropertyOf dt:CD.originalText"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.status">
      <path value="MedicationKnowledge.status"/>
      <short value="active | inactive | entered-in-error"/>
      <definition
                  value="A code to indicate if the medication is in active use.  The stat
us refers to the validity about the information of the medication and not to its medicina
l properties."/>
      <comment
                value="This status is intended to identify if the medication in a local sy
stem is in active use within a drug database or inventory.  For example, a pharmacy syste
m may create a new drug file record for a compounded product &quot;ABC Hospital Special C
ream&quot; with an active status.  At some point in the future, it may be determined that
 the drug record was created with an error and the status is changed to &quot;entered in
error&quot;.   This status is not intended to specify if a medication is part of a partic
ular formulary.  It is possible that the drug record may be referenced by multiple formul
aries or catalogues and each of those entries would have a separate status."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="MedicationKnowledge.status"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="code"/>
```

```
            </type>
            <isModifier value="true"/>
            <isModifierReason
                             value="This element changes the interpretation of all descriptive
  attributes."/>
            <isSummary value="true"/>
            <binding>
              <extension
                          url="http://hl7.org/fhir/StructureDefinition/elementdefinition-binding
Name">
                 <valueString value="MedicationKnowledgeStatus"/>
              </extension>
              <strength value="required"/>
              <description
                           value="A coded concept defining if the medication is in active use."
/>
              <valueSet
                          value="http://hl7.org/fhir/ValueSet/medicationknowledge-status|4.0.0"/>
            </binding>
            <mapping>
              <identity value="rim"/>
              <map value=".statusCode"/>
            </mapping>
        </element>
        <element id="MedicationKnowledge.manufacturer">
            <path value="MedicationKnowledge.manufacturer"/>
            <short value="Manufacturer of the item"/>
            <definition
                        value="Describes the details of the manufacturer of the medication prod
uct.  This is not intended to represent the distributor of a medication product."/>
            <min value="0"/>
            <max value="1"/>
            <base>
              <path value="MedicationKnowledge.manufacturer"/>
              <min value="0"/>
              <max value="1"/>
            </base>
            <type>
              <code value="Reference"/>
              <targetProfile
                              value="http://hl7.org/fhir/StructureDefinition/Organization"/>
            </type>
            <isModifier value="false"/>
            <isSummary value="true"/>
            <mapping>
              <identity value="script10.6"/>
              <map value="no mapping"/>
            </mapping>
            <mapping>
              <identity value="w5"/>
              <map value="FiveWs.actor"/>
            </mapping>
            <mapping>
              <identity value="v2"/>
              <map
                   value="RXD-20-Substance Manufacturer Name / RXG-21-Substance Manufacturer Na
me / RXA-17-Substance Manufacturer Name"/>
```

```xml
        </mapping>
        <mapping>
          <identity value="rim"/>
          <map value=".player.scopingRole[typeCode=MANU].scoper"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.doseForm">
        <path value="MedicationKnowledge.doseForm"/>
        <short value="Dosage Form"/>
        <definition
                  value="The form in which active and/or inert ingredient(s) are physical
ly presented. [Source: NCI EVS - C42636]
Examples: tablet, capsule, solution, cream, etc. that contains a drug substance generally
, but not necessarily, in association with excipients. [Source: ICH Q1A(R2)]
Note: If there is a new dosage form that does not exist in the controlled terminology, th
en propose register this new dosage form during sponsor meetings with FDA."/>
        <comment
                value="When Medication is referenced from MedicationRequest, this is the o
rdered form.  When Medication is referenced within MedicationDispense, this is the dispen
sed form.  When Medication is referenced within MedicationAdministration, this is adminis
tered form."/>
        <min value="1"/>
        <max value="1"/>
        <base>
          <path value="MedicationKnowledge.doseForm"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="CodeableConcept"/>
        </type>
        <mustSupport value="true"/>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <binding>
          <extension
                    url="http://hl7.org/fhir/StructureDefinition/elementdefinition-binding
Name">
            <valueString value="MedicationForm"/>
          </extension>
          <strength value="example"/>
          <description value="A coded concept defining the form of a medication."/>
          <valueSet value="http://hl7.org/fhir/ValueSet/medication-form-codes"/>
        </binding>
        <mapping>
          <identity value="script10.6"/>
          <map
              value="coding.code =  //element(*,DrugCodedType)/FormCode

coding.system = //element(*,DrugCodedType)/FormSourceCode"/>
        </mapping>
        <mapping>
          <identity value="v2"/>
          <map
              value="RXO-5-Requested Dosage Form / RXE-6-Give Dosage Form / RXD-6-Actual D
osage Form / RXG-8-Give Dosage Form / RXA-8-Administered Dosage Form"/>
        </mapping>
```

```xml
      <mapping>
        <identity value="rim"/>
        <map value=".formCode"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.amount">
      <path value="MedicationKnowledge.amount"/>
      <short value="Amount of drug in package"/>
      <definition
                  value="Specific amount of the drug in the packaged product.  For exampl
e, when specifying a product that has the same strength (For example, Insulin glargine 10
0 unit per mL solution for injection), this attribute provides additional clarification o
f the package amount (For example, 3 mL, 10mL, etc.)."/>
      <comment
               value="This is the quantity of medication in a package.  To specify the st
rength of the medication, the Ingredient.strength attribute is used."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="MedicationKnowledge.amount"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="Quantity"/>
        <profile value="http://hl7.org/fhir/StructureDefinition/SimpleQuantity"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="true"/>
      <mapping>
        <identity value="rim"/>
        <map value=".quantity"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.synonym">
      <path value="MedicationKnowledge.synonym"/>
      <slicing>
        <discriminator>
          <type value="value"/>
          <path
                value="extension(&#39;http://fda.gov/cder/fhir/pqcmc/StructureDefinition/
ext-nameType&#39;).valueCode"/>
        </discriminator>
        <rules value="open"/>
      </slicing>
      <short value="Additional names for a medication"/>
      <definition
                  value="Additional names for a medication, for example, the name(s) give
n to a medication in different countries.  For example, acetaminophen and paracetamol or
salbutamol and albuterol."/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="MedicationKnowledge.synonym"/>
        <min value="0"/>
        <max value="*"/>
      </base>
```

```
        <type>
          <code value="string"/>
        </type>
        <mustSupport value="true"/>
        <isModifier value="false"/>
        <isSummary value="true"/>
      </element>
      <element id="MedicationKnowledge.relatedMedicationKnowledge">
        <path value="MedicationKnowledge.relatedMedicationKnowledge"/>
        <short value="Associated or related medication information"/>
        <definition value="Associated or related knowledge about a medication."/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="MedicationKnowledge.relatedMedicationKnowledge"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="BackboneElement"/>
        </type>
        <constraint>
          <key value="ele-1"/>
          <severity value="error"/>
          <human value="All FHIR elements must have a @value or children"/>
          <expression value="hasValue() or (children().count() &gt; id.count())"/>
          <xpath value="@value|f:*|h:div"/>
          <source value="Element"/>
        </constraint>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="MedicationKnowledge.relatedMedicationKnowledge.id">
        <path value="MedicationKnowledge.relatedMedicationKnowledge.id"/>
        <representation value="xmlAttr"/>
        <short value="Unique id for inter-element referencing"/>
        <definition
                    value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Element.id"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="string"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.relatedMedicationKnowledge.extension">
```

```
        <path value="MedicationKnowledge.relatedMedicationKnowledge.extension"/>
        <short value="Additional content defined by implementations"/>
        <definition
                   value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
        <comment
                 value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
        <alias value="extensions"/>
        <alias value="user content"/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="Element.extension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element
               id="MedicationKnowledge.relatedMedicationKnowledge.modifierExtension">
        <path
              value="MedicationKnowledge.relatedMedicationKnowledge.modifierExtension"/>
        <short value="Extensions that cannot be ignored even if unrecognized"/>
        <definition
                   value="May be used to represent additional information that is not part
 of the basic definition of the element and that modifies the understanding of the elemen
t in which it is contained and/or the understanding of the containing element&#39;s desce
ndants. Usually modifier elements provide negation or qualification. To make the use of e
xtensions safe and manageable, there is a strict set of governance applied to the definit
ion and use of extensions. Though any implementer can define an extension, there is a set
 of requirements that SHALL be met as part of the definition of the extension. Applicatio
ns processing a resource are required to check for modifier extensions.

Modifier extensions SHALL NOT change the meaning of any elements on Resource or DomainRes
ource (including cannot change the meaning of modifierExtension itself)."/>
        <comment
                 value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
        <requirements
                      value="Modifier extensions allow for extensions that *cannot* be safe
ly ignored to be clearly distinguished from the vast majority of extensions which can be
```

```
safely ignored.  This promotes interoperability by eliminating the need for implementers
to prohibit the presence of extensions. For further information, see the [definition of m
odifier extensions](http://build.fhir.org/extensibility.html#modifierExtension)."/>
      <alias value="extensions"/>
      <alias value="user content"/>
      <alias value="modifiers"/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="BackboneElement.modifierExtension"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Extension"/>
      </type>
      <isModifier value="true"/>
      <isModifierReason
                        value="Modifier extensions are expected to modify the meaning or
interpretation of the element that contains them"/>
      <isSummary value="true"/>
      <mapping>
        <identity value="rim"/>
        <map value="N/A"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.relatedMedicationKnowledge.type">
      <path value="MedicationKnowledge.relatedMedicationKnowledge.type"/>
      <short value="Category of medicationKnowledge"/>
      <definition
                 value="The category of the associated medication knowledge reference."/
>
      <min value="1"/>
      <max value="1"/>
      <base>
        <path value="MedicationKnowledge.relatedMedicationKnowledge.type"/>
        <min value="1"/>
        <max value="1"/>
      </base>
      <type>
        <code value="CodeableConcept"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="MedicationKnowledge.relatedMedicationKnowledge.reference">
      <path value="MedicationKnowledge.relatedMedicationKnowledge.reference"/>
      <short
             value="Associated documentation about the associated medication knowledge"/>
      <definition
                  value="Associated documentation about the associated medication knowled
ge."/>
      <min value="1"/>
      <max value="*"/>
      <base>
        <path value="MedicationKnowledge.relatedMedicationKnowledge.reference"/>
        <min value="1"/>
```

```
      <max value="*"/>
    </base>
    <type>
      <code value="Reference"/>
      <targetProfile
                  value="http://hl7.org/fhir/StructureDefinition/MedicationKnowledge
"/>
    </type>
    <isModifier value="false"/>
    <isSummary value="false"/>
  </element>
  <element id="MedicationKnowledge.associatedMedication">
    <path value="MedicationKnowledge.associatedMedication"/>
    <short
          value="A medication resource that is associated with this medication"/>
    <definition
              value="Associated or related medications.  For example, if the medicati
on is a branded product (e.g. Crestor), this is the Therapeutic Moeity (e.g. Rosuvastatin
) or if this is a generic medication (e.g. Rosuvastatin), this would link to a branded pr
oduct (e.g. Crestor)."/>
    <min value="0"/>
    <max value="*"/>
    <base>
      <path value="MedicationKnowledge.associatedMedication"/>
      <min value="0"/>
      <max value="*"/>
    </base>
    <type>
      <code value="Reference"/>
      <targetProfile
                  value="http://hl7.org/fhir/StructureDefinition/Medication"/>
    </type>
    <isModifier value="false"/>
    <isSummary value="false"/>
  </element>
  <element id="MedicationKnowledge.productType">
    <path value="MedicationKnowledge.productType"/>
    <short value="Category of the medication or product"/>
    <definition
              value="Category of the medication or product (e.g. branded product, the
rapeutic moeity, generic product, innovator product, etc.)."/>
    <min value="0"/>
    <max value="*"/>
    <base>
      <path value="MedicationKnowledge.productType"/>
      <min value="0"/>
      <max value="*"/>
    </base>
    <type>
      <code value="CodeableConcept"/>
    </type>
    <isModifier value="false"/>
    <isSummary value="false"/>
  </element>
  <element id="MedicationKnowledge.monograph">
    <path value="MedicationKnowledge.monograph"/>
    <short value="Associated documentation about the medication"/>
```

```
        <definition value="Associated documentation about the medication."/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="MedicationKnowledge.monograph"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="BackboneElement"/>
        </type>
        <constraint>
          <key value="ele-1"/>
          <severity value="error"/>
          <human value="All FHIR elements must have a @value or children"/>
          <expression value="hasValue() or (children().count() &gt; id.count())"/>
          <xpath value="@value|f:*|h:div"/>
          <source value="Element"/>
        </constraint>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="MedicationKnowledge.monograph.id">
        <path value="MedicationKnowledge.monograph.id"/>
        <representation value="xmlAttr"/>
        <short value="Unique id for inter-element referencing"/>
        <definition
                    value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Element.id"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="string"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.monograph.extension">
        <path value="MedicationKnowledge.monograph.extension"/>
        <short value="Additional content defined by implementations"/>
        <definition
                    value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
        <comment
                value="There can be no stigma associated with the use of extensions by any
```

```
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
        <alias value="extensions"/>
        <alias value="user content"/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="Element.extension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.monograph.modifierExtension">
        <path value="MedicationKnowledge.monograph.modifierExtension"/>
        <short value="Extensions that cannot be ignored even if unrecognized"/>
        <definition
                    value="May be used to represent additional information that is not part
 of the basic definition of the element and that modifies the understanding of the elemen
t in which it is contained and/or the understanding of the containing element&#39;s desce
ndants. Usually modifier elements provide negation or qualification. To make the use of e
xtensions safe and manageable, there is a strict set of governance applied to the definit
ion and use of extensions. Though any implementer can define an extension, there is a set
 of requirements that SHALL be met as part of the definition of the extension. Applicatio
ns processing a resource are required to check for modifier extensions.

Modifier extensions SHALL NOT change the meaning of any elements on Resource or DomainRes
ource (including cannot change the meaning of modifierExtension itself)."/>
        <comment
                 value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
        <requirements
                       value="Modifier extensions allow for extensions that *cannot* be safe
ly ignored to be clearly distinguished from the vast majority of extensions which can be
safely ignored.  This promotes interoperability by eliminating the need for implementers
to prohibit the presence of extensions. For further information, see the [definition of m
odifier extensions](http://build.fhir.org/extensibility.html#modifierExtension)."/>
        <alias value="extensions"/>
        <alias value="user content"/>
        <alias value="modifiers"/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="BackboneElement.modifierExtension"/>
          <min value="0"/>
          <max value="*"/>
```

```xml
        </base>
        <type>
          <code value="Extension"/>
        </type>
        <isModifier value="true"/>
        <isModifierReason
                           value="Modifier extensions are expected to modify the meaning or
interpretation of the element that contains them"/>
        <isSummary value="true"/>
        <mapping>
          <identity value="rim"/>
          <map value="N/A"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.monograph.type">
        <path value="MedicationKnowledge.monograph.type"/>
        <short value="The category of medication document"/>
        <definition
                    value="The category of documentation about the medication. (e.g. profes
sional monograph, patient education monograph)."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="MedicationKnowledge.monograph.type"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="CodeableConcept"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="MedicationKnowledge.monograph.source">
        <path value="MedicationKnowledge.monograph.source"/>
        <short value="Associated documentation about the medication"/>
        <definition value="Associated documentation about the medication."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="MedicationKnowledge.monograph.source"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="Reference"/>
          <targetProfile
                         value="http://hl7.org/fhir/StructureDefinition/DocumentReference"/
>
          <targetProfile value="http://hl7.org/fhir/StructureDefinition/Media"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="MedicationKnowledge.ingredient">
        <path value="MedicationKnowledge.ingredient"/>
        <short value="Product Component Name"/>
```

```
      <definition
                value="Any ingredient intended for use in the manufacture of a drug pro
duct, including those that may not appear in such drug product. [Source: (21 CFR 210.3(b)
(3)) PAC-ATLS 1998]."/>
      <min value="1"/>
      <max value="*"/>
      <base>
        <path value="MedicationKnowledge.ingredient"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="BackboneElement"/>
      </type>
      <constraint>
        <key value="ele-1"/>
        <severity value="error"/>
        <human value="All FHIR elements must have a @value or children"/>
        <expression value="hasValue() or (children().count() &gt; id.count())"/>
        <xpath value="@value|f:*|h:div"/>
        <source value="Element"/>
      </constraint>
      <mustSupport value="true"/>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="MedicationKnowledge.ingredient.id">
      <path value="MedicationKnowledge.ingredient.id"/>
      <representation value="xmlAttr"/>
      <short value="Unique id for inter-element referencing"/>
      <definition
                value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="Element.id"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="string"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="n/a"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.ingredient.extension">
      <path value="MedicationKnowledge.ingredient.extension"/>
      <slicing id="2">
        <discriminator>
          <type value="value"/>
          <path value="url"/>
        </discriminator>
```

```xml
          <ordered value="false"/>
          <rules value="open"/>
        </slicing>
        <short value="Extension"/>
        <definition value="An Extension"/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="Element.extension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="MedicationKnowledge.ingredient.extension:contentPercent">
        <extension
                  url="http://hl7.org/fhir/StructureDefinition/structuredefinition-standar
ds-status">
          <valueCode value="normative"/>
        </extension>
        <extension
                  url="http://hl7.org/fhir/StructureDefinition/structuredefinition-normati
ve-version">
          <valueCode value="4.0.0"/>
        </extension>
        <path value="MedicationKnowledge.ingredient.extension"/>
        <sliceName value="contentPercent"/>
        <short value="Content percent"/>
        <definition
                  value="The percentage of the component in the drug product. [Source: SM
E Defined]."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Element.extension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
          <profile
                  value="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-contentPer
cent"/>
        </type>
        <condition value="ele-1"/>
        <constraint>
          <key value="ele-1"/>
          <severity value="error"/>
          <human value="All FHIR elements must have a @value or children"/>
          <expression value="hasValue() or (children().count() &gt; id.count())"/>
          <xpath value="@value|f:*|h:div"/>
          <source value="Element"/>
        </constraint>
```

```
          <constraint>
            <key value="ext-1"/>
            <severity value="error"/>
            <human value="Must have either extensions or value[x], not both"/>
            <expression value="extension.exists() != value.exists()"/>
            <xpath
                    value="exists(f:extension)!=exists(f:*[starts-with(local-name(.), &#39;val
ue&#39;)])"/>
            <source value="Extension"/>
          </constraint>
          <mustSupport value="true"/>
          <isModifier value="false"/>
        </element>
        <element id="MedicationKnowledge.ingredient.modifierExtension">
          <path value="MedicationKnowledge.ingredient.modifierExtension"/>
          <short value="Extensions that cannot be ignored even if unrecognized"/>
          <definition
                     value="May be used to represent additional information that is not part
 of the basic definition of the element and that modifies the understanding of the elemen
t in which it is contained and/or the understanding of the containing element&#39;s desce
ndants. Usually modifier elements provide negation or qualification. To make the use of e
xtensions safe and manageable, there is a strict set of governance applied to the definit
ion and use of extensions. Though any implementer can define an extension, there is a set
 of requirements that SHALL be met as part of the definition of the extension. Applicatio
ns processing a resource are required to check for modifier extensions.

Modifier extensions SHALL NOT change the meaning of any elements on Resource or DomainRes
ource (including cannot change the meaning of modifierExtension itself)."/>
          <comment
                    value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
          <requirements
                        value="Modifier extensions allow for extensions that *cannot* be safe
ly ignored to be clearly distinguished from the vast majority of extensions which can be
safely ignored.  This promotes interoperability by eliminating the need for implementers
to prohibit the presence of extensions. For further information, see the [definition of m
odifier extensions](http://build.fhir.org/extensibility.html#modifierExtension)."/>
          <alias value="extensions"/>
          <alias value="user content"/>
          <alias value="modifiers"/>
          <min value="0"/>
          <max value="*"/>
          <base>
            <path value="BackboneElement.modifierExtension"/>
            <min value="0"/>
            <max value="*"/>
          </base>
          <type>
            <code value="Extension"/>
          </type>
          <isModifier value="true"/>
          <isModifierReason
                            value="Modifier extensions are expected to modify the meaning or
interpretation of the element that contains them"/>
          <isSummary value="true"/>
```

```
      <mapping>
        <identity value="rim"/>
        <map value="N/A"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.ingredient.item[x]">
      <path value="MedicationKnowledge.ingredient.item[x]"/>
      <short value="Medication(s) or substance(s) contained in the medication"/>
      <definition
                  value="The actual ingredient - either a substance (simple ingredient) o
r another medication."/>
      <min value="1"/>
      <max value="1"/>
      <base>
        <path value="MedicationKnowledge.ingredient.item[x]"/>
        <min value="1"/>
        <max value="1"/>
      </base>
      <type>
        <code value="CodeableConcept"/>
      </type>
      <type>
        <code value="Reference"/>
        <targetProfile value="http://hl7.org/fhir/StructureDefinition/Substance"/>
      </type>
      <mustSupport value="true"/>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="script10.6"/>
        <map
            value="coding.code = //element(*,MedicationType)/DrugCoded/ProductCode

coding.system = //element(*,MedicationType)/DrugCoded/ProductCodeQualifier

coding.display = //element(*,MedicationType)/DrugDescription"/>
      </mapping>
      <mapping>
        <identity value="v2"/>
        <map
            value="RXC-2-Component Code  if medication: RXO-1-Requested Give Code / RXE-
2-Give Code / RXD-2-Dispense/Give Code / RXG-4-Give Code / RXA-5-Administered Code"/>
      </mapping>
      <mapping>
        <identity value="rim"/>
        <map value=".player"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.ingredient.isActive">
      <path value="MedicationKnowledge.ingredient.isActive"/>
      <short value="Active ingredient indicator"/>
      <definition
                  value="Indication of whether this ingredient affects the therapeutic ac
tion of the drug."/>
      <requirements
                    value="True indicates that the ingredient affects the therapeutic act
ion of the drug (i.e. active).
```

```
False indicates that the ingredient does not affect the therapeutic action of the drug (i
.e. inactive)."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="MedicationKnowledge.ingredient.isActive"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="boolean"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="NA"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.ingredient.strength">
        <path value="MedicationKnowledge.ingredient.strength"/>
        <short value="Strength"/>
        <definition
                  value="The content of an active ingredient expressed quantitatively per
 dosage unit, per unit of volume, or per unit of weight, according to the pharmaceutical
dosage form. This should be the strength as listed on the label. [Source: Adapted from NC
I EVS C53294]
Note: Strength can also be referred to as potency in biologics and other products.  This
information may be captured on the label."/>
        <min value="1"/>
        <max value="*"/>
        <base>
          <path value="MedicationKnowledge.ingredient.strength"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="Ratio"/>
        </type>
        <mustSupport value="true"/>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="script10.6"/>
          <map value="//element(*,DrugCodedType)/Strength"/>
        </mapping>
        <mapping>
          <identity value="v2"/>
          <map
              value="RXC-3-Component Amount &amp; RXC-4-Component Units  if medication: RX
O-2-Requested Give Amount - Minimum &amp; RXO-4-Requested Give Units / RXO-3-Requested Gi
ve Amount - Maximum &amp; RXO-4-Requested Give Units / RXO-11-Requested Dispense Amount &
amp; RXO-12-Requested Dispense Units / RXE-3-Give Amount - Minimum &amp; RXE-5-Give Units
 / RXE-4-Give Amount - Maximum &amp; RXE-5-Give Units / RXE-10-Dispense Amount &amp; RXE-
10-Dispense Units"/>
        </mapping>
        <mapping>
```

```xml
            <identity value="rim"/>
            <map value=".quantity"/>
          </mapping>
        </element>
        <element id="MedicationKnowledge.ingredient.strength.id">
          <path value="MedicationKnowledge.ingredient.strength.id"/>
          <representation value="xmlAttr"/>
          <short value="Unique id for inter-element referencing"/>
          <definition
                    value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
          <min value="0"/>
          <max value="1"/>
          <base>
            <path value="Element.id"/>
            <min value="0"/>
            <max value="1"/>
          </base>
          <type>
            <code value="string"/>
          </type>
          <isModifier value="false"/>
          <isSummary value="false"/>
          <mapping>
            <identity value="rim"/>
            <map value="n/a"/>
          </mapping>
        </element>
        <element id="MedicationKnowledge.ingredient.strength.extension">
          <path value="MedicationKnowledge.ingredient.strength.extension"/>
          <slicing>
            <discriminator>
              <type value="value"/>
              <path value="url"/>
            </discriminator>
            <description value="Extensions are always sliced by (at least) url"/>
            <rules value="open"/>
          </slicing>
          <short value="Additional content defined by implementations"/>
          <definition
                    value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
          <comment
                  value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
          <alias value="extensions"/>
          <alias value="user content"/>
          <min value="0"/>
          <max value="*"/>
          <base>
            <path value="Element.extension"/>
            <min value="0"/>
```

```xml
        <max value="*"/>
      </base>
      <type>
        <code value="Extension"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="n/a"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.ingredient.strength.numerator">
      <path value="MedicationKnowledge.ingredient.strength.numerator"/>
      <short value="Strength Unit"/>
      <definition
                  value="The labeled unit of measure for the content of an active ingredi
ent, expressed quantitatively per dosage unit. [Source: Adapted for NCI EVS C117055]."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="Ratio.numerator"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="Quantity"/>
      </type>
      <mustSupport value="true"/>
      <isModifier value="false"/>
      <isSummary value="true"/>
      <mapping>
        <identity value="rim"/>
        <map value=".numerator"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.ingredient.strength.numerator.id">
      <path value="MedicationKnowledge.ingredient.strength.numerator.id"/>
      <representation value="xmlAttr"/>
      <short value="Unique id for inter-element referencing"/>
      <definition
                  value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="Element.id"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="string"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
```

```
          <map value="n/a"/>
      </mapping>
   </element>
   <element id="MedicationKnowledge.ingredient.strength.numerator.extension">
      <path value="MedicationKnowledge.ingredient.strength.numerator.extension"/>
      <slicing>
        <discriminator>
          <type value="value"/>
          <path value="url"/>
        </discriminator>
        <description value="Extensions are always sliced by (at least) url"/>
        <rules value="open"/>
      </slicing>
      <short value="Additional content defined by implementations"/>
      <definition
                 value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
      <comment
                value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
      <alias value="extensions"/>
      <alias value="user content"/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="Element.extension"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Extension"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="n/a"/>
      </mapping>
   </element>
   <element id="MedicationKnowledge.ingredient.strength.numerator.value">
      <path value="MedicationKnowledge.ingredient.strength.numerator.value"/>
      <short value="Numerical value (with implicit precision)"/>
      <definition
                 value="The value of the measured amount. The value includes an implicit
 precision in the presentation of the value."/>
      <comment
                value="The implicit precision in the value should always be honored. Monet
ary values have their own rules for handling precision (refer to standard accounting text
 books)."/>
      <requirements
                    value="Precision is handled implicitly in almost all cases of measure
ment."/>
```

```
      <min value="1"/>
      <max value="1"/>
      <base>
        <path value="Quantity.value"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="decimal"/>
      </type>
      <mustSupport value="true"/>
      <isModifier value="false"/>
      <isSummary value="true"/>
      <mapping>
        <identity value="v2"/>
        <map value="SN.2  / CQ - N/A"/>
      </mapping>
      <mapping>
        <identity value="rim"/>
        <map
            value="PQ.value, CO.value, MO.value, IVL.high or IVL.low depending on the va
lue"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.ingredient.strength.numerator.comparator">
      <path value="MedicationKnowledge.ingredient.strength.numerator.comparator"/>
      <short value="&lt; | &lt;= | &gt;= | &gt; - how to understand the value"/>
      <definition
                  value="How the value should be understood and represented - whether the
 actual value is greater or less than the stated value due to measurement issues; e.g. if
 the comparator is &quot;&lt;&quot; , then the real value is &lt; stated value."/>
      <requirements
                    value="Need a framework for handling measures where the value is &lt;
5ug/L or &gt;400mg/L due to the limitations of measuring methodology."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="Quantity.comparator"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="code"/>
      </type>
      <meaningWhenMissing
                          value="If there is no comparator, then there is no modification
 of the value"/>
      <isModifier value="true"/>
      <isModifierReason
                        value="This is labeled as &quot;Is Modifier&quot; because the com
parator modifies the interpretation of the value significantly. If there is no comparator
, then there is no modification of the value"/>
      <isSummary value="true"/>
      <binding>
        <extension
                  url="http://hl7.org/fhir/StructureDefinition/elementdefinition-binding
Name">
```

```xml
          <valueString value="QuantityComparator"/>
        </extension>
        <strength value="required"/>
        <description
                    value="How the Quantity should be understood and represented."/>
        <valueSet value="http://hl7.org/fhir/ValueSet/quantity-comparator|4.0.0"/>
      </binding>
      <mapping>
        <identity value="v2"/>
        <map value="SN.1  / CQ.1"/>
      </mapping>
      <mapping>
        <identity value="rim"/>
        <map value="IVL properties"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.ingredient.strength.numerator.unit">
      <extension
                url="http://hl7.org/fhir/StructureDefinition/elementdefinition-translata
ble">
        <valueBoolean value="true"/>
      </extension>
      <path value="MedicationKnowledge.ingredient.strength.numerator.unit"/>
      <short value="Unit representation"/>
      <definition value="A human-readable form of the unit."/>
      <requirements
                  value="There are many representations for units of measure and in man
y contexts, particular representations are fixed and required. I.e. mcg for micrograms."/
>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="Quantity.unit"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="string"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="true"/>
      <mapping>
        <identity value="v2"/>
        <map value="(see OBX.6 etc.) / CQ.2"/>
      </mapping>
      <mapping>
        <identity value="rim"/>
        <map value="PQ.unit"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.ingredient.strength.numerator.system">
      <path value="MedicationKnowledge.ingredient.strength.numerator.system"/>
      <short value="System that defines coded unit form"/>
      <definition value="UCUM."/>
      <requirements
                  value="Need to know the system that defines the coded form of the uni
t."/>
```

```
          <min value="1"/>
          <max value="1"/>
          <base>
            <path value="Quantity.system"/>
            <min value="0"/>
            <max value="1"/>
          </base>
          <type>
            <code value="uri"/>
          </type>
          <fixedUri value="http://unitsofmeasure.org"/>
          <condition value="qty-3"/>
          <mustSupport value="true"/>
          <isModifier value="false"/>
          <isSummary value="true"/>
          <mapping>
            <identity value="v2"/>
            <map value="(see OBX.6 etc.) / CQ.2"/>
          </mapping>
          <mapping>
            <identity value="rim"/>
            <map value="CO.codeSystem, PQ.translation.codeSystem"/>
          </mapping>
        </element>
        <element id="MedicationKnowledge.ingredient.strength.numerator.code">
          <path value="MedicationKnowledge.ingredient.strength.numerator.code"/>
          <short value="Strength Unit of Measure"/>
          <definition
                    value="The labeled unit of measure for the content of an active ingredi
ent, expressed quantitatively per dosage unit. [Source: Adapted for NCI EVS C117055] Exam
ples: mg, g, mL, etc."/>
          <comment
                  value="The preferred system is UCUM, but SNOMED CT can also be used (for c
ustomary units) or ISO 4217 for currency.  The context of use may additionally require a
code from a particular system."/>
          <requirements
                      value="Need a computable form of the unit that is fixed across all fo
rms. UCUM provides this for quantities, but SNOMED CT provides many units of interest."/>
          <min value="1"/>
          <max value="1"/>
          <base>
            <path value="Quantity.code"/>
            <min value="0"/>
            <max value="1"/>
          </base>
          <type>
            <code value="code"/>
          </type>
          <mustSupport value="true"/>
          <isModifier value="false"/>
          <isSummary value="true"/>
          <mapping>
            <identity value="v2"/>
            <map value="(see OBX.6 etc.) / CQ.2"/>
          </mapping>
          <mapping>
            <identity value="rim"/>
```

```xml
        <map value="PQ.code, MO.currency, PQ.translation.code"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.ingredient.strength.denominator">
      <path value="MedicationKnowledge.ingredient.strength.denominator"/>
      <short value="Denominator value"/>
      <definition value="The value of the denominator."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="Ratio.denominator"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="Quantity"/>
      </type>
      <mustSupport value="true"/>
      <isModifier value="false"/>
      <isSummary value="true"/>
      <mapping>
        <identity value="rim"/>
        <map value=".denominator"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.ingredient.strength.denominator.id">
      <path value="MedicationKnowledge.ingredient.strength.denominator.id"/>
      <representation value="xmlAttr"/>
      <short value="Unique id for inter-element referencing"/>
      <definition
                 value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="Element.id"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="string"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="n/a"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.ingredient.strength.denominator.extension">
      <path
            value="MedicationKnowledge.ingredient.strength.denominator.extension"/>
      <slicing>
        <discriminator>
          <type value="value"/>
          <path value="url"/>
        </discriminator>
```

```xml
        <description value="Extensions are always sliced by (at least) url"/>
        <rules value="open"/>
      </slicing>
      <short value="Additional content defined by implementations"/>
      <definition
               value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
      <comment
             value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
      <alias value="extensions"/>
      <alias value="user content"/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="Element.extension"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Extension"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="n/a"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.ingredient.strength.denominator.value">
      <path value="MedicationKnowledge.ingredient.strength.denominator.value"/>
      <short value="Numerical value (with implicit precision)"/>
      <definition
               value="The value of the measured amount. The value includes an implicit
 precision in the presentation of the value."/>
      <comment
             value="The implicit precision in the value should always be honored. Monet
ary values have their own rules for handling precision (refer to standard accounting text
 books)."/>
      <requirements
                 value="Precision is handled implicitly in almost all cases of measure
ment."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="Quantity.value"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="decimal"/>
      </type>
```

```xml
      <fixedDecimal value="1"/>
      <mustSupport value="false"/>
      <isModifier value="false"/>
      <isSummary value="true"/>
      <mapping>
        <identity value="v2"/>
        <map value="SN.2  / CQ - N/A"/>
      </mapping>
      <mapping>
        <identity value="rim"/>
        <map
            value="PQ.value, CO.value, MO.value, IVL.high or IVL.low depending on the va
lue"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.ingredient.strength.denominator.comparator">
      <path
          value="MedicationKnowledge.ingredient.strength.denominator.comparator"/>
      <short value="&lt; | &lt;= | &gt;= | &gt; - how to understand the value"/>
      <definition
                  value="How the value should be understood and represented - whether the
 actual value is greater or less than the stated value due to measurement issues; e.g. if
 the comparator is &quot;&lt;&quot; , then the real value is &lt; stated value."/>
      <requirements
                    value="Need a framework for handling measures where the value is &lt;
5ug/L or &gt;400mg/L due to the limitations of measuring methodology."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="Quantity.comparator"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="code"/>
      </type>
      <meaningWhenMissing
                          value="If there is no comparator, then there is no modification
 of the value"/>
      <isModifier value="true"/>
      <isModifierReason
                        value="This is labeled as &quot;Is Modifier&quot; because the com
parator modifies the interpretation of the value significantly. If there is no comparator
, then there is no modification of the value"/>
      <isSummary value="true"/>
      <binding>
        <extension
                  url="http://hl7.org/fhir/StructureDefinition/elementdefinition-binding
Name">
          <valueString value="QuantityComparator"/>
        </extension>
        <strength value="required"/>
        <description
                    value="How the Quantity should be understood and represented."/>
        <valueSet value="http://hl7.org/fhir/ValueSet/quantity-comparator|4.0.0"/>
      </binding>
      <mapping>
```

```xml
            <identity value="v2"/>
            <map value="SN.1   / CQ.1"/>
          </mapping>
          <mapping>
            <identity value="rim"/>
            <map value="IVL properties"/>
          </mapping>
        </element>
        <element id="MedicationKnowledge.ingredient.strength.denominator.unit">
          <extension
                    url="http://hl7.org/fhir/StructureDefinition/elementdefinition-translata
ble">
            <valueBoolean value="true"/>
          </extension>
          <path value="MedicationKnowledge.ingredient.strength.denominator.unit"/>
          <short value="Unit representation"/>
          <definition value="A human-readable form of the unit."/>
          <requirements
                      value="There are many representations for units of measure and in man
y contexts, particular representations are fixed and required. I.e. mcg for micrograms."/
>
          <min value="0"/>
          <max value="1"/>
          <base>
            <path value="Quantity.unit"/>
            <min value="0"/>
            <max value="1"/>
          </base>
          <type>
            <code value="string"/>
          </type>
          <isModifier value="false"/>
          <isSummary value="true"/>
          <mapping>
            <identity value="v2"/>
            <map value="(see OBX.6 etc.) / CQ.2"/>
          </mapping>
          <mapping>
            <identity value="rim"/>
            <map value="PQ.unit"/>
          </mapping>
        </element>
        <element id="MedicationKnowledge.ingredient.strength.denominator.system">
          <path value="MedicationKnowledge.ingredient.strength.denominator.system"/>
          <short value="System that defines coded unit form"/>
          <definition
                    value="The identification of the system that provides the coded form of
 the unit."/>
          <requirements
                      value="Need to know the system that defines the coded form of the uni
t."/>
          <min value="0"/>
          <max value="1"/>
          <base>
            <path value="Quantity.system"/>
            <min value="0"/>
            <max value="1"/>
```

```
      </base>
      <type>
        <code value="uri"/>
      </type>
      <condition value="qty-3"/>
      <isModifier value="false"/>
      <isSummary value="true"/>
      <mapping>
        <identity value="v2"/>
        <map value="(see OBX.6 etc.) / CQ.2"/>
      </mapping>
      <mapping>
        <identity value="rim"/>
        <map value="CO.codeSystem, PQ.translation.codeSystem"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.ingredient.strength.denominator.code">
      <path value="MedicationKnowledge.ingredient.strength.denominator.code"/>
      <short value="Coded form of the unit"/>
      <definition
                value="A computer processable form of the unit in some unit representat
ion system."/>
      <comment
              value="The preferred system is UCUM, but SNOMED CT can also be used (for c
ustomary units) or ISO 4217 for currency.  The context of use may additionally require a
code from a particular system."/>
      <requirements
                   value="Need a computable form of the unit that is fixed across all fo
rms. UCUM provides this for quantities, but SNOMED CT provides many units of interest."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="Quantity.code"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="code"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="true"/>
      <mapping>
        <identity value="v2"/>
        <map value="(see OBX.6 etc.) / CQ.2"/>
      </mapping>
      <mapping>
        <identity value="rim"/>
        <map value="PQ.code, MO.currency, PQ.translation.code"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.preparationInstruction">
      <path value="MedicationKnowledge.preparationInstruction"/>
      <short value="The instructions for preparing the medication"/>
      <definition value="The instructions for preparing the medication."/>
      <min value="0"/>
      <max value="1"/>
      <base>
```

```
            <path value="MedicationKnowledge.preparationInstruction"/>
            <min value="0"/>
            <max value="1"/>
          </base>
          <type>
            <code value="markdown"/>
          </type>
          <isModifier value="false"/>
          <isSummary value="false"/>
        </element>
        <element id="MedicationKnowledge.intendedRoute">
          <path value="MedicationKnowledge.intendedRoute"/>
          <short value="The intended or approved route of administration"/>
          <definition value="The intended or approved route of administration."/>
          <min value="0"/>
          <max value="*"/>
          <base>
            <path value="MedicationKnowledge.intendedRoute"/>
            <min value="0"/>
            <max value="*"/>
          </base>
          <type>
            <code value="CodeableConcept"/>
          </type>
          <isModifier value="false"/>
          <isSummary value="false"/>
          <binding>
            <extension
                      url="http://hl7.org/fhir/StructureDefinition/elementdefinition-binding
Name">
              <valueString value="MedicationRoute"/>
            </extension>
            <strength value="example"/>
            <description
                      value="A coded concept defining the intended route of administration
."/>
            <valueSet value="http://hl7.org/fhir/ValueSet/route-codes"/>
          </binding>
        </element>
        <element id="MedicationKnowledge.cost">
          <path value="MedicationKnowledge.cost"/>
          <short value="The pricing of the medication"/>
          <definition value="The price of the medication."/>
          <min value="0"/>
          <max value="*"/>
          <base>
            <path value="MedicationKnowledge.cost"/>
            <min value="0"/>
            <max value="*"/>
          </base>
          <type>
            <code value="BackboneElement"/>
          </type>
          <constraint>
            <key value="ele-1"/>
            <severity value="error"/>
            <human value="All FHIR elements must have a @value or children"/>
```

```xml
            <expression value="hasValue() or (children().count() &gt; id.count())"/>
            <xpath value="@value|f:*|h:div"/>
            <source value="Element"/>
        </constraint>
        <isModifier value="false"/>
        <isSummary value="false"/>
    </element>
    <element id="MedicationKnowledge.cost.id">
        <path value="MedicationKnowledge.cost.id"/>
        <representation value="xmlAttr"/>
        <short value="Unique id for inter-element referencing"/>
        <definition
                value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
        <min value="0"/>
        <max value="1"/>
        <base>
            <path value="Element.id"/>
            <min value="0"/>
            <max value="1"/>
        </base>
        <type>
            <code value="string"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
            <identity value="rim"/>
            <map value="n/a"/>
        </mapping>
    </element>
    <element id="MedicationKnowledge.cost.extension">
        <path value="MedicationKnowledge.cost.extension"/>
        <short value="Additional content defined by implementations"/>
        <definition
                value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
        <comment
                value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
        <alias value="extensions"/>
        <alias value="user content"/>
        <min value="0"/>
        <max value="*"/>
        <base>
            <path value="Element.extension"/>
            <min value="0"/>
            <max value="*"/>
        </base>
        <type>
            <code value="Extension"/>
        </type>
```

```xml
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.cost.modifierExtension">
        <path value="MedicationKnowledge.cost.modifierExtension"/>
        <short value="Extensions that cannot be ignored even if unrecognized"/>
        <definition
                   value="May be used to represent additional information that is not part
 of the basic definition of the element and that modifies the understanding of the elemen
t in which it is contained and/or the understanding of the containing element&#39;s desce
ndants. Usually modifier elements provide negation or qualification. To make the use of e
xtensions safe and manageable, there is a strict set of governance applied to the definit
ion and use of extensions. Though any implementer can define an extension, there is a set
 of requirements that SHALL be met as part of the definition of the extension. Applicatio
ns processing a resource are required to check for modifier extensions.

Modifier extensions SHALL NOT change the meaning of any elements on Resource or DomainRes
ource (including cannot change the meaning of modifierExtension itself)."/>
        <comment
                value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
        <requirements
                     value="Modifier extensions allow for extensions that *cannot* be safe
ly ignored to be clearly distinguished from the vast majority of extensions which can be
safely ignored.  This promotes interoperability by eliminating the need for implementers
to prohibit the presence of extensions. For further information, see the [definition of m
odifier extensions](http://build.fhir.org/extensibility.html#modifierExtension)."/>
        <alias value="extensions"/>
        <alias value="user content"/>
        <alias value="modifiers"/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="BackboneElement.modifierExtension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
        </type>
        <isModifier value="true"/>
        <isModifierReason
                          value="Modifier extensions are expected to modify the meaning or
interpretation of the element that contains them"/>
        <isSummary value="true"/>
        <mapping>
          <identity value="rim"/>
          <map value="N/A"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.cost.type">
```

```xml
      <path value="MedicationKnowledge.cost.type"/>
      <short value="The category of the cost information"/>
      <definition
                value="The category of the cost information.  For example, manufacturer
s&#39; cost, patient cost, claim reimbursement cost, actual acquisition cost."/>
      <min value="1"/>
      <max value="1"/>
      <base>
        <path value="MedicationKnowledge.cost.type"/>
        <min value="1"/>
        <max value="1"/>
      </base>
      <type>
        <code value="CodeableConcept"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="MedicationKnowledge.cost.source">
      <path value="MedicationKnowledge.cost.source"/>
      <short value="The source or owner for the price information"/>
      <definition
                value="The source or owner that assigns the price to the medication."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="MedicationKnowledge.cost.source"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="string"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="MedicationKnowledge.cost.cost">
      <path value="MedicationKnowledge.cost.cost"/>
      <short value="The price of the medication"/>
      <definition value="The price of the medication."/>
      <min value="1"/>
      <max value="1"/>
      <base>
        <path value="MedicationKnowledge.cost.cost"/>
        <min value="1"/>
        <max value="1"/>
      </base>
      <type>
        <code value="Money"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="MedicationKnowledge.monitoringProgram">
      <path value="MedicationKnowledge.monitoringProgram"/>
      <short value="Program under which a medication is reviewed"/>
      <definition value="The program under which the medication is reviewed."/>
```

```
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="MedicationKnowledge.monitoringProgram"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="BackboneElement"/>
        </type>
        <constraint>
          <key value="ele-1"/>
          <severity value="error"/>
          <human value="All FHIR elements must have a @value or children"/>
          <expression value="hasValue() or (children().count() &gt; id.count())"/>
          <xpath value="@value|f:*|h:div"/>
          <source value="Element"/>
        </constraint>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="MedicationKnowledge.monitoringProgram.id">
        <path value="MedicationKnowledge.monitoringProgram.id"/>
        <representation value="xmlAttr"/>
        <short value="Unique id for inter-element referencing"/>
        <definition
                  value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Element.id"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="string"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.monitoringProgram.extension">
        <path value="MedicationKnowledge.monitoringProgram.extension"/>
        <short value="Additional content defined by implementations"/>
        <definition
                  value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
        <comment
                value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
```

```
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
      <alias value="extensions"/>
      <alias value="user content"/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="Element.extension"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Extension"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="n/a"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.monitoringProgram.modifierExtension">
      <path value="MedicationKnowledge.monitoringProgram.modifierExtension"/>
      <short value="Extensions that cannot be ignored even if unrecognized"/>
      <definition
                  value="May be used to represent additional information that is not part
 of the basic definition of the element and that modifies the understanding of the elemen
t in which it is contained and/or the understanding of the containing element&#39;s desce
ndants. Usually modifier elements provide negation or qualification. To make the use of e
xtensions safe and manageable, there is a strict set of governance applied to the definit
ion and use of extensions. Though any implementer can define an extension, there is a set
 of requirements that SHALL be met as part of the definition of the extension. Applicatio
ns processing a resource are required to check for modifier extensions.

Modifier extensions SHALL NOT change the meaning of any elements on Resource or DomainRes
ource (including cannot change the meaning of modifierExtension itself)."/>
      <comment
                value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
      <requirements
                    value="Modifier extensions allow for extensions that *cannot* be safe
ly ignored to be clearly distinguished from the vast majority of extensions which can be
safely ignored.  This promotes interoperability by eliminating the need for implementers
to prohibit the presence of extensions. For further information, see the [definition of m
odifier extensions](http://build.fhir.org/extensibility.html#modifierExtension)."/>
      <alias value="extensions"/>
      <alias value="user content"/>
      <alias value="modifiers"/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="BackboneElement.modifierExtension"/>
        <min value="0"/>
        <max value="*"/>
      </base>
```

```xml
      <type>
        <code value="Extension"/>
      </type>
      <isModifier value="true"/>
      <isModifierReason
                      value="Modifier extensions are expected to modify the meaning or
interpretation of the element that contains them"/>
      <isSummary value="true"/>
      <mapping>
        <identity value="rim"/>
        <map value="N/A"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.monitoringProgram.type">
      <path value="MedicationKnowledge.monitoringProgram.type"/>
      <short value="Type of program under which the medication is monitored"/>
      <definition
                  value="Type of program under which the medication is monitored."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="MedicationKnowledge.monitoringProgram.type"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="CodeableConcept"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="MedicationKnowledge.monitoringProgram.name">
      <path value="MedicationKnowledge.monitoringProgram.name"/>
      <short value="Name of the reviewing program"/>
      <definition value="Name of the reviewing program."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="MedicationKnowledge.monitoringProgram.name"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="string"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="MedicationKnowledge.administrationGuidelines">
      <path value="MedicationKnowledge.administrationGuidelines"/>
      <short value="Guidelines for administration of the medication"/>
      <definition value="Guidelines for the administration of the medication."/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="MedicationKnowledge.administrationGuidelines"/>
        <min value="0"/>
```

```xml
          <max value="*"/>
        </base>
        <type>
          <code value="BackboneElement"/>
        </type>
        <constraint>
          <key value="ele-1"/>
          <severity value="error"/>
          <human value="All FHIR elements must have a @value or children"/>
          <expression value="hasValue() or (children().count() &gt; id.count())"/>
          <xpath value="@value|f:*|h:div"/>
          <source value="Element"/>
        </constraint>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="MedicationKnowledge.administrationGuidelines.id">
        <path value="MedicationKnowledge.administrationGuidelines.id"/>
        <representation value="xmlAttr"/>
        <short value="Unique id for inter-element referencing"/>
        <definition
                    value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Element.id"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="string"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.administrationGuidelines.extension">
        <path value="MedicationKnowledge.administrationGuidelines.extension"/>
        <short value="Additional content defined by implementations"/>
        <definition
                    value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
        <comment
                value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
        <alias value="extensions"/>
        <alias value="user content"/>
        <min value="0"/>
```

```xml
        <max value="*"/>
        <base>
          <path value="Element.extension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.administrationGuidelines.modifierExtension">
        <path
              value="MedicationKnowledge.administrationGuidelines.modifierExtension"/>
        <short value="Extensions that cannot be ignored even if unrecognized"/>
        <definition
                    value="May be used to represent additional information that is not part
 of the basic definition of the element and that modifies the understanding of the elemen
t in which it is contained and/or the understanding of the containing element&#39;s desce
ndants. Usually modifier elements provide negation or qualification. To make the use of e
xtensions safe and manageable, there is a strict set of governance applied to the definit
ion and use of extensions. Though any implementer can define an extension, there is a set
 of requirements that SHALL be met as part of the definition of the extension. Applicatio
ns processing a resource are required to check for modifier extensions.

Modifier extensions SHALL NOT change the meaning of any elements on Resource or DomainRes
ource (including cannot change the meaning of modifierExtension itself)."/>
        <comment
                 value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
        <requirements
                      value="Modifier extensions allow for extensions that *cannot* be safe
ly ignored to be clearly distinguished from the vast majority of extensions which can be
safely ignored.  This promotes interoperability by eliminating the need for implementers
to prohibit the presence of extensions. For further information, see the [definition of m
odifier extensions](http://build.fhir.org/extensibility.html#modifierExtension)."/>
        <alias value="extensions"/>
        <alias value="user content"/>
        <alias value="modifiers"/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="BackboneElement.modifierExtension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
        </type>
        <isModifier value="true"/>
```

```xml
        <isModifierReason
                        value="Modifier extensions are expected to modify the meaning or
interpretation of the element that contains them"/>
        <isSummary value="true"/>
        <mapping>
          <identity value="rim"/>
          <map value="N/A"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.administrationGuidelines.dosage">
        <path value="MedicationKnowledge.administrationGuidelines.dosage"/>
        <short value="Dosage for the medication for the specific guidelines"/>
        <definition value="Dosage for the medication for the specific guidelines."/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="MedicationKnowledge.administrationGuidelines.dosage"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="BackboneElement"/>
        </type>
        <constraint>
          <key value="ele-1"/>
          <severity value="error"/>
          <human value="All FHIR elements must have a @value or children"/>
          <expression value="hasValue() or (children().count() &gt; id.count())"/>
          <xpath value="@value|f:*|h:div"/>
          <source value="Element"/>
        </constraint>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="MedicationKnowledge.administrationGuidelines.dosage.id">
        <path value="MedicationKnowledge.administrationGuidelines.dosage.id"/>
        <representation value="xmlAttr"/>
        <short value="Unique id for inter-element referencing"/>
        <definition
                  value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Element.id"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="string"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
```

```
      </element>
      <element id="MedicationKnowledge.administrationGuidelines.dosage.extension">
        <path
              value="MedicationKnowledge.administrationGuidelines.dosage.extension"/>
        <short value="Additional content defined by implementations"/>
        <definition
                    value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
        <comment
                  value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
        <alias value="extensions"/>
        <alias value="user content"/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="Element.extension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element
              id="MedicationKnowledge.administrationGuidelines.dosage.modifierExtension">
        <path
              value="MedicationKnowledge.administrationGuidelines.dosage.modifierExtension"
/>
        <short value="Extensions that cannot be ignored even if unrecognized"/>
        <definition
                    value="May be used to represent additional information that is not part
 of the basic definition of the element and that modifies the understanding of the elemen
t in which it is contained and/or the understanding of the containing element&#39;s desce
ndants. Usually modifier elements provide negation or qualification. To make the use of e
xtensions safe and manageable, there is a strict set of governance applied to the definit
ion and use of extensions. Though any implementer can define an extension, there is a set
 of requirements that SHALL be met as part of the definition of the extension. Applicatio
ns processing a resource are required to check for modifier extensions.

Modifier extensions SHALL NOT change the meaning of any elements on Resource or DomainRes
ource (including cannot change the meaning of modifierExtension itself)."/>
        <comment
                  value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
```

```
on to retain a core level of simplicity for everyone."/>
      <requirements
                    value="Modifier extensions allow for extensions that *cannot* be safe
ly ignored to be clearly distinguished from the vast majority of extensions which can be
safely ignored.  This promotes interoperability by eliminating the need for implementers
to prohibit the presence of extensions. For further information, see the [definition of m
odifier extensions](http://build.fhir.org/extensibility.html#modifierExtension)."/>
      <alias value="extensions"/>
      <alias value="user content"/>
      <alias value="modifiers"/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="BackboneElement.modifierExtension"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Extension"/>
      </type>
      <isModifier value="true"/>
      <isModifierReason
                        value="Modifier extensions are expected to modify the meaning or
interpretation of the element that contains them"/>
      <isSummary value="true"/>
      <mapping>
        <identity value="rim"/>
        <map value="N/A"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.administrationGuidelines.dosage.type">
      <path value="MedicationKnowledge.administrationGuidelines.dosage.type"/>
      <short value="Type of dosage"/>
      <definition
                  value="The type of dosage (for example, prophylaxis, maintenance, thera
peutic, etc.)."/>
      <min value="1"/>
      <max value="1"/>
      <base>
        <path value="MedicationKnowledge.administrationGuidelines.dosage.type"/>
        <min value="1"/>
        <max value="1"/>
      </base>
      <type>
        <code value="CodeableConcept"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="MedicationKnowledge.administrationGuidelines.dosage.dosage">
      <path value="MedicationKnowledge.administrationGuidelines.dosage.dosage"/>
      <short value="Dosage for the medication for the specific guidelines"/>
      <definition value="Dosage for the medication for the specific guidelines."/>
      <min value="1"/>
      <max value="*"/>
      <base>
        <path value="MedicationKnowledge.administrationGuidelines.dosage.dosage"/>
```

```xml
        <min value="1"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Dosage"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="MedicationKnowledge.administrationGuidelines.indication[x]">
      <path value="MedicationKnowledge.administrationGuidelines.indication[x]"/>
      <short
            value="Indication for use that apply to the specific administration guidelin
es"/>
      <definition
                value="Indication for use that apply to the specific administration gui
delines."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="MedicationKnowledge.administrationGuidelines.indication[x]"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="CodeableConcept"/>
      </type>
      <type>
        <code value="Reference"/>
        <targetProfile
                      value="http://hl7.org/fhir/StructureDefinition/ObservationDefiniti
on"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element
            id="MedicationKnowledge.administrationGuidelines.patientCharacteristics">
      <path
            value="MedicationKnowledge.administrationGuidelines.patientCharacteristics"/>
      <short
            value="Characteristics of the patient that are relevant to the administratio
n guidelines"/>
      <definition
                value="Characteristics of the patient that are relevant to the administ
ration guidelines (for example, height, weight, gender, etc.)."/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path
            value="MedicationKnowledge.administrationGuidelines.patientCharacteristics"
/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="BackboneElement"/>
```

```xml
        </type>
        <constraint>
          <key value="ele-1"/>
          <severity value="error"/>
          <human value="All FHIR elements must have a @value or children"/>
          <expression value="hasValue() or (children().count() &gt; id.count())"/>
          <xpath value="@value|f:*|h:div"/>
          <source value="Element"/>
        </constraint>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element
              id="MedicationKnowledge.administrationGuidelines.patientCharacteristics.id">
        <path
              value="MedicationKnowledge.administrationGuidelines.patientCharacteristics.id
"/>
        <representation value="xmlAttr"/>
        <short value="Unique id for inter-element referencing"/>
        <definition
                  value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Element.id"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="string"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element
              id="MedicationKnowledge.administrationGuidelines.patientCharacteristics.exte
nsion">
        <path
              value="MedicationKnowledge.administrationGuidelines.patientCharacteristics.ex
tension"/>
        <short value="Additional content defined by implementations"/>
        <definition
                  value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
        <comment
                value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
```

```xml
        <alias value="extensions"/>
        <alias value="user content"/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="Element.extension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element
              id="MedicationKnowledge.administrationGuidelines.patientCharacteristics.modi
fierExtension">
        <path
            value="MedicationKnowledge.administrationGuidelines.patientCharacteristics.mo
difierExtension"/>
        <short value="Extensions that cannot be ignored even if unrecognized"/>
        <definition
                  value="May be used to represent additional information that is not part
 of the basic definition of the element and that modifies the understanding of the elemen
t in which it is contained and/or the understanding of the containing element&#39;s desce
ndants. Usually modifier elements provide negation or qualification. To make the use of e
xtensions safe and manageable, there is a strict set of governance applied to the definit
ion and use of extensions. Though any implementer can define an extension, there is a set
 of requirements that SHALL be met as part of the definition of the extension. Applicatio
ns processing a resource are required to check for modifier extensions.

Modifier extensions SHALL NOT change the meaning of any elements on Resource or DomainRes
ource (including cannot change the meaning of modifierExtension itself)."/>
        <comment
                value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
        <requirements
                    value="Modifier extensions allow for extensions that *cannot* be safe
ly ignored to be clearly distinguished from the vast majority of extensions which can be
safely ignored.  This promotes interoperability by eliminating the need for implementers
to prohibit the presence of extensions. For further information, see the [definition of m
odifier extensions](http://build.fhir.org/extensibility.html#modifierExtension)."/>
        <alias value="extensions"/>
        <alias value="user content"/>
        <alias value="modifiers"/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="BackboneElement.modifierExtension"/>
          <min value="0"/>
```

```
        <max value="*"/>
      </base>
      <type>
        <code value="Extension"/>
      </type>
      <isModifier value="true"/>
      <isModifierReason
                        value="Modifier extensions are expected to modify the meaning or
interpretation of the element that contains them"/>
      <isSummary value="true"/>
      <mapping>
        <identity value="rim"/>
        <map value="N/A"/>
      </mapping>
    </element>
    <element
            id="MedicationKnowledge.administrationGuidelines.patientCharacteristics.char
acteristic[x]">
      <path
            value="MedicationKnowledge.administrationGuidelines.patientCharacteristics.ch
aracteristic[x]"/>
      <short
            value="Specific characteristic that is relevant to the administration guidel
ine"/>
      <definition
                  value="Specific characteristic that is relevant to the administration g
uideline (e.g. height, weight, gender)."/>
      <min value="1"/>
      <max value="1"/>
      <base>
        <path
            value="MedicationKnowledge.administrationGuidelines.patientCharacteristics.
characteristic[x]"/>
        <min value="1"/>
        <max value="1"/>
      </base>
      <type>
        <code value="CodeableConcept"/>
      </type>
      <type>
        <code value="Quantity"/>
        <profile value="http://hl7.org/fhir/StructureDefinition/SimpleQuantity"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element
            id="MedicationKnowledge.administrationGuidelines.patientCharacteristics.valu
e">
      <path
            value="MedicationKnowledge.administrationGuidelines.patientCharacteristics.va
lue"/>
      <short value="The specific characteristic"/>
      <definition
                  value="The specific characteristic (e.g. height, weight, gender, etc.).
"/>
      <min value="0"/>
```

```xml
      <max value="*"/>
      <base>
       <path
              value="MedicationKnowledge.administrationGuidelines.patientCharacteristics.
value"/>
       <min value="0"/>
       <max value="*"/>
      </base>
      <type>
       <code value="string"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="MedicationKnowledge.medicineClassification">
      <path value="MedicationKnowledge.medicineClassification"/>
      <short
             value="Categorization of the medication within a formulary or classification
 system"/>
      <definition
                  value="Categorization of the medication within a formulary or classific
ation system."/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="MedicationKnowledge.medicineClassification"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="BackboneElement"/>
      </type>
      <constraint>
        <key value="ele-1"/>
        <severity value="error"/>
        <human value="All FHIR elements must have a @value or children"/>
        <expression value="hasValue() or (children().count() &gt; id.count())"/>
        <xpath value="@value|f:*|h:div"/>
        <source value="Element"/>
      </constraint>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="MedicationKnowledge.medicineClassification.id">
      <path value="MedicationKnowledge.medicineClassification.id"/>
      <representation value="xmlAttr"/>
      <short value="Unique id for inter-element referencing"/>
      <definition
                  value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="Element.id"/>
        <min value="0"/>
        <max value="1"/>
      </base>
```

```
        <type>
          <code value="string"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.medicineClassification.extension">
        <path value="MedicationKnowledge.medicineClassification.extension"/>
        <short value="Additional content defined by implementations"/>
        <definition
                   value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
        <comment
                 value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
        <alias value="extensions"/>
        <alias value="user content"/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="Element.extension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.medicineClassification.modifierExtension">
        <path value="MedicationKnowledge.medicineClassification.modifierExtension"/>
        <short value="Extensions that cannot be ignored even if unrecognized"/>
        <definition
                   value="May be used to represent additional information that is not part
 of the basic definition of the element and that modifies the understanding of the elemen
t in which it is contained and/or the understanding of the containing element&#39;s desce
ndants. Usually modifier elements provide negation or qualification. To make the use of e
xtensions safe and manageable, there is a strict set of governance applied to the definit
ion and use of extensions. Though any implementer can define an extension, there is a set
 of requirements that SHALL be met as part of the definition of the extension. Applicatio
ns processing a resource are required to check for modifier extensions.

Modifier extensions SHALL NOT change the meaning of any elements on Resource or DomainRes
```

```
ource (including cannot change the meaning of modifierExtension itself)."/>
      <comment
               value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
      <requirements
                    value="Modifier extensions allow for extensions that *cannot* be safe
ly ignored to be clearly distinguished from the vast majority of extensions which can be
safely ignored.  This promotes interoperability by eliminating the need for implementers
to prohibit the presence of extensions. For further information, see the [definition of m
odifier extensions](http://build.fhir.org/extensibility.html#modifierExtension)."/>
      <alias value="extensions"/>
      <alias value="user content"/>
      <alias value="modifiers"/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="BackboneElement.modifierExtension"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Extension"/>
      </type>
      <isModifier value="true"/>
      <isModifierReason
                        value="Modifier extensions are expected to modify the meaning or
interpretation of the element that contains them"/>
      <isSummary value="true"/>
      <mapping>
        <identity value="rim"/>
        <map value="N/A"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.medicineClassification.type">
      <path value="MedicationKnowledge.medicineClassification.type"/>
      <short
             value="The type of category for the medication (for example, therapeutic cla
ssification, therapeutic sub-classification)"/>
      <definition
                  value="The type of category for the medication (for example, therapeuti
c classification, therapeutic sub-classification)."/>
      <min value="1"/>
      <max value="1"/>
      <base>
        <path value="MedicationKnowledge.medicineClassification.type"/>
        <min value="1"/>
        <max value="1"/>
      </base>
      <type>
        <code value="CodeableConcept"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="MedicationKnowledge.medicineClassification.classification">
```

```
        <path value="MedicationKnowledge.medicineClassification.classification"/>
        <short value="Specific category assigned to the medication"/>
        <definition
                    value="Specific category assigned to the medication (e.g. anti-infectiv
e, anti-hypertensive, antibiotic, etc.)."/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="MedicationKnowledge.medicineClassification.classification"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="CodeableConcept"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="MedicationKnowledge.packaging">
        <path value="MedicationKnowledge.packaging"/>
        <short value="Details about packaged medications"/>
        <definition
                    value="Information that only applies to packages (not products)."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="MedicationKnowledge.packaging"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="BackboneElement"/>
        </type>
        <constraint>
          <key value="ele-1"/>
          <severity value="error"/>
          <human value="All FHIR elements must have a @value or children"/>
          <expression value="hasValue() or (children().count() &gt; id.count())"/>
          <xpath value="@value|f:*|h:div"/>
          <source value="Element"/>
        </constraint>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="MedicationKnowledge.packaging.id">
        <path value="MedicationKnowledge.packaging.id"/>
        <representation value="xmlAttr"/>
        <short value="Unique id for inter-element referencing"/>
        <definition
                    value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Element.id"/>
          <min value="0"/>
          <max value="1"/>
```

```
        </base>
        <type>
          <code value="string"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.packaging.extension">
        <path value="MedicationKnowledge.packaging.extension"/>
        <short value="Additional content defined by implementations"/>
        <definition
                   value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
        <comment
               value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
        <alias value="extensions"/>
        <alias value="user content"/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="Element.extension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.packaging.modifierExtension">
        <path value="MedicationKnowledge.packaging.modifierExtension"/>
        <short value="Extensions that cannot be ignored even if unrecognized"/>
        <definition
                   value="May be used to represent additional information that is not part
 of the basic definition of the element and that modifies the understanding of the elemen
t in which it is contained and/or the understanding of the containing element&#39;s desce
ndants. Usually modifier elements provide negation or qualification. To make the use of e
xtensions safe and manageable, there is a strict set of governance applied to the definit
ion and use of extensions. Though any implementer can define an extension, there is a set
 of requirements that SHALL be met as part of the definition of the extension. Applicatio
ns processing a resource are required to check for modifier extensions.
```

```
Modifier extensions SHALL NOT change the meaning of any elements on Resource or DomainRes
ource (including cannot change the meaning of modifierExtension itself)."/>
      <comment
              value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
      <requirements
                    value="Modifier extensions allow for extensions that *cannot* be safe
ly ignored to be clearly distinguished from the vast majority of extensions which can be
safely ignored.  This promotes interoperability by eliminating the need for implementers
to prohibit the presence of extensions. For further information, see the [definition of m
odifier extensions](http://build.fhir.org/extensibility.html#modifierExtension)."/>
      <alias value="extensions"/>
      <alias value="user content"/>
      <alias value="modifiers"/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="BackboneElement.modifierExtension"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Extension"/>
      </type>
      <isModifier value="true"/>
      <isModifierReason
                        value="Modifier extensions are expected to modify the meaning or
interpretation of the element that contains them"/>
      <isSummary value="true"/>
      <mapping>
        <identity value="rim"/>
        <map value="N/A"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.packaging.type">
      <path value="MedicationKnowledge.packaging.type"/>
      <short
            value="A code that defines the specific type of packaging that the medicatio
n can be found in"/>
      <definition
                  value="A code that defines the specific type of packaging that the medi
cation can be found in (e.g. blister sleeve, tube, bottle)."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="MedicationKnowledge.packaging.type"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="CodeableConcept"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <binding>
```

```
                <extension
                        url="http://hl7.org/fhir/StructureDefinition/elementdefinition-binding
Name">
            <valueString value="MedicationPackageType"/>
          </extension>
          <strength value="example"/>
          <description
                        value="A coded concept defining the type of packaging of a medicatio
n."/>
          <valueSet
                    value="http://hl7.org/fhir/ValueSet/medicationknowledge-package-type"/>
        </binding>
      </element>
      <element id="MedicationKnowledge.packaging.quantity">
        <path value="MedicationKnowledge.packaging.quantity"/>
        <short
               value="The number of product units the package would contain if fully loaded
"/>
        <definition
                    value="The number of product units the package would contain if fully l
oaded."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="MedicationKnowledge.packaging.quantity"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="Quantity"/>
          <profile value="http://hl7.org/fhir/StructureDefinition/SimpleQuantity"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="MedicationKnowledge.drugCharacteristic">
        <path value="MedicationKnowledge.drugCharacteristic"/>
        <short value="Specifies descriptive properties of the medicine"/>
        <definition
                    value="Specifies descriptive properties of the medicine, such as color,
 shape, imprints, etc."/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="MedicationKnowledge.drugCharacteristic"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="BackboneElement"/>
        </type>
        <constraint>
          <key value="ele-1"/>
          <severity value="error"/>
          <human value="All FHIR elements must have a @value or children"/>
          <expression value="hasValue() or (children().count() &gt; id.count())"/>
          <xpath value="@value|f:*|h:div"/>
```

```
              <source value="Element"/>
          </constraint>
          <isModifier value="false"/>
          <isSummary value="false"/>
        </element>
        <element id="MedicationKnowledge.drugCharacteristic.id">
          <path value="MedicationKnowledge.drugCharacteristic.id"/>
          <representation value="xmlAttr"/>
          <short value="Unique id for inter-element referencing"/>
          <definition
                      value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
          <min value="0"/>
          <max value="1"/>
          <base>
            <path value="Element.id"/>
            <min value="0"/>
            <max value="1"/>
          </base>
          <type>
            <code value="string"/>
          </type>
          <isModifier value="false"/>
          <isSummary value="false"/>
          <mapping>
            <identity value="rim"/>
            <map value="n/a"/>
          </mapping>
        </element>
        <element id="MedicationKnowledge.drugCharacteristic.extension">
          <path value="MedicationKnowledge.drugCharacteristic.extension"/>
          <short value="Additional content defined by implementations"/>
          <definition
                      value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
          <comment
                   value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
          <alias value="extensions"/>
          <alias value="user content"/>
          <min value="0"/>
          <max value="*"/>
          <base>
            <path value="Element.extension"/>
            <min value="0"/>
            <max value="*"/>
          </base>
          <type>
            <code value="Extension"/>
          </type>
          <isModifier value="false"/>
          <isSummary value="false"/>
```

```xml
            <mapping>
              <identity value="rim"/>
              <map value="n/a"/>
            </mapping>
          </element>
          <element id="MedicationKnowledge.drugCharacteristic.modifierExtension">
            <path value="MedicationKnowledge.drugCharacteristic.modifierExtension"/>
            <short value="Extensions that cannot be ignored even if unrecognized"/>
            <definition
                      value="May be used to represent additional information that is not part
 of the basic definition of the element and that modifies the understanding of the elemen
t in which it is contained and/or the understanding of the containing element&#39;s desce
ndants. Usually modifier elements provide negation or qualification. To make the use of e
xtensions safe and manageable, there is a strict set of governance applied to the definit
ion and use of extensions. Though any implementer can define an extension, there is a set
 of requirements that SHALL be met as part of the definition of the extension. Applicatio
ns processing a resource are required to check for modifier extensions.

Modifier extensions SHALL NOT change the meaning of any elements on Resource or DomainRes
ource (including cannot change the meaning of modifierExtension itself)."/>
            <comment
                    value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
            <requirements
                        value="Modifier extensions allow for extensions that *cannot* be safe
ly ignored to be clearly distinguished from the vast majority of extensions which can be
safely ignored.  This promotes interoperability by eliminating the need for implementers
to prohibit the presence of extensions. For further information, see the [definition of m
odifier extensions](http://build.fhir.org/extensibility.html#modifierExtension)."/>
            <alias value="extensions"/>
            <alias value="user content"/>
            <alias value="modifiers"/>
            <min value="0"/>
            <max value="*"/>
            <base>
              <path value="BackboneElement.modifierExtension"/>
              <min value="0"/>
              <max value="*"/>
            </base>
            <type>
              <code value="Extension"/>
            </type>
            <isModifier value="true"/>
            <isModifierReason
                            value="Modifier extensions are expected to modify the meaning or
interpretation of the element that contains them"/>
            <isSummary value="true"/>
            <mapping>
              <identity value="rim"/>
              <map value="N/A"/>
            </mapping>
          </element>
          <element id="MedicationKnowledge.drugCharacteristic.type">
            <path value="MedicationKnowledge.drugCharacteristic.type"/>
            <short value="Code specifying the type of characteristic of medication"/>
```

```
        <definition
                   value="A code specifying which characteristic of the medicine is being
described (for example, colour, shape, imprint)."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="MedicationKnowledge.drugCharacteristic.type"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="CodeableConcept"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <binding>
        <extension
                   url="http://hl7.org/fhir/StructureDefinition/elementdefinition-binding
Name">
          <valueString value="MedicationCharacteristic"/>
        </extension>
        <strength value="example"/>
        <description
                     value="A coded concept defining the characteristic types of a medica
tion."/>
        <valueSet
                   value="http://hl7.org/fhir/ValueSet/medicationknowledge-characteristic"
/>
      </binding>
    </element>
    <element id="MedicationKnowledge.drugCharacteristic.value[x]">
      <path value="MedicationKnowledge.drugCharacteristic.value[x]"/>
      <short value="Description of the characteristic"/>
      <definition value="Description of the characteristic."/>
      <comment
               value="The description should be provided as a CodeableConcept, SimpleQuan
tity or an image.  The description can be a string only when these others are not availab
le."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="MedicationKnowledge.drugCharacteristic.value[x]"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="CodeableConcept"/>
      </type>
      <type>
        <code value="string"/>
      </type>
      <type>
        <code value="Quantity"/>
        <profile value="http://hl7.org/fhir/StructureDefinition/SimpleQuantity"/>
      </type>
      <type>
        <code value="base64Binary"/>
```

```
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="MedicationKnowledge.contraindication">
        <path value="MedicationKnowledge.contraindication"/>
        <short value="Potential clinical issue with or between medication(s)"/>
        <definition
                  value="Potential clinical issue with or between medication(s) (for exam
ple, drug-drug interaction, drug-disease contraindication, drug-allergy interaction, etc.
)."/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="MedicationKnowledge.contraindication"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Reference"/>
          <targetProfile
                      value="http://hl7.org/fhir/StructureDefinition/DetectedIssue"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="MedicationKnowledge.regulatory">
        <path value="MedicationKnowledge.regulatory"/>
        <short value="Regulatory information about a medication"/>
        <definition value="Regulatory information about a medication."/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="MedicationKnowledge.regulatory"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="BackboneElement"/>
        </type>
        <constraint>
          <key value="ele-1"/>
          <severity value="error"/>
          <human value="All FHIR elements must have a @value or children"/>
          <expression value="hasValue() or (children().count() &gt; id.count())"/>
          <xpath value="@value|f:*|h:div"/>
          <source value="Element"/>
        </constraint>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="MedicationKnowledge.regulatory.id">
        <path value="MedicationKnowledge.regulatory.id"/>
        <representation value="xmlAttr"/>
        <short value="Unique id for inter-element referencing"/>
        <definition
                  value="Unique id for the element within a resource (for internal refere
```

```
nces). This may be any string value that does not contain spaces."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="Element.id"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="string"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="n/a"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.regulatory.extension">
      <path value="MedicationKnowledge.regulatory.extension"/>
      <short value="Additional content defined by implementations"/>
      <definition
                 value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
      <comment
               value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
      <alias value="extensions"/>
      <alias value="user content"/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="Element.extension"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Extension"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="n/a"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.regulatory.modifierExtension">
      <path value="MedicationKnowledge.regulatory.modifierExtension"/>
      <short value="Extensions that cannot be ignored even if unrecognized"/>
      <definition
                 value="May be used to represent additional information that is not part
 of the basic definition of the element and that modifies the understanding of the elemen
```

t in which it is contained and/or the understanding of the containing element's desce
ndants. Usually modifier elements provide negation or qualification. To make the use of e
xtensions safe and manageable, there is a strict set of governance applied to the definit
ion and use of extensions. Though any implementer can define an extension, there is a set
 of requirements that SHALL be met as part of the definition of the extension. Applicatio
ns processing a resource are required to check for modifier extensions.

Modifier extensions SHALL NOT change the meaning of any elements on Resource or DomainRes
ource (including cannot change the meaning of modifierExtension itself)."/>
      <comment
              value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions. The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
      <requirements
                   value="Modifier extensions allow for extensions that *cannot* be safe
ly ignored to be clearly distinguished from the vast majority of extensions which can be
safely ignored. This promotes interoperability by eliminating the need for implementers
to prohibit the presence of extensions. For further information, see the [definition of m
odifier extensions](http://build.fhir.org/extensibility.html#modifierExtension)."/>
      <alias value="extensions"/>
      <alias value="user content"/>
      <alias value="modifiers"/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="BackboneElement.modifierExtension"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Extension"/>
      </type>
      <isModifier value="true"/>
      <isModifierReason
                      value="Modifier extensions are expected to modify the meaning or
interpretation of the element that contains them"/>
      <isSummary value="true"/>
      <mapping>
        <identity value="rim"/>
        <map value="N/A"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.regulatory.regulatoryAuthority">
      <path value="MedicationKnowledge.regulatory.regulatoryAuthority"/>
      <short value="Specifies the authority of the regulation"/>
      <definition value="The authority that is specifying the regulations."/>
      <min value="1"/>
      <max value="1"/>
      <base>
        <path value="MedicationKnowledge.regulatory.regulatoryAuthority"/>
        <min value="1"/>
        <max value="1"/>
      </base>
      <type>
        <code value="Reference"/>
        <targetProfile

```
                              value="http://hl7.org/fhir/StructureDefinition/Organization"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
    </element>
    <element id="MedicationKnowledge.regulatory.substitution">
        <path value="MedicationKnowledge.regulatory.substitution"/>
        <short
                value="Specifies if changes are allowed when dispensing a medication from a
regulatory perspective"/>
        <definition
                    value="Specifies if changes are allowed when dispensing a medication fr
om a regulatory perspective."/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="MedicationKnowledge.regulatory.substitution"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="BackboneElement"/>
        </type>
        <constraint>
          <key value="ele-1"/>
          <severity value="error"/>
          <human value="All FHIR elements must have a @value or children"/>
          <expression value="hasValue() or (children().count() &gt; id.count())"/>
          <xpath value="@value|f:*|h:div"/>
          <source value="Element"/>
        </constraint>
        <isModifier value="false"/>
        <isSummary value="false"/>
    </element>
    <element id="MedicationKnowledge.regulatory.substitution.id">
        <path value="MedicationKnowledge.regulatory.substitution.id"/>
        <representation value="xmlAttr"/>
        <short value="Unique id for inter-element referencing"/>
        <definition
                    value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Element.id"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="string"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
```

```
        </element>
        <element id="MedicationKnowledge.regulatory.substitution.extension">
          <path value="MedicationKnowledge.regulatory.substitution.extension"/>
          <short value="Additional content defined by implementations"/>
          <definition
                  value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
          <comment
                value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
          <alias value="extensions"/>
          <alias value="user content"/>
          <min value="0"/>
          <max value="*"/>
          <base>
            <path value="Element.extension"/>
            <min value="0"/>
            <max value="*"/>
          </base>
          <type>
            <code value="Extension"/>
          </type>
          <isModifier value="false"/>
          <isSummary value="false"/>
          <mapping>
            <identity value="rim"/>
            <map value="n/a"/>
          </mapping>
        </element>
        <element id="MedicationKnowledge.regulatory.substitution.modifierExtension">
          <path
              value="MedicationKnowledge.regulatory.substitution.modifierExtension"/>
          <short value="Extensions that cannot be ignored even if unrecognized"/>
          <definition
                  value="May be used to represent additional information that is not part
 of the basic definition of the element and that modifies the understanding of the elemen
t in which it is contained and/or the understanding of the containing element&#39;s desce
ndants. Usually modifier elements provide negation or qualification. To make the use of e
xtensions safe and manageable, there is a strict set of governance applied to the definit
ion and use of extensions. Though any implementer can define an extension, there is a set
 of requirements that SHALL be met as part of the definition of the extension. Applicatio
ns processing a resource are required to check for modifier extensions.

Modifier extensions SHALL NOT change the meaning of any elements on Resource or DomainRes
ource (including cannot change the meaning of modifierExtension itself)."/>
          <comment
                value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
          <requirements
                      value="Modifier extensions allow for extensions that *cannot* be safe
```

```
ly ignored to be clearly distinguished from the vast majority of extensions which can be
safely ignored.  This promotes interoperability by eliminating the need for implementers
to prohibit the presence of extensions. For further information, see the [definition of m
odifier extensions](http://build.fhir.org/extensibility.html#modifierExtension)."/>
      <alias value="extensions"/>
      <alias value="user content"/>
      <alias value="modifiers"/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="BackboneElement.modifierExtension"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Extension"/>
      </type>
      <isModifier value="true"/>
      <isModifierReason
                     value="Modifier extensions are expected to modify the meaning or
interpretation of the element that contains them"/>
      <isSummary value="true"/>
      <mapping>
        <identity value="rim"/>
        <map value="N/A"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.regulatory.substitution.type">
      <path value="MedicationKnowledge.regulatory.substitution.type"/>
      <short value="Specifies the type of substitution allowed"/>
      <definition value="Specifies the type of substitution allowed."/>
      <min value="1"/>
      <max value="1"/>
      <base>
        <path value="MedicationKnowledge.regulatory.substitution.type"/>
        <min value="1"/>
        <max value="1"/>
      </base>
      <type>
        <code value="CodeableConcept"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="MedicationKnowledge.regulatory.substitution.allowed">
      <path value="MedicationKnowledge.regulatory.substitution.allowed"/>
      <short
            value="Specifies if regulation allows for changes in the medication when dis
pensing"/>
      <definition
                 value="Specifies if regulation allows for changes in the medication whe
n dispensing."/>
      <min value="1"/>
      <max value="1"/>
      <base>
        <path value="MedicationKnowledge.regulatory.substitution.allowed"/>
        <min value="1"/>
```

```
          <max value="1"/>
        </base>
        <type>
          <code value="boolean"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="MedicationKnowledge.regulatory.schedule">
        <path value="MedicationKnowledge.regulatory.schedule"/>
        <short value="Specifies the schedule of a medication in jurisdiction"/>
        <definition
                   value="Specifies the schedule of a medication in jurisdiction."/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="MedicationKnowledge.regulatory.schedule"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="BackboneElement"/>
        </type>
        <constraint>
          <key value="ele-1"/>
          <severity value="error"/>
          <human value="All FHIR elements must have a @value or children"/>
          <expression value="hasValue() or (children().count() &gt; id.count())"/>
          <xpath value="@value|f:*|h:div"/>
          <source value="Element"/>
        </constraint>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="MedicationKnowledge.regulatory.schedule.id">
        <path value="MedicationKnowledge.regulatory.schedule.id"/>
        <representation value="xmlAttr"/>
        <short value="Unique id for inter-element referencing"/>
        <definition
                   value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Element.id"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="string"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
```

```
      </element>
    <element id="MedicationKnowledge.regulatory.schedule.extension">
      <path value="MedicationKnowledge.regulatory.schedule.extension"/>
      <short value="Additional content defined by implementations"/>
      <definition
              value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
      <comment
             value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
      <alias value="extensions"/>
      <alias value="user content"/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="Element.extension"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Extension"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="n/a"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.regulatory.schedule.modifierExtension">
      <path value="MedicationKnowledge.regulatory.schedule.modifierExtension"/>
      <short value="Extensions that cannot be ignored even if unrecognized"/>
      <definition
              value="May be used to represent additional information that is not part
 of the basic definition of the element and that modifies the understanding of the elemen
t in which it is contained and/or the understanding of the containing element&#39;s desce
ndants. Usually modifier elements provide negation or qualification. To make the use of e
xtensions safe and manageable, there is a strict set of governance applied to the definit
ion and use of extensions. Though any implementer can define an extension, there is a set
 of requirements that SHALL be met as part of the definition of the extension. Applicatio
ns processing a resource are required to check for modifier extensions.

Modifier extensions SHALL NOT change the meaning of any elements on Resource or DomainRes
ource (including cannot change the meaning of modifierExtension itself)."/>
      <comment
             value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
      <requirements
                 value="Modifier extensions allow for extensions that *cannot* be safe
ly ignored to be clearly distinguished from the vast majority of extensions which can be
```

```
safely ignored.  This promotes interoperability by eliminating the need for implementers
to prohibit the presence of extensions. For further information, see the [definition of m
odifier extensions](http://build.fhir.org/extensibility.html#modifierExtension)."/>
      <alias value="extensions"/>
      <alias value="user content"/>
      <alias value="modifiers"/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="BackboneElement.modifierExtension"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Extension"/>
      </type>
      <isModifier value="true"/>
      <isModifierReason
                        value="Modifier extensions are expected to modify the meaning or
interpretation of the element that contains them"/>
      <isSummary value="true"/>
      <mapping>
        <identity value="rim"/>
        <map value="N/A"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.regulatory.schedule.schedule">
      <path value="MedicationKnowledge.regulatory.schedule.schedule"/>
      <short value="Specifies the specific drug schedule"/>
      <definition value="Specifies the specific drug schedule."/>
      <min value="1"/>
      <max value="1"/>
      <base>
        <path value="MedicationKnowledge.regulatory.schedule.schedule"/>
        <min value="1"/>
        <max value="1"/>
      </base>
      <type>
        <code value="CodeableConcept"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="MedicationKnowledge.regulatory.maxDispense">
      <path value="MedicationKnowledge.regulatory.maxDispense"/>
      <short
            value="The maximum number of units of the medication that can be dispensed i
n a period"/>
      <definition
                  value="The maximum number of units of the medication that can be dispen
sed in a period."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="MedicationKnowledge.regulatory.maxDispense"/>
        <min value="0"/>
        <max value="1"/>
```

```
        </base>
        <type>
          <code value="BackboneElement"/>
        </type>
        <constraint>
          <key value="ele-1"/>
          <severity value="error"/>
          <human value="All FHIR elements must have a @value or children"/>
          <expression value="hasValue() or (children().count() &gt; id.count())"/>
          <xpath value="@value|f:*|h:div"/>
          <source value="Element"/>
        </constraint>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="MedicationKnowledge.regulatory.maxDispense.id">
        <path value="MedicationKnowledge.regulatory.maxDispense.id"/>
        <representation value="xmlAttr"/>
        <short value="Unique id for inter-element referencing"/>
        <definition
                  value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Element.id"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="string"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.regulatory.maxDispense.extension">
        <path value="MedicationKnowledge.regulatory.maxDispense.extension"/>
        <short value="Additional content defined by implementations"/>
        <definition
                  value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
        <comment
                value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
        <alias value="extensions"/>
        <alias value="user content"/>
        <min value="0"/>
        <max value="*"/>
```

```xml
      <base>
        <path value="Element.extension"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Extension"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="n/a"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.regulatory.maxDispense.modifierExtension">
      <path value="MedicationKnowledge.regulatory.maxDispense.modifierExtension"/>
      <short value="Extensions that cannot be ignored even if unrecognized"/>
      <definition
                  value="May be used to represent additional information that is not part
 of the basic definition of the element and that modifies the understanding of the elemen
t in which it is contained and/or the understanding of the containing element&#39;s desce
ndants. Usually modifier elements provide negation or qualification. To make the use of e
xtensions safe and manageable, there is a strict set of governance applied to the definit
ion and use of extensions. Though any implementer can define an extension, there is a set
 of requirements that SHALL be met as part of the definition of the extension. Applicatio
ns processing a resource are required to check for modifier extensions.

Modifier extensions SHALL NOT change the meaning of any elements on Resource or DomainRes
ource (including cannot change the meaning of modifierExtension itself)."/>
      <comment
              value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
      <requirements
                    value="Modifier extensions allow for extensions that *cannot* be safe
ly ignored to be clearly distinguished from the vast majority of extensions which can be
safely ignored.  This promotes interoperability by eliminating the need for implementers
to prohibit the presence of extensions. For further information, see the [definition of m
odifier extensions](http://build.fhir.org/extensibility.html#modifierExtension)."/>
      <alias value="extensions"/>
      <alias value="user content"/>
      <alias value="modifiers"/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="BackboneElement.modifierExtension"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Extension"/>
      </type>
      <isModifier value="true"/>
      <isModifierReason
                        value="Modifier extensions are expected to modify the meaning or
```

```
interpretation of the element that contains them"/>
      <isSummary value="true"/>
      <mapping>
        <identity value="rim"/>
        <map value="N/A"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.regulatory.maxDispense.quantity">
      <path value="MedicationKnowledge.regulatory.maxDispense.quantity"/>
      <short
              value="The maximum number of units of the medication that can be dispensed"/
>
      <definition
                  value="The maximum number of units of the medication that can be dispen
sed."/>
      <min value="1"/>
      <max value="1"/>
      <base>
        <path value="MedicationKnowledge.regulatory.maxDispense.quantity"/>
        <min value="1"/>
        <max value="1"/>
      </base>
      <type>
        <code value="Quantity"/>
        <profile value="http://hl7.org/fhir/StructureDefinition/SimpleQuantity"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="MedicationKnowledge.regulatory.maxDispense.period">
      <path value="MedicationKnowledge.regulatory.maxDispense.period"/>
      <short value="The period that applies to the maximum number of units"/>
      <definition
                  value="The period that applies to the maximum number of units."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="MedicationKnowledge.regulatory.maxDispense.period"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="Duration"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="MedicationKnowledge.kinetics">
      <path value="MedicationKnowledge.kinetics"/>
      <short
              value="The time course of drug absorption, distribution, metabolism and excr
etion of a medication from the body"/>
      <definition
                  value="The time course of drug absorption, distribution, metabolism and
 excretion of a medication from the body."/>
      <min value="0"/>
      <max value="*"/>
```

```xml
      <base>
        <path value="MedicationKnowledge.kinetics"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="BackboneElement"/>
      </type>
      <constraint>
        <key value="ele-1"/>
        <severity value="error"/>
        <human value="All FHIR elements must have a @value or children"/>
        <expression value="hasValue() or (children().count() &gt; id.count())"/>
        <xpath value="@value|f:*|h:div"/>
        <source value="Element"/>
      </constraint>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="MedicationKnowledge.kinetics.id">
      <path value="MedicationKnowledge.kinetics.id"/>
      <representation value="xmlAttr"/>
      <short value="Unique id for inter-element referencing"/>
      <definition
                 value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="Element.id"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="string"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="n/a"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.kinetics.extension">
      <path value="MedicationKnowledge.kinetics.extension"/>
      <short value="Additional content defined by implementations"/>
      <definition
                 value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
      <comment
               value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
```

```xml
        <alias value="extensions"/>
        <alias value="user content"/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="Element.extension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.kinetics.modifierExtension">
        <path value="MedicationKnowledge.kinetics.modifierExtension"/>
        <short value="Extensions that cannot be ignored even if unrecognized"/>
        <definition
                  value="May be used to represent additional information that is not part
 of the basic definition of the element and that modifies the understanding of the elemen
t in which it is contained and/or the understanding of the containing element&#39;s desce
ndants. Usually modifier elements provide negation or qualification. To make the use of e
xtensions safe and manageable, there is a strict set of governance applied to the definit
ion and use of extensions. Though any implementer can define an extension, there is a set
 of requirements that SHALL be met as part of the definition of the extension. Applicatio
ns processing a resource are required to check for modifier extensions.

Modifier extensions SHALL NOT change the meaning of any elements on Resource or DomainRes
ource (including cannot change the meaning of modifierExtension itself)."/>
        <comment
                value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
        <requirements
                     value="Modifier extensions allow for extensions that *cannot* be safe
ly ignored to be clearly distinguished from the vast majority of extensions which can be
safely ignored.  This promotes interoperability by eliminating the need for implementers
to prohibit the presence of extensions. For further information, see the [definition of m
odifier extensions](http://build.fhir.org/extensibility.html#modifierExtension)."/>
        <alias value="extensions"/>
        <alias value="user content"/>
        <alias value="modifiers"/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="BackboneElement.modifierExtension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
```

```
        </type>
        <isModifier value="true"/>
        <isModifierReason
                         value="Modifier extensions are expected to modify the meaning or
interpretation of the element that contains them"/>
        <isSummary value="true"/>
        <mapping>
          <identity value="rim"/>
          <map value="N/A"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.kinetics.areaUnderCurve">
        <path value="MedicationKnowledge.kinetics.areaUnderCurve"/>
        <short
              value="The drug concentration measured at certain discrete points in time"/>
        <definition
                    value="The drug concentration measured at certain discrete points in ti
me."/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="MedicationKnowledge.kinetics.areaUnderCurve"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Quantity"/>
          <profile value="http://hl7.org/fhir/StructureDefinition/SimpleQuantity"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="MedicationKnowledge.kinetics.lethalDose50">
        <path value="MedicationKnowledge.kinetics.lethalDose50"/>
        <short value="The median lethal dose of a drug"/>
        <definition value="The median lethal dose of a drug."/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="MedicationKnowledge.kinetics.lethalDose50"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Quantity"/>
          <profile value="http://hl7.org/fhir/StructureDefinition/SimpleQuantity"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="MedicationKnowledge.kinetics.halfLifePeriod">
        <path value="MedicationKnowledge.kinetics.halfLifePeriod"/>
        <short
              value="Time required for concentration in the body to decrease by half"/>
        <definition
                    value="The time required for any specified property (e.g., the concentr
ation of a substance in the body) to decrease by half."/>
```

```xml
          <min value="0"/>
          <max value="1"/>
          <base>
            <path value="MedicationKnowledge.kinetics.halfLifePeriod"/>
            <min value="0"/>
            <max value="1"/>
          </base>
          <type>
            <code value="Duration"/>
          </type>
          <isModifier value="false"/>
          <isSummary value="false"/>
        </element>
      </snapshot>
      <differential>
        <element id="MedicationKnowledge">
          <path value="MedicationKnowledge"/>
          <mustSupport value="false"/>
          <isModifier value="false"/>
        </element>
        <element id="MedicationKnowledge.extension:productType">
          <path value="MedicationKnowledge.extension"/>
          <sliceName value="productType"/>
          <short value="Specification Type"/>
          <definition
                   value="A classification of specification related to the kind of the ent
ity it is referencing. [Source: SME Defined]."/>
          <min value="1"/>
          <max value="1"/>
          <type>
            <code value="Extension"/>
            <profile
                    value="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-productTyp
e"/>
          </type>
          <mustSupport value="true"/>
          <isModifier value="false"/>
        </element>
        <element id="MedicationKnowledge.extension:productType.valueCode">
          <path value="MedicationKnowledge.extension.valueCode"/>
          <short value="Drug Product"/>
          <min value="1"/>
          <max value="1"/>
          <type>
            <code value="code"/>
          </type>
          <fixedCode value="product"/>
          <mustSupport value="true"/>
          <isModifier value="false"/>
        </element>
        <element id="MedicationKnowledge.code">
          <path value="MedicationKnowledge.code"/>
          <min value="1"/>
          <max value="1"/>
          <mustSupport value="true"/>
          <isModifier value="false"/>
        </element>
```

```
    <element id="MedicationKnowledge.code.text">
      <path value="MedicationKnowledge.code.text"/>
      <short value="Non-proprietary Name"/>
      <definition
                value="A name unprotected by trademark rights that is entirely in the p
ublic domain. It may be used without restriction by the public at large, both lay and pro
fessional. [Source: http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRe
quirements/ElectronicSubmissions/DataStandardsManualmonographs/ucm071638.htm ]."/>
      <min value="1"/>
      <max value="1"/>
      <mustSupport value="true"/>
      <isModifier value="false"/>
    </element>
    <element id="MedicationKnowledge.doseForm">
      <path value="MedicationKnowledge.doseForm"/>
      <short value="Dosage Form"/>
      <definition
                value="The form in which active and/or inert ingredient(s) are physical
ly presented. [Source: NCI EVS - C42636]
Examples: tablet, capsule, solution, cream, etc. that contains a drug substance generally
, but not necessarily, in association with excipients. [Source: ICH Q1A(R2)]
Note: If there is a new dosage form that does not exist in the controlled terminology, th
en propose register this new dosage form during sponsor meetings with FDA."/>
      <min value="1"/>
      <max value="1"/>
      <mustSupport value="true"/>
      <isModifier value="false"/>
    </element>
    <element id="MedicationKnowledge.synonym">
      <path value="MedicationKnowledge.synonym"/>
      <slicing>
        <discriminator>
          <type value="value"/>
          <path
                value="extension(&#39;http://fda.gov/cder/fhir/pqcmc/StructureDefinition/
ext-nameType&#39;).valueCode"/>
        </discriminator>
        <rules value="open"/>
      </slicing>
      <min value="0"/>
      <max value="*"/>
      <mustSupport value="true"/>
      <isModifier value="false"/>
    </element>
    <element id="MedicationKnowledge.synonym.extension:proprietaryNameType">
      <path value="MedicationKnowledge.synonym.extension"/>
      <sliceName value="proprietaryNameType"/>
      <short value="Proprietary Name"/>
      <definition
                value="The exclusive name of a drug substance or drug product owned by
a company under trademark law regardless of registration status with the Patent and Trade
mark Office (PTO). [Source: http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubm
issionRequirements/ElectronicSubmissions/DataStandardsManualmonographs/ucm071683.htm]
Note:  Excludes dosage form, route of administration and strength.
Example:  Tylenol."/>
      <min value="1"/>
      <max value="1"/>
```

```
      <type>
        <code value="Extension"/>
        <profile
                value="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-nameType"/
>
      </type>
      <mustSupport value="true"/>
      <isModifier value="false"/>
    </element>
    <element
            id="MedicationKnowledge.synonym.extension:proprietaryNameType.valueCode">
      <path value="MedicationKnowledge.synonym.extension.valueCode"/>
      <definition value="proprietary  or nonProprietary."/>
      <min value="1"/>
      <max value="1"/>
      <type>
        <code value="code"/>
      </type>
      <fixedCode value="proprietary"/>
      <mustSupport value="true"/>
      <isModifier value="false"/>
    </element>
    <element id="MedicationKnowledge.ingredient">
      <path value="MedicationKnowledge.ingredient"/>
      <short value="Product Component Name"/>
      <definition
                value="Any ingredient intended for use in the manufacture of a drug pro
duct, including those that may not appear in such drug product. [Source: (21 CFR 210.3(b)
(3)) PAC-ATLS 1998]."/>
      <min value="1"/>
      <max value="*"/>
      <mustSupport value="true"/>
      <isModifier value="false"/>
    </element>
    <element id="MedicationKnowledge.ingredient.extension:contentPercent">
      <path value="MedicationKnowledge.ingredient.extension"/>
      <sliceName value="contentPercent"/>
      <short value="Content percent"/>
      <definition
                value="The percentage of the component in the drug product. [Source: SM
E Defined]."/>
      <min value="0"/>
      <max value="1"/>
      <type>
        <code value="Extension"/>
        <profile
                value="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-contentPer
cent"/>
      </type>
      <mustSupport value="true"/>
      <isModifier value="false"/>
    </element>
    <element id="MedicationKnowledge.ingredient.itemReference">
      <path value="MedicationKnowledge.ingredient.itemReference"/>
      <min value="1"/>
      <max value="1"/>
      <mustSupport value="true"/>
```

```xml
          <isModifier value="false"/>
    </element>
    <element id="MedicationKnowledge.ingredient.strength">
      <path value="MedicationKnowledge.ingredient.strength"/>
      <short value="Strength"/>
      <definition
                value="The content of an active ingredient expressed quantitatively per
 dosage unit, per unit of volume, or per unit of weight, according to the pharmaceutical
dosage form. This should be the strength as listed on the label. [Source: Adapted from NC
I EVS C53294]
Note: Strength can also be referred to as potency in biologics and other products.  This
information may be captured on the label."/>
      <min value="1"/>
      <max value="*"/>
      <mustSupport value="true"/>
      <isModifier value="false"/>
    </element>
    <element id="MedicationKnowledge.ingredient.strength.numerator">
      <path value="MedicationKnowledge.ingredient.strength.numerator"/>
      <short value="Strength Unit"/>
      <definition
                value="The labeled unit of measure for the content of an active ingredi
ent, expressed quantitatively per dosage unit. [Source: Adapted for NCI EVS C117055]."/>
      <min value="0"/>
      <max value="1"/>
      <mustSupport value="true"/>
      <isModifier value="false"/>
    </element>
    <element id="MedicationKnowledge.ingredient.strength.numerator.value">
      <path value="MedicationKnowledge.ingredient.strength.numerator.value"/>
      <min value="1"/>
      <max value="1"/>
      <mustSupport value="true"/>
      <isModifier value="false"/>
    </element>
    <element id="MedicationKnowledge.ingredient.strength.numerator.system">
      <path value="MedicationKnowledge.ingredient.strength.numerator.system"/>
      <definition value="UCUM."/>
      <min value="1"/>
      <max value="1"/>
      <type>
        <code value="uri"/>
      </type>
      <fixedUri value="http://unitsofmeasure.org"/>
      <mustSupport value="true"/>
      <isModifier value="false"/>
    </element>
    <element id="MedicationKnowledge.ingredient.strength.numerator.code">
      <path value="MedicationKnowledge.ingredient.strength.numerator.code"/>
      <short value="Strength Unit of Measure"/>
      <definition
                value="The labeled unit of measure for the content of an active ingredi
ent, expressed quantitatively per dosage unit. [Source: Adapted for NCI EVS C117055] Exam
ples: mg, g, mL, etc."/>
      <min value="1"/>
      <max value="1"/>
      <type>
```

```xml
          <code value="code"/>
        </type>
        <mustSupport value="true"/>
        <isModifier value="false"/>
      </element>
      <element id="MedicationKnowledge.ingredient.strength.denominator">
        <path value="MedicationKnowledge.ingredient.strength.denominator"/>
        <min value="0"/>
        <max value="1"/>
        <mustSupport value="true"/>
        <isModifier value="false"/>
      </element>
      <element id="MedicationKnowledge.ingredient.strength.denominator.value">
        <path value="MedicationKnowledge.ingredient.strength.denominator.value"/>
        <type>
          <code value="decimal"/>
        </type>
        <fixedDecimal value="1"/>
        <mustSupport value="false"/>
        <isModifier value="false"/>
      </element>
    </differential>
</StructureDefinition>
```

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| Content | Detailed Descriptions | Mappings | Examples | XML |

StructureDefinition: PQCMC_MedicationKnowledge - Mappings

Mappings for the Profile.

Mappings for RIM Mapping (http://hl7.org/v3)

PQCMC_MedicationKnowledge	
MedicationKnowledge	Entity. Role, or Act
text	Act.text?
contained	N/A
extension	
extension (productType)	
id	n/a
extension	n/a
url	N/A
valueCode	N/A
modifierExtension	N/A
code	.code
id	n/a
extension	n/a
coding	union(., ./translation)
coding (UNII)	union(., ./translation)
id	n/a
extension	n/a
system	./codeSystem
version	./codeSystemVersion
code	./code
display	CV.displayName
userSelected	CD.codingRationale
coding (CASNumber)	union(., ./translation)
id	n/a
extension	n/a
system	./codeSystem
version	./codeSystemVersion

code	./code
display	CV.displayName
userSelected	CD.codingRationale
coding (INN)	union(., ./translation)
id	n/a
extension	n/a
system	./codeSystem
version	./codeSystemVersion
code	./code
display	CV.displayName
userSelected	CD.codingRationale
coding (USAN)	union(., ./translation)
id	n/a
extension	n/a
system	./codeSystem
version	./codeSystemVersion
code	./code
display	CV.displayName
userSelected	CD.codingRationale
coding (IUPACName)	union(., ./translation)
id	n/a
extension	n/a
system	./codeSystem
version	./codeSystemVersion
code	./code
display	CV.displayName
userSelected	CD.codingRationale
coding (@default)	union(., ./translation)
id	n/a
extension	n/a
system	./codeSystem
version	./codeSystemVersion
code	./code
display	CV.displayName
userSelected	CD.codingRationale
text	./originalText[mediaType/code="text/plain"]/data
status	.statusCode
manufacturer	.player.scopingRole[typeCode=MANU].scoper
doseForm	.formCode
amount	.quantity
relatedMedicationKnowledge	
id	n/a

extension	n/a
modifierExtension	N/A
monograph	
id	n/a
extension	n/a
modifierExtension	N/A
ingredient	
id	n/a
extension	n/a
modifierExtension	N/A
itemReference	.player
isActive	NA
strength	.quantity
cost	
id	n/a
extension	n/a
modifierExtension	N/A
monitoringProgram	
id	n/a
extension	n/a
modifierExtension	N/A
administrationGuidelines	
id	n/a
extension	n/a
modifierExtension	N/A
dosage	
id	n/a
extension	n/a
modifierExtension	N/A
patientCharacteristics	
id	n/a
extension	n/a
modifierExtension	N/A
medicineClassification	
id	n/a
extension	n/a
modifierExtension	N/A
packaging	
id	n/a
extension	n/a
modifierExtension	N/A
drugCharacteristic	

id	n/a
extension	n/a
modifierExtension	N/A
regulatory	
id	n/a
extension	n/a
modifierExtension	N/A
substitution	
id	n/a
extension	n/a
modifierExtension	N/A
schedule	
id	n/a
extension	n/a
modifierExtension	N/A
maxDispense	
id	n/a
extension	n/a
modifierExtension	N/A
kinetics	
id	n/a
extension	n/a
modifierExtension	N/A

Mappings for Mapping to NCPDP SCRIPT 10.6 (http://ncpdp.org/SCRIPT10_6)

PQCMC_MedicationKnowledge	
MedicationKnowledge	
code	coding.code = //element(*,MedicationType)/DrugCoded/ProductCode coding.system = //element(*,MedicationType)/DrugCoded/ProductCodeQualifier coding.display = //element(*,MedicationType)/DrugDescription
manufacturer	no mapping
doseForm	coding.code = //element(*,DrugCodedType)/FormCode coding.system = //element(*,DrugCodedType)/FormSourceCode
ingredient	
itemReference	coding.code = //element(*,MedicationType)/DrugCoded/ProductCode coding.system = //element(*,MedicationType)/DrugCoded/ProductCodeQualifier coding.display = //element(*,MedicationType)/DrugDescription
strength	//element(*,DrugCodedType)/Strength

Mappings for FiveWs Pattern Mapping (http://hl7.org/fhir/fivews)

PQCMC_MedicationKnowledge	
MedicationKnowledge	
code	FiveWs.class
manufacturer	FiveWs.actor

Mappings for HL7 v2 Mapping (http://hl7.org/v2)

PQCMC_MedicationKnowledge	
MedicationKnowledge	
code	RXO-1.1-Requested Give Code.code / RXE-2.1-Give Code.code / RXD-2.1-Dispense/Give Code.code / RXG-4.1-Give Code.code /RXA-5.1-Administered Code.code / RXC-2.1 Component Code
coding	C*E.1-8, C*E.10-22
coding (UNII)	C*E.1-8, C*E.10-22
system	C*E.3
version	C*E.7
code	C*E.1
display	C*E.2 - but note this is not well followed
userSelected	Sometimes implied by being first
coding (CASNumber)	C*E.1-8, C*E.10-22
system	C*E.3
version	C*E.7
code	C*E.1
display	C*E.2 - but note this is not well followed
userSelected	Sometimes implied by being first
coding (INN)	C*E.1-8, C*E.10-22
system	C*E.3
version	C*E.7
code	C*E.1
display	C*E.2 - but note this is not well followed
userSelected	Sometimes implied by being first
coding (USAN)	C*E.1-8, C*E.10-22
system	C*E.3
version	C*E.7
code	C*E.1
display	C*E.2 - but note this is not well followed
userSelected	Sometimes implied by being first
coding (IUPACName)	C*E.1-8, C*E.10-22
system	C*E.3
version	C*E.7
code	C*E.1
display	C*E.2 - but note this is not well followed
userSelected	Sometimes implied by being first
coding (@default)	C*E.1-8, C*E.10-22
system	C*E.3
version	C*E.7

code	C*E.1
display	C*E.2 - but note this is not well followed
userSelected	Sometimes implied by being first
text	C*E.9. But note many systems use C*E.2 for this
manufacturer	RXD-20-Substance Manufacturer Name / RXG-21-Substance Manufacturer Name / RXA-17-Substance Manufacturer Name
doseForm	RXO-5-Requested Dosage Form / RXE-6-Give Dosage Form / RXD-6-Actual Dosage Form / RXG-8-Give Dosage Form / RXA-8-Administered Dosage Form
ingredient	
itemReference	RXC-2-Component Code if medication: RXO-1-Requested Give Code / RXE-2-Give Code / RXD-2-Dispense/Give Code / RXG-4-Give Code / RXA-5-Administered Code
strength	RXC-3-Component Amount & RXC-4-Component Units if medication: RXO-2-Requested Give Amount - Minimum & RXO-4-Requested Give Units / RXO-3-Requested Give Amount - Maximum & RXO-4-Requested Give Units / RXO-11-Requested Dispense Amount & RXO-12-Requested Dispense Units / RXE-3-Give Amount - Minimum & RXE-5-Give Units / RXE-4-Give Amount - Maximum & RXE-5-Give Units / RXE-10-Dispense Amount & RXE-10-Dispense Units

FDA

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| Content | Detailed Descriptions | Mappings | Examples | XML |

StructureDefinition: PQCMC_MedicationKnowledge - Examples

No examples are currently available for the Profile.

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Content   Detailed Descriptions   Mappings   Examples   **XML**

StructureDefinition: PQCMC_MedicationKnowledge - XML Profile

XML representation of the drugsubstance Profile.

Narrative view of the profile

```
<StructureDefinition xmlns="http://hl7.org/fhir">
  <id value="drugsubstance"/>
  <text>
    <status value="generated"/>
    <div xmlns="http://www.w3.org/1999/xhtml"><table border="0" cellpadding="0" cellspaci
ng="0" style="border: 0px #F0F0F0 solid; font-size: 11px; font-family: verdana; vertical-
align: top;"><tr style="border: 1px #F0F0F0 solid; font-size: 11px; font-family: verdana;
 vertical-align: top;"><th style="vertical-align: top; text-align : left; background-colo
r: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><a href="
http://build.fhir.org/formats.html#table" title="The logical name of the element">Name</a
></th><th style="vertical-align: top; text-align : left; background-color: white; border:
 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><a href="http://build.fhir
.org/formats.html#table" title="Information about the use of the element">Flags</a></th><
th style="vertical-align: top; text-align : left; background-color: white; border: 0px #F
0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><a href="http://build.fhir.org/fo
rmats.html#table" title="Minimum and Maximum # of times the the element can appear in the
 instance">Card.</a></th><th style="width: 100px" class="hierarchy"><a href="http://build
.fhir.org/formats.html#table" title="Reference to the type of the element">Type</a></th><
th style="vertical-align: top; text-align : left; background-color: white; border: 0px #F
0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><a href="http://build.fhir.org/fo
rmats.html#table" title="Additional information about the element">Description &amp; Cons
traints</a><span style="float: right"><a href="http://build.fhir.org/formats.html#table"
title="Legend for this format"><img src="http://build.fhir.org/help16.png" alt="doco" sty
le="background-color: inherit"/></a></span></th></tr><tr style="border: 0px #F0F0F0 solid
; padding:0px; vertical-align: top; background-color: white;"><td style="vertical-align:
top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4
px 0px 4px; white-space: nowrap; background-image: url(tbl_bck1.png)" class="hierarchy"><
img src="tbl_spacer.png" alt="." style="background-color: inherit" class="hierarchy"/><im
g src="icon_element.gif" alt="." style="background-color: white; background-color: inheri
t" title="Element" class="hierarchy"/> <a href="drugsubstance-definitions.html#Medication
Knowledge">MedicationKnowledge</a><a name="MedicationKnowledge"> </a></td><td style="vert
ical-align: top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; p
adding:0px 4px 0px 4px" class="hierarchy"/><td style="vertical-align: top; text-align : l
eft; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="
hierarchy"/><td style="vertical-align: top; text-align : left; background-color: white; b
order: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"/><td style="vertical
-align: top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; paddi
```

```
ng:0px 4px 0px 4px" class="hierarchy"/></tr>
<tr style="border: 0px #F0F0F0 solid; padding:0px; vertical-align: top; background-color:
 white;"><td style="vertical-align: top; text-align : left; background-color: white; bord
er: 0px #F0F0F0 solid; padding:0px 4px 0px 4px; white-space: nowrap; background-image: ur
l(tbl_bck15.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="background-c
olor: inherit" class="hierarchy"/><img src="tbl_vjoin.png" alt="." style="background-colo
r: inherit" class="hierarchy"/><img src="icon_extension_simple.png" alt="." style="backgr
ound-color: white; background-color: inherit" title="Simple Extension" class="hierarchy"/
> <a href="drugsubstance-definitions.html#MedicationKnowledge.extension:productType" titl
e="Extension URL = http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-productType">ex
t-productType</a><a name="MedicationKnowledge.extension"> </a></td><td style="vertical-al
ign: top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:
0px 4px 0px 4px" class="hierarchy"><span style="padding-left: 3px; padding-right: 3px; co
lor: white; background-color: red" title="This element must be supported">S</span></td><t
d style="vertical-align: top; text-align : left; background-color: white; border: 0px #F0
F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy">1..1</td><td style="vertical-align
: top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px
 4px 0px 4px" class="hierarchy"><a href="http://build.fhir.org/datatypes.html#code">code<
/a></td><td style="vertical-align: top; text-align : left; background-color: white; borde
r: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy">Specification Type<br/><
span style="font-weight:bold">URL: </span><a href="http://build.fhir.org/extension-ext-pr
oductType.html">http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-productType</a></t
d></tr>
<tr style="border: 0px #F0F0F0 solid; padding:0px; vertical-align: top; background-color:
 white;"><td style="vertical-align: top; text-align : left; background-color: white; bord
er: 0px #F0F0F0 solid; padding:0px 4px 0px 4px; white-space: nowrap; background-image: ur
l(tbl_bck142.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="background-
color: inherit" class="hierarchy"/><img src="tbl_vline.png" alt="." style="background-col
or: inherit" class="hierarchy"/><img src="tbl_vjoin_end_slice.png" alt="." style="backgro
und-color: inherit" class="hierarchy"/><img src="icon_slice.png" alt="." style="backgroun
d-color: white; background-color: inherit" title="Slice Definition" class="hierarchy"/> <
a style="font-style: italic" href="drugsubstance-definitions.html#MedicationKnowledge.ext
ension:productType.valueCode">valueCode</a><a name="MedicationKnowledge.extension.valueCo
de"> </a></td><td style="vertical-align: top; text-align : left; background-color: white;
 border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><span style="paddi
ng-left: 3px; padding-right: 3px; color: white; background-color: red; font-style: italic
" title="This element must be supported">S</span></td><td style="vertical-align: top; tex
t-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4
px" class="hierarchy"/><td style="vertical-align: top; text-align : left; background-colo
r: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><a style=
"font-style: italic" href="http://build.fhir.org/datatypes.html#code">code</a></td><td st
yle="vertical-align: top; text-align : left; background-color: white; border: 0px #F0F0F0
 solid; padding:0px 4px 0px 4px" class="hierarchy"><span style="font-style: italic">Drug
Substance</span><br style="font-style: italic"/><span style="font-weight:bold; font-style
: italic">Slice: </span><span style="font-style: italic">Unordered, Open by value:@valueC
ode</span><br style="font-style: italic"/><span style="font-weight:bold; font-style: ital
ic">Fixed Value: </span><span style="color: darkgreen; font-style: italic">substance</spa
n></td></tr>
<tr style="border: 0px #F0F0F0 solid; padding:0px; vertical-align: top; background-color:
 white;"><td style="vertical-align: top; text-align : left; background-color: white; bord
er: 0px #F0F0F0 solid; padding:0px 4px 0px 4px; white-space: nowrap; background-image: ur
l(tbl_bck11.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="background-c
olor: inherit" class="hierarchy"/><img src="tbl_vjoin.png" alt="." style="background-colo
r: inherit" class="hierarchy"/><img src="icon_element.gif" alt="." style="background-colo
r: white; background-color: inherit" title="Element" class="hierarchy"/> <a href="drugsub
stance-definitions.html#MedicationKnowledge.code">code</a><a name="MedicationKnowledge.co
de"> </a></td><td style="vertical-align: top; text-align : left; background-color: white;
```

```
border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><span style="paddi
ng-left: 3px; padding-right: 3px; color: white; background-color: red" title="This elemen
t must be supported">S</span></td><td style="vertical-align: top; text-align : left; back
ground-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy
">1..*</td><td style="vertical-align: top; text-align : left; background-color: white; bo
rder: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"/><td style="vertical-
align: top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; paddin
g:0px 4px 0px 4px" class="hierarchy"/></tr>
<tr style="border: 0px #F0F0F0 solid; padding:0px; vertical-align: top; background-color:
 white;"><td style="vertical-align: top; text-align : left; background-color: white; bord
er: 0px #F0F0F0 solid; padding:0px 4px 0px 4px; white-space: nowrap; background-image: ur
l(tbl_bck112.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="background-
color: inherit" class="hierarchy"/><img src="tbl_vline.png" alt="." style="background-col
or: inherit" class="hierarchy"/><img src="tbl_vjoin.png" alt="." style="background-color:
 inherit" class="hierarchy"/><img src="icon_slice.png" alt="." style="background-color: w
hite; background-color: inherit" title="Slice Definition" class="hierarchy"/> <a style="f
ont-style: italic" href="drugsubstance-definitions.html#MedicationKnowledge.code.coding">
coding</a><a name="MedicationKnowledge.code.coding"> </a></td><td style="vertical-align:
top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4
px 0px 4px" class="hierarchy"><span style="padding-left: 3px; padding-right: 3px; color:
white; background-color: red; font-style: italic" title="This element must be supported">
S</span></td><td style="vertical-align: top; text-align : left; background-color: white;
border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"/><td style="vertica
l-align: top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padd
ing:0px 4px 0px 4px" class="hierarchy"/><td style="vertical-align: top; text-align : left
; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hie
rarchy"><span style="font-weight:bold; font-style: italic">Slice: </span><span style="fon
t-style: italic">Unordered, Open by value:system</span></td></tr>
<tr style="border: 0px #F0F0F0 solid; padding:0px; vertical-align: top; background-color:
 white;"><td style="vertical-align: top; text-align : left; background-color: white; bord
er: 0px #F0F0F0 solid; padding:0px 4px 0px 4px; white-space: nowrap; background-image: ur
l(tbl_bck115.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="background-
color: inherit" class="hierarchy"/><img src="tbl_vline.png" alt="." style="background-col
or: inherit" class="hierarchy"/><img src="tbl_vjoin.png" alt="." style="background-color:
 inherit" class="hierarchy"/><img src="icon_element.gif" alt="." style="background-color:
 white; background-color: inherit" title="Element" class="hierarchy"/> <a href="drugsubst
ance-definitions.html#MedicationKnowledge.code.coding:UNII" title="Slice UNII: The UNII i
s a non-proprietary, free, unique, unambiguous, non-semantic, alphanumeric identifier bas
ed on a substance's molecular structure and/or descriptive information. [Source: Substanc
e Registration System – Unique identifier] Example: 362O9ITL9D Note: If a UNII does not e
xist, please go to Substance Registration System – Unique identifier.">coding</a><a name=
"MedicationKnowledge.code.coding"> </a></td><td style="vertical-align: top; text-align :
left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class=
"hierarchy"><span style="padding-left: 3px; padding-right: 3px; color: white; background-
color: red" title="This element must be supported">S</span></td><td style="vertical-align
: top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px
 4px 0px 4px" class="hierarchy">1..1</td><td style="vertical-align: top; text-align : lef
t; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hi
erarchy"/><td style="vertical-align: top; text-align : left; background-color: white; bor
der: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy">UNII code</td></tr>
<tr style="border: 0px #F0F0F0 solid; padding:0px; vertical-align: top; background-color:
 white;"><td style="vertical-align: top; text-align : left; background-color: white; bord
er: 0px #F0F0F0 solid; padding:0px 4px 0px 4px; white-space: nowrap; background-image: ur
l(tbl_bck1150.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="background
-color: inherit" class="hierarchy"/><img src="tbl_vline.png" alt="." style="background-co
lor: inherit" class="hierarchy"/><img src="tbl_vline.png" alt="." style="background-color
: inherit" class="hierarchy"/><img src="tbl_vjoin_slice.png" alt="." style="background-co
```

```
lor: inherit" class="hierarchy"/><img src="icon_primitive.png" alt="." style="background-
color: white; background-color: inherit" title="Primitive Data Type" class="hierarchy"/>
<a href="drugsubstance-definitions.html#MedicationKnowledge.code.coding:UNII.system">syst
em</a><a name="MedicationKnowledge.code.coding.system"> </a></td><td style="vertical-alig
n: top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0p
x 4px 0px 4px" class="hierarchy"><span style="padding-left: 3px; padding-right: 3px; colo
r: white; background-color: red" title="This element must be supported">S</span></td><td
style="vertical-align: top; text-align : left; background-color: white; border: 0px #F0F0
F0 solid; padding:0px 4px 0px 4px" class="hierarchy">1..1</td><td style="vertical-align:
top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4
px 0px 4px" class="hierarchy"><a href="http://build.fhir.org/datatypes.html#uri">uri</a><
/td><td style="vertical-align: top; text-align : left; background-color: white; border: 0
px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><span style="font-weight:bol
d">Fixed Value: </span><span style="color: darkgreen">http://www.fda.gov/ForIndustry/Data
Standards/SubstanceRegistrationSystem-UniqueIngredientIdentifierUNII/default.html</span><
/td></tr>
<tr style="border: 0px #F0F0F0 solid; padding:0px; vertical-align: top; background-color:
 white;"><td style="vertical-align: top; text-align : left; background-color: white; bord
er: 0px #F0F0F0 solid; padding:0px 4px 0px 4px; white-space: nowrap; background-image: ur
l(tbl_bck1140.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="background
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ance-definitions.html#MedicationKnowledge.code.coding:CASNumber" title="Slice CASNumber:
Chemical Abstract Service (CAS) Registry Numbers (often referred to as CAS RNs or CAS Num
bers) are used to provide unmistakable identifiers for chemical substances. A CAS Registr
y Number itself has no inherent chemical significance but provides a way to identify a ch
emical substance or molecular structure when there are many possible systematic, generic,
 proprietary or trivial names. [Source: Adapted from CAS.org] Example: CAS [103-90-2].">c
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l Nonproprietary Names (INN) is a unique name that is globally recognized and is public p
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onproprietary name assigned to drugs and biologics by the United States Adopted Names Cou
ncil [Source: SME Defined] Example: acetaminophen.">coding</a><a name="MedicationKnowledg
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d">Fixed Value: </span><span style="color: darkgreen">https://www.ama-assn.org/about-ama/
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ance-definitions.html#MedicationKnowledge.code.coding:IUPACName" title="Slice IUPACName:
A name assigned to a chemical substance according to the systematic nomenclature rules de
fined by the International Union of Pure and Applied Chemistry (IUPAC). [Source: SME Defi
ned] Example: N-(4-hydroxyphenyl) acetamide.">coding</a><a name="MedicationKnowledge.code
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d-color: white; background-color: inherit" title="Element" class="hierarchy"/> <a href="d
rugsubstance-definitions.html#MedicationKnowledge.code.coding:IUPACName.code">code</a><a
name="MedicationKnowledge.code.coding.code"> </a></td><td style="vertical-align: top; tex
t-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4
px" class="hierarchy"><span style="padding-left: 3px; padding-right: 3px; color: white; b
ackground-color: red" title="This element must be supported">S</span></td><td style="vert
ical-align: top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; p
adding:0px 4px 0px 4px" class="hierarchy">1..1</td><td style="vertical-align: top; text-a
lign : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px"
 class="hierarchy"/><td style="vertical-align: top; text-align : left; background-color:
white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"/></tr>
```

```
<tr style="border: 0px #F0F0F0 solid; padding:0px; vertical-align: top; background-color:
 white;"><td style="vertical-align: top; text-align : left; background-color: white; bord
er: 0px #F0F0F0 solid; padding:0px 4px 0px 4px; white-space: nowrap; background-image: ur
l(tbl_bck115.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="background-
color: inherit" class="hierarchy"/><img src="tbl_vline.png" alt="." style="background-col
or: inherit" class="hierarchy"/><img src="tbl_vjoin.png" alt="." style="background-color:
 inherit" class="hierarchy"/><img src="icon_element.gif" alt="." style="background-color:
 white; background-color: inherit" title="Element" class="hierarchy"/> <a href="drugsubst
ance-definitions.html#MedicationKnowledge.code.coding:@default" title="Slice @default: ">
coding</a><a name="MedicationKnowledge.code.coding"> </a></td><td style="vertical-align:
top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4
px 0px 4px" class="hierarchy"><span style="padding-left: 3px; padding-right: 3px; color:
white; background-color: red" title="This element must be supported">S</span></td><td sty
le="vertical-align: top; text-align : left; background-color: white; border: 0px #F0F0F0
solid; padding:0px 4px 0px 4px" class="hierarchy">0..*</td><td style="vertical-align: top
; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px
0px 4px" class="hierarchy"/><td style="vertical-align: top; text-align : left; background
-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"/></t
r>
<tr style="border: 0px #F0F0F0 solid; padding:0px; vertical-align: top; background-color:
 white;"><td style="vertical-align: top; text-align : left; background-color: white; bord
er: 0px #F0F0F0 solid; padding:0px 4px 0px 4px; white-space: nowrap; background-image: ur
l(tbl_bck1140.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="background
-color: inherit" class="hierarchy"/><img src="tbl_vline.png" alt="." style="background-co
lor: inherit" class="hierarchy"/><img src="tbl_vline.png" alt="." style="background-color
: inherit" class="hierarchy"/><img src="tbl_vjoin_end_slice.png" alt="." style="backgroun
d-color: inherit" class="hierarchy"/><img src="icon_element.gif" alt="." style="backgroun
d-color: white; background-color: inherit" title="Element" class="hierarchy"/> <a href="d
rugsubstance-definitions.html#MedicationKnowledge.code.coding:@default.code" title="An in
ternal identifier assigned by the sponsor to this drug substance. [Source: SME Defined]."
>code</a><a name="MedicationKnowledge.code.coding.code"> </a></td><td style="vertical-ali
gn: top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0
px 4px 0px 4px" class="hierarchy"><span style="padding-left: 3px; padding-right: 3px; col
or: white; background-color: red" title="This element must be supported">S</span></td><td
 style="vertical-align: top; text-align : left; background-color: white; border: 0px #F0F
0F0 solid; padding:0px 4px 0px 4px" class="hierarchy">1..1</td><td style="vertical-align:
 top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px
4px 0px 4px" class="hierarchy"/><td style="vertical-align: top; text-align : left; backgr
ound-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy">
Company code</td></tr>
<tr style="border: 0px #F0F0F0 solid; padding:0px; vertical-align: top; background-color:
 white;"><td style="vertical-align: top; text-align : left; background-color: white; bord
er: 0px #F0F0F0 solid; padding:0px 4px 0px 4px; white-space: nowrap; background-image: ur
l(tbl_bck100.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="background-
color: inherit" class="hierarchy"/><img src="tbl_vline.png" alt="." style="background-col
or: inherit" class="hierarchy"/><img src="tbl_vjoin_end.png" alt="." style="background-co
lor: inherit" class="hierarchy"/><img src="icon_element.gif" alt="." style="background-co
lor: white; background-color: inherit" title="Element" class="hierarchy"/> <a href="drugs
ubstance-definitions.html#MedicationKnowledge.code.text" title="A commonly used name or a
 systematic name assigned to the chemical or compound. [Source: SME Defined] Examples: ac
etaminophen; acetamide, N-(4-hydroxyphenyl)-; 4hydroxyacetanilide.">text</a><a name="Medi
cationKnowledge.code.text"> </a></td><td style="vertical-align: top; text-align : left; b
ackground-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierar
chy"><span style="padding-left: 3px; padding-right: 3px; color: white; background-color:
red" title="This element must be supported">S</span></td><td style="vertical-align: top;
text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0p
x 4px" class="hierarchy">1..1</td><td style="vertical-align: top; text-align : left; back
```

```
ground-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy
"/><td style="vertical-align: top; text-align : left; background-color: white; border: 0p
x #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy">Chemical Name</td></tr>
<tr style="border: 0px #F0F0F0 solid; padding:0px; vertical-align: top; background-color:
 white;"><td style="vertical-align: top; text-align : left; background-color: white; bord
er: 0px #F0F0F0 solid; padding:0px 4px 0px 4px; white-space: nowrap; background-image: ur
l(tbl_bck01.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="background-c
olor: inherit" class="hierarchy"/><img src="tbl_vjoin_end.png" alt="." style="background-
color: inherit" class="hierarchy"/><img src="icon_element.gif" alt="." style="background-
color: white; background-color: inherit" title="Element" class="hierarchy"/> <a href="dru
gsubstance-definitions.html#MedicationKnowledge.ingredient">ingredient</a><a name="Medica
tionKnowledge.ingredient"> </a></td><td style="vertical-align: top; text-align : left; ba
ckground-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarc
hy"><span style="padding-left: 3px; padding-right: 3px; color: white; background-color: r
ed" title="This element must be supported">S</span></td><td style="vertical-align: top; t
ext-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px
 4px" class="hierarchy">0..*</td><td style="vertical-align: top; text-align : left; backg
round-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"
/><td style="vertical-align: top; text-align : left; background-color: white; border: 0px
 #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"/></tr>
<tr style="border: 0px #F0F0F0 solid; padding:0px; vertical-align: top; background-color:
 white;"><td style="vertical-align: top; text-align : left; background-color: white; bord
er: 0px #F0F0F0 solid; padding:0px 4px 0px 4px; white-space: nowrap; background-image: ur
l(tbl_bck000.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="background-
color: inherit" class="hierarchy"/><img src="tbl_blank.png" alt="." style="background-col
or: inherit" class="hierarchy"/><img src="tbl_vjoin_end.png" alt="." style="background-co
lor: inherit" class="hierarchy"/><img src="icon_reference.png" alt="." style="background-
color: white; background-color: inherit" title="Reference to another Resource" class="hie
rarchy"/> <a href="drugsubstance-definitions.html#MedicationKnowledge.ingredient.itemRefe
rence">itemReference</a><a name="MedicationKnowledge.ingredient.itemReference"> </a></td>
<td style="vertical-align: top; text-align : left; background-color: white; border: 0px #
F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><span style="padding-left: 3px;
padding-right: 3px; color: white; background-color: red" title="This element must be supp
orted">S</span></td><td style="vertical-align: top; text-align : left; background-color:
white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy">1..1</td><td
 style="vertical-align: top; text-align : left; background-color: white; border: 0px #F0F
0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><a href="http://build.fhir.org/refe
rences.html">Reference</a>(http://fda.gov/cder/fhir/pqcmc/StructureDefinition/rawingredie
nt)</td><td style="vertical-align: top; text-align : left; background-color: white; borde
r: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"/></tr>
<tr><td colspan="5" class="hierarchy"><br/><a href="http://build.fhir.org/formats.html#ta
ble" title="Legend for this format"><img src="http://build.fhir.org/help16.png" alt="doco
" style="background-color: inherit"/> Documentation for this format</a></td></tr></table>
</div>
  </text>
  <url value="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/drugsubstance"/>
  <version value="current"/>
  <name value="PQCMC_MedicationKnowledge"/>
  <status value="draft"/>
  <experimental value="false"/>
  <date value="2018-10-05T00:00:00-04:00"/>
  <publisher value="U.S. FDA - CDER division"/>
  <contact>
    <telecom>
      <system value="url"/>
      <value value="https://www.fda.gov/Drugs/default.htm"/>
    </telecom>
```

```
        </contact>
        <description
                    value="Describes the different levels of drug product whose chemical, manu
facturing and controls processes can be evaluated."/>
        <fhirVersion value="4.0.0"/>
        <mapping>
          <identity value="rim"/>
          <uri value="http://hl7.org/v3"/>
          <name value="RIM Mapping"/>
        </mapping>
        <mapping>
          <identity value="script10.6"/>
          <uri value="http://ncpdp.org/SCRIPT10_6"/>
          <name value="Mapping to NCPDP SCRIPT 10.6"/>
        </mapping>
        <mapping>
          <identity value="w5"/>
          <uri value="http://hl7.org/fhir/fivews"/>
          <name value="FiveWs Pattern Mapping"/>
        </mapping>
        <mapping>
          <identity value="v2"/>
          <uri value="http://hl7.org/v2"/>
          <name value="HL7 v2 Mapping"/>
        </mapping>
        <kind value="resource"/>
        <abstract value="false"/>
        <type value="MedicationKnowledge"/>
        <baseDefinition
                    value="http://hl7.org/fhir/StructureDefinition/MedicationKnowledge"/>
        <derivation value="constraint"/>
        <snapshot>
          <element id="MedicationKnowledge">
            <path value="MedicationKnowledge"/>
            <short value="Definition of Medication Knowledge"/>
            <definition
                    value="Information about a medication that is used to support knowledge
."/>
            <min value="0"/>
            <max value="*"/>
            <base>
              <path value="MedicationKnowledge"/>
              <min value="0"/>
              <max value="*"/>
            </base>
            <constraint>
              <key value="dom-2"/>
              <severity value="error"/>
              <human
                    value="If the resource is contained in another resource, it SHALL NOT cont
ain nested Resources"/>
              <expression value="contained.contained.empty()"/>
              <xpath value="not(parent::f:contained and f:contained)"/>
              <source value="DomainResource"/>
            </constraint>
            <constraint>
              <key value="dom-4"/>
```

```xml
          <severity value="error"/>
          <human
                value="If a resource is contained in another resource, it SHALL NOT have a
 meta.versionId or a meta.lastUpdated"/>
          <expression
                    value="contained.meta.versionId.empty() and contained.meta.lastUpdate
d.empty()"/>
          <xpath
                value="not(exists(f:contained/*/f:meta/f:versionId)) and not(exists(f:cont
ained/*/f:meta/f:lastUpdated))"/>
          <source value="DomainResource"/>
       </constraint>
       <constraint>
          <key value="dom-3"/>
          <severity value="error"/>
          <human
                value="If the resource is contained in another resource, it SHALL be refer
red to from elsewhere in the resource or SHALL refer to the containing resource"/>
          <expression
                    value="contained.where((((&#39;#&#39;+id in (%resource.descendants().r
eference | %resource.descendants().as(canonical) | %resource.descendants().as(uri) | %res
ource.descendants().as(url))) or descendants().where(reference = &#39;#&#39;).exists() or
 descendants().where(as(canonical) = &#39;#&#39;).exists() or descendants().where(as(cano
nical) = &#39;#&#39;).exists())).not()).trace(&#39;unmatched&#39;, id).empty()"/>
          <xpath
                value="not(exists(for $contained in f:contained return $contained[not(pare
nt::*/descendant::f:reference/@value=concat(&#39;#&#39;, $contained/*/id/@value) or desce
ndant::f:reference[@value=&#39;#&#39;])]))"/>
          <source value="DomainResource"/>
       </constraint>
       <constraint>
          <extension
                    url="http://hl7.org/fhir/StructureDefinition/elementdefinition-bestpra
ctice">
             <valueBoolean value="true"/>
          </extension>
          <extension
                    url="http://hl7.org/fhir/StructureDefinition/elementdefinition-bestpra
ctice-explanation">
             <valueMarkdown
                          value="When a resource has no narrative, only systems that fully
 understand the data can display the resource to a human safely. Including a human readab
le representation in the resource makes for a much more robust eco-system and cheaper han
dling of resources by intermediary systems. Some ecosystems restrict distribution of reso
urces to only those systems that do fully understand the resources, and as a consequence
implementers may believe that the narrative is superfluous. However experience shows that
 such eco-systems often open up to new participants over time."/>
          </extension>
          <key value="dom-6"/>
          <severity value="warning"/>
          <human value="A resource should have narrative for robust management"/>
          <expression value="text.div.exists()"/>
          <xpath value="exists(f:text/h:div)"/>
          <source value="DomainResource"/>
       </constraint>
       <constraint>
          <key value="dom-5"/>
```

```xml
        <severity value="error"/>
        <human
                value="If a resource is contained in another resource, it SHALL NOT have a
 security label"/>
        <expression value="contained.meta.security.empty()"/>
        <xpath value="not(exists(f:contained/*/f:meta/f:security))"/>
        <source value="DomainResource"/>
      </constraint>
      <mustSupport value="false"/>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="Entity. Role, or Act"/>
      </mapping>
      <mapping>
        <identity value="rim"/>
        <map value="Todo"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.id">
      <path value="MedicationKnowledge.id"/>
      <short value="Logical id of this artifact"/>
      <definition
                value="The logical id of the resource, as used in the URL for the resou
rce. Once assigned, this value never changes."/>
      <comment
                value="The only time that a resource does not have an id is when it is bei
ng submitted to the server using a create operation."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="Resource.id"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="id"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="true"/>
    </element>
    <element id="MedicationKnowledge.meta">
      <path value="MedicationKnowledge.meta"/>
      <short value="Metadata about the resource"/>
      <definition
                value="The metadata about the resource. This is content that is maintai
ned by the infrastructure. Changes to the content might not always be associated with ver
sion changes to the resource."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="Resource.meta"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
```

```xml
          <code value="Meta"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="true"/>
      </element>
      <element id="MedicationKnowledge.implicitRules">
        <path value="MedicationKnowledge.implicitRules"/>
        <short value="A set of rules under which this content was created"/>
        <definition
                   value="A reference to a set of rules that were followed when the resour
ce was constructed, and which must be understood when processing the content. Often, this
 is a reference to an implementation guide that defines the special rules along with othe
r profiles etc."/>
        <comment
                 value="Asserting this rule set restricts the content to be only understood
 by a limited set of trading partners. This inherently limits the usefulness of the data
in the long term. However, the existing health eco-system is highly fractured, and not ye
t ready to define, collect, and exchange data in a generally computable sense. Wherever p
ossible, implementers and/or specification writers should avoid using this element. Often
, when used, the URL is a reference to an implementation guide that defines these special
 rules as part of it&#39;s narrative along with other profiles, value sets, etc."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Resource.implicitRules"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="uri"/>
        </type>
        <isModifier value="true"/>
        <isModifierReason
                         value="This element is labeled as a modifier because the implicit
 rules may provide additional knowledge about the resource that modifies it&#39;s meaning
 or interpretation"/>
        <isSummary value="true"/>
      </element>
      <element id="MedicationKnowledge.language">
        <path value="MedicationKnowledge.language"/>
        <short value="Language of the resource content"/>
        <definition value="The base language in which the resource is written."/>
        <comment
                 value="Language is provided to support indexing and accessibility (typical
ly, services such as text to speech use the language tag). The html language tag in the n
arrative applies  to the narrative. The language tag on the resource may be used to speci
fy the language of other presentations generated from the data in the resource. Not all t
he content has to be in the base language. The Resource.language should not be assumed to
 apply to the narrative automatically. If a language is specified, it should it also be s
pecified on the div element in the html (see rules in HTML5 for information about the rel
ationship between xml:lang and the html lang attribute)."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Resource.language"/>
          <min value="0"/>
          <max value="1"/>
```

```xml
        </base>
        <type>
          <code value="code"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <binding>
          <extension
                  url="http://hl7.org/fhir/StructureDefinition/elementdefinition-maxValu
eSet">
            <valueCanonical value="http://hl7.org/fhir/ValueSet/all-languages"/>
          </extension>
          <extension
                  url="http://hl7.org/fhir/StructureDefinition/elementdefinition-binding
Name">
            <valueString value="Language"/>
          </extension>
          <extension
                  url="http://hl7.org/fhir/StructureDefinition/elementdefinition-isCommo
nBinding">
            <valueBoolean value="true"/>
          </extension>
          <strength value="preferred"/>
          <description value="A human language."/>
          <valueSet value="http://hl7.org/fhir/ValueSet/languages"/>
        </binding>
      </element>
      <element id="MedicationKnowledge.text">
        <path value="MedicationKnowledge.text"/>
        <short value="Text summary of the resource, for human interpretation"/>
        <definition
                  value="A human-readable narrative that contains a summary of the resour
ce and can be used to represent the content of the resource to a human. The narrative nee
d not encode all the structured data, but is required to contain sufficient detail to mak
e it &quot;clinically safe&quot; for a human to just read the narrative. Resource definit
ions may define what content should be represented in the narrative to ensure clinical sa
fety."/>
        <comment
                  value="Contained resources do not have narrative. Resources that are not c
ontained SHOULD have a narrative. In some cases, a resource may only have text with littl
e or no additional discrete data (as long as all minOccurs=1 elements are satisfied).  Th
is may be necessary for data from legacy systems where information is captured as a &quot
;text blob&quot; or where text is additionally entered raw or narrated and encoded inform
ation is added later."/>
        <alias value="narrative"/>
        <alias value="html"/>
        <alias value="xhtml"/>
        <alias value="display"/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="DomainResource.text"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="Narrative"/>
```

```xml
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="Act.text?"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.contained">
        <path value="MedicationKnowledge.contained"/>
        <short value="Contained, inline Resources"/>
        <definition
                   value="These resources do not have an independent existence apart from
the resource that contains them - they cannot be identified independently, and nor th
ey have their own independent transaction scope."/>
        <comment
                 value="This should never be done when the content can be identified proper
ly, as once identification is lost, it is extremely difficult (and context dependent) to
restore it again. Contained resources may have profiles and tags In their meta elements,
but SHALL NOT have security labels."/>
        <alias value="inline resources"/>
        <alias value="anonymous resources"/>
        <alias value="contained resources"/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="DomainResource.contained"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Resource"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="N/A"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.extension">
        <path value="MedicationKnowledge.extension"/>
        <slicing id="3">
          <discriminator>
            <type value="value"/>
            <path value="url"/>
          </discriminator>
          <ordered value="false"/>
          <rules value="open"/>
        </slicing>
        <short value="Extension"/>
        <definition value="An Extension"/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="DomainResource.extension"/>
          <min value="0"/>
```

```xml
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="MedicationKnowledge.extension:productType">
        <extension
                  url="http://hl7.org/fhir/StructureDefinition/structuredefinition-standar
ds-status">
          <valueCode value="normative"/>
        </extension>
        <extension
                  url="http://hl7.org/fhir/StructureDefinition/structuredefinition-normati
ve-version">
          <valueCode value="4.0.0"/>
        </extension>
        <path value="MedicationKnowledge.extension"/>
        <sliceName value="productType"/>
        <short value="Specification Type"/>
        <definition
                  value="A classification of specification related to the kind of the ent
ity it is referencing. [Source: SME Defined]."/>
        <min value="1"/>
        <max value="1"/>
        <base>
          <path value="DomainResource.extension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
          <profile
                  value="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-productTyp
e"/>
        </type>
        <condition value="ele-1"/>
        <constraint>
          <key value="ele-1"/>
          <severity value="error"/>
          <human value="All FHIR elements must have a @value or children"/>
          <expression value="hasValue() or (children().count() &gt; id.count())"/>
          <xpath value="@value|f:*|h:div"/>
          <source value="Element"/>
        </constraint>
        <constraint>
          <key value="ext-1"/>
          <severity value="error"/>
          <human value="Must have either extensions or value[x], not both"/>
          <expression value="extension.exists() != value.exists()"/>
          <xpath
                  value="exists(f:extension)!=exists(f:*[starts-with(local-name(.), &#39;val
ue&#39;)])"/>
          <source value="Extension"/>
        </constraint>
```

```xml
      <mustSupport value="true"/>
      <isModifier value="false"/>
    </element>
    <element id="MedicationKnowledge.extension:productType.id">
      <path value="MedicationKnowledge.extension.id"/>
      <representation value="xmlAttr"/>
      <short value="Unique id for inter-element referencing"/>
      <definition
                  value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="Element.id"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="string"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="n/a"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.extension:productType.extension">
      <path value="MedicationKnowledge.extension.extension"/>
      <slicing>
        <discriminator>
          <type value="value"/>
          <path value="url"/>
        </discriminator>
        <description value="Extensions are always sliced by (at least) url"/>
        <rules value="open"/>
      </slicing>
      <short value="Additional content defined by implementations"/>
      <definition
                  value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
      <comment
                value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
      <alias value="extensions"/>
      <alias value="user content"/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="Element.extension"/>
        <min value="0"/>
        <max value="*"/>
```

```
      </base>
      <type>
        <code value="Extension"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="n/a"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.extension:productType.url">
      <path value="MedicationKnowledge.extension.url"/>
      <representation value="xmlAttr"/>
      <short value="identifies the meaning of the extension"/>
      <definition
                value="Source of the definition for the extension code - a logical name
 or a URL."/>
      <comment
              value="The definition may point directly to a computable or human-readable
 definition of the extensibility codes, or it may be a logical URI as declared in some ot
her specification. The definition SHALL be a URI for the Structure Definition defining th
e extension."/>
      <min value="1"/>
      <max value="1"/>
      <base>
        <path value="Extension.url"/>
        <min value="1"/>
        <max value="1"/>
      </base>
      <type>
        <code value="uri"/>
      </type>
      <fixedUri
              value="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-productType
"/>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="N/A"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.extension:productType.valueCode">
      <path value="MedicationKnowledge.extension.valueCode"/>
      <slicing>
        <discriminator>
          <type value="value"/>
          <path value="@valueCode"/>
        </discriminator>
        <rules value="open"/>
      </slicing>
      <short value="Drug Substance"/>
      <definition
                value="Value of extension - must be one of a constrained set of the dat
a types (see [Extensibility](http://build.fhir.org/extensibility.html) for a list)."/>
      <min value="1"/>
```

```xml
      <max value="1"/>
      <base>
        <path value="Extension.value[x]"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="code"/>
      </type>
      <fixedCode value="substance"/>
      <mustSupport value="true"/>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="N/A"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.modifierExtension">
      <path value="MedicationKnowledge.modifierExtension"/>
      <short value="Extensions that cannot be ignored"/>
      <definition
               value="May be used to represent additional information that is not part
 of the basic definition of the resource and that modifies the understanding of the eleme
nt that contains it and/or the understanding of the containing element&#39;s descendants.
 Usually modifier elements provide negation or qualification. To make the use of extensio
ns safe and manageable, there is a strict set of governance applied to the definition and
 use of extensions. Though any implementer is allowed to define an extension, there is a
set of requirements that SHALL be met as part of the definition of the extension. Applica
tions processing a resource are required to check for modifier extensions.

Modifier extensions SHALL NOT change the meaning of any elements on Resource or DomainRes
ource (including cannot change the meaning of modifierExtension itself)."/>
      <comment
              value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
      <requirements
                   value="Modifier extensions allow for extensions that *cannot* be safe
ly ignored to be clearly distinguished from the vast majority of extensions which can be
safely ignored.  This promotes interoperability by eliminating the need for implementers
to prohibit the presence of extensions. For further information, see the [definition of m
odifier extensions](http://build.fhir.org/extensibility.html#modifierExtension)."/>
      <alias value="extensions"/>
      <alias value="user content"/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="DomainResource.modifierExtension"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Extension"/>
      </type>
      <isModifier value="true"/>
```

```xml
        <isModifierReason
                         value="Modifier extensions are expected to modify the meaning or
interpretation of the resource that contains them"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="N/A"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.code">
      <path value="MedicationKnowledge.code"/>
      <short value="Code that identifies this medication"/>
      <definition
                   value="A code that specifies this medication, or a textual description
if no code is available. Usage note: This could be a standard medication code such as a c
ode from RxNorm, SNOMED CT, IDMP etc. It could also be a national or local formulary code
, optionally with translations to other code systems."/>
      <comment
                value="Depending on the context of use, the code that was actually selecte
d by the user (prescriber, dispenser, etc.) will have the coding.userSelected set to true
. As described in the coding datatype: &quot;A coding may be marked as a &quot;userSelec
ted&quot; if a user selected the particular coded value in a user interface (e.g. the use
r selects an item in a pick-list). If a user selected coding exists, it is the preferred
choice for performing translations etc. Other codes can only be literal translations to a
lternative code systems, or codes at a lower level of granularity (e.g. a generic code fo
r a vendor-specific primary one)."/>
      <min value="1"/>
      <max value="*"/>
      <base>
        <path value="MedicationKnowledge.code"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="CodeableConcept"/>
      </type>
      <mustSupport value="true"/>
      <isModifier value="false"/>
      <isSummary value="true"/>
      <binding>
        <extension
                     url="http://hl7.org/fhir/StructureDefinition/elementdefinition-binding
Name">
          <valueString value="MedicationFormalRepresentation"/>
        </extension>
        <strength value="example"/>
        <description
                       value="A coded concept that defines the type of a medication."/>
        <valueSet value="http://hl7.org/fhir/ValueSet/medication-codes"/>
      </binding>
      <mapping>
        <identity value="script10.6"/>
        <map
             value="coding.code = //element(*,MedicationType)/DrugCoded/ProductCode

coding.system = //element(*,MedicationType)/DrugCoded/ProductCodeQualifier
```

```
coding.display = //element(*,MedicationType)/DrugDescription"/>
      </mapping>
      <mapping>
        <identity value="w5"/>
        <map value="FiveWs.class"/>
      </mapping>
      <mapping>
        <identity value="v2"/>
        <map
              value="RXO-1.1-Requested Give Code.code / RXE-2.1-Give Code.code / RXD-2.1-D
ispense/Give Code.code / RXG-4.1-Give Code.code /RXA-5.1-Administered Code.code / RXC-2.1
 Component Code"/>
      </mapping>
      <mapping>
        <identity value="rim"/>
        <map value=".code"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.code.id">
      <path value="MedicationKnowledge.code.id"/>
      <representation value="xmlAttr"/>
      <short value="Unique id for inter-element referencing"/>
      <definition
                  value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="Element.id"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="string"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="n/a"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.code.extension">
      <path value="MedicationKnowledge.code.extension"/>
      <slicing>
        <discriminator>
          <type value="value"/>
          <path value="url"/>
        </discriminator>
        <description value="Extensions are always sliced by (at least) url"/>
        <rules value="open"/>
      </slicing>
      <short value="Additional content defined by implementations"/>
      <definition
                  value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
```

```
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
      <comment
              value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
      <alias value="extensions"/>
      <alias value="user content"/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="Element.extension"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Extension"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="n/a"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.code.coding">
      <path value="MedicationKnowledge.code.coding"/>
      <slicing>
        <discriminator>
          <type value="value"/>
          <path value="system"/>
        </discriminator>
        <rules value="open"/>
      </slicing>
      <short value="Code defined by a terminology system"/>
      <definition value="A reference to a code defined by a terminology system."/>
      <comment
              value="Codes may be defined very casually in enumerations, or code lists,
up to very formal definitions such as SNOMED CT - see the HL7 v3 Core Principles for more
 information.  Ordering of codings is undefined and SHALL NOT be used to infer meaning. G
enerally, at most only one of the coding values will be labeled as UserSelected = true."/
>
      <requirements
                   value="Allows for alternative encodings within a code system, and tra
nslations to other code systems."/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="CodeableConcept.coding"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Coding"/>
      </type>
      <mustSupport value="true"/>
```

```xml
          <isModifier value="false"/>
          <isSummary value="true"/>
          <mapping>
            <identity value="v2"/>
            <map value="C*E.1-8, C*E.10-22"/>
          </mapping>
          <mapping>
            <identity value="rim"/>
            <map value="union(., ./translation)"/>
          </mapping>
          <mapping>
            <identity value="orim"/>
            <map value="fhir:CodeableConcept.coding rdfs:subPropertyOf dt:CD.coding"/>
          </mapping>
        </element>
        <element id="MedicationKnowledge.code.coding:UNII">
          <path value="MedicationKnowledge.code.coding"/>
          <sliceName value="UNII"/>
          <short value="UNII code"/>
          <definition
                    value="The UNII is a non-proprietary, free, unique, unambiguous, non-se
mantic, alphanumeric identifier based on a substance's molecular structure and/or descrip
tive information. [Source: Substance Registration System – Unique identifier] Example: 36
2O9ITL9D Note: If a UNII does not exist, please go to Substance Registration System – Uni
que identifier."/>
          <comment
                  value="Codes may be defined very casually in enumerations, or code lists,
up to very formal definitions such as SNOMED CT - see the HL7 v3 Core Principles for more
 information.  Ordering of codings is undefined and SHALL NOT be used to infer meaning. G
enerally, at most only one of the coding values will be labeled as UserSelected = true."/
>
          <requirements
                      value="Allows for alternative encodings within a code system, and tra
nslations to other code systems."/>
          <min value="1"/>
          <max value="1"/>
          <base>
            <path value="CodeableConcept.coding"/>
            <min value="0"/>
            <max value="*"/>
          </base>
          <type>
            <code value="Coding"/>
          </type>
          <mustSupport value="true"/>
          <isModifier value="false"/>
          <isSummary value="true"/>
          <mapping>
            <identity value="v2"/>
            <map value="C*E.1-8, C*E.10-22"/>
          </mapping>
          <mapping>
            <identity value="rim"/>
            <map value="union(., ./translation)"/>
          </mapping>
          <mapping>
            <identity value="orim"/>
```

```xml
          <map value="fhir:CodeableConcept.coding rdfs:subPropertyOf dt:CD.coding"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.code.coding:UNII.id">
        <path value="MedicationKnowledge.code.coding.id"/>
        <representation value="xmlAttr"/>
        <short value="Unique id for inter-element referencing"/>
        <definition
                   value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Element.id"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="string"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.code.coding:UNII.extension">
        <path value="MedicationKnowledge.code.coding.extension"/>
        <slicing>
          <discriminator>
            <type value="value"/>
            <path value="url"/>
          </discriminator>
          <description value="Extensions are always sliced by (at least) url"/>
          <rules value="open"/>
        </slicing>
        <short value="Additional content defined by implementations"/>
        <definition
                   value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
        <comment
                value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
        <alias value="extensions"/>
        <alias value="user content"/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="Element.extension"/>
          <min value="0"/>
          <max value="*"/>
```

```xml
      </base>
      <type>
        <code value="Extension"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="n/a"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.code.coding:UNII.system">
      <path value="MedicationKnowledge.code.coding.system"/>
      <short value="Identity of the terminology system"/>
      <definition
                 value="The identification of the code system that defines the meaning o
f the symbol in the code."/>
      <comment
               value="The URI may be an OID (urn:oid:...) or a UUID (urn:uuid:...).  OIDs
 and UUIDs SHALL be references to the HL7 OID registry. Otherwise, the URI should come fr
om HL7&#39;s list of FHIR defined special URIs or it should reference to some definition
that establishes the system clearly and unambiguously."/>
      <requirements
                   value="Need to be unambiguous about the source of the definition of t
he symbol."/>
      <min value="1"/>
      <max value="1"/>
      <base>
        <path value="Coding.system"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="uri"/>
      </type>
      <fixedUri
               value="http://www.fda.gov/ForIndustry/DataStandards/SubstanceRegistration
System-UniqueIngredientIdentifierUNII/default.html"/>
      <mustSupport value="true"/>
      <isModifier value="false"/>
      <isSummary value="true"/>
      <mapping>
        <identity value="v2"/>
        <map value="C*E.3"/>
      </mapping>
      <mapping>
        <identity value="rim"/>
        <map value="./codeSystem"/>
      </mapping>
      <mapping>
        <identity value="orim"/>
        <map
            value="fhir:Coding.system rdfs:subPropertyOf dt:CDCoding.codeSystem"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.code.coding:UNII.version">
      <path value="MedicationKnowledge.code.coding.version"/>
```

```xml
        <short value="Version of the system - if relevant"/>
        <definition
                    value="The version of the code system which was used when choosing this
 code. Note that a well-maintained code system does not need the version reported, becaus
e the meaning of codes is consistent across versions. However this cannot consistently be
 assured, and when the meaning is not guaranteed to be consistent, the version SHOULD be
exchanged."/>
        <comment
                value="Where the terminology does not clearly define what string should be
 used to identify code system versions, the recommendation is to use the date (expressed
in FHIR date format) on which that version was officially published as the version date."
/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Coding.version"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="string"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="true"/>
        <mapping>
          <identity value="v2"/>
          <map value="C*E.7"/>
        </mapping>
        <mapping>
          <identity value="rim"/>
          <map value="./codeSystemVersion"/>
        </mapping>
        <mapping>
          <identity value="orim"/>
          <map
              value="fhir:Coding.version rdfs:subPropertyOf dt:CDCoding.codeSystemVersion"
/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.code.coding:UNII.code">
        <path value="MedicationKnowledge.code.coding.code"/>
        <short value="Symbol in syntax defined by the system"/>
        <definition
                    value="A symbol in syntax defined by the system. The symbol may be a pr
edefined code or an expression in a syntax defined by the coding system (e.g. post-coordi
nation)."/>
        <requirements value="Need to refer to a particular code in the system."/>
        <min value="1"/>
        <max value="1"/>
        <base>
          <path value="Coding.code"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="code"/>
        </type>
```

```xml
      <mustSupport value="true"/>
      <isModifier value="false"/>
      <isSummary value="true"/>
      <mapping>
        <identity value="v2"/>
        <map value="C*E.1"/>
      </mapping>
      <mapping>
        <identity value="rim"/>
        <map value="./code"/>
      </mapping>
      <mapping>
        <identity value="orim"/>
        <map value="fhir:Coding.code rdfs:subPropertyOf dt:CDCoding.code"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.code.coding:UNII.display">
      <extension
                 url="http://hl7.org/fhir/StructureDefinition/elementdefinition-translata
ble">
        <valueBoolean value="true"/>
      </extension>
      <path value="MedicationKnowledge.code.coding.display"/>
      <short value="Representation defined by the system"/>
      <definition
                  value="A representation of the meaning of the code in the system, follo
wing the rules of the system."/>
      <requirements
                    value="Need to be able to carry a human-readable meaning of the code
for readers that do not know  the system."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="Coding.display"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="string"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="true"/>
      <mapping>
        <identity value="v2"/>
        <map value="C*E.2 - but note this is not well followed"/>
      </mapping>
      <mapping>
        <identity value="rim"/>
        <map value="CV.displayName"/>
      </mapping>
      <mapping>
        <identity value="orim"/>
        <map
             value="fhir:Coding.display rdfs:subPropertyOf dt:CDCoding.displayName"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.code.coding:UNII.userSelected">
```

```
        <path value="MedicationKnowledge.code.coding.userSelected"/>
        <short value="If this coding was chosen directly by the user"/>
        <definition
                  value="Indicates that this coding was chosen by a user directly - e.g.
off a pick list of available items (codes or displays)."/>
        <comment
                value="Amongst a set of alternatives, a directly chosen code is the most a
ppropriate starting point for new translations. There is some ambiguity about what exactl
y &#39;directly chosen&#39; implies, and trading partner agreement may be needed to clari
fy the use of this element and its consequences more completely."/>
        <requirements
                      value="This has been identified as a clinical safety criterium - that
 this exact system/code pair was chosen explicitly, rather than inferred by the system ba
sed on some rules or language processing."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Coding.userSelected"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="boolean"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="true"/>
        <mapping>
          <identity value="v2"/>
          <map value="Sometimes implied by being first"/>
        </mapping>
        <mapping>
          <identity value="rim"/>
          <map value="CD.codingRationale"/>
        </mapping>
        <mapping>
          <identity value="orim"/>
          <map
              value="fhir:Coding.userSelected fhir:mapsTo dt:CDCoding.codingRationale. fhi
r:Coding.userSelected fhir:hasMap fhir:Coding.userSelected.map. fhir:Coding.userSelected.
map a fhir:Map;   fhir:target dt:CDCoding.codingRationale. fhir:Coding.userSelected\#true
 a [    fhir:source &quot;true&quot;;    fhir:target dt:CDCoding.codingRationale\#O   ]
"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.code.coding:CASNumber">
        <path value="MedicationKnowledge.code.coding"/>
        <sliceName value="CASNumber"/>
        <short value="CAS number"/>
        <definition
                  value="Chemical Abstract Service (CAS) Registry Numbers (often referred
 to as CAS RNs or CAS Numbers) are used to provide unmistakable identifiers for chemical
substances. A CAS Registry Number itself has no inherent chemical significance but provid
es a way to identify a chemical substance or molecular structure when there are many poss
ible systematic, generic, proprietary or trivial names. [Source: Adapted from CAS.org] Ex
ample: CAS [103-90-2]."/>
        <comment
                value="Codes may be defined very casually in enumerations, or code lists,
```

```
up to very formal definitions such as SNOMED CT - see the HL7 v3 Core Principles for more
 information.  Ordering of codings is undefined and SHALL NOT be used to infer meaning. G
enerally, at most only one of the coding values will be labeled as UserSelected = true."/
>
      <requirements
                   value="Allows for alternative encodings within a code system, and tra
nslations to other code systems."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="CodeableConcept.coding"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Coding"/>
      </type>
      <mustSupport value="true"/>
      <isModifier value="false"/>
      <isSummary value="true"/>
      <mapping>
        <identity value="v2"/>
        <map value="C*E.1-8, C*E.10-22"/>
      </mapping>
      <mapping>
        <identity value="rim"/>
        <map value="union(., ./translation)"/>
      </mapping>
      <mapping>
        <identity value="orim"/>
        <map value="fhir:CodeableConcept.coding rdfs:subPropertyOf dt:CD.coding"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.code.coding:CASNumber.id">
      <path value="MedicationKnowledge.code.coding.id"/>
      <representation value="xmlAttr"/>
      <short value="Unique id for inter-element referencing"/>
      <definition
                 value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="Element.id"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="string"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="n/a"/>
      </mapping>
    </element>
```

```xml
      <element id="MedicationKnowledge.code.coding:CASNumber.extension">
        <path value="MedicationKnowledge.code.coding.extension"/>
        <slicing>
          <discriminator>
            <type value="value"/>
            <path value="url"/>
          </discriminator>
          <description value="Extensions are always sliced by (at least) url"/>
          <rules value="open"/>
        </slicing>
        <short value="Additional content defined by implementations"/>
        <definition
                  value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
        <comment
                value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
        <alias value="extensions"/>
        <alias value="user content"/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="Element.extension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.code.coding:CASNumber.system">
        <path value="MedicationKnowledge.code.coding.system"/>
        <short value="Identity of the terminology system"/>
        <definition
                  value="The identification of the code system that defines the meaning o
f the symbol in the code."/>
        <comment
                value="The URI may be an OID (urn:oid:...) or a UUID (urn:uuid:...).  OIDs
 and UUIDs SHALL be references to the HL7 OID registry. Otherwise, the URI should come fr
om HL7&#39;s list of FHIR defined special URIs or it should reference to some definition
that establishes the system clearly and unambiguously."/>
        <requirements
                     value="Need to be unambiguous about the source of the definition of t
he symbol."/>
        <min value="1"/>
        <max value="1"/>
```

```xml
    <base>
      <path value="Coding.system"/>
      <min value="0"/>
      <max value="1"/>
    </base>
    <type>
      <code value="uri"/>
    </type>
    <fixedUri value="https://www.cas.org/"/>
    <mustSupport value="true"/>
    <isModifier value="false"/>
    <isSummary value="true"/>
    <mapping>
      <identity value="v2"/>
      <map value="C*E.3"/>
    </mapping>
    <mapping>
      <identity value="rim"/>
      <map value="./codeSystem"/>
    </mapping>
    <mapping>
      <identity value="orim"/>
      <map
          value="fhir:Coding.system rdfs:subPropertyOf dt:CDCoding.codeSystem"/>
    </mapping>
  </element>
  <element id="MedicationKnowledge.code.coding:CASNumber.version">
    <path value="MedicationKnowledge.code.coding.version"/>
    <short value="Version of the system - if relevant"/>
    <definition
                value="The version of the code system which was used when choosing this
 code. Note that a well-maintained code system does not need the version reported, becaus
e the meaning of codes is consistent across versions. However this cannot consistently be
 assured, and when the meaning is not guaranteed to be consistent, the version SHOULD be
exchanged."/>
    <comment
             value="Where the terminology does not clearly define what string should be
 used to identify code system versions, the recommendation is to use the date (expressed
in FHIR date format) on which that version was officially published as the version date."
/>
    <min value="0"/>
    <max value="1"/>
    <base>
      <path value="Coding.version"/>
      <min value="0"/>
      <max value="1"/>
    </base>
    <type>
      <code value="string"/>
    </type>
    <isModifier value="false"/>
    <isSummary value="true"/>
    <mapping>
      <identity value="v2"/>
      <map value="C*E.7"/>
    </mapping>
    <mapping>
```

```xml
          <identity value="rim"/>
          <map value="./codeSystemVersion"/>
        </mapping>
        <mapping>
          <identity value="orim"/>
          <map
                value="fhir:Coding.version rdfs:subPropertyOf dt:CDCoding.codeSystemVersion"
/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.code.coding:CASNumber.code">
        <path value="MedicationKnowledge.code.coding.code"/>
        <short value="Symbol in syntax defined by the system"/>
        <definition
                value="A symbol in syntax defined by the system. The symbol may be a pr
edefined code or an expression in a syntax defined by the coding system (e.g. post-coordi
nation)."/>
        <requirements value="Need to refer to a particular code in the system."/>
        <min value="1"/>
        <max value="1"/>
        <base>
          <path value="Coding.code"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="code"/>
        </type>
        <mustSupport value="true"/>
        <isModifier value="false"/>
        <isSummary value="true"/>
        <mapping>
          <identity value="v2"/>
          <map value="C*E.1"/>
        </mapping>
        <mapping>
          <identity value="rim"/>
          <map value="./code"/>
        </mapping>
        <mapping>
          <identity value="orim"/>
          <map value="fhir:Coding.code rdfs:subPropertyOf dt:CDCoding.code"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.code.coding:CASNumber.display">
        <extension
                url="http://hl7.org/fhir/StructureDefinition/elementdefinition-translata
ble">
          <valueBoolean value="true"/>
        </extension>
        <path value="MedicationKnowledge.code.coding.display"/>
        <short value="Representation defined by the system"/>
        <definition
                value="A representation of the meaning of the code in the system, follo
wing the rules of the system."/>
        <requirements
                    value="Need to be able to carry a human-readable meaning of the code
```

```
for readers that do not know  the system."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="Coding.display"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="string"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="true"/>
      <mapping>
        <identity value="v2"/>
        <map value="C*E.2 - but note this is not well followed"/>
      </mapping>
      <mapping>
        <identity value="rim"/>
        <map value="CV.displayName"/>
      </mapping>
      <mapping>
        <identity value="orim"/>
        <map
            value="fhir:Coding.display rdfs:subPropertyOf dt:CDCoding.displayName"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.code.coding:CASNumber.userSelected">
      <path value="MedicationKnowledge.code.coding.userSelected"/>
      <short value="If this coding was chosen directly by the user"/>
      <definition
                 value="Indicates that this coding was chosen by a user directly - e.g.
off a pick list of available items (codes or displays)."/>
      <comment
              value="Amongst a set of alternatives, a directly chosen code is the most a
ppropriate starting point for new translations. There is some ambiguity about what exactl
y &#39;directly chosen&#39; implies, and trading partner agreement may be needed to clari
fy the use of this element and its consequences more completely."/>
      <requirements
                    value="This has been identified as a clinical safety criterium - that
 this exact system/code pair was chosen explicitly, rather than inferred by the system ba
sed on some rules or language processing."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="Coding.userSelected"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="boolean"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="true"/>
      <mapping>
        <identity value="v2"/>
        <map value="Sometimes implied by being first"/>
```

```xml
      </mapping>
      <mapping>
        <identity value="rim"/>
        <map value="CD.codingRationale"/>
      </mapping>
      <mapping>
        <identity value="orim"/>
        <map
            value="fhir:Coding.userSelected fhir:mapsTo dt:CDCoding.codingRationale. fhi
r:Coding.userSelected fhir:hasMap fhir:Coding.userSelected.map. fhir:Coding.userSelected.
map a fhir:Map;   fhir:target dt:CDCoding.codingRationale. fhir:Coding.userSelected\#true
 a [     fhir:source &quot;true&quot;;     fhir:target dt:CDCoding.codingRationale\#O   ]
"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.code.coding:INN">
      <path value="MedicationKnowledge.code.coding"/>
      <sliceName value="INN"/>
      <short value="INN"/>
      <definition
                value="International Nonproprietary Names (INN) is a unique name that i
s globally recognized and is public property. A nonproprietary name is also known as a ge
neric name. [Source: International Nonproprietary Names]."/>
      <comment
              value="Codes may be defined very casually in enumerations, or code lists,
up to very formal definitions such as SNOMED CT - see the HL7 v3 Core Principles for more
 information.  Ordering of codings is undefined and SHALL NOT be used to infer meaning. G
enerally, at most only one of the coding values will be labeled as UserSelected = true."/
>
      <requirements
                   value="Allows for alternative encodings within a code system, and tra
nslations to other code systems."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="CodeableConcept.coding"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Coding"/>
      </type>
      <mustSupport value="true"/>
      <isModifier value="false"/>
      <isSummary value="true"/>
      <mapping>
        <identity value="v2"/>
        <map value="C*E.1-8, C*E.10-22"/>
      </mapping>
      <mapping>
        <identity value="rim"/>
        <map value="union(., ./translation)"/>
      </mapping>
      <mapping>
        <identity value="orim"/>
        <map value="fhir:CodeableConcept.coding rdfs:subPropertyOf dt:CD.coding"/>
      </mapping>
```

```
      </element>
      <element id="MedicationKnowledge.code.coding:INN.id">
        <path value="MedicationKnowledge.code.coding.id"/>
        <representation value="xmlAttr"/>
        <short value="Unique id for inter-element referencing"/>
        <definition
                  value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Element.id"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="string"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.code.coding:INN.extension">
        <path value="MedicationKnowledge.code.coding.extension"/>
        <slicing>
          <discriminator>
            <type value="value"/>
            <path value="url"/>
          </discriminator>
          <description value="Extensions are always sliced by (at least) url"/>
          <rules value="open"/>
        </slicing>
        <short value="Additional content defined by implementations"/>
        <definition
                  value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
        <comment
                value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
        <alias value="extensions"/>
        <alias value="user content"/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="Element.extension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
```

```xml
        <code value="Extension"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="n/a"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.code.coding:INN.system">
      <path value="MedicationKnowledge.code.coding.system"/>
      <short value="Identity of the terminology system"/>
      <definition
                 value="The identification of the code system that defines the meaning o
f the symbol in the code."/>
      <comment
               value="The URI may be an OID (urn:oid:...) or a UUID (urn:uuid:...).  OIDs
 and UUIDs SHALL be references to the HL7 OID registry. Otherwise, the URI should come fr
om HL7&#39;s list of FHIR defined special URIs or it should reference to some definition
that establishes the system clearly and unambiguously."/>
      <requirements
                   value="Need to be unambiguous about the source of the definition of t
he symbol."/>
      <min value="1"/>
      <max value="1"/>
      <base>
        <path value="Coding.system"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="uri"/>
      </type>
      <fixedUri value="https://www.who.int/medicines/services/inn/en/"/>
      <mustSupport value="true"/>
      <isModifier value="false"/>
      <isSummary value="true"/>
      <mapping>
        <identity value="v2"/>
        <map value="C*E.3"/>
      </mapping>
      <mapping>
        <identity value="rim"/>
        <map value="./codeSystem"/>
      </mapping>
      <mapping>
        <identity value="orim"/>
        <map
            value="fhir:Coding.system rdfs:subPropertyOf dt:CDCoding.codeSystem"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.code.coding:INN.version">
      <path value="MedicationKnowledge.code.coding.version"/>
      <short value="Version of the system - if relevant"/>
      <definition
                 value="The version of the code system which was used when choosing this
 code. Note that a well-maintained code system does not need the version reported, becaus
```

```
e the meaning of codes is consistent across versions. However this cannot consistently be
 assured, and when the meaning is not guaranteed to be consistent, the version SHOULD be
exchanged."/>
      <comment
                value="Where the terminology does not clearly define what string should be
 used to identify code system versions, the recommendation is to use the date (expressed
in FHIR date format) on which that version was officially published as the version date."
/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="Coding.version"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="string"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="true"/>
      <mapping>
        <identity value="v2"/>
        <map value="C*E.7"/>
      </mapping>
      <mapping>
        <identity value="rim"/>
        <map value="./codeSystemVersion"/>
      </mapping>
      <mapping>
        <identity value="orim"/>
        <map
            value="fhir:Coding.version rdfs:subPropertyOf dt:CDCoding.codeSystemVersion"
/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.code.coding:INN.code">
      <path value="MedicationKnowledge.code.coding.code"/>
      <short value="Symbol in syntax defined by the system"/>
      <definition
                value="A symbol in syntax defined by the system. The symbol may be a pr
edefined code or an expression in a syntax defined by the coding system (e.g. post-coordi
nation)."/>
      <requirements value="Need to refer to a particular code in the system."/>
      <min value="1"/>
      <max value="1"/>
      <base>
        <path value="Coding.code"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="code"/>
      </type>
      <mustSupport value="true"/>
      <isModifier value="false"/>
      <isSummary value="true"/>
      <mapping>
```

```xml
          <identity value="v2"/>
          <map value="C*E.1"/>
        </mapping>
        <mapping>
          <identity value="rim"/>
          <map value="./code"/>
        </mapping>
        <mapping>
          <identity value="orim"/>
          <map value="fhir:Coding.code rdfs:subPropertyOf dt:CDCoding.code"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.code.coding:INN.display">
        <extension
                  url="http://hl7.org/fhir/StructureDefinition/elementdefinition-translata
ble">
          <valueBoolean value="true"/>
        </extension>
        <path value="MedicationKnowledge.code.coding.display"/>
        <short value="Representation defined by the system"/>
        <definition
                    value="A representation of the meaning of the code in the system, follo
wing the rules of the system."/>
        <requirements
                      value="Need to be able to carry a human-readable meaning of the code
for readers that do not know  the system."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Coding.display"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="string"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="true"/>
        <mapping>
          <identity value="v2"/>
          <map value="C*E.2 - but note this is not well followed"/>
        </mapping>
        <mapping>
          <identity value="rim"/>
          <map value="CV.displayName"/>
        </mapping>
        <mapping>
          <identity value="orim"/>
          <map
              value="fhir:Coding.display rdfs:subPropertyOf dt:CDCoding.displayName"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.code.coding:INN.userSelected">
        <path value="MedicationKnowledge.code.coding.userSelected"/>
        <short value="If this coding was chosen directly by the user"/>
        <definition
                    value="Indicates that this coding was chosen by a user directly - e.g.
```

```
off a pick list of available items (codes or displays)."/>
      <comment
              value="Amongst a set of alternatives, a directly chosen code is the most a
ppropriate starting point for new translations. There is some ambiguity about what exactl
y &#39;directly chosen&#39; implies, and trading partner agreement may be needed to clari
fy the use of this element and its consequences more completely."/>
      <requirements
                    value="This has been identified as a clinical safety criterium - that
 this exact system/code pair was chosen explicitly, rather than inferred by the system ba
sed on some rules or language processing."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="Coding.userSelected"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="boolean"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="true"/>
      <mapping>
        <identity value="v2"/>
        <map value="Sometimes implied by being first"/>
      </mapping>
      <mapping>
        <identity value="rim"/>
        <map value="CD.codingRationale"/>
      </mapping>
      <mapping>
        <identity value="orim"/>
        <map
             value="fhir:Coding.userSelected fhir:mapsTo dt:CDCoding.codingRationale. fhi
r:Coding.userSelected fhir:hasMap fhir:Coding.userSelected.map. fhir:Coding.userSelected.
map a fhir:Map;   fhir:target dt:CDCoding.codingRationale. fhir:Coding.userSelected\#true
 a [    fhir:source &quot;true&quot;;    fhir:target dt:CDCoding.codingRationale\#O   ]
"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.code.coding:USAN">
      <path value="MedicationKnowledge.code.coding"/>
      <sliceName value="USAN"/>
      <short value="USAN"/>
      <definition
                  value="A unique nonproprietary name assigned to drugs and biologics by
the United States Adopted Names Council [Source: SME Defined] Example: acetaminophen."/>
      <comment
              value="Codes may be defined very casually in enumerations, or code lists,
up to very formal definitions such as SNOMED CT - see the HL7 v3 Core Principles for more
 information.  Ordering of codings is undefined and SHALL NOT be used to infer meaning. G
enerally, at most only one of the coding values will be labeled as UserSelected = true."/
>
      <requirements
                    value="Allows for alternative encodings within a code system, and tra
nslations to other code systems."/>
      <min value="0"/>
```

```
        <max value="1"/>
        <base>
          <path value="CodeableConcept.coding"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Coding"/>
        </type>
        <mustSupport value="true"/>
        <isModifier value="false"/>
        <isSummary value="true"/>
        <mapping>
          <identity value="v2"/>
          <map value="C*E.1-8, C*E.10-22"/>
        </mapping>
        <mapping>
          <identity value="rim"/>
          <map value="union(., ./translation)"/>
        </mapping>
        <mapping>
          <identity value="orim"/>
          <map value="fhir:CodeableConcept.coding rdfs:subPropertyOf dt:CD.coding"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.code.coding:USAN.id">
        <path value="MedicationKnowledge.code.coding.id"/>
        <representation value="xmlAttr"/>
        <short value="Unique id for inter-element referencing"/>
        <definition
                   value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Element.id"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="string"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.code.coding:USAN.extension">
        <path value="MedicationKnowledge.code.coding.extension"/>
        <slicing>
          <discriminator>
            <type value="value"/>
            <path value="url"/>
          </discriminator>
          <description value="Extensions are always sliced by (at least) url"/>
```

```
              <rules value="open"/>
          </slicing>
          <short value="Additional content defined by implementations"/>
          <definition
                    value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
          <comment
                  value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
          <alias value="extensions"/>
          <alias value="user content"/>
          <min value="0"/>
          <max value="*"/>
          <base>
            <path value="Element.extension"/>
            <min value="0"/>
            <max value="*"/>
          </base>
          <type>
            <code value="Extension"/>
          </type>
          <isModifier value="false"/>
          <isSummary value="false"/>
          <mapping>
            <identity value="rim"/>
            <map value="n/a"/>
          </mapping>
        </element>
        <element id="MedicationKnowledge.code.coding:USAN.system">
          <path value="MedicationKnowledge.code.coding.system"/>
          <short value="Identity of the terminology system"/>
          <definition
                    value="The identification of the code system that defines the meaning o
f the symbol in the code."/>
          <comment
                  value="The URI may be an OID (urn:oid:...) or a UUID (urn:uuid:...).  OIDs
 and UUIDs SHALL be references to the HL7 OID registry. Otherwise, the URI should come fr
om HL7&#39;s list of FHIR defined special URIs or it should reference to some definition
that establishes the system clearly and unambiguously."/>
          <requirements
                       value="Need to be unambiguous about the source of the definition of t
he symbol."/>
          <min value="1"/>
          <max value="1"/>
          <base>
            <path value="Coding.system"/>
            <min value="0"/>
            <max value="1"/>
          </base>
          <type>
            <code value="uri"/>
          </type>
```

```
        <fixedUri
                value="https://www.ama-assn.org/about-ama/united-states-adopted-names"/>
        <mustSupport value="true"/>
        <isModifier value="false"/>
        <isSummary value="true"/>
        <mapping>
          <identity value="v2"/>
          <map value="C*E.3"/>
        </mapping>
        <mapping>
          <identity value="rim"/>
          <map value="./codeSystem"/>
        </mapping>
        <mapping>
          <identity value="orim"/>
          <map
              value="fhir:Coding.system rdfs:subPropertyOf dt:CDCoding.codeSystem"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.code.coding:USAN.version">
        <path value="MedicationKnowledge.code.coding.version"/>
        <short value="Version of the system - if relevant"/>
        <definition
                  value="The version of the code system which was used when choosing this
 code. Note that a well-maintained code system does not need the version reported, becaus
e the meaning of codes is consistent across versions. However this cannot consistently be
 assured, and when the meaning is not guaranteed to be consistent, the version SHOULD be
exchanged."/>
        <comment
               value="Where the terminology does not clearly define what string should be
 used to identify code system versions, the recommendation is to use the date (expressed
in FHIR date format) on which that version was officially published as the version date."
/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Coding.version"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="string"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="true"/>
        <mapping>
          <identity value="v2"/>
          <map value="C*E.7"/>
        </mapping>
        <mapping>
          <identity value="rim"/>
          <map value="./codeSystemVersion"/>
        </mapping>
        <mapping>
          <identity value="orim"/>
          <map
              value="fhir:Coding.version rdfs:subPropertyOf dt:CDCoding.codeSystemVersion"
```

```xml
/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.code.coding:USAN.code">
      <path value="MedicationKnowledge.code.coding.code"/>
      <short value="Symbol in syntax defined by the system"/>
      <definition
                  value="A symbol in syntax defined by the system. The symbol may be a pr
edefined code or an expression in a syntax defined by the coding system (e.g. post-coordi
nation)."/>
      <requirements value="Need to refer to a particular code in the system."/>
      <min value="1"/>
      <max value="1"/>
      <base>
        <path value="Coding.code"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="code"/>
      </type>
      <mustSupport value="true"/>
      <isModifier value="false"/>
      <isSummary value="true"/>
      <mapping>
        <identity value="v2"/>
        <map value="C*E.1"/>
      </mapping>
      <mapping>
        <identity value="rim"/>
        <map value="./code"/>
      </mapping>
      <mapping>
        <identity value="orim"/>
        <map value="fhir:Coding.code rdfs:subPropertyOf dt:CDCoding.code"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.code.coding:USAN.display">
      <extension
                url="http://hl7.org/fhir/StructureDefinition/elementdefinition-translata
ble">
        <valueBoolean value="true"/>
      </extension>
      <path value="MedicationKnowledge.code.coding.display"/>
      <short value="Representation defined by the system"/>
      <definition
                  value="A representation of the meaning of the code in the system, follo
wing the rules of the system."/>
      <requirements
                    value="Need to be able to carry a human-readable meaning of the code
for readers that do not know  the system."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="Coding.display"/>
        <min value="0"/>
        <max value="1"/>
```

```
        </base>
        <type>
          <code value="string"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="true"/>
        <mapping>
          <identity value="v2"/>
          <map value="C*E.2 - but note this is not well followed"/>
        </mapping>
        <mapping>
          <identity value="rim"/>
          <map value="CV.displayName"/>
        </mapping>
        <mapping>
          <identity value="orim"/>
          <map
              value="fhir:Coding.display rdfs:subPropertyOf dt:CDCoding.displayName"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.code.coding:USAN.userSelected">
        <path value="MedicationKnowledge.code.coding.userSelected"/>
        <short value="If this coding was chosen directly by the user"/>
        <definition
                  value="Indicates that this coding was chosen by a user directly - e.g.
off a pick list of available items (codes or displays)."/>
        <comment
                value="Amongst a set of alternatives, a directly chosen code is the most a
ppropriate starting point for new translations. There is some ambiguity about what exactl
y &#39;directly chosen&#39; implies, and trading partner agreement may be needed to clari
fy the use of this element and its consequences more completely."/>
        <requirements
                      value="This has been identified as a clinical safety criterium - that
 this exact system/code pair was chosen explicitly, rather than inferred by the system ba
sed on some rules or language processing."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Coding.userSelected"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="boolean"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="true"/>
        <mapping>
          <identity value="v2"/>
          <map value="Sometimes implied by being first"/>
        </mapping>
        <mapping>
          <identity value="rim"/>
          <map value="CD.codingRationale"/>
        </mapping>
        <mapping>
          <identity value="orim"/>
```

```xml
        <map
              value="fhir:Coding.userSelected fhir:mapsTo dt:CDCoding.codingRationale. fhi
r:Coding.userSelected fhir:hasMap fhir:Coding.userSelected.map. fhir:Coding.userSelected.
map a fhir:Map;   fhir:target dt:CDCoding.codingRationale. fhir:Coding.userSelected\#true
 a [     fhir:source &quot;true&quot;;      fhir:target dt:CDCoding.codingRationale\#O    ]
"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.code.coding:IUPACName">
      <path value="MedicationKnowledge.code.coding"/>
      <sliceName value="IUPACName"/>
      <short value="IUPAC Name"/>
      <definition
                value="A name assigned to a chemical substance according to the systema
tic nomenclature rules defined by the International Union of Pure and Applied Chemistry (
IUPAC). [Source: SME Defined] Example: N-(4-hydroxyphenyl) acetamide."/>
      <comment
              value="Codes may be defined very casually in enumerations, or code lists,
up to very formal definitions such as SNOMED CT - see the HL7 v3 Core Principles for more
 information.  Ordering of codings is undefined and SHALL NOT be used to infer meaning. G
enerally, at most only one of the coding values will be labeled as UserSelected = true."/
>
      <requirements
                  value="Allows for alternative encodings within a code system, and tra
nslations to other code systems."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="CodeableConcept.coding"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Coding"/>
      </type>
      <mustSupport value="true"/>
      <isModifier value="false"/>
      <isSummary value="true"/>
      <mapping>
        <identity value="v2"/>
        <map value="C*E.1-8, C*E.10-22"/>
      </mapping>
      <mapping>
        <identity value="rim"/>
        <map value="union(., ./translation)"/>
      </mapping>
      <mapping>
        <identity value="orim"/>
        <map value="fhir:CodeableConcept.coding rdfs:subPropertyOf dt:CD.coding"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.code.coding:IUPACName.id">
      <path value="MedicationKnowledge.code.coding.id"/>
      <representation value="xmlAttr"/>
      <short value="Unique id for inter-element referencing"/>
      <definition
                value="Unique id for the element within a resource (for internal refere
```

```
nces). This may be any string value that does not contain spaces."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Element.id"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="string"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.code.coding:IUPACName.extension">
        <path value="MedicationKnowledge.code.coding.extension"/>
        <slicing>
          <discriminator>
            <type value="value"/>
            <path value="url"/>
          </discriminator>
          <description value="Extensions are always sliced by (at least) url"/>
          <rules value="open"/>
        </slicing>
        <short value="Additional content defined by implementations"/>
        <definition
                  value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
        <comment
              value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
        <alias value="extensions"/>
        <alias value="user content"/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="Element.extension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
```

```
        </mapping>
      </element>
      <element id="MedicationKnowledge.code.coding:IUPACName.system">
        <path value="MedicationKnowledge.code.coding.system"/>
        <short value="Identity of the terminology system"/>
        <definition
                   value="The identification of the code system that defines the meaning o
f the symbol in the code."/>
        <comment
                  value="The URI may be an OID (urn:oid:...) or a UUID (urn:uuid:...).  OIDs
 and UUIDs SHALL be references to the HL7 OID registry. Otherwise, the URI should come fr
om HL7&#39;s list of FHIR defined special URIs or it should reference to some definition
that establishes the system clearly and unambiguously."/>
        <requirements
                     value="Need to be unambiguous about the source of the definition of t
he symbol."/>
        <min value="1"/>
        <max value="1"/>
        <base>
          <path value="Coding.system"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="uri"/>
        </type>
        <fixedUri
                  value="https://iupac.org/who-we-are/divisions/division-details/inchi/"/>
        <mustSupport value="true"/>
        <isModifier value="false"/>
        <isSummary value="true"/>
        <mapping>
          <identity value="v2"/>
          <map value="C*E.3"/>
        </mapping>
        <mapping>
          <identity value="rim"/>
          <map value="./codeSystem"/>
        </mapping>
        <mapping>
          <identity value="orim"/>
          <map
               value="fhir:Coding.system rdfs:subPropertyOf dt:CDCoding.codeSystem"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.code.coding:IUPACName.version">
        <path value="MedicationKnowledge.code.coding.version"/>
        <short value="Version of the system - if relevant"/>
        <definition
                   value="The version of the code system which was used when choosing this
 code. Note that a well-maintained code system does not need the version reported, becaus
e the meaning of codes is consistent across versions. However this cannot consistently be
 assured, and when the meaning is not guaranteed to be consistent, the version SHOULD be
exchanged."/>
        <comment
                 value="Where the terminology does not clearly define what string should be
 used to identify code system versions, the recommendation is to use the date (expressed
```

```xml
in FHIR date format) on which that version was officially published as the version date."
/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Coding.version"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="string"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="true"/>
        <mapping>
          <identity value="v2"/>
          <map value="C*E.7"/>
        </mapping>
        <mapping>
          <identity value="rim"/>
          <map value="./codeSystemVersion"/>
        </mapping>
        <mapping>
          <identity value="orim"/>
          <map
              value="fhir:Coding.version rdfs:subPropertyOf dt:CDCoding.codeSystemVersion"
/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.code.coding:IUPACName.code">
        <path value="MedicationKnowledge.code.coding.code"/>
        <short value="Symbol in syntax defined by the system"/>
        <definition
                  value="A symbol in syntax defined by the system. The symbol may be a pr
edefined code or an expression in a syntax defined by the coding system (e.g. post-coordi
nation)."/>
        <requirements value="Need to refer to a particular code in the system."/>
        <min value="1"/>
        <max value="1"/>
        <base>
          <path value="Coding.code"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="code"/>
        </type>
        <mustSupport value="true"/>
        <isModifier value="false"/>
        <isSummary value="true"/>
        <mapping>
          <identity value="v2"/>
          <map value="C*E.1"/>
        </mapping>
        <mapping>
          <identity value="rim"/>
          <map value="./code"/>
```

```xml
      </mapping>
      <mapping>
        <identity value="orim"/>
        <map value="fhir:Coding.code rdfs:subPropertyOf dt:CDCoding.code"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.code.coding:IUPACName.display">
      <extension
                url="http://hl7.org/fhir/StructureDefinition/elementdefinition-translata
ble">
        <valueBoolean value="true"/>
      </extension>
      <path value="MedicationKnowledge.code.coding.display"/>
      <short value="Representation defined by the system"/>
      <definition
                value="A representation of the meaning of the code in the system, follo
wing the rules of the system."/>
      <requirements
                    value="Need to be able to carry a human-readable meaning of the code
for readers that do not know  the system."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="Coding.display"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="string"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="true"/>
      <mapping>
        <identity value="v2"/>
        <map value="C*E.2 - but note this is not well followed"/>
      </mapping>
      <mapping>
        <identity value="rim"/>
        <map value="CV.displayName"/>
      </mapping>
      <mapping>
        <identity value="orim"/>
        <map
            value="fhir:Coding.display rdfs:subPropertyOf dt:CDCoding.displayName"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.code.coding:IUPACName.userSelected">
      <path value="MedicationKnowledge.code.coding.userSelected"/>
      <short value="If this coding was chosen directly by the user"/>
      <definition
                value="Indicates that this coding was chosen by a user directly - e.g.
off a pick list of available items (codes or displays)."/>
      <comment
              value="Amongst a set of alternatives, a directly chosen code is the most a
ppropriate starting point for new translations. There is some ambiguity about what exactl
y &#39;directly chosen&#39; implies, and trading partner agreement may be needed to clari
fy the use of this element and its consequences more completely."/>
```

```xml
      <requirements
                 value="This has been identified as a clinical safety criterium - that
 this exact system/code pair was chosen explicitly, rather than inferred by the system ba
sed on some rules or language processing."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="Coding.userSelected"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="boolean"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="true"/>
      <mapping>
        <identity value="v2"/>
        <map value="Sometimes implied by being first"/>
      </mapping>
      <mapping>
        <identity value="rim"/>
        <map value="CD.codingRationale"/>
      </mapping>
      <mapping>
        <identity value="orim"/>
        <map
             value="fhir:Coding.userSelected fhir:mapsTo dt:CDCoding.codingRationale. fhi
r:Coding.userSelected fhir:hasMap fhir:Coding.userSelected.map. fhir:Coding.userSelected.
map a fhir:Map;   fhir:target dt:CDCoding.codingRationale. fhir:Coding.userSelected\#true
 a [     fhir:source &quot;true&quot;;     fhir:target dt:CDCoding.codingRationale\#0   ]
"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.code.coding:@default">
      <path value="MedicationKnowledge.code.coding"/>
      <sliceName value="@default"/>
      <short value="Code defined by a terminology system"/>
      <definition value="A reference to a code defined by a terminology system."/>
      <comment
                value="Codes may be defined very casually in enumerations, or code lists,
up to very formal definitions such as SNOMED CT - see the HL7 v3 Core Principles for more
 information.  Ordering of codings is undefined and SHALL NOT be used to infer meaning. G
enerally, at most only one of the coding values will be labeled as UserSelected = true."/
>
      <requirements
                 value="Allows for alternative encodings within a code system, and tra
nslations to other code systems."/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="CodeableConcept.coding"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Coding"/>
```

```xml
        </type>
        <mustSupport value="true"/>
        <isModifier value="false"/>
        <isSummary value="true"/>
        <mapping>
          <identity value="v2"/>
          <map value="C*E.1-8, C*E.10-22"/>
        </mapping>
        <mapping>
          <identity value="rim"/>
          <map value="union(., ./translation)"/>
        </mapping>
        <mapping>
          <identity value="orim"/>
          <map value="fhir:CodeableConcept.coding rdfs:subPropertyOf dt:CD.coding"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.code.coding:@default.id">
        <path value="MedicationKnowledge.code.coding.id"/>
        <representation value="xmlAttr"/>
        <short value="Unique id for inter-element referencing"/>
        <definition
                  value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Element.id"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="string"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.code.coding:@default.extension">
        <path value="MedicationKnowledge.code.coding.extension"/>
        <slicing>
          <discriminator>
            <type value="value"/>
            <path value="url"/>
          </discriminator>
          <description value="Extensions are always sliced by (at least) url"/>
          <rules value="open"/>
        </slicing>
        <short value="Additional content defined by implementations"/>
        <definition
                  value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
```

```
 be met as part of the definition of the extension."/>
      <comment
               value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
      <alias value="extensions"/>
      <alias value="user content"/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="Element.extension"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Extension"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="n/a"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.code.coding:@default.system">
      <path value="MedicationKnowledge.code.coding.system"/>
      <short value="Identity of the terminology system"/>
      <definition
               value="The identification of the code system that defines the meaning o
f the symbol in the code."/>
      <comment
               value="The URI may be an OID (urn:oid:...) or a UUID (urn:uuid:...).  OIDs
 and UUIDs SHALL be references to the HL7 OID registry. Otherwise, the URI should come fr
om HL7&#39;s list of FHIR defined special URIs or it should reference to some definition
that establishes the system clearly and unambiguously."/>
      <requirements
                 value="Need to be unambiguous about the source of the definition of t
he symbol."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="Coding.system"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="uri"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="true"/>
      <mapping>
        <identity value="v2"/>
        <map value="C*E.3"/>
      </mapping>
      <mapping>
        <identity value="rim"/>
```

```xml
        <map value="./codeSystem"/>
      </mapping>
      <mapping>
        <identity value="orim"/>
        <map
            value="fhir:Coding.system rdfs:subPropertyOf dt:CDCoding.codeSystem"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.code.coding:@default.version">
      <path value="MedicationKnowledge.code.coding.version"/>
      <short value="Version of the system - if relevant"/>
      <definition
                value="The version of the code system which was used when choosing this
 code. Note that a well-maintained code system does not need the version reported, becaus
e the meaning of codes is consistent across versions. However this cannot consistently be
 assured, and when the meaning is not guaranteed to be consistent, the version SHOULD be
exchanged."/>
      <comment
              value="Where the terminology does not clearly define what string should be
 used to identify code system versions, the recommendation is to use the date (expressed
in FHIR date format) on which that version was officially published as the version date."
/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="Coding.version"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="string"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="true"/>
      <mapping>
        <identity value="v2"/>
        <map value="C*E.7"/>
      </mapping>
      <mapping>
        <identity value="rim"/>
        <map value="./codeSystemVersion"/>
      </mapping>
      <mapping>
        <identity value="orim"/>
        <map
            value="fhir:Coding.version rdfs:subPropertyOf dt:CDCoding.codeSystemVersion"
/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.code.coding:@default.code">
      <path value="MedicationKnowledge.code.coding.code"/>
      <short value="Company code"/>
      <definition
                value="An internal identifier assigned by the sponsor to this drug subs
tance. [Source: SME Defined]."/>
      <requirements value="Need to refer to a particular code in the system."/>
      <min value="1"/>
```

```xml
        <max value="1"/>
        <base>
          <path value="Coding.code"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="code"/>
        </type>
        <mustSupport value="true"/>
        <isModifier value="false"/>
        <isSummary value="true"/>
        <mapping>
          <identity value="v2"/>
          <map value="C*E.1"/>
        </mapping>
        <mapping>
          <identity value="rim"/>
          <map value="./code"/>
        </mapping>
        <mapping>
          <identity value="orim"/>
          <map value="fhir:Coding.code rdfs:subPropertyOf dt:CDCoding.code"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.code.coding:@default.display">
        <extension
                   url="http://hl7.org/fhir/StructureDefinition/elementdefinition-translata
ble">
          <valueBoolean value="true"/>
        </extension>
        <path value="MedicationKnowledge.code.coding.display"/>
        <short value="Representation defined by the system"/>
        <definition
                    value="A representation of the meaning of the code in the system, follo
wing the rules of the system."/>
        <requirements
                      value="Need to be able to carry a human-readable meaning of the code
for readers that do not know  the system."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Coding.display"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="string"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="true"/>
        <mapping>
          <identity value="v2"/>
          <map value="C*E.2 - but note this is not well followed"/>
        </mapping>
        <mapping>
          <identity value="rim"/>
```

```
          <map value="CV.displayName"/>
        </mapping>
        <mapping>
          <identity value="orim"/>
          <map
              value="fhir:Coding.display rdfs:subPropertyOf dt:CDCoding.displayName"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.code.coding:@default.userSelected">
        <path value="MedicationKnowledge.code.coding.userSelected"/>
        <short value="If this coding was chosen directly by the user"/>
        <definition
                  value="Indicates that this coding was chosen by a user directly - e.g.
off a pick list of available items (codes or displays)."/>
        <comment
              value="Amongst a set of alternatives, a directly chosen code is the most a
ppropriate starting point for new translations. There is some ambiguity about what exactl
y &#39;directly chosen&#39; implies, and trading partner agreement may be needed to clari
fy the use of this element and its consequences more completely."/>
        <requirements
                    value="This has been identified as a clinical safety criterium - that
 this exact system/code pair was chosen explicitly, rather than inferred by the system ba
sed on some rules or language processing."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Coding.userSelected"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="boolean"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="true"/>
        <mapping>
          <identity value="v2"/>
          <map value="Sometimes implied by being first"/>
        </mapping>
        <mapping>
          <identity value="rim"/>
          <map value="CD.codingRationale"/>
        </mapping>
        <mapping>
          <identity value="orim"/>
          <map
              value="fhir:Coding.userSelected fhir:mapsTo dt:CDCoding.codingRationale. fhi
r:Coding.userSelected fhir:hasMap fhir:Coding.userSelected.map. fhir:Coding.userSelected.
map a fhir:Map;   fhir:target dt:CDCoding.codingRationale. fhir:Coding.userSelected\#true
 a [     fhir:source &quot;true&quot;;     fhir:target dt:CDCoding.codingRationale\#O   ]
"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.code.text">
        <extension
                  url="http://hl7.org/fhir/StructureDefinition/elementdefinition-translata
ble">
```

```xml
            <valueBoolean value="true"/>
        </extension>
        <path value="MedicationKnowledge.code.text"/>
        <short value="Chemical Name"/>
        <definition
                    value="A commonly used name or a systematic name assigned to the chemic
al or compound. [Source: SME Defined] Examples: acetaminophen; acetamide, N-(4-hydroxyphe
nyl)-; 4hydroxyacetanilide."/>
        <comment
                value="Very often the text is the same as a displayName of one of the codi
ngs."/>
        <requirements
                    value="The codes from the terminologies do not always capture the cor
rect meaning with all the nuances of the human using them, or sometimes there is no appro
priate code at all. In these cases, the text is used to capture the full meaning of the s
ource."/>
        <min value="1"/>
        <max value="1"/>
        <base>
          <path value="CodeableConcept.text"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="string"/>
        </type>
        <mustSupport value="true"/>
        <isModifier value="false"/>
        <isSummary value="true"/>
        <mapping>
          <identity value="v2"/>
          <map value="C*E.9. But note many systems use C*E.2 for this"/>
        </mapping>
        <mapping>
          <identity value="rim"/>
          <map value="./originalText[mediaType/code=&quot;text/plain&quot;]/data"/>
        </mapping>
        <mapping>
          <identity value="orim"/>
          <map
              value="fhir:CodeableConcept.text rdfs:subPropertyOf dt:CD.originalText"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.status">
        <path value="MedicationKnowledge.status"/>
        <short value="active | inactive | entered-in-error"/>
        <definition
                    value="A code to indicate if the medication is in active use.  The stat
us refers to the validity about the information of the medication and not to its medicina
l properties."/>
        <comment
                value="This status is intended to identify if the medication in a local sy
stem is in active use within a drug database or inventory.  For example, a pharmacy syste
m may create a new drug file record for a compounded product &quot;ABC Hospital Special C
ream&quot; with an active status.  At some point in the future, it may be determined that
 the drug record was created with an error and the status is changed to &quot;entered in
error&quot;.   This status is not intended to specify if a medication is part of a partic
```

```
ular formulary.  It is possible that the drug record may be referenced by multiple formul
aries or catalogues and each of those entries would have a separate status."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="MedicationKnowledge.status"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="code"/>
      </type>
      <isModifier value="true"/>
      <isModifierReason
                       value="This element changes the interpretation of all descriptive
 attributes."/>
      <isSummary value="true"/>
      <binding>
        <extension
                   url="http://hl7.org/fhir/StructureDefinition/elementdefinition-binding
Name">
          <valueString value="MedicationKnowledgeStatus"/>
        </extension>
        <strength value="required"/>
        <description
                     value="A coded concept defining if the medication is in active use."
/>
        <valueSet
                   value="http://hl7.org/fhir/ValueSet/medicationknowledge-status|4.0.0"/>
      </binding>
      <mapping>
        <identity value="rim"/>
        <map value=".statusCode"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.manufacturer">
      <path value="MedicationKnowledge.manufacturer"/>
      <short value="Manufacturer of the item"/>
      <definition
                  value="Describes the details of the manufacturer of the medication prod
uct.  This is not intended to represent the distributor of a medication product."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="MedicationKnowledge.manufacturer"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="Reference"/>
        <targetProfile
                       value="http://hl7.org/fhir/StructureDefinition/Organization"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="true"/>
      <mapping>
        <identity value="script10.6"/>
```

```
          <map value="no mapping"/>
        </mapping>
        <mapping>
          <identity value="w5"/>
          <map value="FiveWs.actor"/>
        </mapping>
        <mapping>
          <identity value="v2"/>
          <map
              value="RXD-20-Substance Manufacturer Name / RXG-21-Substance Manufacturer Na
me / RXA-17-Substance Manufacturer Name"/>
        </mapping>
        <mapping>
          <identity value="rim"/>
          <map value=".player.scopingRole[typeCode=MANU].scoper"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.doseForm">
        <path value="MedicationKnowledge.doseForm"/>
        <short value="powder | tablets | capsule +"/>
        <definition
                  value="Describes the form of the item.  Powder; tablets; capsule."/>
        <comment
                value="When Medication is referenced from MedicationRequest, this is the o
rdered form.  When Medication is referenced within MedicationDispense, this is the dispen
sed form.  When Medication is referenced within MedicationAdministration, this is adminis
tered form."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="MedicationKnowledge.doseForm"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="CodeableConcept"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <binding>
          <extension
                    url="http://hl7.org/fhir/StructureDefinition/elementdefinition-binding
Name">
            <valueString value="MedicationForm"/>
          </extension>
          <strength value="example"/>
          <description value="A coded concept defining the form of a medication."/>
          <valueSet value="http://hl7.org/fhir/ValueSet/medication-form-codes"/>
        </binding>
        <mapping>
          <identity value="script10.6"/>
          <map
              value="coding.code =  //element(*,DrugCodedType)/FormCode

coding.system = //element(*,DrugCodedType)/FormSourceCode"/>
        </mapping>
        <mapping>
```

```
            <identity value="v2"/>
            <map
                value="RXO-5-Requested Dosage Form / RXE-6-Give Dosage Form / RXD-6-Actual D
osage Form / RXG-8-Give Dosage Form / RXA-8-Administered Dosage Form"/>
        </mapping>
        <mapping>
          <identity value="rim"/>
          <map value=".formCode"/>
        </mapping>
    </element>
    <element id="MedicationKnowledge.amount">
        <path value="MedicationKnowledge.amount"/>
        <short value="Amount of drug in package"/>
        <definition
                    value="Specific amount of the drug in the packaged product.  For exampl
e, when specifying a product that has the same strength (For example, Insulin glargine 10
0 unit per mL solution for injection), this attribute provides additional clarification o
f the package amount (For example, 3 mL, 10mL, etc.)."/>
        <comment
                value="This is the quantity of medication in a package.  To specify the st
rength of the medication, the Ingredient.strength attribute is used."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="MedicationKnowledge.amount"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="Quantity"/>
          <profile value="http://hl7.org/fhir/StructureDefinition/SimpleQuantity"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="true"/>
        <mapping>
          <identity value="rim"/>
          <map value=".quantity"/>
        </mapping>
    </element>
    <element id="MedicationKnowledge.synonym">
        <path value="MedicationKnowledge.synonym"/>
        <short value="Additional names for a medication"/>
        <definition
                    value="Additional names for a medication, for example, the name(s) give
n to a medication in different countries.  For example, acetaminophen and paracetamol or
salbutamol and albuterol."/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="MedicationKnowledge.synonym"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="string"/>
        </type>
        <isModifier value="false"/>
```

```xml
        <isSummary value="true"/>
    </element>
    <element id="MedicationKnowledge.relatedMedicationKnowledge">
      <path value="MedicationKnowledge.relatedMedicationKnowledge"/>
      <short value="Associated or related medication information"/>
      <definition value="Associated or related knowledge about a medication."/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="MedicationKnowledge.relatedMedicationKnowledge"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="BackboneElement"/>
      </type>
      <constraint>
        <key value="ele-1"/>
        <severity value="error"/>
        <human value="All FHIR elements must have a @value or children"/>
        <expression value="hasValue() or (children().count() &gt; id.count())"/>
        <xpath value="@value|f:*|h:div"/>
        <source value="Element"/>
      </constraint>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="MedicationKnowledge.relatedMedicationKnowledge.id">
      <path value="MedicationKnowledge.relatedMedicationKnowledge.id"/>
      <representation value="xmlAttr"/>
      <short value="Unique id for inter-element referencing"/>
      <definition
                 value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="Element.id"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="string"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="n/a"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.relatedMedicationKnowledge.extension">
      <path value="MedicationKnowledge.relatedMedicationKnowledge.extension"/>
      <short value="Additional content defined by implementations"/>
      <definition
                 value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
```

```
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
      <comment
              value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
      <alias value="extensions"/>
      <alias value="user content"/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="Element.extension"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Extension"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="n/a"/>
      </mapping>
    </element>
    <element
            id="MedicationKnowledge.relatedMedicationKnowledge.modifierExtension">
      <path
          value="MedicationKnowledge.relatedMedicationKnowledge.modifierExtension"/>
      <short value="Extensions that cannot be ignored even if unrecognized"/>
      <definition
                value="May be used to represent additional information that is not part
 of the basic definition of the element and that modifies the understanding of the elemen
t in which it is contained and/or the understanding of the containing element&#39;s desce
ndants. Usually modifier elements provide negation or qualification. To make the use of e
xtensions safe and manageable, there is a strict set of governance applied to the definit
ion and use of extensions. Though any implementer can define an extension, there is a set
 of requirements that SHALL be met as part of the definition of the extension. Applicatio
ns processing a resource are required to check for modifier extensions.

Modifier extensions SHALL NOT change the meaning of any elements on Resource or DomainRes
ource (including cannot change the meaning of modifierExtension itself)."/>
      <comment
              value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
      <requirements
                  value="Modifier extensions allow for extensions that *cannot* be safe
ly ignored to be clearly distinguished from the vast majority of extensions which can be
safely ignored.  This promotes interoperability by eliminating the need for implementers
to prohibit the presence of extensions. For further information, see the [definition of m
odifier extensions](http://build.fhir.org/extensibility.html#modifierExtension)."/>
      <alias value="extensions"/>
      <alias value="user content"/>
```

```xml
        <alias value="modifiers"/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="BackboneElement.modifierExtension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
        </type>
        <isModifier value="true"/>
        <isModifierReason
                        value="Modifier extensions are expected to modify the meaning or
interpretation of the element that contains them"/>
        <isSummary value="true"/>
        <mapping>
          <identity value="rim"/>
          <map value="N/A"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.relatedMedicationKnowledge.type">
        <path value="MedicationKnowledge.relatedMedicationKnowledge.type"/>
        <short value="Category of medicationKnowledge"/>
        <definition
                  value="The category of the associated medication knowledge reference."/
>
        <min value="1"/>
        <max value="1"/>
        <base>
          <path value="MedicationKnowledge.relatedMedicationKnowledge.type"/>
          <min value="1"/>
          <max value="1"/>
        </base>
        <type>
          <code value="CodeableConcept"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="MedicationKnowledge.relatedMedicationKnowledge.reference">
        <path value="MedicationKnowledge.relatedMedicationKnowledge.reference"/>
        <short
              value="Associated documentation about the associated medication knowledge"/>
        <definition
                  value="Associated documentation about the associated medication knowled
ge."/>
        <min value="1"/>
        <max value="*"/>
        <base>
          <path value="MedicationKnowledge.relatedMedicationKnowledge.reference"/>
          <min value="1"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Reference"/>
          <targetProfile
```

```
                            value="http://hl7.org/fhir/StructureDefinition/MedicationKnowledge
"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="MedicationKnowledge.associatedMedication">
      <path value="MedicationKnowledge.associatedMedication"/>
      <short
            value="A medication resource that is associated with this medication"/>
      <definition
                  value="Associated or related medications.  For example, if the medicati
on is a branded product (e.g. Crestor), this is the Therapeutic Moeity (e.g. Rosuvastatin
) or if this is a generic medication (e.g. Rosuvastatin), this would link to a branded pr
oduct (e.g. Crestor)."/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="MedicationKnowledge.associatedMedication"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Reference"/>
        <targetProfile
                        value="http://hl7.org/fhir/StructureDefinition/Medication"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="MedicationKnowledge.productType">
      <path value="MedicationKnowledge.productType"/>
      <short value="Category of the medication or product"/>
      <definition
                  value="Category of the medication or product (e.g. branded product, the
rapeutic moeity, generic product, innovator product, etc.)."/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="MedicationKnowledge.productType"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="CodeableConcept"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="MedicationKnowledge.monograph">
      <path value="MedicationKnowledge.monograph"/>
      <short value="Associated documentation about the medication"/>
      <definition value="Associated documentation about the medication."/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="MedicationKnowledge.monograph"/>
```

```
            <min value="0"/>
            <max value="*"/>
          </base>
          <type>
            <code value="BackboneElement"/>
          </type>
          <constraint>
            <key value="ele-1"/>
            <severity value="error"/>
            <human value="All FHIR elements must have a @value or children"/>
            <expression value="hasValue() or (children().count() &gt; id.count())"/>
            <xpath value="@value|f:*|h:div"/>
            <source value="Element"/>
          </constraint>
          <isModifier value="false"/>
          <isSummary value="false"/>
        </element>
        <element id="MedicationKnowledge.monograph.id">
          <path value="MedicationKnowledge.monograph.id"/>
          <representation value="xmlAttr"/>
          <short value="Unique id for inter-element referencing"/>
          <definition
                    value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
          <min value="0"/>
          <max value="1"/>
          <base>
            <path value="Element.id"/>
            <min value="0"/>
            <max value="1"/>
          </base>
          <type>
            <code value="string"/>
          </type>
          <isModifier value="false"/>
          <isSummary value="false"/>
          <mapping>
            <identity value="rim"/>
            <map value="n/a"/>
          </mapping>
        </element>
        <element id="MedicationKnowledge.monograph.extension">
          <path value="MedicationKnowledge.monograph.extension"/>
          <short value="Additional content defined by implementations"/>
          <definition
                    value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
          <comment
                  value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
          <alias value="extensions"/>
          <alias value="user content"/>
```

```xml
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="Element.extension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.monograph.modifierExtension">
        <path value="MedicationKnowledge.monograph.modifierExtension"/>
        <short value="Extensions that cannot be ignored even if unrecognized"/>
        <definition
                   value="May be used to represent additional information that is not part
 of the basic definition of the element and that modifies the understanding of the elemen
t in which it is contained and/or the understanding of the containing element&#39;s desce
ndants. Usually modifier elements provide negation or qualification. To make the use of e
xtensions safe and manageable, there is a strict set of governance applied to the definit
ion and use of extensions. Though any implementer can define an extension, there is a set
 of requirements that SHALL be met as part of the definition of the extension. Applicatio
ns processing a resource are required to check for modifier extensions.

Modifier extensions SHALL NOT change the meaning of any elements on Resource or DomainRes
ource (including cannot change the meaning of modifierExtension itself)."/>
        <comment
                 value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
        <requirements
                     value="Modifier extensions allow for extensions that *cannot* be safe
ly ignored to be clearly distinguished from the vast majority of extensions which can be
safely ignored.  This promotes interoperability by eliminating the need for implementers
to prohibit the presence of extensions. For further information, see the [definition of m
odifier extensions](http://build.fhir.org/extensibility.html#modifierExtension)."/>
        <alias value="extensions"/>
        <alias value="user content"/>
        <alias value="modifiers"/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="BackboneElement.modifierExtension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
        </type>
        <isModifier value="true"/>
```

```xml
            <isModifierReason
                        value="Modifier extensions are expected to modify the meaning or
interpretation of the element that contains them"/>
        <isSummary value="true"/>
        <mapping>
          <identity value="rim"/>
          <map value="N/A"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.monograph.type">
        <path value="MedicationKnowledge.monograph.type"/>
        <short value="The category of medication document"/>
        <definition
                    value="The category of documentation about the medication. (e.g. profes
sional monograph, patient education monograph)."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="MedicationKnowledge.monograph.type"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="CodeableConcept"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="MedicationKnowledge.monograph.source">
        <path value="MedicationKnowledge.monograph.source"/>
        <short value="Associated documentation about the medication"/>
        <definition value="Associated documentation about the medication."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="MedicationKnowledge.monograph.source"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="Reference"/>
          <targetProfile
                        value="http://hl7.org/fhir/StructureDefinition/DocumentReference"/
>
          <targetProfile value="http://hl7.org/fhir/StructureDefinition/Media"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="MedicationKnowledge.ingredient">
        <path value="MedicationKnowledge.ingredient"/>
        <short value="Active or inactive ingredient"/>
        <definition
                    value="Identifies a particular constituent of interest in the product."
/>
        <min value="0"/>
        <max value="*"/>
```

```xml
      <base>
        <path value="MedicationKnowledge.ingredient"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="BackboneElement"/>
      </type>
      <constraint>
        <key value="ele-1"/>
        <severity value="error"/>
        <human value="All FHIR elements must have a @value or children"/>
        <expression value="hasValue() or (children().count() &gt; id.count())"/>
        <xpath value="@value|f:*|h:div"/>
        <source value="Element"/>
      </constraint>
      <mustSupport value="true"/>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="MedicationKnowledge.ingredient.id">
      <path value="MedicationKnowledge.ingredient.id"/>
      <representation value="xmlAttr"/>
      <short value="Unique id for inter-element referencing"/>
      <definition
                  value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="Element.id"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="string"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="n/a"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.ingredient.extension">
      <path value="MedicationKnowledge.ingredient.extension"/>
      <short value="Additional content defined by implementations"/>
      <definition
                  value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
      <comment
                value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
```

```
on to retain a core level of simplicity for everyone."/>
      <alias value="extensions"/>
      <alias value="user content"/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="Element.extension"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Extension"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="n/a"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.ingredient.modifierExtension">
      <path value="MedicationKnowledge.ingredient.modifierExtension"/>
      <short value="Extensions that cannot be ignored even if unrecognized"/>
      <definition
                 value="May be used to represent additional information that is not part
 of the basic definition of the element and that modifies the understanding of the elemen
t in which it is contained and/or the understanding of the containing element&#39;s desce
ndants. Usually modifier elements provide negation or qualification. To make the use of e
xtensions safe and manageable, there is a strict set of governance applied to the definit
ion and use of extensions. Though any implementer can define an extension, there is a set
 of requirements that SHALL be met as part of the definition of the extension. Applicatio
ns processing a resource are required to check for modifier extensions.

Modifier extensions SHALL NOT change the meaning of any elements on Resource or DomainRes
ource (including cannot change the meaning of modifierExtension itself)."/>
      <comment
              value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
      <requirements
                    value="Modifier extensions allow for extensions that *cannot* be safe
ly ignored to be clearly distinguished from the vast majority of extensions which can be
safely ignored.  This promotes interoperability by eliminating the need for implementers
to prohibit the presence of extensions. For further information, see the [definition of m
odifier extensions](http://build.fhir.org/extensibility.html#modifierExtension)."/>
      <alias value="extensions"/>
      <alias value="user content"/>
      <alias value="modifiers"/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="BackboneElement.modifierExtension"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
```

```xml
          <code value="Extension"/>
        </type>
        <isModifier value="true"/>
        <isModifierReason
                          value="Modifier extensions are expected to modify the meaning or
interpretation of the element that contains them"/>
        <isSummary value="true"/>
        <mapping>
          <identity value="rim"/>
          <map value="N/A"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.ingredient.itemReference">
        <path value="MedicationKnowledge.ingredient.itemReference"/>
        <short value="Medication(s) or substance(s) contained in the medication"/>
        <definition
                    value="The actual ingredient - either a substance (simple ingredient) o
r another medication."/>
        <min value="1"/>
        <max value="1"/>
        <base>
          <path value="MedicationKnowledge.ingredient.item[x]"/>
          <min value="1"/>
          <max value="1"/>
        </base>
        <type>
          <code value="Reference"/>
          <targetProfile
                          value="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/rawingre
dient"/>
        </type>
        <mustSupport value="true"/>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="script10.6"/>
          <map
              value="coding.code = //element(*,MedicationType)/DrugCoded/ProductCode

coding.system = //element(*,MedicationType)/DrugCoded/ProductCodeQualifier

coding.display = //element(*,MedicationType)/DrugDescription"/>
        </mapping>
        <mapping>
          <identity value="v2"/>
          <map
              value="RXC-2-Component Code  if medication: RXO-1-Requested Give Code / RXE-
2-Give Code / RXD-2-Dispense/Give Code / RXG-4-Give Code / RXA-5-Administered Code"/>
        </mapping>
        <mapping>
          <identity value="rim"/>
          <map value=".player"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.ingredient.isActive">
        <path value="MedicationKnowledge.ingredient.isActive"/>
        <short value="Active ingredient indicator"/>
```

```
        <definition
                value="Indication of whether this ingredient affects the therapeutic ac
tion of the drug."/>
        <requirements
                    value="True indicates that the ingredient affects the therapeutic act
ion of the drug (i.e. active).
False indicates that the ingredient does not affect the therapeutic action of the drug (i
.e. inactive)."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="MedicationKnowledge.ingredient.isActive"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="boolean"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="NA"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.ingredient.strength">
        <path value="MedicationKnowledge.ingredient.strength"/>
        <short value="Quantity of ingredient present"/>
        <definition
                value="Specifies how many (or how much) of the items there are in this
Medication.  For example, 250 mg per tablet.  This is expressed as a ratio where the nume
rator is 250mg and the denominator is 1 tablet."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="MedicationKnowledge.ingredient.strength"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="Ratio"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="script10.6"/>
          <map value="//element(*,DrugCodedType)/Strength"/>
        </mapping>
        <mapping>
          <identity value="v2"/>
          <map
            value="RXC-3-Component Amount &amp; RXC-4-Component Units  if medication: RX
O-2-Requested Give Amount - Minimum &amp; RXO-4-Requested Give Units / RXO-3-Requested Gi
ve Amount - Maximum &amp; RXO-4-Requested Give Units / RXO-11-Requested Dispense Amount &amp;
amp; RXO-12-Requested Dispense Units / RXE-3-Give Amount - Minimum &amp; RXE-5-Give Units
 / RXE-4-Give Amount - Maximum &amp; RXE-5-Give Units / RXE-10-Dispense Amount &amp; RXE-
10-Dispense Units"/>
```

```xml
        </mapping>
        <mapping>
          <identity value="rim"/>
          <map value=".quantity"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.preparationInstruction">
        <path value="MedicationKnowledge.preparationInstruction"/>
        <short value="The instructions for preparing the medication"/>
        <definition value="The instructions for preparing the medication."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="MedicationKnowledge.preparationInstruction"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="markdown"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="MedicationKnowledge.intendedRoute">
        <path value="MedicationKnowledge.intendedRoute"/>
        <short value="The intended or approved route of administration"/>
        <definition value="The intended or approved route of administration."/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="MedicationKnowledge.intendedRoute"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="CodeableConcept"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <binding>
          <extension
                    url="http://hl7.org/fhir/StructureDefinition/elementdefinition-binding
Name">
            <valueString value="MedicationRoute"/>
          </extension>
          <strength value="example"/>
          <description
                    value="A coded concept defining the intended route of administration
."/>
          <valueSet value="http://hl7.org/fhir/ValueSet/route-codes"/>
        </binding>
      </element>
      <element id="MedicationKnowledge.cost">
        <path value="MedicationKnowledge.cost"/>
        <short value="The pricing of the medication"/>
        <definition value="The price of the medication."/>
        <min value="0"/>
```

```xml
        <max value="*"/>
        <base>
          <path value="MedicationKnowledge.cost"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="BackboneElement"/>
        </type>
        <constraint>
          <key value="ele-1"/>
          <severity value="error"/>
          <human value="All FHIR elements must have a @value or children"/>
          <expression value="hasValue() or (children().count() &gt; id.count())"/>
          <xpath value="@value|f:*|h:div"/>
          <source value="Element"/>
        </constraint>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="MedicationKnowledge.cost.id">
        <path value="MedicationKnowledge.cost.id"/>
        <representation value="xmlAttr"/>
        <short value="Unique id for inter-element referencing"/>
        <definition
                  value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Element.id"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="string"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.cost.extension">
        <path value="MedicationKnowledge.cost.extension"/>
        <short value="Additional content defined by implementations"/>
        <definition
                  value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
        <comment
                value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
```

```xml
on to retain a core level of simplicity for everyone."/>
      <alias value="extensions"/>
      <alias value="user content"/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="Element.extension"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Extension"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="n/a"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.cost.modifierExtension">
      <path value="MedicationKnowledge.cost.modifierExtension"/>
      <short value="Extensions that cannot be ignored even if unrecognized"/>
      <definition
                  value="May be used to represent additional information that is not part
 of the basic definition of the element and that modifies the understanding of the elemen
t in which it is contained and/or the understanding of the containing element&#39;s desce
ndants. Usually modifier elements provide negation or qualification. To make the use of e
xtensions safe and manageable, there is a strict set of governance applied to the definit
ion and use of extensions. Though any implementer can define an extension, there is a set
 of requirements that SHALL be met as part of the definition of the extension. Applicatio
ns processing a resource are required to check for modifier extensions.

Modifier extensions SHALL NOT change the meaning of any elements on Resource or DomainRes
ource (including cannot change the meaning of modifierExtension itself)."/>
      <comment
               value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
      <requirements
                    value="Modifier extensions allow for extensions that *cannot* be safe
ly ignored to be clearly distinguished from the vast majority of extensions which can be
safely ignored.  This promotes interoperability by eliminating the need for implementers
to prohibit the presence of extensions. For further information, see the [definition of m
odifier extensions](http://build.fhir.org/extensibility.html#modifierExtension)."/>
      <alias value="extensions"/>
      <alias value="user content"/>
      <alias value="modifiers"/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="BackboneElement.modifierExtension"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
```

```xml
        <code value="Extension"/>
      </type>
      <isModifier value="true"/>
      <isModifierReason
                        value="Modifier extensions are expected to modify the meaning or
interpretation of the element that contains them"/>
      <isSummary value="true"/>
      <mapping>
        <identity value="rim"/>
        <map value="N/A"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.cost.type">
      <path value="MedicationKnowledge.cost.type"/>
      <short value="The category of the cost information"/>
      <definition
                  value="The category of the cost information.  For example, manufacturer
s&#39; cost, patient cost, claim reimbursement cost, actual acquisition cost."/>
      <min value="1"/>
      <max value="1"/>
      <base>
        <path value="MedicationKnowledge.cost.type"/>
        <min value="1"/>
        <max value="1"/>
      </base>
      <type>
        <code value="CodeableConcept"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="MedicationKnowledge.cost.source">
      <path value="MedicationKnowledge.cost.source"/>
      <short value="The source or owner for the price information"/>
      <definition
                  value="The source or owner that assigns the price to the medication."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="MedicationKnowledge.cost.source"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="string"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="MedicationKnowledge.cost.cost">
      <path value="MedicationKnowledge.cost.cost"/>
      <short value="The price of the medication"/>
      <definition value="The price of the medication."/>
      <min value="1"/>
      <max value="1"/>
      <base>
        <path value="MedicationKnowledge.cost.cost"/>
```

```xml
        <min value="1"/>
        <max value="1"/>
      </base>
      <type>
        <code value="Money"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="MedicationKnowledge.monitoringProgram">
      <path value="MedicationKnowledge.monitoringProgram"/>
      <short value="Program under which a medication is reviewed"/>
      <definition value="The program under which the medication is reviewed."/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="MedicationKnowledge.monitoringProgram"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="BackboneElement"/>
      </type>
      <constraint>
        <key value="ele-1"/>
        <severity value="error"/>
        <human value="All FHIR elements must have a @value or children"/>
        <expression value="hasValue() or (children().count() &gt; id.count())"/>
        <xpath value="@value|f:*|h:div"/>
        <source value="Element"/>
      </constraint>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="MedicationKnowledge.monitoringProgram.id">
      <path value="MedicationKnowledge.monitoringProgram.id"/>
      <representation value="xmlAttr"/>
      <short value="Unique id for inter-element referencing"/>
      <definition
                 value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="Element.id"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="string"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="n/a"/>
      </mapping>
```

```xml
        </element>
        <element id="MedicationKnowledge.monitoringProgram.extension">
          <path value="MedicationKnowledge.monitoringProgram.extension"/>
          <short value="Additional content defined by implementations"/>
          <definition
                    value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
          <comment
                  value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
          <alias value="extensions"/>
          <alias value="user content"/>
          <min value="0"/>
          <max value="*"/>
          <base>
            <path value="Element.extension"/>
            <min value="0"/>
            <max value="*"/>
          </base>
          <type>
            <code value="Extension"/>
          </type>
          <isModifier value="false"/>
          <isSummary value="false"/>
          <mapping>
            <identity value="rim"/>
            <map value="n/a"/>
          </mapping>
        </element>
        <element id="MedicationKnowledge.monitoringProgram.modifierExtension">
          <path value="MedicationKnowledge.monitoringProgram.modifierExtension"/>
          <short value="Extensions that cannot be ignored even if unrecognized"/>
          <definition
                    value="May be used to represent additional information that is not part
 of the basic definition of the element and that modifies the understanding of the elemen
t in which it is contained and/or the understanding of the containing element&#39;s desce
ndants. Usually modifier elements provide negation or qualification. To make the use of e
xtensions safe and manageable, there is a strict set of governance applied to the definit
ion and use of extensions. Though any implementer can define an extension, there is a set
 of requirements that SHALL be met as part of the definition of the extension. Applicatio
ns processing a resource are required to check for modifier extensions.

Modifier extensions SHALL NOT change the meaning of any elements on Resource or DomainRes
ource (including cannot change the meaning of modifierExtension itself)."/>
          <comment
                  value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
          <requirements
                    value="Modifier extensions allow for extensions that *cannot* be safe
ly ignored to be clearly distinguished from the vast majority of extensions which can be
```

```
safely ignored.  This promotes interoperability by eliminating the need for implementers
to prohibit the presence of extensions. For further information, see the [definition of m
odifier extensions](http://build.fhir.org/extensibility.html#modifierExtension)."/>
      <alias value="extensions"/>
      <alias value="user content"/>
      <alias value="modifiers"/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="BackboneElement.modifierExtension"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Extension"/>
      </type>
      <isModifier value="true"/>
      <isModifierReason
                        value="Modifier extensions are expected to modify the meaning or
interpretation of the element that contains them"/>
      <isSummary value="true"/>
      <mapping>
        <identity value="rim"/>
        <map value="N/A"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.monitoringProgram.type">
      <path value="MedicationKnowledge.monitoringProgram.type"/>
      <short value="Type of program under which the medication is monitored"/>
      <definition
                  value="Type of program under which the medication is monitored."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="MedicationKnowledge.monitoringProgram.type"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="CodeableConcept"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="MedicationKnowledge.monitoringProgram.name">
      <path value="MedicationKnowledge.monitoringProgram.name"/>
      <short value="Name of the reviewing program"/>
      <definition value="Name of the reviewing program."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="MedicationKnowledge.monitoringProgram.name"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="string"/>
```

```xml
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="MedicationKnowledge.administrationGuidelines">
        <path value="MedicationKnowledge.administrationGuidelines"/>
        <short value="Guidelines for administration of the medication"/>
        <definition value="Guidelines for the administration of the medication."/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="MedicationKnowledge.administrationGuidelines"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="BackboneElement"/>
        </type>
        <constraint>
          <key value="ele-1"/>
          <severity value="error"/>
          <human value="All FHIR elements must have a @value or children"/>
          <expression value="hasValue() or (children().count() &gt; id.count())"/>
          <xpath value="@value|f:*|h:div"/>
          <source value="Element"/>
        </constraint>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="MedicationKnowledge.administrationGuidelines.id">
        <path value="MedicationKnowledge.administrationGuidelines.id"/>
        <representation value="xmlAttr"/>
        <short value="Unique id for inter-element referencing"/>
        <definition
                    value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Element.id"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="string"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.administrationGuidelines.extension">
        <path value="MedicationKnowledge.administrationGuidelines.extension"/>
        <short value="Additional content defined by implementations"/>
        <definition
```

```
                        value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
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      <comment
               value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
      <alias value="extensions"/>
      <alias value="user content"/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="Element.extension"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Extension"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="n/a"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.administrationGuidelines.modifierExtension">
      <path
            value="MedicationKnowledge.administrationGuidelines.modifierExtension"/>
      <short value="Extensions that cannot be ignored even if unrecognized"/>
      <definition
                 value="May be used to represent additional information that is not part
 of the basic definition of the element and that modifies the understanding of the elemen
t in which it is contained and/or the understanding of the containing element&#39;s desce
ndants. Usually modifier elements provide negation or qualification. To make the use of e
xtensions safe and manageable, there is a strict set of governance applied to the definit
ion and use of extensions. Though any implementer can define an extension, there is a set
 of requirements that SHALL be met as part of the definition of the extension. Applicatio
ns processing a resource are required to check for modifier extensions.

Modifier extensions SHALL NOT change the meaning of any elements on Resource or DomainRes
ource (including cannot change the meaning of modifierExtension itself)."/>
      <comment
               value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
      <requirements
                    value="Modifier extensions allow for extensions that *cannot* be safe
ly ignored to be clearly distinguished from the vast majority of extensions which can be
safely ignored.  This promotes interoperability by eliminating the need for implementers
to prohibit the presence of extensions. For further information, see the [definition of m
odifier extensions](http://build.fhir.org/extensibility.html#modifierExtension)."/>
      <alias value="extensions"/>
```

```xml
        <alias value="user content"/>
        <alias value="modifiers"/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="BackboneElement.modifierExtension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
        </type>
        <isModifier value="true"/>
        <isModifierReason
                          value="Modifier extensions are expected to modify the meaning or
interpretation of the element that contains them"/>
        <isSummary value="true"/>
        <mapping>
          <identity value="rim"/>
          <map value="N/A"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.administrationGuidelines.dosage">
        <path value="MedicationKnowledge.administrationGuidelines.dosage"/>
        <short value="Dosage for the medication for the specific guidelines"/>
        <definition value="Dosage for the medication for the specific guidelines."/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="MedicationKnowledge.administrationGuidelines.dosage"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="BackboneElement"/>
        </type>
        <constraint>
          <key value="ele-1"/>
          <severity value="error"/>
          <human value="All FHIR elements must have a @value or children"/>
          <expression value="hasValue() or (children().count() &gt; id.count())"/>
          <xpath value="@value|f:*|h:div"/>
          <source value="Element"/>
        </constraint>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="MedicationKnowledge.administrationGuidelines.dosage.id">
        <path value="MedicationKnowledge.administrationGuidelines.dosage.id"/>
        <representation value="xmlAttr"/>
        <short value="Unique id for inter-element referencing"/>
        <definition
                    value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
        <min value="0"/>
        <max value="1"/>
        <base>
```

```
          <path value="Element.id"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="string"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.administrationGuidelines.dosage.extension">
        <path
              value="MedicationKnowledge.administrationGuidelines.dosage.extension"/>
        <short value="Additional content defined by implementations"/>
        <definition
                  value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
        <comment
                value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
        <alias value="extensions"/>
        <alias value="user content"/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="Element.extension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element
              id="MedicationKnowledge.administrationGuidelines.dosage.modifierExtension">
        <path
              value="MedicationKnowledge.administrationGuidelines.dosage.modifierExtension"
/>
        <short value="Extensions that cannot be ignored even if unrecognized"/>
        <definition
                  value="May be used to represent additional information that is not part
 of the basic definition of the element and that modifies the understanding of the elemen
```

t in which it is contained and/or the understanding of the containing element's desce
ndants. Usually modifier elements provide negation or qualification. To make the use of e
xtensions safe and manageable, there is a strict set of governance applied to the definit
ion and use of extensions. Though any implementer can define an extension, there is a set
 of requirements that SHALL be met as part of the definition of the extension. Applicatio
ns processing a resource are required to check for modifier extensions.

Modifier extensions SHALL NOT change the meaning of any elements on Resource or DomainRes
ource (including cannot change the meaning of modifierExtension itself)."/>
      <comment
                value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions. The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
      <requirements
                    value="Modifier extensions allow for extensions that *cannot* be safe
ly ignored to be clearly distinguished from the vast majority of extensions which can be
safely ignored. This promotes interoperability by eliminating the need for implementers
to prohibit the presence of extensions. For further information, see the [definition of m
odifier extensions](http://build.fhir.org/extensibility.html#modifierExtension)."/>
      <alias value="extensions"/>
      <alias value="user content"/>
      <alias value="modifiers"/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="BackboneElement.modifierExtension"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Extension"/>
      </type>
      <isModifier value="true"/>
      <isModifierReason
                        value="Modifier extensions are expected to modify the meaning or
interpretation of the element that contains them"/>
      <isSummary value="true"/>
      <mapping>
        <identity value="rim"/>
        <map value="N/A"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.administrationGuidelines.dosage.type">
      <path value="MedicationKnowledge.administrationGuidelines.dosage.type"/>
      <short value="Type of dosage"/>
      <definition
                  value="The type of dosage (for example, prophylaxis, maintenance, thera
peutic, etc.)."/>
      <min value="1"/>
      <max value="1"/>
      <base>
        <path value="MedicationKnowledge.administrationGuidelines.dosage.type"/>
        <min value="1"/>
        <max value="1"/>
      </base>
      <type>

```
          <code value="CodeableConcept"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="MedicationKnowledge.administrationGuidelines.dosage.dosage">
        <path value="MedicationKnowledge.administrationGuidelines.dosage.dosage"/>
        <short value="Dosage for the medication for the specific guidelines"/>
        <definition value="Dosage for the medication for the specific guidelines."/>
        <min value="1"/>
        <max value="*"/>
        <base>
          <path value="MedicationKnowledge.administrationGuidelines.dosage.dosage"/>
          <min value="1"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Dosage"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="MedicationKnowledge.administrationGuidelines.indication[x]">
        <path value="MedicationKnowledge.administrationGuidelines.indication[x]"/>
        <short
              value="Indication for use that apply to the specific administration guidelin
es"/>
        <definition
                   value="Indication for use that apply to the specific administration gui
delines."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="MedicationKnowledge.administrationGuidelines.indication[x]"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="CodeableConcept"/>
        </type>
        <type>
          <code value="Reference"/>
          <targetProfile
                        value="http://hl7.org/fhir/StructureDefinition/ObservationDefiniti
on"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element
              id="MedicationKnowledge.administrationGuidelines.patientCharacteristics">
        <path
             value="MedicationKnowledge.administrationGuidelines.patientCharacteristics"/>
        <short
              value="Characteristics of the patient that are relevant to the administratio
n guidelines"/>
        <definition
```

```
                         value="Characteristics of the patient that are relevant to the administ
ration guidelines (for example, height, weight, gender, etc.)."/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path
                 value="MedicationKnowledge.administrationGuidelines.patientCharacteristics"
/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="BackboneElement"/>
        </type>
        <constraint>
          <key value="ele-1"/>
          <severity value="error"/>
          <human value="All FHIR elements must have a @value or children"/>
          <expression value="hasValue() or (children().count() &gt; id.count())"/>
          <xpath value="@value|f:*|h:div"/>
          <source value="Element"/>
        </constraint>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element
                id="MedicationKnowledge.administrationGuidelines.patientCharacteristics.id">
        <path
              value="MedicationKnowledge.administrationGuidelines.patientCharacteristics.id
"/>
        <representation value="xmlAttr"/>
        <short value="Unique id for inter-element referencing"/>
        <definition
                    value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Element.id"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="string"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element
                id="MedicationKnowledge.administrationGuidelines.patientCharacteristics.exte
nsion">
        <path
              value="MedicationKnowledge.administrationGuidelines.patientCharacteristics.ex
```

```
tension"/>
      <short value="Additional content defined by implementations"/>
      <definition
              value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
      <comment
              value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
      <alias value="extensions"/>
      <alias value="user content"/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="Element.extension"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Extension"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="n/a"/>
      </mapping>
    </element>
    <element
            id="MedicationKnowledge.administrationGuidelines.patientCharacteristics.modi
fierExtension">
      <path
          value="MedicationKnowledge.administrationGuidelines.patientCharacteristics.mo
difierExtension"/>
      <short value="Extensions that cannot be ignored even if unrecognized"/>
      <definition
              value="May be used to represent additional information that is not part
 of the basic definition of the element and that modifies the understanding of the elemen
t in which it is contained and/or the understanding of the containing element&#39;s desce
ndants. Usually modifier elements provide negation or qualification. To make the use of e
xtensions safe and manageable, there is a strict set of governance applied to the definit
ion and use of extensions. Though any implementer can define an extension, there is a set
 of requirements that SHALL be met as part of the definition of the extension. Applicatio
ns processing a resource are required to check for modifier extensions.

Modifier extensions SHALL NOT change the meaning of any elements on Resource or DomainRes
ource (including cannot change the meaning of modifierExtension itself)."/>
      <comment
              value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
      <requirements
```

```
                            value="Modifier extensions allow for extensions that *cannot* be safe
ly ignored to be clearly distinguished from the vast majority of extensions which can be
safely ignored.  This promotes interoperability by eliminating the need for implementers
to prohibit the presence of extensions. For further information, see the [definition of m
odifier extensions](http://build.fhir.org/extensibility.html#modifierExtension)."/>
      <alias value="extensions"/>
      <alias value="user content"/>
      <alias value="modifiers"/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="BackboneElement.modifierExtension"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Extension"/>
      </type>
      <isModifier value="true"/>
      <isModifierReason
                        value="Modifier extensions are expected to modify the meaning or
interpretation of the element that contains them"/>
      <isSummary value="true"/>
      <mapping>
        <identity value="rim"/>
        <map value="N/A"/>
      </mapping>
    </element>
    <element
            id="MedicationKnowledge.administrationGuidelines.patientCharacteristics.char
acteristic[x]">
      <path
            value="MedicationKnowledge.administrationGuidelines.patientCharacteristics.ch
aracteristic[x]"/>
      <short
            value="Specific characteristic that is relevant to the administration guidel
ine"/>
      <definition
                  value="Specific characteristic that is relevant to the administration g
uideline (e.g. height, weight, gender)."/>
      <min value="1"/>
      <max value="1"/>
      <base>
        <path
              value="MedicationKnowledge.administrationGuidelines.patientCharacteristics.
characteristic[x]"/>
        <min value="1"/>
        <max value="1"/>
      </base>
      <type>
        <code value="CodeableConcept"/>
      </type>
      <type>
        <code value="Quantity"/>
        <profile value="http://hl7.org/fhir/StructureDefinition/SimpleQuantity"/>
      </type>
      <isModifier value="false"/>
```

```xml
      <isSummary value="false"/>
    </element>
    <element
            id="MedicationKnowledge.administrationGuidelines.patientCharacteristics.valu
e">
      <path
          value="MedicationKnowledge.administrationGuidelines.patientCharacteristics.va
lue"/>
      <short value="The specific characteristic"/>
      <definition
                value="The specific characteristic (e.g. height, weight, gender, etc.).
"/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path
              value="MedicationKnowledge.administrationGuidelines.patientCharacteristics.
value"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="string"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="MedicationKnowledge.medicineClassification">
      <path value="MedicationKnowledge.medicineClassification"/>
      <short
            value="Categorization of the medication within a formulary or classification
 system"/>
      <definition
                value="Categorization of the medication within a formulary or classific
ation system."/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="MedicationKnowledge.medicineClassification"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="BackboneElement"/>
      </type>
      <constraint>
        <key value="ele-1"/>
        <severity value="error"/>
        <human value="All FHIR elements must have a @value or children"/>
        <expression value="hasValue() or (children().count() &gt; id.count())"/>
        <xpath value="@value|f:*|h:div"/>
        <source value="Element"/>
      </constraint>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="MedicationKnowledge.medicineClassification.id">
```

```xml
      <path value="MedicationKnowledge.medicineClassification.id"/>
      <representation value="xmlAttr"/>
      <short value="Unique id for inter-element referencing"/>
      <definition
                 value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="Element.id"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="string"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="n/a"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.medicineClassification.extension">
      <path value="MedicationKnowledge.medicineClassification.extension"/>
      <short value="Additional content defined by implementations"/>
      <definition
                 value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
      <comment
               value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
      <alias value="extensions"/>
      <alias value="user content"/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="Element.extension"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Extension"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="n/a"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.medicineClassification.modifierExtension">
```

```xml
      <path value="MedicationKnowledge.medicineClassification.modifierExtension"/>
      <short value="Extensions that cannot be ignored even if unrecognized"/>
      <definition
                  value="May be used to represent additional information that is not part
 of the basic definition of the element and that modifies the understanding of the elemen
t in which it is contained and/or the understanding of the containing element&#39;s desce
ndants. Usually modifier elements provide negation or qualification. To make the use of e
xtensions safe and manageable, there is a strict set of governance applied to the definit
ion and use of extensions. Though any implementer can define an extension, there is a set
 of requirements that SHALL be met as part of the definition of the extension. Applicatio
ns processing a resource are required to check for modifier extensions.

Modifier extensions SHALL NOT change the meaning of any elements on Resource or DomainRes
ource (including cannot change the meaning of modifierExtension itself)."/>
      <comment
               value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
      <requirements
                    value="Modifier extensions allow for extensions that *cannot* be safe
ly ignored to be clearly distinguished from the vast majority of extensions which can be
safely ignored.  This promotes interoperability by eliminating the need for implementers
to prohibit the presence of extensions. For further information, see the [definition of m
odifier extensions](http://build.fhir.org/extensibility.html#modifierExtension)."/>
      <alias value="extensions"/>
      <alias value="user content"/>
      <alias value="modifiers"/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="BackboneElement.modifierExtension"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Extension"/>
      </type>
      <isModifier value="true"/>
      <isModifierReason
                        value="Modifier extensions are expected to modify the meaning or
interpretation of the element that contains them"/>
      <isSummary value="true"/>
      <mapping>
        <identity value="rim"/>
        <map value="N/A"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.medicineClassification.type">
      <path value="MedicationKnowledge.medicineClassification.type"/>
      <short
             value="The type of category for the medication (for example, therapeutic cla
ssification, therapeutic sub-classification)"/>
      <definition
                  value="The type of category for the medication (for example, therapeuti
c classification, therapeutic sub-classification)."/>
      <min value="1"/>
```

```xml
        <max value="1"/>
        <base>
          <path value="MedicationKnowledge.medicineClassification.type"/>
          <min value="1"/>
          <max value="1"/>
        </base>
        <type>
          <code value="CodeableConcept"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="MedicationKnowledge.medicineClassification.classification">
        <path value="MedicationKnowledge.medicineClassification.classification"/>
        <short value="Specific category assigned to the medication"/>
        <definition
                   value="Specific category assigned to the medication (e.g. anti-infectiv
e, anti-hypertensive, antibiotic, etc.)."/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="MedicationKnowledge.medicineClassification.classification"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="CodeableConcept"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="MedicationKnowledge.packaging">
        <path value="MedicationKnowledge.packaging"/>
        <short value="Details about packaged medications"/>
        <definition
                   value="Information that only applies to packages (not products)."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="MedicationKnowledge.packaging"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="BackboneElement"/>
        </type>
        <constraint>
          <key value="ele-1"/>
          <severity value="error"/>
          <human value="All FHIR elements must have a @value or children"/>
          <expression value="hasValue() or (children().count() &gt; id.count())"/>
          <xpath value="@value|f:*|h:div"/>
          <source value="Element"/>
        </constraint>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
```

```
      <element id="MedicationKnowledge.packaging.id">
        <path value="MedicationKnowledge.packaging.id"/>
        <representation value="xmlAttr"/>
        <short value="Unique id for inter-element referencing"/>
        <definition
                   value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Element.id"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="string"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.packaging.extension">
        <path value="MedicationKnowledge.packaging.extension"/>
        <short value="Additional content defined by implementations"/>
        <definition
                   value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
        <comment
                 value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
        <alias value="extensions"/>
        <alias value="user content"/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="Element.extension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
```

```xml
      <element id="MedicationKnowledge.packaging.modifierExtension">
        <path value="MedicationKnowledge.packaging.modifierExtension"/>
        <short value="Extensions that cannot be ignored even if unrecognized"/>
        <definition
                    value="May be used to represent additional information that is not part
 of the basic definition of the element and that modifies the understanding of the elemen
t in which it is contained and/or the understanding of the containing element&#39;s desce
ndants. Usually modifier elements provide negation or qualification. To make the use of e
xtensions safe and manageable, there is a strict set of governance applied to the definit
ion and use of extensions. Though any implementer can define an extension, there is a set
 of requirements that SHALL be met as part of the definition of the extension. Applicatio
ns processing a resource are required to check for modifier extensions.

Modifier extensions SHALL NOT change the meaning of any elements on Resource or DomainRes
ource (including cannot change the meaning of modifierExtension itself)."/>
        <comment
                  value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
        <requirements
                      value="Modifier extensions allow for extensions that *cannot* be safe
ly ignored to be clearly distinguished from the vast majority of extensions which can be
safely ignored.  This promotes interoperability by eliminating the need for implementers
to prohibit the presence of extensions. For further information, see the [definition of m
odifier extensions](http://build.fhir.org/extensibility.html#modifierExtension)."/>
        <alias value="extensions"/>
        <alias value="user content"/>
        <alias value="modifiers"/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="BackboneElement.modifierExtension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
        </type>
        <isModifier value="true"/>
        <isModifierReason
                          value="Modifier extensions are expected to modify the meaning or
interpretation of the element that contains them"/>
        <isSummary value="true"/>
        <mapping>
          <identity value="rim"/>
          <map value="N/A"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.packaging.type">
        <path value="MedicationKnowledge.packaging.type"/>
        <short
              value="A code that defines the specific type of packaging that the medicatio
n can be found in"/>
        <definition
                    value="A code that defines the specific type of packaging that the medi
cation can be found in (e.g. blister sleeve, tube, bottle)."/>
```

```xml
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="MedicationKnowledge.packaging.type"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="CodeableConcept"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <binding>
          <extension
                    url="http://hl7.org/fhir/StructureDefinition/elementdefinition-binding
Name">
            <valueString value="MedicationPackageType"/>
          </extension>
          <strength value="example"/>
          <description
                      value="A coded concept defining the type of packaging of a medicatio
n."/>
          <valueSet
                    value="http://hl7.org/fhir/ValueSet/medicationknowledge-package-type"/>
        </binding>
      </element>
      <element id="MedicationKnowledge.packaging.quantity">
        <path value="MedicationKnowledge.packaging.quantity"/>
        <short
              value="The number of product units the package would contain if fully loaded
"/>
        <definition
                    value="The number of product units the package would contain if fully l
oaded."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="MedicationKnowledge.packaging.quantity"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="Quantity"/>
          <profile value="http://hl7.org/fhir/StructureDefinition/SimpleQuantity"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="MedicationKnowledge.drugCharacteristic">
        <path value="MedicationKnowledge.drugCharacteristic"/>
        <short value="Specifies descriptive properties of the medicine"/>
        <definition
                    value="Specifies descriptive properties of the medicine, such as color,
 shape, imprints, etc."/>
        <min value="0"/>
        <max value="*"/>
        <base>
```

```
            <path value="MedicationKnowledge.drugCharacteristic"/>
            <min value="0"/>
            <max value="*"/>
          </base>
          <type>
            <code value="BackboneElement"/>
          </type>
          <constraint>
            <key value="ele-1"/>
            <severity value="error"/>
            <human value="All FHIR elements must have a @value or children"/>
            <expression value="hasValue() or (children().count() &gt; id.count())"/>
            <xpath value="@value|f:*|h:div"/>
            <source value="Element"/>
          </constraint>
          <isModifier value="false"/>
          <isSummary value="false"/>
        </element>
        <element id="MedicationKnowledge.drugCharacteristic.id">
          <path value="MedicationKnowledge.drugCharacteristic.id"/>
          <representation value="xmlAttr"/>
          <short value="Unique id for inter-element referencing"/>
          <definition
                    value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
          <min value="0"/>
          <max value="1"/>
          <base>
            <path value="Element.id"/>
            <min value="0"/>
            <max value="1"/>
          </base>
          <type>
            <code value="string"/>
          </type>
          <isModifier value="false"/>
          <isSummary value="false"/>
          <mapping>
            <identity value="rim"/>
            <map value="n/a"/>
          </mapping>
        </element>
        <element id="MedicationKnowledge.drugCharacteristic.extension">
          <path value="MedicationKnowledge.drugCharacteristic.extension"/>
          <short value="Additional content defined by implementations"/>
          <definition
                    value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
          <comment
                  value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
          <alias value="extensions"/>
```

```xml
        <alias value="user content"/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="Element.extension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.drugCharacteristic.modifierExtension">
        <path value="MedicationKnowledge.drugCharacteristic.modifierExtension"/>
        <short value="Extensions that cannot be ignored even if unrecognized"/>
        <definition
                   value="May be used to represent additional information that is not part
 of the basic definition of the element and that modifies the understanding of the elemen
t in which it is contained and/or the understanding of the containing element&#39;s desce
ndants. Usually modifier elements provide negation or qualification. To make the use of e
xtensions safe and manageable, there is a strict set of governance applied to the definit
ion and use of extensions. Though any implementer can define an extension, there is a set
 of requirements that SHALL be met as part of the definition of the extension. Applicatio
ns processing a resource are required to check for modifier extensions.

Modifier extensions SHALL NOT change the meaning of any elements on Resource or DomainRes
ource (including cannot change the meaning of modifierExtension itself)."/>
        <comment
                value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
        <requirements
                     value="Modifier extensions allow for extensions that *cannot* be safe
ly ignored to be clearly distinguished from the vast majority of extensions which can be
safely ignored.  This promotes interoperability by eliminating the need for implementers
to prohibit the presence of extensions. For further information, see the [definition of m
odifier extensions](http://build.fhir.org/extensibility.html#modifierExtension)."/>
        <alias value="extensions"/>
        <alias value="user content"/>
        <alias value="modifiers"/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="BackboneElement.modifierExtension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
        </type>
```

```xml
          <isModifier value="true"/>
          <isModifierReason
                          value="Modifier extensions are expected to modify the meaning or
interpretation of the element that contains them"/>
          <isSummary value="true"/>
          <mapping>
            <identity value="rim"/>
            <map value="N/A"/>
          </mapping>
        </element>
        <element id="MedicationKnowledge.drugCharacteristic.type">
          <path value="MedicationKnowledge.drugCharacteristic.type"/>
          <short value="Code specifying the type of characteristic of medication"/>
          <definition
                    value="A code specifying which characteristic of the medicine is being
described (for example, colour, shape, imprint)."/>
          <min value="0"/>
          <max value="1"/>
          <base>
            <path value="MedicationKnowledge.drugCharacteristic.type"/>
            <min value="0"/>
            <max value="1"/>
          </base>
          <type>
            <code value="CodeableConcept"/>
          </type>
          <isModifier value="false"/>
          <isSummary value="false"/>
          <binding>
            <extension
                      url="http://hl7.org/fhir/StructureDefinition/elementdefinition-binding
Name">
              <valueString value="MedicationCharacteristic"/>
            </extension>
            <strength value="example"/>
            <description
                        value="A coded concept defining the characteristic types of a medica
tion."/>
            <valueSet
                      value="http://hl7.org/fhir/ValueSet/medicationknowledge-characteristic"
/>
          </binding>
        </element>
        <element id="MedicationKnowledge.drugCharacteristic.value[x]">
          <path value="MedicationKnowledge.drugCharacteristic.value[x]"/>
          <short value="Description of the characteristic"/>
          <definition value="Description of the characteristic."/>
          <comment
                  value="The description should be provided as a CodeableConcept, SimpleQuan
tity or an image.  The description can be a string only when these others are not availab
le."/>
          <min value="0"/>
          <max value="1"/>
          <base>
            <path value="MedicationKnowledge.drugCharacteristic.value[x]"/>
            <min value="0"/>
            <max value="1"/>
```

```xml
        </base>
        <type>
          <code value="CodeableConcept"/>
        </type>
        <type>
          <code value="string"/>
        </type>
        <type>
          <code value="Quantity"/>
          <profile value="http://hl7.org/fhir/StructureDefinition/SimpleQuantity"/>
        </type>
        <type>
          <code value="base64Binary"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="MedicationKnowledge.contraindication">
        <path value="MedicationKnowledge.contraindication"/>
        <short value="Potential clinical issue with or between medication(s)"/>
        <definition
                   value="Potential clinical issue with or between medication(s) (for exam
ple, drug-drug interaction, drug-disease contraindication, drug-allergy interaction, etc.
)."/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="MedicationKnowledge.contraindication"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Reference"/>
          <targetProfile
                       value="http://hl7.org/fhir/StructureDefinition/DetectedIssue"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="MedicationKnowledge.regulatory">
        <path value="MedicationKnowledge.regulatory"/>
        <short value="Regulatory information about a medication"/>
        <definition value="Regulatory information about a medication."/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="MedicationKnowledge.regulatory"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="BackboneElement"/>
        </type>
        <constraint>
          <key value="ele-1"/>
          <severity value="error"/>
          <human value="All FHIR elements must have a @value or children"/>
```

```
            <expression value="hasValue() or (children().count() &gt; id.count())"/>
            <xpath value="@value|f:*|h:div"/>
            <source value="Element"/>
          </constraint>
          <isModifier value="false"/>
          <isSummary value="false"/>
        </element>
        <element id="MedicationKnowledge.regulatory.id">
          <path value="MedicationKnowledge.regulatory.id"/>
          <representation value="xmlAttr"/>
          <short value="Unique id for inter-element referencing"/>
          <definition
                    value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
          <min value="0"/>
          <max value="1"/>
          <base>
            <path value="Element.id"/>
            <min value="0"/>
            <max value="1"/>
          </base>
          <type>
            <code value="string"/>
          </type>
          <isModifier value="false"/>
          <isSummary value="false"/>
          <mapping>
            <identity value="rim"/>
            <map value="n/a"/>
          </mapping>
        </element>
        <element id="MedicationKnowledge.regulatory.extension">
          <path value="MedicationKnowledge.regulatory.extension"/>
          <short value="Additional content defined by implementations"/>
          <definition
                    value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
          <comment
                  value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
          <alias value="extensions"/>
          <alias value="user content"/>
          <min value="0"/>
          <max value="*"/>
          <base>
            <path value="Element.extension"/>
            <min value="0"/>
            <max value="*"/>
          </base>
          <type>
            <code value="Extension"/>
          </type>
```

```xml
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.regulatory.modifierExtension">
        <path value="MedicationKnowledge.regulatory.modifierExtension"/>
        <short value="Extensions that cannot be ignored even if unrecognized"/>
        <definition
                    value="May be used to represent additional information that is not part
 of the basic definition of the element and that modifies the understanding of the elemen
t in which it is contained and/or the understanding of the containing element&#39;s desce
ndants. Usually modifier elements provide negation or qualification. To make the use of e
xtensions safe and manageable, there is a strict set of governance applied to the definit
ion and use of extensions. Though any implementer can define an extension, there is a set
 of requirements that SHALL be met as part of the definition of the extension. Applicatio
ns processing a resource are required to check for modifier extensions.

Modifier extensions SHALL NOT change the meaning of any elements on Resource or DomainRes
ource (including cannot change the meaning of modifierExtension itself)."/>
        <comment
                 value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
        <requirements
                      value="Modifier extensions allow for extensions that *cannot* be safe
ly ignored to be clearly distinguished from the vast majority of extensions which can be
safely ignored.  This promotes interoperability by eliminating the need for implementers
to prohibit the presence of extensions. For further information, see the [definition of m
odifier extensions](http://build.fhir.org/extensibility.html#modifierExtension)."/>
        <alias value="extensions"/>
        <alias value="user content"/>
        <alias value="modifiers"/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="BackboneElement.modifierExtension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
        </type>
        <isModifier value="true"/>
        <isModifierReason
                          value="Modifier extensions are expected to modify the meaning or
interpretation of the element that contains them"/>
        <isSummary value="true"/>
        <mapping>
          <identity value="rim"/>
          <map value="N/A"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.regulatory.regulatoryAuthority">
```

```xml
      <path value="MedicationKnowledge.regulatory.regulatoryAuthority"/>
      <short value="Specifies the authority of the regulation"/>
      <definition value="The authority that is specifying the regulations."/>
      <min value="1"/>
      <max value="1"/>
      <base>
        <path value="MedicationKnowledge.regulatory.regulatoryAuthority"/>
        <min value="1"/>
        <max value="1"/>
      </base>
      <type>
        <code value="Reference"/>
        <targetProfile
                     value="http://hl7.org/fhir/StructureDefinition/Organization"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="MedicationKnowledge.regulatory.substitution">
      <path value="MedicationKnowledge.regulatory.substitution"/>
      <short
              value="Specifies if changes are allowed when dispensing a medication from a
regulatory perspective"/>
      <definition
                  value="Specifies if changes are allowed when dispensing a medication fr
om a regulatory perspective."/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="MedicationKnowledge.regulatory.substitution"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="BackboneElement"/>
      </type>
      <constraint>
        <key value="ele-1"/>
        <severity value="error"/>
        <human value="All FHIR elements must have a @value or children"/>
        <expression value="hasValue() or (children().count() &gt; id.count())"/>
        <xpath value="@value|f:*|h:div"/>
        <source value="Element"/>
      </constraint>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="MedicationKnowledge.regulatory.substitution.id">
      <path value="MedicationKnowledge.regulatory.substitution.id"/>
      <representation value="xmlAttr"/>
      <short value="Unique id for inter-element referencing"/>
      <definition
                  value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
      <min value="0"/>
      <max value="1"/>
      <base>
```

```xml
        <path value="Element.id"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="string"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="n/a"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.regulatory.substitution.extension">
      <path value="MedicationKnowledge.regulatory.substitution.extension"/>
      <short value="Additional content defined by implementations"/>
      <definition
                value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
      <comment
              value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
      <alias value="extensions"/>
      <alias value="user content"/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="Element.extension"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Extension"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="n/a"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.regulatory.substitution.modifierExtension">
      <path
            value="MedicationKnowledge.regulatory.substitution.modifierExtension"/>
      <short value="Extensions that cannot be ignored even if unrecognized"/>
      <definition
                value="May be used to represent additional information that is not part
 of the basic definition of the element and that modifies the understanding of the elemen
t in which it is contained and/or the understanding of the containing element&#39;s desce
ndants. Usually modifier elements provide negation or qualification. To make the use of e
xtensions safe and manageable, there is a strict set of governance applied to the definit
```

```
ion and use of extensions. Though any implementer can define an extension, there is a set
 of requirements that SHALL be met as part of the definition of the extension. Applicatio
ns processing a resource are required to check for modifier extensions.

Modifier extensions SHALL NOT change the meaning of any elements on Resource or DomainRes
ource (including cannot change the meaning of modifierExtension itself)."/>
        <comment
                  value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
        <requirements
                      value="Modifier extensions allow for extensions that *cannot* be safe
ly ignored to be clearly distinguished from the vast majority of extensions which can be
safely ignored.  This promotes interoperability by eliminating the need for implementers
to prohibit the presence of extensions. For further information, see the [definition of m
odifier extensions](http://build.fhir.org/extensibility.html#modifierExtension)."/>
        <alias value="extensions"/>
        <alias value="user content"/>
        <alias value="modifiers"/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="BackboneElement.modifierExtension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
        </type>
        <isModifier value="true"/>
        <isModifierReason
                          value="Modifier extensions are expected to modify the meaning or
interpretation of the element that contains them"/>
        <isSummary value="true"/>
        <mapping>
          <identity value="rim"/>
          <map value="N/A"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.regulatory.substitution.type">
        <path value="MedicationKnowledge.regulatory.substitution.type"/>
        <short value="Specifies the type of substitution allowed"/>
        <definition value="Specifies the type of substitution allowed."/>
        <min value="1"/>
        <max value="1"/>
        <base>
          <path value="MedicationKnowledge.regulatory.substitution.type"/>
          <min value="1"/>
          <max value="1"/>
        </base>
        <type>
          <code value="CodeableConcept"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
```

```xml
        <element id="MedicationKnowledge.regulatory.substitution.allowed">
          <path value="MedicationKnowledge.regulatory.substitution.allowed"/>
          <short
                value="Specifies if regulation allows for changes in the medication when dis
pensing"/>
          <definition
                    value="Specifies if regulation allows for changes in the medication whe
n dispensing."/>
          <min value="1"/>
          <max value="1"/>
          <base>
            <path value="MedicationKnowledge.regulatory.substitution.allowed"/>
            <min value="1"/>
            <max value="1"/>
          </base>
          <type>
            <code value="boolean"/>
          </type>
          <isModifier value="false"/>
          <isSummary value="false"/>
        </element>
        <element id="MedicationKnowledge.regulatory.schedule">
          <path value="MedicationKnowledge.regulatory.schedule"/>
          <short value="Specifies the schedule of a medication in jurisdiction"/>
          <definition
                    value="Specifies the schedule of a medication in jurisdiction."/>
          <min value="0"/>
          <max value="*"/>
          <base>
            <path value="MedicationKnowledge.regulatory.schedule"/>
            <min value="0"/>
            <max value="*"/>
          </base>
          <type>
            <code value="BackboneElement"/>
          </type>
          <constraint>
            <key value="ele-1"/>
            <severity value="error"/>
            <human value="All FHIR elements must have a @value or children"/>
            <expression value="hasValue() or (children().count() &gt; id.count())"/>
            <xpath value="@value|f:*|h:div"/>
            <source value="Element"/>
          </constraint>
          <isModifier value="false"/>
          <isSummary value="false"/>
        </element>
        <element id="MedicationKnowledge.regulatory.schedule.id">
          <path value="MedicationKnowledge.regulatory.schedule.id"/>
          <representation value="xmlAttr"/>
          <short value="Unique id for inter-element referencing"/>
          <definition
                    value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
          <min value="0"/>
          <max value="1"/>
          <base>
```

```
          <path value="Element.id"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="string"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.regulatory.schedule.extension">
        <path value="MedicationKnowledge.regulatory.schedule.extension"/>
        <short value="Additional content defined by implementations"/>
        <definition
                   value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
        <comment
                value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
        <alias value="extensions"/>
        <alias value="user content"/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="Element.extension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.regulatory.schedule.modifierExtension">
        <path value="MedicationKnowledge.regulatory.schedule.modifierExtension"/>
        <short value="Extensions that cannot be ignored even if unrecognized"/>
        <definition
                   value="May be used to represent additional information that is not part
 of the basic definition of the element and that modifies the understanding of the elemen
t in which it is contained and/or the understanding of the containing element&#39;s desce
ndants. Usually modifier elements provide negation or qualification. To make the use of e
xtensions safe and manageable, there is a strict set of governance applied to the definit
ion and use of extensions. Though any implementer can define an extension, there is a set
```

```
 of requirements that SHALL be met as part of the definition of the extension. Applicatio
ns processing a resource are required to check for modifier extensions.

Modifier extensions SHALL NOT change the meaning of any elements on Resource or DomainRes
ource (including cannot change the meaning of modifierExtension itself)."/>
      <comment
               value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
      <requirements
                    value="Modifier extensions allow for extensions that *cannot* be safe
ly ignored to be clearly distinguished from the vast majority of extensions which can be
safely ignored.  This promotes interoperability by eliminating the need for implementers
to prohibit the presence of extensions. For further information, see the [definition of m
odifier extensions](http://build.fhir.org/extensibility.html#modifierExtension)."/>
      <alias value="extensions"/>
      <alias value="user content"/>
      <alias value="modifiers"/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="BackboneElement.modifierExtension"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Extension"/>
      </type>
      <isModifier value="true"/>
      <isModifierReason
                        value="Modifier extensions are expected to modify the meaning or
interpretation of the element that contains them"/>
      <isSummary value="true"/>
      <mapping>
        <identity value="rim"/>
        <map value="N/A"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.regulatory.schedule.schedule">
      <path value="MedicationKnowledge.regulatory.schedule.schedule"/>
      <short value="Specifies the specific drug schedule"/>
      <definition value="Specifies the specific drug schedule."/>
      <min value="1"/>
      <max value="1"/>
      <base>
        <path value="MedicationKnowledge.regulatory.schedule.schedule"/>
        <min value="1"/>
        <max value="1"/>
      </base>
      <type>
        <code value="CodeableConcept"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="MedicationKnowledge.regulatory.maxDispense">
```

```xml
        <path value="MedicationKnowledge.regulatory.maxDispense"/>
        <short
                value="The maximum number of units of the medication that can be dispensed i
n a period"/>
        <definition
                    value="The maximum number of units of the medication that can be dispen
sed in a period."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="MedicationKnowledge.regulatory.maxDispense"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="BackboneElement"/>
        </type>
        <constraint>
          <key value="ele-1"/>
          <severity value="error"/>
          <human value="All FHIR elements must have a @value or children"/>
          <expression value="hasValue() or (children().count() &gt; id.count())"/>
          <xpath value="@value|f:*|h:div"/>
          <source value="Element"/>
        </constraint>
        <isModifier value="false"/>
        <isSummary value="false"/>
    </element>
    <element id="MedicationKnowledge.regulatory.maxDispense.id">
        <path value="MedicationKnowledge.regulatory.maxDispense.id"/>
        <representation value="xmlAttr"/>
        <short value="Unique id for inter-element referencing"/>
        <definition
                    value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Element.id"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="string"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
    </element>
    <element id="MedicationKnowledge.regulatory.maxDispense.extension">
        <path value="MedicationKnowledge.regulatory.maxDispense.extension"/>
        <short value="Additional content defined by implementations"/>
        <definition
                    value="May be used to represent additional information that is not part
```

```
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
      <comment
                value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
      <alias value="extensions"/>
      <alias value="user content"/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="Element.extension"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Extension"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="n/a"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.regulatory.maxDispense.modifierExtension">
      <path value="MedicationKnowledge.regulatory.maxDispense.modifierExtension"/>
      <short value="Extensions that cannot be ignored even if unrecognized"/>
      <definition
                  value="May be used to represent additional information that is not part
 of the basic definition of the element and that modifies the understanding of the elemen
t in which it is contained and/or the understanding of the containing element&#39;s desce
ndants. Usually modifier elements provide negation or qualification. To make the use of e
xtensions safe and manageable, there is a strict set of governance applied to the definit
ion and use of extensions. Though any implementer can define an extension, there is a set
 of requirements that SHALL be met as part of the definition of the extension. Applicatio
ns processing a resource are required to check for modifier extensions.

Modifier extensions SHALL NOT change the meaning of any elements on Resource or DomainRes
ource (including cannot change the meaning of modifierExtension itself)."/>
      <comment
                value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
      <requirements
                    value="Modifier extensions allow for extensions that *cannot* be safe
ly ignored to be clearly distinguished from the vast majority of extensions which can be
safely ignored.  This promotes interoperability by eliminating the need for implementers
to prohibit the presence of extensions. For further information, see the [definition of m
odifier extensions](http://build.fhir.org/extensibility.html#modifierExtension)."/>
      <alias value="extensions"/>
      <alias value="user content"/>
      <alias value="modifiers"/>
```

```xml
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="BackboneElement.modifierExtension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
        </type>
        <isModifier value="true"/>
        <isModifierReason
                        value="Modifier extensions are expected to modify the meaning or
interpretation of the element that contains them"/>
        <isSummary value="true"/>
        <mapping>
          <identity value="rim"/>
          <map value="N/A"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.regulatory.maxDispense.quantity">
        <path value="MedicationKnowledge.regulatory.maxDispense.quantity"/>
        <short
              value="The maximum number of units of the medication that can be dispensed"/
>
        <definition
                    value="The maximum number of units of the medication that can be dispen
sed."/>
        <min value="1"/>
        <max value="1"/>
        <base>
          <path value="MedicationKnowledge.regulatory.maxDispense.quantity"/>
          <min value="1"/>
          <max value="1"/>
        </base>
        <type>
          <code value="Quantity"/>
          <profile value="http://hl7.org/fhir/StructureDefinition/SimpleQuantity"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="MedicationKnowledge.regulatory.maxDispense.period">
        <path value="MedicationKnowledge.regulatory.maxDispense.period"/>
        <short value="The period that applies to the maximum number of units"/>
        <definition
                    value="The period that applies to the maximum number of units."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="MedicationKnowledge.regulatory.maxDispense.period"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="Duration"/>
        </type>
```

```xml
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="MedicationKnowledge.kinetics">
        <path value="MedicationKnowledge.kinetics"/>
        <short
              value="The time course of drug absorption, distribution, metabolism and excr
etion of a medication from the body"/>
        <definition
                   value="The time course of drug absorption, distribution, metabolism and
 excretion of a medication from the body."/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="MedicationKnowledge.kinetics"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="BackboneElement"/>
        </type>
        <constraint>
          <key value="ele-1"/>
          <severity value="error"/>
          <human value="All FHIR elements must have a @value or children"/>
          <expression value="hasValue() or (children().count() &gt; id.count())"/>
          <xpath value="@value|f:*|h:div"/>
          <source value="Element"/>
        </constraint>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="MedicationKnowledge.kinetics.id">
        <path value="MedicationKnowledge.kinetics.id"/>
        <representation value="xmlAttr"/>
        <short value="Unique id for inter-element referencing"/>
        <definition
                   value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Element.id"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="string"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.kinetics.extension">
```

```
      <path value="MedicationKnowledge.kinetics.extension"/>
      <short value="Additional content defined by implementations"/>
      <definition
               value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
      <comment
              value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
      <alias value="extensions"/>
      <alias value="user content"/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="Element.extension"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Extension"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="n/a"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.kinetics.modifierExtension">
      <path value="MedicationKnowledge.kinetics.modifierExtension"/>
      <short value="Extensions that cannot be ignored even if unrecognized"/>
      <definition
               value="May be used to represent additional information that is not part
 of the basic definition of the element and that modifies the understanding of the elemen
t in which it is contained and/or the understanding of the containing element&#39;s desce
ndants. Usually modifier elements provide negation or qualification. To make the use of e
xtensions safe and manageable, there is a strict set of governance applied to the definit
ion and use of extensions. Though any implementer can define an extension, there is a set
 of requirements that SHALL be met as part of the definition of the extension. Applicatio
ns processing a resource are required to check for modifier extensions.

Modifier extensions SHALL NOT change the meaning of any elements on Resource or DomainRes
ource (including cannot change the meaning of modifierExtension itself)."/>
      <comment
              value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
      <requirements
                  value="Modifier extensions allow for extensions that *cannot* be safe
ly ignored to be clearly distinguished from the vast majority of extensions which can be
safely ignored.  This promotes interoperability by eliminating the need for implementers
to prohibit the presence of extensions. For further information, see the [definition of m
```

```xml
odifier extensions](http://build.fhir.org/extensibility.html#modifierExtension)."/>
        <alias value="extensions"/>
        <alias value="user content"/>
        <alias value="modifiers"/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="BackboneElement.modifierExtension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
        </type>
        <isModifier value="true"/>
        <isModifierReason
                          value="Modifier extensions are expected to modify the meaning or
interpretation of the element that contains them"/>
        <isSummary value="true"/>
        <mapping>
          <identity value="rim"/>
          <map value="N/A"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.kinetics.areaUnderCurve">
        <path value="MedicationKnowledge.kinetics.areaUnderCurve"/>
        <short
              value="The drug concentration measured at certain discrete points in time"/>
        <definition
                    value="The drug concentration measured at certain discrete points in ti
me."/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="MedicationKnowledge.kinetics.areaUnderCurve"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Quantity"/>
          <profile value="http://hl7.org/fhir/StructureDefinition/SimpleQuantity"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="MedicationKnowledge.kinetics.lethalDose50">
        <path value="MedicationKnowledge.kinetics.lethalDose50"/>
        <short value="The median lethal dose of a drug"/>
        <definition value="The median lethal dose of a drug."/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="MedicationKnowledge.kinetics.lethalDose50"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
```

```xml
          <code value="Quantity"/>
          <profile value="http://hl7.org/fhir/StructureDefinition/SimpleQuantity"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="MedicationKnowledge.kinetics.halfLifePeriod">
        <path value="MedicationKnowledge.kinetics.halfLifePeriod"/>
        <short
                value="Time required for concentration in the body to decrease by half"/>
        <definition
                    value="The time required for any specified property (e.g., the concentr
ation of a substance in the body) to decrease by half."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="MedicationKnowledge.kinetics.halfLifePeriod"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="Duration"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
    </snapshot>
    <differential>
      <element id="MedicationKnowledge">
        <path value="MedicationKnowledge"/>
        <mustSupport value="false"/>
        <isModifier value="false"/>
      </element>
      <element id="MedicationKnowledge.extension:productType">
        <path value="MedicationKnowledge.extension"/>
        <sliceName value="productType"/>
        <short value="Specification Type"/>
        <definition
                    value="A classification of specification related to the kind of the ent
ity it is referencing. [Source: SME Defined]."/>
        <min value="1"/>
        <max value="1"/>
        <type>
          <code value="Extension"/>
          <profile
                    value="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/ext-productTyp
e"/>
        </type>
        <mustSupport value="true"/>
        <isModifier value="false"/>
      </element>
      <element id="MedicationKnowledge.extension:productType.valueCode">
        <path value="MedicationKnowledge.extension.valueCode"/>
        <slicing>
          <discriminator>
            <type value="value"/>
            <path value="@valueCode"/>
```

```xml
        </discriminator>
        <rules value="open"/>
      </slicing>
      <short value="Drug Substance"/>
      <min value="1"/>
      <max value="1"/>
      <type>
        <code value="code"/>
      </type>
      <fixedCode value="substance"/>
      <mustSupport value="true"/>
      <isModifier value="false"/>
    </element>
    <element id="MedicationKnowledge.code">
      <path value="MedicationKnowledge.code"/>
      <min value="1"/>
      <max value="*"/>
      <mustSupport value="true"/>
      <isModifier value="false"/>
    </element>
    <element id="MedicationKnowledge.code.coding">
      <path value="MedicationKnowledge.code.coding"/>
      <slicing>
        <discriminator>
          <type value="value"/>
          <path value="system"/>
        </discriminator>
        <rules value="open"/>
      </slicing>
      <mustSupport value="true"/>
      <isModifier value="false"/>
    </element>
    <element id="MedicationKnowledge.code.coding:UNII">
      <path value="MedicationKnowledge.code.coding"/>
      <sliceName value="UNII"/>
      <short value="UNII code"/>
      <definition
                value="The UNII is a non-proprietary, free, unique, unambiguous, non-se
mantic, alphanumeric identifier based on a substance's molecular structure and/or descrip
tive information. [Source: Substance Registration System – Unique identifier] Example: 36
2O9ITL9D Note: If a UNII does not exist, please go to Substance Registration System – Uni
que identifier."/>
      <min value="1"/>
      <max value="1"/>
      <mustSupport value="true"/>
      <isModifier value="false"/>
    </element>
    <element id="MedicationKnowledge.code.coding:UNII.system">
      <path value="MedicationKnowledge.code.coding.system"/>
      <min value="1"/>
      <max value="1"/>
      <type>
        <code value="uri"/>
      </type>
      <fixedUri
                value="http://www.fda.gov/ForIndustry/DataStandards/SubstanceRegistration
System-UniqueIngredientIdentifierUNII/default.html"/>
```

```xml
        <mustSupport value="true"/>
        <isModifier value="false"/>
      </element>
      <element id="MedicationKnowledge.code.coding:UNII.code">
        <path value="MedicationKnowledge.code.coding.code"/>
        <min value="1"/>
        <max value="1"/>
        <mustSupport value="true"/>
        <isModifier value="false"/>
      </element>
      <element id="MedicationKnowledge.code.coding:CASNumber">
        <path value="MedicationKnowledge.code.coding"/>
        <sliceName value="CASNumber"/>
        <short value="CAS number"/>
        <definition
                  value="Chemical Abstract Service (CAS) Registry Numbers (often referred
 to as CAS RNs or CAS Numbers) are used to provide unmistakable identifiers for chemical
substances. A CAS Registry Number itself has no inherent chemical significance but provid
es a way to identify a chemical substance or molecular structure when there are many poss
ible systematic, generic, proprietary or trivial names. [Source: Adapted from CAS.org] Ex
ample: CAS [103-90-2]."/>
        <min value="0"/>
        <max value="1"/>
        <mustSupport value="true"/>
        <isModifier value="false"/>
      </element>
      <element id="MedicationKnowledge.code.coding:CASNumber.system">
        <path value="MedicationKnowledge.code.coding.system"/>
        <min value="1"/>
        <max value="1"/>
        <type>
          <code value="uri"/>
        </type>
        <fixedUri value="https://www.cas.org/"/>
        <mustSupport value="true"/>
        <isModifier value="false"/>
      </element>
      <element id="MedicationKnowledge.code.coding:CASNumber.code">
        <path value="MedicationKnowledge.code.coding.code"/>
        <min value="1"/>
        <max value="1"/>
        <mustSupport value="true"/>
        <isModifier value="false"/>
      </element>
      <element id="MedicationKnowledge.code.coding:INN">
        <path value="MedicationKnowledge.code.coding"/>
        <sliceName value="INN"/>
        <short value="INN"/>
        <definition
                  value="International Nonproprietary Names (INN) is a unique name that i
s globally recognized and is public property. A nonproprietary name is also known as a ge
neric name. [Source: International Nonproprietary Names]."/>
        <min value="0"/>
        <max value="1"/>
        <mustSupport value="true"/>
        <isModifier value="false"/>
      </element>
```

```xml
        <element id="MedicationKnowledge.code.coding:INN.system">
          <path value="MedicationKnowledge.code.coding.system"/>
          <min value="1"/>
          <max value="1"/>
          <type>
            <code value="uri"/>
          </type>
          <fixedUri value="https://www.who.int/medicines/services/inn/en/"/>
          <mustSupport value="true"/>
          <isModifier value="false"/>
        </element>
        <element id="MedicationKnowledge.code.coding:INN.code">
          <path value="MedicationKnowledge.code.coding.code"/>
          <min value="1"/>
          <max value="1"/>
          <mustSupport value="true"/>
          <isModifier value="false"/>
        </element>
        <element id="MedicationKnowledge.code.coding:USAN">
          <path value="MedicationKnowledge.code.coding"/>
          <sliceName value="USAN"/>
          <short value="USAN"/>
          <definition
                   value="A unique nonproprietary name assigned to drugs and biologics by
the United States Adopted Names Council [Source: SME Defined] Example: acetaminophen."/>
          <min value="0"/>
          <max value="1"/>
          <mustSupport value="true"/>
          <isModifier value="false"/>
        </element>
        <element id="MedicationKnowledge.code.coding:USAN.system">
          <path value="MedicationKnowledge.code.coding.system"/>
          <min value="1"/>
          <max value="1"/>
          <type>
            <code value="uri"/>
          </type>
          <fixedUri
                   value="https://www.ama-assn.org/about-ama/united-states-adopted-names"/>
          <mustSupport value="true"/>
          <isModifier value="false"/>
        </element>
        <element id="MedicationKnowledge.code.coding:USAN.code">
          <path value="MedicationKnowledge.code.coding.code"/>
          <min value="1"/>
          <max value="1"/>
          <mustSupport value="true"/>
          <isModifier value="false"/>
        </element>
        <element id="MedicationKnowledge.code.coding:IUPACName">
          <path value="MedicationKnowledge.code.coding"/>
          <sliceName value="IUPACName"/>
          <short value="IUPAC Name"/>
          <definition
                   value="A name assigned to a chemical substance according to the systema
tic nomenclature rules defined by the International Union of Pure and Applied Chemistry (
IUPAC). [Source: SME Defined] Example: N-(4-hydroxyphenyl) acetamide."/>
```

```xml
          <min value="0"/>
          <max value="1"/>
          <mustSupport value="true"/>
          <isModifier value="false"/>
        </element>
        <element id="MedicationKnowledge.code.coding:IUPACName.system">
          <path value="MedicationKnowledge.code.coding.system"/>
          <min value="1"/>
          <max value="1"/>
          <type>
            <code value="uri"/>
          </type>
          <fixedUri
                  value="https://iupac.org/who-we-are/divisions/division-details/inchi/"/>
          <mustSupport value="true"/>
          <isModifier value="false"/>
        </element>
        <element id="MedicationKnowledge.code.coding:IUPACName.code">
          <path value="MedicationKnowledge.code.coding.code"/>
          <min value="1"/>
          <max value="1"/>
          <mustSupport value="true"/>
          <isModifier value="false"/>
        </element>
        <element id="MedicationKnowledge.code.coding:@default">
          <path value="MedicationKnowledge.code.coding"/>
          <sliceName value="@default"/>
          <min value="0"/>
          <max value="*"/>
          <mustSupport value="true"/>
          <isModifier value="false"/>
        </element>
        <element id="MedicationKnowledge.code.coding:@default.code">
          <path value="MedicationKnowledge.code.coding.code"/>
          <short value="Company code"/>
          <definition
                  value="An internal identifier assigned by the sponsor to this drug subs
tance. [Source: SME Defined]."/>
          <min value="1"/>
          <max value="1"/>
          <mustSupport value="true"/>
          <isModifier value="false"/>
        </element>
        <element id="MedicationKnowledge.code.text">
          <path value="MedicationKnowledge.code.text"/>
          <short value="Chemical Name"/>
          <definition
                  value="A commonly used name or a systematic name assigned to the chemic
al or compound. [Source: SME Defined] Examples: acetaminophen; acetamide, N-(4-hydroxyphe
nyl)-; 4hydroxyacetanilide."/>
          <min value="1"/>
          <max value="1"/>
          <mustSupport value="true"/>
          <isModifier value="false"/>
        </element>
        <element id="MedicationKnowledge.ingredient">
          <path value="MedicationKnowledge.ingredient"/>
```

```
            <min value="0"/>
            <max value="*"/>
            <mustSupport value="true"/>
            <isModifier value="false"/>
        </element>
        <element id="MedicationKnowledge.ingredient.itemReference">
            <path value="MedicationKnowledge.ingredient.itemReference"/>
            <min value="1"/>
            <max value="1"/>
            <type>
                <code value="Reference"/>
                <targetProfile
                            value="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/rawingre
dient"/>
            </type>
            <mustSupport value="true"/>
            <isModifier value="false"/>
        </element>
    </differential>
</StructureDefinition>
```

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| Content | Detailed Descriptions | Mappings | Examples | XML |

StructureDefinition: PQCMC_Substance - Mappings

Mappings for the Profile.

Mappings for RIM Mapping (http://hl7.org/v3)

PQCMC_Substance	
MedicationKnowledge	Entity. Role, or Act
text	Act.text?
contained	N/A
extension	N/A
modifierExtension	N/A
code	.code
id	n/a
extension	n/a
coding	union(., ./translation)
coding (UNII)	union(., ./translation)
id	n/a
extension	n/a
system	./codeSystem
version	./codeSystemVersion
code	./code
display	CV.displayName
userSelected	CD.codingRationale
coding (CASNumber)	union(., ./translation)
id	n/a
extension	n/a
system	./codeSystem
version	./codeSystemVersion
code	./code
display	CV.displayName
userSelected	CD.codingRationale
text	./originalText[mediaType/code="text/plain"]/data
status	.statusCode

manufacturer	.player.scopingRole[typeCode=MANU].scoper
doseForm	.formCode
amount	.quantity
relatedMedicationKnowledge	
id	n/a
extension	n/a
modifierExtension	N/A
monograph	
id	n/a
extension	n/a
modifierExtension	N/A
ingredient	
id	n/a
extension	n/a
modifierExtension	N/A
item[x]	.player
isActive	NA
strength	.quantity
cost	
id	n/a
extension	n/a
modifierExtension	N/A
monitoringProgram	
id	n/a
extension	n/a
modifierExtension	N/A
administrationGuidelines	
id	n/a
extension	n/a
modifierExtension	N/A
dosage	
id	n/a
extension	n/a
modifierExtension	N/A
patientCharacteristics	
id	n/a
extension	n/a
modifierExtension	N/A
medicineClassification	
id	n/a
extension	n/a
modifierExtension	N/A

packaging	
id	n/a
extension	n/a
modifierExtension	N/A
drugCharacteristic	
id	n/a
extension	n/a
modifierExtension	N/A
regulatory	
id	n/a
extension	n/a
modifierExtension	N/A
substitution	
id	n/a
extension	n/a
modifierExtension	N/A
schedule	
id	n/a
extension	n/a
modifierExtension	N/A
maxDispense	
id	n/a
extension	n/a
modifierExtension	N/A
kinetics	
id	n/a
extension	n/a
modifierExtension	N/A

Mappings for Mapping to NCPDP SCRIPT 10.6 (http://ncpdp.org/SCRIPT10_6)

PQCMC_Substance	
MedicationKnowledge	
code	coding.code = //element(*,MedicationType)/DrugCoded/ProductCode coding.system = //element(*,MedicationType)/DrugCoded/ProductCodeQualifier coding.display = //element(*,MedicationType)/DrugDescription
manufacturer	no mapping
doseForm	coding.code = //element(*,DrugCodedType)/FormCode coding.system = //element(*,DrugCodedType)/FormSourceCode
ingredient	
item[x]	coding.code = //element(*,MedicationType)/DrugCoded/ProductCode coding.system = //element(*,MedicationType)/DrugCoded/ProductCodeQualifier coding.display = //element(*,MedicationType)/DrugDescription
strength	//element(*,DrugCodedType)/Strength

Mappings for FiveWs Pattern Mapping (http://hl7.org/fhir/fivews)

PQCMC_Substance	
MedicationKnowledge	
code	FiveWs.class
manufacturer	FiveWs.actor

Mappings for HL7 v2 Mapping (http://hl7.org/v2)

PQCMC_Substance	
MedicationKnowledge	
code	RXO-1.1-Requested Give Code.code / RXE-2.1-Give Code.code / RXD-2.1-Dispense/Give Code.code / RXG-4.1-Give Code.code /RXA-5.1-Administered Code.code / RXC-2.1 Component Code
coding	C*E.1-8, C*E.10-22
coding (UNII)	C*E.1-8, C*E.10-22
system	C*E.3
version	C*E.7
code	C*E.1
display	C*E.2 - but note this is not well followed
userSelected	Sometimes implied by being first
coding (CASNumber)	C*E.1-8, C*E.10-22
system	C*E.3
version	C*E.7
code	C*E.1
display	C*E.2 - but note this is not well followed
userSelected	Sometimes implied by being first
text	C*E.9. But note many systems use C*E.2 for this
manufacturer	RXD-20-Substance Manufacturer Name / RXG-21-Substance Manufacturer Name / RXA-17-Substance Manufacturer Name
doseForm	RXO-5-Requested Dosage Form / RXE-6-Give Dosage Form / RXD-6-Actual Dosage Form / RXG-8-Give Dosage Form / RXA-8-Administered Dosage Form
ingredient	
item[x]	RXC-2-Component Code if medication: RXO-1-Requested Give Code / RXE-2-Give Code / RXD-2-Dispense/Give Code / RXG-4-Give Code / RXA-5-Administered Code
strength	RXC-3-Component Amount & RXC-4-Component Units if medication: RXO-2-Requested Give Amount - Minimum & RXO-4-Requested Give Units / RXO-3-Requested Give Amount - Maximum & RXO-4-Requested Give Units / RXO-11-Requested Dispense Amount & RXO-12-Requested Dispense Units / RXE-3-Give Amount - Minimum & RXE-5-Give Units / RXE-4-Give Amount - Maximum & RXE-5-Give Units / RXE-10-Dispense Amount & RXE-10-Dispense Units

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Content | Detailed Descriptions | Mappings | **Examples** | XML

StructureDefinition: PQCMC_Substance - Examples

No examples are currently available for the Profile.

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Content   Detailed Descriptions   Mappings   Examples   XML

StructureDefinition: PQCMC_Substance - XML Profile

XML representation of the rawingredient Profile.

Narrative view of the profile

```
<StructureDefinition xmlns="http://hl7.org/fhir">
  <id value="rawingredient"/>
  <text>
    <status value="generated"/>
    <div xmlns="http://www.w3.org/1999/xhtml"><table border="0" cellpadding="0" cellspaci
ng="0" style="border: 0px #F0F0F0 solid; font-size: 11px; font-family: verdana; vertical-
align: top;"><tr style="border: 1px #F0F0F0 solid; font-size: 11px; font-family: verdana;
 vertical-align: top;"><th style="vertical-align: top; text-align : left; background-colo
r: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><a href="
http://build.fhir.org/formats.html#table" title="The logical name of the element">Name</a
></th><th style="vertical-align: top; text-align : left; background-color: white; border:
 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><a href="http://build.fhir
.org/formats.html#table" title="Information about the use of the element">Flags</a></th><
th style="vertical-align: top; text-align : left; background-color: white; border: 0px #F
0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><a href="http://build.fhir.org/fo
rmats.html#table" title="Minimum and Maximum # of times the the element can appear in the
 instance">Card.</a></th><th style="width: 100px" class="hierarchy"><a href="http://build
.fhir.org/formats.html#table" title="Reference to the type of the element">Type</a></th><
th style="vertical-align: top; text-align : left; background-color: white; border: 0px #F
0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><a href="http://build.fhir.org/fo
rmats.html#table" title="Additional information about the element">Description &amp; Cons
traints</a><span style="float: right"><a href="http://build.fhir.org/formats.html#table"
title="Legend for this format"><img src="http://build.fhir.org/help16.png" alt="doco" sty
le="background-color: inherit"/></a></span></th></tr><tr style="border: 0px #F0F0F0 solid
; padding:0px; vertical-align: top; background-color: white;"><td style="vertical-align:
top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4
px 0px 4px; white-space: nowrap; background-image: url(tbl_bck1.png)" class="hierarchy"><
img src="tbl_spacer.png" alt="." style="background-color: inherit" class="hierarchy"/><im
g src="icon_element.gif" alt="." style="background-color: white; background-color: inheri
t" title="Element" class="hierarchy"/> <a href="rawingredient-definitions.html#Medication
Knowledge" title="Sets minimum expectations for questionnaire support for SDC-conformant
systems, including a number of extensions around display and behavior.">MedicationKnowled
ge</a><a name="MedicationKnowledge"> </a></td><td style="vertical-align: top; text-align
: left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" clas
s="hierarchy"/><td style="vertical-align: top; text-align : left; background-color: white
; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"/><td style="verti
cal-align: top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; pa
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ft; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="h
ierarchy"/></tr>
<tr style="border: 0px #F0F0F0 solid; padding:0px; vertical-align: top; background-color:
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er: 0px #F0F0F0 solid; padding:0px 4px 0px 4px; white-space: nowrap; background-image: ur
l(tbl_bck01.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="background-c
olor: inherit" class="hierarchy"/><img src="tbl_vjoin_end.png" alt="." style="background-
color: inherit" class="hierarchy"/><img src="icon_element.gif" alt="." style="background-
color: white; background-color: inherit" title="Element" class="hierarchy"/> <a href="raw
ingredient-definitions.html#MedicationKnowledge.code">code</a><a name="MedicationKnowledg
e.code"> </a></td><td style="vertical-align: top; text-align : left; background-color: wh
ite; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><span style="p
adding-left: 3px; padding-right: 3px; color: white; background-color: red" title="This el
ement must be supported">S</span></td><td style="vertical-align: top; text-align : left;
background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hiera
rchy">1..*</td><td style="vertical-align: top; text-align : left; background-color: white
; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"/><td style="verti
cal-align: top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; pa
dding:0px 4px 0px 4px" class="hierarchy"/></tr>
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er: 0px #F0F0F0 solid; padding:0px 4px 0px 4px; white-space: nowrap; background-image: ur
l(tbl_bck012.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="background-
color: inherit" class="hierarchy"/><img src="tbl_blank.png" alt="." style="background-col
or: inherit" class="hierarchy"/><img src="tbl_vjoin.png" alt="." style="background-color:
 inherit" class="hierarchy"/><img src="icon_slice.png" alt="." style="background-color: w
hite; background-color: inherit" title="Slice Definition" class="hierarchy"/> <a style="f
ont-style: italic" href="rawingredient-definitions.html#MedicationKnowledge.code.coding">
coding</a><a name="MedicationKnowledge.code.coding"> </a></td><td style="vertical-align:
top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4
px 0px 4px" class="hierarchy"><span style="padding-left: 3px; padding-right: 3px; color:
white; background-color: red; font-style: italic" title="This element must be supported">
S</span></td><td style="vertical-align: top; text-align : left; background-color: white;
border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"/><td style="vertica
l-align: top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padd
ing:0px 4px 0px 4px" class="hierarchy"/><td style="vertical-align: top; text-align : left
; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hie
rarchy"><span style="font-weight:bold; font-style: italic">Slice: </span><span style="fon
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<tr style="border: 0px #F0F0F0 solid; padding:0px; vertical-align: top; background-color:
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l(tbl_bck015.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="background-
color: inherit" class="hierarchy"/><img src="tbl_blank.png" alt="." style="background-col
or: inherit" class="hierarchy"/><img src="tbl_vjoin.png" alt="." style="background-color:
 inherit" class="hierarchy"/><img src="icon_element.gif" alt="." style="background-color:
 white; background-color: inherit" title="Element" class="hierarchy"/> <a href="rawingred
ient-definitions.html#MedicationKnowledge.code.coding:UNII" title="Slice UNII: ">coding</
a><a name="MedicationKnowledge.code.coding"> </a></td><td style="vertical-align: top; tex
t-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4
px" class="hierarchy"><span style="padding-left: 3px; padding-right: 3px; color: white; b
ackground-color: red" title="This element must be supported">S</span></td><td style="vert
ical-align: top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; p
adding:0px 4px 0px 4px" class="hierarchy">1..1</td><td style="vertical-align: top; text-a
lign : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px"
 class="hierarchy"/><td style="vertical-align: top; text-align : left; background-color:
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white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"/></tr>
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l(tbl_bck0150.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="background
-color: inherit" class="hierarchy"/><img src="tbl_blank.png" alt="." style="background-co
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: inherit" class="hierarchy"/><img src="tbl_vjoin_slice.png" alt="." style="background-co
lor: inherit" class="hierarchy"/><img src="icon_primitive.png" alt="." style="background-
color: white; background-color: inherit" title="Primitive Data Type" class="hierarchy"/>
<a href="rawingredient-definitions.html#MedicationKnowledge.code.coding:UNII.system">syst
em</a><a name="MedicationKnowledge.code.coding.system"> </a></td><td style="vertical-alig
n: top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0p
x 4px 0px 4px" class="hierarchy"><span style="padding-left: 3px; padding-right: 3px; colo
r: white; background-color: red" title="This element must be supported">S</span></td><td
style="vertical-align: top; text-align : left; background-color: white; border: 0px #F0F0
F0 solid; padding:0px 4px 0px 4px" class="hierarchy">1..1</td><td style="vertical-align:
top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4
px 0px 4px" class="hierarchy"><a href="http://build.fhir.org/datatypes.html#uri">uri</a><
/td><td style="vertical-align: top; text-align : left; background-color: white; border: 0
px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><span style="font-weight:bol
d">Fixed Value: </span><span style="color: darkgreen">http://todo.org/CodeSystem/UNII</sp
an></td></tr>
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: inherit" class="hierarchy"/><img src="tbl_vjoin_end_slice.png" alt="." style="backgroun
d-color: inherit" class="hierarchy"/><img src="icon_element.gif" alt="." style="backgroun
d-color: white; background-color: inherit" title="Element" class="hierarchy"/> <a href="r
awingredient-definitions.html#MedicationKnowledge.code.coding:UNII.code" title="The UNII
is a non-proprietary, free, unique, unambiguous, non-semantic, alphanumeric identifier ba
sed on a substance's molecular structure and/or descriptive information. [Source: http://
www.fda.gov/ForIndustry/DataStandards/SubstanceRegistrationSystem-UniqueIngredientIdentif
ierUNII/]
Example: 36O9ITL9D
Note: If a UNII does not exist, please go to
http://www.fda.gov/ForIndustry/DataStandards/SubstanceRegistrationSystem-UniqueIngredient
IdentifierUNII/.">code</a><a name="MedicationKnowledge.code.coding.code"> </a></td><td st
yle="vertical-align: top; text-align : left; background-color: white; border: 0px #F0F0F0
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g-right: 3px; color: white; background-color: red" title="This element must be supported"
>S</span></td><td style="vertical-align: top; text-align : left; background-color: white;
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lid; padding:0px 4px 0px 4px" class="hierarchy"/><td style="vertical-align: top; text-ali
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l(tbl_bck015.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="background-
color: inherit" class="hierarchy"/><img src="tbl_blank.png" alt="." style="background-col
or: inherit" class="hierarchy"/><img src="tbl_vjoin.png" alt="." style="background-color:
 inherit" class="hierarchy"/><img src="icon_element.gif" alt="." style="background-color:
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```
white; background-color: inherit" title="Element" class="hierarchy"/> <a href="rawingred
ient-definitions.html#MedicationKnowledge.code.coding:CASNumber" title="Slice CASNumber:
">coding</a><a name="MedicationKnowledge.code.coding"> </a></td><td style="vertical-align
: top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px
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: white; background-color: red" title="This element must be supported">S</span></td><td s
tyle="vertical-align: top; text-align : left; background-color: white; border: 0px #F0F0F
0 solid; padding:0px 4px 0px 4px" class="hierarchy">1..1</td><td style="vertical-align: t
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x 0px 4px" class="hierarchy"/><td style="vertical-align: top; text-align : left; backgrou
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lor: inherit" class="hierarchy"/><img src="tbl_vline.png" alt="." style="background-color
: inherit" class="hierarchy"/><img src="tbl_vjoin_slice.png" alt="." style="background-co
lor: inherit" class="hierarchy"/><img src="icon_primitive.png" alt="." style="background-
color: white; background-color: inherit" title="Primitive Data Type" class="hierarchy"/>
<a href="rawingredient-definitions.html#MedicationKnowledge.code.coding:CASNumber.system"
>system</a><a name="MedicationKnowledge.code.coding.system"> </a></td><td style="vertical
-align: top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; paddi
ng:0px 4px 0px 4px" class="hierarchy"><span style="padding-left: 3px; padding-right: 3px;
 color: white; background-color: red" title="This element must be supported">S</span></td
><td style="vertical-align: top; text-align : left; background-color: white; border: 0px
#F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy">1..1</td><td style="vertical-al
ign: top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:
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er: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><span style="font-weigh
t:bold">Fixed Value: </span><span style="color: darkgreen">http://todo.org/CodeSystem/CAS
Number</span></td></tr>
<tr style="border: 0px #F0F0F0 solid; padding:0px; vertical-align: top; background-color:
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l(tbl_bck0140.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="background
-color: inherit" class="hierarchy"/><img src="tbl_blank.png" alt="." style="background-co
lor: inherit" class="hierarchy"/><img src="tbl_vline.png" alt="." style="background-color
: inherit" class="hierarchy"/><img src="tbl_vjoin_end_slice.png" alt="." style="backgroun
d-color: inherit" class="hierarchy"/><img src="icon_element.gif" alt="." style="backgroun
d-color: white; background-color: inherit" title="Element" class="hierarchy"/> <a href="r
awingredient-definitions.html#MedicationKnowledge.code.coding:CASNumber.code" title="Chem
ical Abstract Service (CAS) Registry Numbers (often referred to as CAS RNs or CAS Numbers
) are used to provide unmistakable identifiers for chemical substances. A CAS Registry Nu
mber itself has no inherent chemical significance but provides a way to identify a chemic
al substance or molecular structure when there are many possible systematic, generic, pro
prietary or trivial names. [Source: Adapted from CAS.org]
Example: CAS [103-90-2].">code</a><a name="MedicationKnowledge.code.coding.code"> </a></t
d><td style="vertical-align: top; text-align : left; background-color: white; border: 0px
 #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><span style="padding-left: 3px
; padding-right: 3px; color: white; background-color: red" title="This element must be su
pported">S</span></td><td style="vertical-align: top; text-align : left; background-color
: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy">1..1</td><
td style="vertical-align: top; text-align : left; background-color: white; border: 0px #F
0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"/><td style="vertical-align: top;
```

```
text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0p
x 4px" class="hierarchy">CAS number</td></tr>
<tr style="border: 0px #F0F0F0 solid; padding:0px; vertical-align: top; background-color:
 white;"><td style="vertical-align: top; text-align : left; background-color: white; bord
er: 0px #F0F0F0 solid; padding:0px 4px 0px 4px; white-space: nowrap; background-image: ur
l(tbl_bck000.png)" class="hierarchy"><img src="tbl_spacer.png" alt="." style="background-
color: inherit" class="hierarchy"/><img src="tbl_blank.png" alt="." style="background-col
or: inherit" class="hierarchy"/><img src="tbl_vjoin_end.png" alt="." style="background-co
lor: inherit" class="hierarchy"/><img src="icon_element.gif" alt="." style="background-co
lor: white; background-color: inherit" title="Element" class="hierarchy"/> <a href="rawin
gredient-definitions.html#MedicationKnowledge.code.text" title="Any ingredient intended f
or use in the manufacture of a drug product, including those that may not appear in such
drug product. [Source: (21 CFR 210.3(b)(3)) PAC-ATLS 1998].">text</a><a name="MedicationK
nowledge.code.text"> </a></td><td style="vertical-align: top; text-align : left; backgrou
nd-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"><s
pan style="padding-left: 3px; padding-right: 3px; color: white; background-color: red" ti
tle="This element must be supported">S</span></td><td style="vertical-align: top; text-al
ign : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px"
class="hierarchy">1..1</td><td style="vertical-align: top; text-align : left; background-
color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px" class="hierarchy"/><td
style="vertical-align: top; text-align : left; background-color: white; border: 0px #F0F0
F0 solid; padding:0px 4px 0px 4px" class="hierarchy">Name</td></tr>
<tr><td colspan="5" class="hierarchy"><br/><a href="http://build.fhir.org/formats.html#ta
ble" title="Legend for this format"><img src="http://build.fhir.org/help16.png" alt="doco
" style="background-color: inherit"/> Documentation for this format</a></td></tr></table>
</div>
  </text>
  <url value="http://fda.gov/cder/fhir/pqcmc/StructureDefinition/rawingredient"/>
  <version value="current"/>
  <name value="PQCMC_Substance"/>
  <status value="draft"/>
  <experimental value="false"/>
  <date value="2018-10-05T00:00:00-04:00"/>
  <publisher value="U.S. FDA - CDER division"/>
  <contact>
    <telecom>
      <system value="url"/>
      <value value="https://www.fda.gov/Drugs/default.htm"/>
    </telecom>
  </contact>
  <description
              value="Describes the protocol for checking the chemical, manufacturing and
 controls associated with a particular drug product."/>
  <fhirVersion value="4.0.0"/>
  <mapping>
    <identity value="rim"/>
    <uri value="http://hl7.org/v3"/>
    <name value="RIM Mapping"/>
  </mapping>
  <mapping>
    <identity value="script10.6"/>
    <uri value="http://ncpdp.org/SCRIPT10_6"/>
    <name value="Mapping to NCPDP SCRIPT 10.6"/>
  </mapping>
  <mapping>
    <identity value="w5"/>
    <uri value="http://hl7.org/fhir/fivews"/>
```

```
      <name value="FiveWs Pattern Mapping"/>
  </mapping>
  <mapping>
    <identity value="v2"/>
    <uri value="http://hl7.org/v2"/>
    <name value="HL7 v2 Mapping"/>
  </mapping>
  <kind value="resource"/>
  <abstract value="false"/>
  <type value="MedicationKnowledge"/>
  <baseDefinition
                value="http://hl7.org/fhir/StructureDefinition/MedicationKnowledge"/>
  <derivation value="constraint"/>
  <snapshot>
    <element id="MedicationKnowledge">
      <path value="MedicationKnowledge"/>
      <short value="Definition of Medication Knowledge"/>
      <definition
                value="Sets minimum expectations for questionnaire support for SDC-conf
ormant systems, including a number of extensions around display and behavior."/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="MedicationKnowledge"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <constraint>
        <key value="dom-2"/>
        <severity value="error"/>
        <human
                value="If the resource is contained in another resource, it SHALL NOT cont
ain nested Resources"/>
        <expression value="contained.contained.empty()"/>
        <xpath value="not(parent::f:contained and f:contained)"/>
        <source value="DomainResource"/>
      </constraint>
      <constraint>
        <key value="dom-4"/>
        <severity value="error"/>
        <human
                value="If a resource is contained in another resource, it SHALL NOT have a
 meta.versionId or a meta.lastUpdated"/>
        <expression
                    value="contained.meta.versionId.empty() and contained.meta.lastUpdate
d.empty()"/>
        <xpath
                value="not(exists(f:contained/*/f:meta/f:versionId)) and not(exists(f:cont
ained/*/f:meta/f:lastUpdated))"/>
        <source value="DomainResource"/>
      </constraint>
      <constraint>
        <key value="dom-3"/>
        <severity value="error"/>
        <human
                value="If the resource is contained in another resource, it SHALL be refer
red to from elsewhere in the resource or SHALL refer to the containing resource"/>
```

```xml
            <expression
                    value="contained.where((('#'+id in (%resource.descendants().r
eference | %resource.descendants().as(canonical) | %resource.descendants().as(uri) | %res
ource.descendants().as(url))) or descendants().where(reference = '#').exists() or
 descendants().where(as(canonical) = '#').exists() or descendants().where(as(cano
nical) = '#').exists()).not()).trace('unmatched', id).empty()"/>
            <xpath
                value="not(exists(for $contained in f:contained return $contained[not(pare
nt::*/descendant::f:reference/@value=concat('#', $contained/*/id/@value) or desce
ndant::f:reference[@value='#'])]))"/>
            <source value="DomainResource"/>
        </constraint>
        <constraint>
            <extension
                    url="http://hl7.org/fhir/StructureDefinition/elementdefinition-bestpra
ctice">
                <valueBoolean value="true"/>
            </extension>
            <extension
                    url="http://hl7.org/fhir/StructureDefinition/elementdefinition-bestpra
ctice-explanation">
                <valueMarkdown
                        value="When a resource has no narrative, only systems that fully
 understand the data can display the resource to a human safely. Including a human readab
le representation in the resource makes for a much more robust eco-system and cheaper han
dling of resources by intermediary systems. Some ecosystems restrict distribution of reso
urces to only those systems that do fully understand the resources, and as a consequence
implementers may believe that the narrative is superfluous. However experience shows that
 such eco-systems often open up to new participants over time."/>
            </extension>
            <key value="dom-6"/>
            <severity value="warning"/>
            <human value="A resource should have narrative for robust management"/>
            <expression value="text.div.exists()"/>
            <xpath value="exists(f:text/h:div)"/>
            <source value="DomainResource"/>
        </constraint>
        <constraint>
            <key value="dom-5"/>
            <severity value="error"/>
            <human
                value="If a resource is contained in another resource, it SHALL NOT have a
 security label"/>
            <expression value="contained.meta.security.empty()"/>
            <xpath value="not(exists(f:contained/*/f:meta/f:security))"/>
            <source value="DomainResource"/>
        </constraint>
        <mustSupport value="false"/>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
            <identity value="rim"/>
            <map value="Entity. Role, or Act"/>
        </mapping>
        <mapping>
            <identity value="rim"/>
            <map value="Todo"/>
```

```
          </mapping>
      </element>
      <element id="MedicationKnowledge.id">
        <path value="MedicationKnowledge.id"/>
        <short value="Logical id of this artifact"/>
        <definition
                  value="The logical id of the resource, as used in the URL for the resou
rce. Once assigned, this value never changes."/>
        <comment
                value="The only time that a resource does not have an id is when it is bei
ng submitted to the server using a create operation."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Resource.id"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="id"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="true"/>
      </element>
      <element id="MedicationKnowledge.meta">
        <path value="MedicationKnowledge.meta"/>
        <short value="Metadata about the resource"/>
        <definition
                  value="The metadata about the resource. This is content that is maintai
ned by the infrastructure. Changes to the content might not always be associated with ver
sion changes to the resource."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Resource.meta"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="Meta"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="true"/>
      </element>
      <element id="MedicationKnowledge.implicitRules">
        <path value="MedicationKnowledge.implicitRules"/>
        <short value="A set of rules under which this content was created"/>
        <definition
                  value="A reference to a set of rules that were followed when the resour
ce was constructed, and which must be understood when processing the content. Often, this
 is a reference to an implementation guide that defines the special rules along with othe
r profiles etc."/>
        <comment
                value="Asserting this rule set restricts the content to be only understood
 by a limited set of trading partners. This inherently limits the usefulness of the data
in the long term. However, the existing health eco-system is highly fractured, and not ye
t ready to define, collect, and exchange data in a generally computable sense. Wherever p
```

```
ossible, implementers and/or specification writers should avoid using this element. Often
, when used, the URL is a reference to an implementation guide that defines these special
 rules as part of it&#39;s narrative along with other profiles, value sets, etc."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="Resource.implicitRules"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="uri"/>
      </type>
      <isModifier value="true"/>
      <isModifierReason
                        value="This element is labeled as a modifier because the implicit
 rules may provide additional knowledge about the resource that modifies it&#39;s meaning
 or interpretation"/>
      <isSummary value="true"/>
    </element>
    <element id="MedicationKnowledge.language">
      <path value="MedicationKnowledge.language"/>
      <short value="Language of the resource content"/>
      <definition value="The base language in which the resource is written."/>
      <comment
              value="Language is provided to support indexing and accessibility (typical
ly, services such as text to speech use the language tag). The html language tag in the n
arrative applies  to the narrative. The language tag on the resource may be used to speci
fy the language of other presentations generated from the data in the resource. Not all t
he content has to be in the base language. The Resource.language should not be assumed to
 apply to the narrative automatically. If a language is specified, it should it also be s
pecified on the div element in the html (see rules in HTML5 for information about the rel
ationship between xml:lang and the html lang attribute)."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="Resource.language"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="code"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <binding>
        <extension
                   url="http://hl7.org/fhir/StructureDefinition/elementdefinition-maxValu
eSet">
          <valueCanonical value="http://hl7.org/fhir/ValueSet/all-languages"/>
        </extension>
        <extension
                   url="http://hl7.org/fhir/StructureDefinition/elementdefinition-binding
Name">
          <valueString value="Language"/>
        </extension>
        <extension
```

```
                    url="http://hl7.org/fhir/StructureDefinition/elementdefinition-isCommo
nBinding">
            <valueBoolean value="true"/>
          </extension>
          <strength value="preferred"/>
          <description value="A human language."/>
          <valueSet value="http://hl7.org/fhir/ValueSet/languages"/>
        </binding>
      </element>
      <element id="MedicationKnowledge.text">
        <path value="MedicationKnowledge.text"/>
        <short value="Text summary of the resource, for human interpretation"/>
        <definition
                    value="A human-readable narrative that contains a summary of the resour
ce and can be used to represent the content of the resource to a human. The narrative nee
d not encode all the structured data, but is required to contain sufficient detail to mak
e it &quot;clinically safe&quot; for a human to just read the narrative. Resource definit
ions may define what content should be represented in the narrative to ensure clinical sa
fety."/>
        <comment
                value="Contained resources do not have narrative. Resources that are not c
ontained SHOULD have a narrative. In some cases, a resource may only have text with littl
e or no additional discrete data (as long as all minOccurs=1 elements are satisfied).  Th
is may be necessary for data from legacy systems where information is captured as a &quot
;text blob&quot; or where text is additionally entered raw or narrated and encoded inform
ation is added later."/>
        <alias value="narrative"/>
        <alias value="html"/>
        <alias value="xhtml"/>
        <alias value="display"/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="DomainResource.text"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="Narrative"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="Act.text?"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.contained">
        <path value="MedicationKnowledge.contained"/>
        <short value="Contained, inline Resources"/>
        <definition
                    value="These resources do not have an independent existence apart from
the resource that contains them - they cannot be identified independently, and nor can th
ey have their own independent transaction scope."/>
        <comment
                value="This should never be done when the content can be identified proper
ly, as once identification is lost, it is extremely difficult (and context dependent) to
```

```xml
restore it again. Contained resources may have profiles and tags In their meta elements,
but SHALL NOT have security labels."/>
      <alias value="inline resources"/>
      <alias value="anonymous resources"/>
      <alias value="contained resources"/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="DomainResource.contained"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Resource"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="N/A"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.extension">
      <path value="MedicationKnowledge.extension"/>
      <short value="Additional content defined by implementations"/>
      <definition
                  value="May be used to represent additional information that is not part
 of the basic definition of the resource. To make the use of extensions safe and manageab
le, there is a strict set of governance  applied to the definition and use of extensions.
 Though any implementer can define an extension, there is a set of requirements that SHAL
L be met as part of the definition of the extension."/>
      <comment
                value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
      <alias value="extensions"/>
      <alias value="user content"/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="DomainResource.extension"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Extension"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="N/A"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.modifierExtension">
      <path value="MedicationKnowledge.modifierExtension"/>
```

```
      <short value="Extensions that cannot be ignored"/>
      <definition
              value="May be used to represent additional information that is not part
 of the basic definition of the resource and that modifies the understanding of the eleme
nt that contains it and/or the understanding of the containing element&#39;s descendants.
 Usually modifier elements provide negation or qualification. To make the use of extensio
ns safe and manageable, there is a strict set of governance applied to the definition and
 use of extensions. Though any implementer is allowed to define an extension, there is a
set of requirements that SHALL be met as part of the definition of the extension. Applica
tions processing a resource are required to check for modifier extensions.

Modifier extensions SHALL NOT change the meaning of any elements on Resource or DomainRes
ource (including cannot change the meaning of modifierExtension itself)."/>
      <comment
              value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
      <requirements
                   value="Modifier extensions allow for extensions that *cannot* be safe
ly ignored to be clearly distinguished from the vast majority of extensions which can be
safely ignored.  This promotes interoperability by eliminating the need for implementers
to prohibit the presence of extensions. For further information, see the [definition of m
odifier extensions](http://build.fhir.org/extensibility.html#modifierExtension)."/>
      <alias value="extensions"/>
      <alias value="user content"/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="DomainResource.modifierExtension"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Extension"/>
      </type>
      <isModifier value="true"/>
      <isModifierReason
                        value="Modifier extensions are expected to modify the meaning or
interpretation of the resource that contains them"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="N/A"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.code">
      <path value="MedicationKnowledge.code"/>
      <short value="Code that identifies this medication"/>
      <definition
              value="A code that specifies this medication, or a textual description
if no code is available. Usage note: This could be a standard medication code such as a c
ode from RxNorm, SNOMED CT, IDMP etc. It could also be a national or local formulary code
, optionally with translations to other code systems."/>
      <comment
              value="Depending on the context of use, the code that was actually selecte
d by the user (prescriber, dispenser, etc.) will have the coding.userSelected set to true
```

```
.  As described in the coding datatype: &quot;A coding may be marked as a &quot;userSelec
ted&quot; if a user selected the particular coded value in a user interface (e.g. the use
r selects an item in a pick-list). If a user selected coding exists, it is the preferred
choice for performing translations etc. Other codes can only be literal translations to a
lternative code systems, or codes at a lower level of granularity (e.g. a generic code fo
r a vendor-specific primary one)."/>
      <min value="1"/>
      <max value="*"/>
      <base>
        <path value="MedicationKnowledge.code"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="CodeableConcept"/>
      </type>
      <mustSupport value="true"/>
      <isModifier value="false"/>
      <isSummary value="true"/>
      <binding>
        <extension
                 url="http://hl7.org/fhir/StructureDefinition/elementdefinition-binding
Name">
          <valueString value="MedicationFormalRepresentation"/>
        </extension>
        <strength value="example"/>
        <description
                   value="A coded concept that defines the type of a medication."/>
        <valueSet value="http://hl7.org/fhir/ValueSet/medication-codes"/>
      </binding>
      <mapping>
        <identity value="script10.6"/>
        <map
            value="coding.code = //element(*,MedicationType)/DrugCoded/ProductCode

coding.system = //element(*,MedicationType)/DrugCoded/ProductCodeQualifier

coding.display = //element(*,MedicationType)/DrugDescription"/>
      </mapping>
      <mapping>
        <identity value="w5"/>
        <map value="FiveWs.class"/>
      </mapping>
      <mapping>
        <identity value="v2"/>
        <map
            value="RXO-1.1-Requested Give Code.code / RXE-2.1-Give Code.code / RXD-2.1-D
ispense/Give Code.code / RXG-4.1-Give Code.code /RXA-5.1-Administered Code.code / RXC-2.1
 Component Code"/>
      </mapping>
      <mapping>
        <identity value="rim"/>
        <map value=".code"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.code.id">
      <path value="MedicationKnowledge.code.id"/>
```

```xml
        <representation value="xmlAttr"/>
        <short value="Unique id for inter-element referencing"/>
        <definition
                   value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Element.id"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="string"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.code.extension">
        <path value="MedicationKnowledge.code.extension"/>
        <slicing>
          <discriminator>
            <type value="value"/>
            <path value="url"/>
          </discriminator>
          <description value="Extensions are always sliced by (at least) url"/>
          <rules value="open"/>
        </slicing>
        <short value="Additional content defined by implementations"/>
        <definition
                   value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
        <comment
                value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
        <alias value="extensions"/>
        <alias value="user content"/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="Element.extension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
        </type>
        <isModifier value="false"/>
```

```xml
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.code.coding">
        <path value="MedicationKnowledge.code.coding"/>
        <slicing>
          <discriminator>
            <type value="value"/>
            <path value="system"/>
          </discriminator>
          <rules value="open"/>
        </slicing>
        <short value="Code defined by a terminology system"/>
        <definition value="A reference to a code defined by a terminology system."/>
        <comment
                  value="Codes may be defined very casually in enumerations, or code lists,
up to very formal definitions such as SNOMED CT - see the HL7 v3 Core Principles for more
 information.  Ordering of codings is undefined and SHALL NOT be used to infer meaning. G
enerally, at most only one of the coding values will be labeled as UserSelected = true."/
>
        <requirements
                     value="Allows for alternative encodings within a code system, and tra
nslations to other code systems."/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="CodeableConcept.coding"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Coding"/>
        </type>
        <mustSupport value="true"/>
        <isModifier value="false"/>
        <isSummary value="true"/>
        <mapping>
          <identity value="v2"/>
          <map value="C*E.1-8, C*E.10-22"/>
        </mapping>
        <mapping>
          <identity value="rim"/>
          <map value="union(., ./translation)"/>
        </mapping>
        <mapping>
          <identity value="orim"/>
          <map value="fhir:CodeableConcept.coding rdfs:subPropertyOf dt:CD.coding"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.code.coding:UNII">
        <path value="MedicationKnowledge.code.coding"/>
        <sliceName value="UNII"/>
        <short value="Code defined by a terminology system"/>
        <definition value="A reference to a code defined by a terminology system."/>
```

```xml
      <comment
                value="Codes may be defined very casually in enumerations, or code lists,
up to very formal definitions such as SNOMED CT - see the HL7 v3 Core Principles for more
 information.  Ordering of codings is undefined and SHALL NOT be used to infer meaning. G
enerally, at most only one of the coding values will be labeled as UserSelected = true."/
>
      <requirements
                    value="Allows for alternative encodings within a code system, and tra
nslations to other code systems."/>
      <min value="1"/>
      <max value="1"/>
      <base>
        <path value="CodeableConcept.coding"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Coding"/>
      </type>
      <mustSupport value="true"/>
      <isModifier value="false"/>
      <isSummary value="true"/>
      <mapping>
        <identity value="v2"/>
        <map value="C*E.1-8, C*E.10-22"/>
      </mapping>
      <mapping>
        <identity value="rim"/>
        <map value="union(., ./translation)"/>
      </mapping>
      <mapping>
        <identity value="orim"/>
        <map value="fhir:CodeableConcept.coding rdfs:subPropertyOf dt:CD.coding"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.code.coding:UNII.id">
      <path value="MedicationKnowledge.code.coding.id"/>
      <representation value="xmlAttr"/>
      <short value="Unique id for inter-element referencing"/>
      <definition
                value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="Element.id"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="string"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="n/a"/>
```

```
        </mapping>
      </element>
      <element id="MedicationKnowledge.code.coding:UNII.extension">
        <path value="MedicationKnowledge.code.coding.extension"/>
        <slicing>
          <discriminator>
            <type value="value"/>
            <path value="url"/>
          </discriminator>
          <description value="Extensions are always sliced by (at least) url"/>
          <rules value="open"/>
        </slicing>
        <short value="Additional content defined by implementations"/>
        <definition
                  value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
        <comment
                value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
        <alias value="extensions"/>
        <alias value="user content"/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="Element.extension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.code.coding:UNII.system">
        <path value="MedicationKnowledge.code.coding.system"/>
        <short value="Identity of the terminology system"/>
        <definition
                  value="The identification of the code system that defines the meaning o
f the symbol in the code."/>
        <comment
                value="The URI may be an OID (urn:oid:...) or a UUID (urn:uuid:...).  OIDs
 and UUIDs SHALL be references to the HL7 OID registry. Otherwise, the URI should come fr
om HL7&#39;s list of FHIR defined special URIs or it should reference to some definition
that establishes the system clearly and unambiguously."/>
        <requirements
                  value="Need to be unambiguous about the source of the definition of t
he symbol."/>
```

```xml
          <min value="1"/>
          <max value="1"/>
          <base>
            <path value="Coding.system"/>
            <min value="0"/>
            <max value="1"/>
          </base>
          <type>
            <code value="uri"/>
          </type>
          <fixedUri value="http://todo.org/CodeSystem/UNII"/>
          <mustSupport value="true"/>
          <isModifier value="false"/>
          <isSummary value="true"/>
          <mapping>
            <identity value="v2"/>
            <map value="C*E.3"/>
          </mapping>
          <mapping>
            <identity value="rim"/>
            <map value="./codeSystem"/>
          </mapping>
          <mapping>
            <identity value="orim"/>
            <map
                 value="fhir:Coding.system rdfs:subPropertyOf dt:CDCoding.codeSystem"/>
          </mapping>
        </element>
        <element id="MedicationKnowledge.code.coding:UNII.version">
          <path value="MedicationKnowledge.code.coding.version"/>
          <short value="Version of the system - if relevant"/>
          <definition
                      value="The version of the code system which was used when choosing this
 code. Note that a well-maintained code system does not need the version reported, becaus
e the meaning of codes is consistent across versions. However this cannot consistently be
 assured, and when the meaning is not guaranteed to be consistent, the version SHOULD be
exchanged."/>
          <comment
                   value="Where the terminology does not clearly define what string should be
 used to identify code system versions, the recommendation is to use the date (expressed
in FHIR date format) on which that version was officially published as the version date."
/>
          <min value="0"/>
          <max value="1"/>
          <base>
            <path value="Coding.version"/>
            <min value="0"/>
            <max value="1"/>
          </base>
          <type>
            <code value="string"/>
          </type>
          <isModifier value="false"/>
          <isSummary value="true"/>
          <mapping>
            <identity value="v2"/>
            <map value="C*E.7"/>
```

```xml
        </mapping>
        <mapping>
          <identity value="rim"/>
          <map value="./codeSystemVersion"/>
        </mapping>
        <mapping>
          <identity value="orim"/>
          <map
              value="fhir:Coding.version rdfs:subPropertyOf dt:CDCoding.codeSystemVersion"
/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.code.coding:UNII.code">
        <path value="MedicationKnowledge.code.coding.code"/>
        <short value="UNII code"/>
        <definition
                value="The UNII is a non-proprietary, free, unique, unambiguous, non-se
mantic, alphanumeric identifier based on a substance's molecular structure and/or descrip
tive information. [Source: http://www.fda.gov/ForIndustry/DataStandards/SubstanceRegistra
tionSystem-UniqueIngredientIdentifierUNII/]
Example: 362O9ITL9D
Note: If a UNII does not exist, please go to
http://www.fda.gov/ForIndustry/DataStandards/SubstanceRegistrationSystem-UniqueIngredient
IdentifierUNII/."/>
        <requirements value="Need to refer to a particular code in the system."/>
        <min value="1"/>
        <max value="1"/>
        <base>
          <path value="Coding.code"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="code"/>
        </type>
        <mustSupport value="true"/>
        <isModifier value="false"/>
        <isSummary value="true"/>
        <mapping>
          <identity value="v2"/>
          <map value="C*E.1"/>
        </mapping>
        <mapping>
          <identity value="rim"/>
          <map value="./code"/>
        </mapping>
        <mapping>
          <identity value="orim"/>
          <map value="fhir:Coding.code rdfs:subPropertyOf dt:CDCoding.code"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.code.coding:UNII.display">
        <extension
                url="http://hl7.org/fhir/StructureDefinition/elementdefinition-translata
ble">
          <valueBoolean value="true"/>
        </extension>
```

```
        <path value="MedicationKnowledge.code.coding.display"/>
        <short value="Representation defined by the system"/>
        <definition
                  value="A representation of the meaning of the code in the system, follo
wing the rules of the system."/>
        <requirements
                     value="Need to be able to carry a human-readable meaning of the code
for readers that do not know  the system."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Coding.display"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="string"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="true"/>
        <mapping>
          <identity value="v2"/>
          <map value="C*E.2 - but note this is not well followed"/>
        </mapping>
        <mapping>
          <identity value="rim"/>
          <map value="CV.displayName"/>
        </mapping>
        <mapping>
          <identity value="orim"/>
          <map
              value="fhir:Coding.display rdfs:subPropertyOf dt:CDCoding.displayName"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.code.coding:UNII.userSelected">
        <path value="MedicationKnowledge.code.coding.userSelected"/>
        <short value="If this coding was chosen directly by the user"/>
        <definition
                  value="Indicates that this coding was chosen by a user directly - e.g.
off a pick list of available items (codes or displays)."/>
        <comment
                value="Amongst a set of alternatives, a directly chosen code is the most a
ppropriate starting point for new translations. There is some ambiguity about what exactl
y &#39;directly chosen&#39; implies, and trading partner agreement may be needed to clari
fy the use of this element and its consequences more completely."/>
        <requirements
                     value="This has been identified as a clinical safety criterium - that
 this exact system/code pair was chosen explicitly, rather than inferred by the system ba
sed on some rules or language processing."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Coding.userSelected"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
```

```xml
          <code value="boolean"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="true"/>
        <mapping>
          <identity value="v2"/>
          <map value="Sometimes implied by being first"/>
        </mapping>
        <mapping>
          <identity value="rim"/>
          <map value="CD.codingRationale"/>
        </mapping>
        <mapping>
          <identity value="orim"/>
          <map
              value="fhir:Coding.userSelected fhir:mapsTo dt:CDCoding.codingRationale. fhi
r:Coding.userSelected fhir:hasMap fhir:Coding.userSelected.map. fhir:Coding.userSelected.
map a fhir:Map;   fhir:target dt:CDCoding.codingRationale. fhir:Coding.userSelected\#true
 a [     fhir:source &quot;true&quot;;       fhir:target dt:CDCoding.codingRationale\#0    ]
"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.code.coding:CASNumber">
        <path value="MedicationKnowledge.code.coding"/>
        <sliceName value="CASNumber"/>
        <short value="Code defined by a terminology system"/>
        <definition value="A reference to a code defined by a terminology system."/>
        <comment
                value="Codes may be defined very casually in enumerations, or code lists,
up to very formal definitions such as SNOMED CT - see the HL7 v3 Core Principles for more
 information.  Ordering of codings is undefined and SHALL NOT be used to infer meaning. G
enerally, at most only one of the coding values will be labeled as UserSelected = true."/
>
        <requirements
                    value="Allows for alternative encodings within a code system, and tra
nslations to other code systems."/>
        <min value="1"/>
        <max value="1"/>
        <base>
          <path value="CodeableConcept.coding"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Coding"/>
        </type>
        <mustSupport value="true"/>
        <isModifier value="false"/>
        <isSummary value="true"/>
        <mapping>
          <identity value="v2"/>
          <map value="C*E.1-8, C*E.10-22"/>
        </mapping>
        <mapping>
          <identity value="rim"/>
          <map value="union(., ./translation)"/>
        </mapping>
```

```xml
      <mapping>
        <identity value="orim"/>
        <map value="fhir:CodeableConcept.coding rdfs:subPropertyOf dt:CD.coding"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.code.coding:CASNumber.id">
      <path value="MedicationKnowledge.code.coding.id"/>
      <representation value="xmlAttr"/>
      <short value="Unique id for inter-element referencing"/>
      <definition
                  value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="Element.id"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="string"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="n/a"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.code.coding:CASNumber.extension">
      <path value="MedicationKnowledge.code.coding.extension"/>
      <slicing>
        <discriminator>
          <type value="value"/>
          <path value="url"/>
        </discriminator>
        <description value="Extensions are always sliced by (at least) url"/>
        <rules value="open"/>
      </slicing>
      <short value="Additional content defined by implementations"/>
      <definition
                  value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
      <comment
                value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
      <alias value="extensions"/>
      <alias value="user content"/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="Element.extension"/>
```

```xml
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.code.coding:CASNumber.system">
        <path value="MedicationKnowledge.code.coding.system"/>
        <short value="Identity of the terminology system"/>
        <definition
                    value="The identification of the code system that defines the meaning o
f the symbol in the code."/>
        <comment
                 value="The URI may be an OID (urn:oid:...) or a UUID (urn:uuid:...).  OIDs
 and UUIDs SHALL be references to the HL7 OID registry. Otherwise, the URI should come fr
om HL7&#39;s list of FHIR defined special URIs or it should reference to some definition
that establishes the system clearly and unambiguously."/>
        <requirements
                       value="Need to be unambiguous about the source of the definition of t
he symbol."/>
        <min value="1"/>
        <max value="1"/>
        <base>
          <path value="Coding.system"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="uri"/>
        </type>
        <fixedUri value="http://todo.org/CodeSystem/CASNumber"/>
        <mustSupport value="true"/>
        <isModifier value="false"/>
        <isSummary value="true"/>
        <mapping>
          <identity value="v2"/>
          <map value="C*E.3"/>
        </mapping>
        <mapping>
          <identity value="rim"/>
          <map value="./codeSystem"/>
        </mapping>
        <mapping>
          <identity value="orim"/>
          <map
               value="fhir:Coding.system rdfs:subPropertyOf dt:CDCoding.codeSystem"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.code.coding:CASNumber.version">
        <path value="MedicationKnowledge.code.coding.version"/>
```

```
        <short value="Version of the system - if relevant"/>
        <definition
                  value="The version of the code system which was used when choosing this
 code. Note that a well-maintained code system does not need the version reported, becaus
e the meaning of codes is consistent across versions. However this cannot consistently be
 assured, and when the meaning is not guaranteed to be consistent, the version SHOULD be
exchanged."/>
        <comment
                value="Where the terminology does not clearly define what string should be
 used to identify code system versions, the recommendation is to use the date (expressed
in FHIR date format) on which that version was officially published as the version date."
/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Coding.version"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="string"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="true"/>
        <mapping>
          <identity value="v2"/>
          <map value="C*E.7"/>
        </mapping>
        <mapping>
          <identity value="rim"/>
          <map value="./codeSystemVersion"/>
        </mapping>
        <mapping>
          <identity value="orim"/>
          <map
              value="fhir:Coding.version rdfs:subPropertyOf dt:CDCoding.codeSystemVersion"
/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.code.coding:CASNumber.code">
        <path value="MedicationKnowledge.code.coding.code"/>
        <short value="CAS number"/>
        <definition
                  value="Chemical Abstract Service (CAS) Registry Numbers (often referred
 to as CAS RNs or CAS Numbers) are used to provide unmistakable identifiers for chemical
substances. A CAS Registry Number itself has no inherent chemical significance but provid
es a way to identify a chemical substance or molecular structure when there are many poss
ible systematic, generic, proprietary or trivial names. [Source: Adapted from CAS.org]
Example: CAS [103-90-2]."/>
        <requirements value="Need to refer to a particular code in the system."/>
        <min value="1"/>
        <max value="1"/>
        <base>
          <path value="Coding.code"/>
          <min value="0"/>
          <max value="1"/>
        </base>
```

```xml
        <type>
          <code value="code"/>
        </type>
        <mustSupport value="true"/>
        <isModifier value="false"/>
        <isSummary value="true"/>
        <mapping>
          <identity value="v2"/>
          <map value="C*E.1"/>
        </mapping>
        <mapping>
          <identity value="rim"/>
          <map value="./code"/>
        </mapping>
        <mapping>
          <identity value="orim"/>
          <map value="fhir:Coding.code rdfs:subPropertyOf dt:CDCoding.code"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.code.coding:CASNumber.display">
        <extension
                  url="http://hl7.org/fhir/StructureDefinition/elementdefinition-translata
ble">
          <valueBoolean value="true"/>
        </extension>
        <path value="MedicationKnowledge.code.coding.display"/>
        <short value="Representation defined by the system"/>
        <definition
                    value="A representation of the meaning of the code in the system, follo
wing the rules of the system."/>
        <requirements
                      value="Need to be able to carry a human-readable meaning of the code
for readers that do not know  the system."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Coding.display"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="string"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="true"/>
        <mapping>
          <identity value="v2"/>
          <map value="C*E.2 - but note this is not well followed"/>
        </mapping>
        <mapping>
          <identity value="rim"/>
          <map value="CV.displayName"/>
        </mapping>
        <mapping>
          <identity value="orim"/>
          <map
              value="fhir:Coding.display rdfs:subPropertyOf dt:CDCoding.displayName"/>
```

```xml
          </mapping>
        </element>
        <element id="MedicationKnowledge.code.coding:CASNumber.userSelected">
          <path value="MedicationKnowledge.code.coding.userSelected"/>
          <short value="If this coding was chosen directly by the user"/>
          <definition
                    value="Indicates that this coding was chosen by a user directly - e.g.
off a pick list of available items (codes or displays)."/>
          <comment
                  value="Amongst a set of alternatives, a directly chosen code is the most a
ppropriate starting point for new translations. There is some ambiguity about what exactl
y &#39;directly chosen&#39; implies, and trading partner agreement may be needed to clari
fy the use of this element and its consequences more completely."/>
          <requirements
                      value="This has been identified as a clinical safety criterium - that
 this exact system/code pair was chosen explicitly, rather than inferred by the system ba
sed on some rules or language processing."/>
          <min value="0"/>
          <max value="1"/>
          <base>
            <path value="Coding.userSelected"/>
            <min value="0"/>
            <max value="1"/>
          </base>
          <type>
            <code value="boolean"/>
          </type>
          <isModifier value="false"/>
          <isSummary value="true"/>
          <mapping>
            <identity value="v2"/>
            <map value="Sometimes implied by being first"/>
          </mapping>
          <mapping>
            <identity value="rim"/>
            <map value="CD.codingRationale"/>
          </mapping>
          <mapping>
            <identity value="orim"/>
            <map
                  value="fhir:Coding.userSelected fhir:mapsTo dt:CDCoding.codingRationale. fhi
r:Coding.userSelected fhir:hasMap fhir:Coding.userSelected.map. fhir:Coding.userSelected.
map a fhir:Map;   fhir:target dt:CDCoding.codingRationale. fhir:Coding.userSelected\#true
 a [    fhir:source &quot;true&quot;;     fhir:target dt:CDCoding.codingRationale\#O    ]
"/>
          </mapping>
        </element>
        <element id="MedicationKnowledge.code.text">
          <extension
                    url="http://hl7.org/fhir/StructureDefinition/elementdefinition-translata
ble">
            <valueBoolean value="true"/>
          </extension>
          <path value="MedicationKnowledge.code.text"/>
          <short value="Name"/>
          <definition
                    value="Any ingredient intended for use in the manufacture of a drug pro
```

```
duct, including those that may not appear in such drug product. [Source: (21 CFR 210.3(b)
(3)) PAC-ATLS 1998]."/>
      <comment
              value="Very often the text is the same as a displayName of one of the codi
ngs."/>
      <requirements
                    value="The codes from the terminologies do not always capture the cor
rect meaning with all the nuances of the human using them, or sometimes there is no appro
priate code at all. In these cases, the text is used to capture the full meaning of the s
ource."/>
      <min value="1"/>
      <max value="1"/>
      <base>
        <path value="CodeableConcept.text"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="string"/>
      </type>
      <mustSupport value="true"/>
      <isModifier value="false"/>
      <isSummary value="true"/>
      <mapping>
        <identity value="v2"/>
        <map value="C*E.9. But note many systems use C*E.2 for this"/>
      </mapping>
      <mapping>
        <identity value="rim"/>
        <map value="./originalText[mediaType/code=&quot;text/plain&quot;]/data"/>
      </mapping>
      <mapping>
        <identity value="orim"/>
        <map
             value="fhir:CodeableConcept.text rdfs:subPropertyOf dt:CD.originalText"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.status">
      <path value="MedicationKnowledge.status"/>
      <short value="active | inactive | entered-in-error"/>
      <definition
                 value="A code to indicate if the medication is in active use.  The stat
us refers to the validity about the information of the medication and not to its medicina
l properties."/>
      <comment
              value="This status is intended to identify if the medication in a local sy
stem is in active use within a drug database or inventory.  For example, a pharmacy syste
m may create a new drug file record for a compounded product &quot;ABC Hospital Special C
ream&quot; with an active status.  At some point in the future, it may be determined that
 the drug record was created with an error and the status is changed to &quot;entered in
error&quot;.   This status is not intended to specify if a medication is part of a partic
ular formulary.  It is possible that the drug record may be referenced by multiple formul
aries or catalogues and each of those entries would have a separate status."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="MedicationKnowledge.status"/>
```

```xml
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="code"/>
        </type>
        <isModifier value="true"/>
        <isModifierReason
                        value="This element changes the interpretation of all descriptive
 attributes."/>
        <isSummary value="true"/>
        <binding>
          <extension
                    url="http://hl7.org/fhir/StructureDefinition/elementdefinition-binding
Name">
            <valueString value="MedicationKnowledgeStatus"/>
          </extension>
          <strength value="required"/>
          <description
                       value="A coded concept defining if the medication is in active use."
/>
          <valueSet
                    value="http://hl7.org/fhir/ValueSet/medicationknowledge-status|4.0.0"/>
        </binding>
        <mapping>
          <identity value="rim"/>
          <map value=".statusCode"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.manufacturer">
        <path value="MedicationKnowledge.manufacturer"/>
        <short value="Manufacturer of the item"/>
        <definition
                    value="Describes the details of the manufacturer of the medication prod
uct.  This is not intended to represent the distributor of a medication product."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="MedicationKnowledge.manufacturer"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="Reference"/>
          <targetProfile
                         value="http://hl7.org/fhir/StructureDefinition/Organization"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="true"/>
        <mapping>
          <identity value="script10.6"/>
          <map value="no mapping"/>
        </mapping>
        <mapping>
          <identity value="w5"/>
          <map value="FiveWs.actor"/>
        </mapping>
```

```xml
      <mapping>
        <identity value="v2"/>
        <map
              value="RXD-20-Substance Manufacturer Name / RXG-21-Substance Manufacturer Na
me / RXA-17-Substance Manufacturer Name"/>
      </mapping>
      <mapping>
        <identity value="rim"/>
        <map value=".player.scopingRole[typeCode=MANU].scoper"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.doseForm">
      <path value="MedicationKnowledge.doseForm"/>
      <short value="powder | tablets | capsule +"/>
      <definition
                  value="Describes the form of the item.  Powder; tablets; capsule."/>
      <comment
                value="When Medication is referenced from MedicationRequest, this is the o
rdered form.  When Medication is referenced within MedicationDispense, this is the dispen
sed form.  When Medication is referenced within MedicationAdministration, this is adminis
tered form."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="MedicationKnowledge.doseForm"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="CodeableConcept"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <binding>
        <extension
                  url="http://hl7.org/fhir/StructureDefinition/elementdefinition-binding
Name">
          <valueString value="MedicationForm"/>
        </extension>
        <strength value="example"/>
        <description value="A coded concept defining the form of a medication."/>
        <valueSet value="http://hl7.org/fhir/ValueSet/medication-form-codes"/>
      </binding>
      <mapping>
        <identity value="script10.6"/>
        <map
              value="coding.code =  //element(*,DrugCodedType)/FormCode

coding.system = //element(*,DrugCodedType)/FormSourceCode"/>
      </mapping>
      <mapping>
        <identity value="v2"/>
        <map
              value="RXO-5-Requested Dosage Form / RXE-6-Give Dosage Form / RXD-6-Actual D
osage Form / RXG-8-Give Dosage Form / RXA-8-Administered Dosage Form"/>
      </mapping>
      <mapping>
```

```xml
          <identity value="rim"/>
          <map value=".formCode"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.amount">
        <path value="MedicationKnowledge.amount"/>
        <short value="Amount of drug in package"/>
        <definition
                  value="Specific amount of the drug in the packaged product.  For exampl
e, when specifying a product that has the same strength (For example, Insulin glargine 10
0 unit per mL solution for injection), this attribute provides additional clarification o
f the package amount (For example, 3 mL, 10mL, etc.)."/>
        <comment
                value="This is the quantity of medication in a package.  To specify the st
rength of the medication, the Ingredient.strength attribute is used."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="MedicationKnowledge.amount"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="Quantity"/>
          <profile value="http://hl7.org/fhir/StructureDefinition/SimpleQuantity"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="true"/>
        <mapping>
          <identity value="rim"/>
          <map value=".quantity"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.synonym">
        <path value="MedicationKnowledge.synonym"/>
        <short value="Additional names for a medication"/>
        <definition
                  value="Additional names for a medication, for example, the name(s) give
n to a medication in different countries.  For example, acetaminophen and paracetamol or
salbutamol and albuterol."/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="MedicationKnowledge.synonym"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="string"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="true"/>
      </element>
      <element id="MedicationKnowledge.relatedMedicationKnowledge">
        <path value="MedicationKnowledge.relatedMedicationKnowledge"/>
        <short value="Associated or related medication information"/>
        <definition value="Associated or related knowledge about a medication."/>
```

```xml
          <min value="0"/>
          <max value="*"/>
          <base>
            <path value="MedicationKnowledge.relatedMedicationKnowledge"/>
            <min value="0"/>
            <max value="*"/>
          </base>
          <type>
            <code value="BackboneElement"/>
          </type>
          <constraint>
            <key value="ele-1"/>
            <severity value="error"/>
            <human value="All FHIR elements must have a @value or children"/>
            <expression value="hasValue() or (children().count() &gt; id.count())"/>
            <xpath value="@value|f:*|h:div"/>
            <source value="Element"/>
          </constraint>
          <isModifier value="false"/>
          <isSummary value="false"/>
      </element>
      <element id="MedicationKnowledge.relatedMedicationKnowledge.id">
          <path value="MedicationKnowledge.relatedMedicationKnowledge.id"/>
          <representation value="xmlAttr"/>
          <short value="Unique id for inter-element referencing"/>
          <definition
                    value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
          <min value="0"/>
          <max value="1"/>
          <base>
            <path value="Element.id"/>
            <min value="0"/>
            <max value="1"/>
          </base>
          <type>
            <code value="string"/>
          </type>
          <isModifier value="false"/>
          <isSummary value="false"/>
          <mapping>
            <identity value="rim"/>
            <map value="n/a"/>
          </mapping>
      </element>
      <element id="MedicationKnowledge.relatedMedicationKnowledge.extension">
          <path value="MedicationKnowledge.relatedMedicationKnowledge.extension"/>
          <short value="Additional content defined by implementations"/>
          <definition
                    value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
          <comment
                  value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
```

```
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
      <alias value="extensions"/>
      <alias value="user content"/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="Element.extension"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Extension"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="n/a"/>
      </mapping>
    </element>
    <element
            id="MedicationKnowledge.relatedMedicationKnowledge.modifierExtension">
      <path
            value="MedicationKnowledge.relatedMedicationKnowledge.modifierExtension"/>
      <short value="Extensions that cannot be ignored even if unrecognized"/>
      <definition
                value="May be used to represent additional information that is not part
 of the basic definition of the element and that modifies the understanding of the elemen
t in which it is contained and/or the understanding of the containing element&#39;s desce
ndants. Usually modifier elements provide negation or qualification. To make the use of e
xtensions safe and manageable, there is a strict set of governance applied to the definit
ion and use of extensions. Though any implementer can define an extension, there is a set
 of requirements that SHALL be met as part of the definition of the extension. Applicatio
ns processing a resource are required to check for modifier extensions.

Modifier extensions SHALL NOT change the meaning of any elements on Resource or DomainRes
ource (including cannot change the meaning of modifierExtension itself)."/>
      <comment
                value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
      <requirements
                    value="Modifier extensions allow for extensions that *cannot* be safe
ly ignored to be clearly distinguished from the vast majority of extensions which can be
safely ignored.  This promotes interoperability by eliminating the need for implementers
to prohibit the presence of extensions. For further information, see the [definition of m
odifier extensions](http://build.fhir.org/extensibility.html#modifierExtension)."/>
      <alias value="extensions"/>
      <alias value="user content"/>
      <alias value="modifiers"/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="BackboneElement.modifierExtension"/>
        <min value="0"/>
```

```xml
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
        </type>
        <isModifier value="true"/>
        <isModifierReason
                          value="Modifier extensions are expected to modify the meaning or
interpretation of the element that contains them"/>
        <isSummary value="true"/>
        <mapping>
          <identity value="rim"/>
          <map value="N/A"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.relatedMedicationKnowledge.type">
        <path value="MedicationKnowledge.relatedMedicationKnowledge.type"/>
        <short value="Category of medicationKnowledge"/>
        <definition
                   value="The category of the associated medication knowledge reference."/
>
        <min value="1"/>
        <max value="1"/>
        <base>
          <path value="MedicationKnowledge.relatedMedicationKnowledge.type"/>
          <min value="1"/>
          <max value="1"/>
        </base>
        <type>
          <code value="CodeableConcept"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="MedicationKnowledge.relatedMedicationKnowledge.reference">
        <path value="MedicationKnowledge.relatedMedicationKnowledge.reference"/>
        <short
              value="Associated documentation about the associated medication knowledge"/>
        <definition
                   value="Associated documentation about the associated medication knowled
ge."/>
        <min value="1"/>
        <max value="*"/>
        <base>
          <path value="MedicationKnowledge.relatedMedicationKnowledge.reference"/>
          <min value="1"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Reference"/>
          <targetProfile
                         value="http://hl7.org/fhir/StructureDefinition/MedicationKnowledge
"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
```

```
    <element id="MedicationKnowledge.associatedMedication">
      <path value="MedicationKnowledge.associatedMedication"/>
      <short
            value="A medication resource that is associated with this medication"/>
      <definition
                  value="Associated or related medications.  For example, if the medicati
on is a branded product (e.g. Crestor), this is the Therapeutic Moeity (e.g. Rosuvastatin
) or if this is a generic medication (e.g. Rosuvastatin), this would link to a branded pr
oduct (e.g. Crestor)."/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="MedicationKnowledge.associatedMedication"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Reference"/>
        <targetProfile
                      value="http://hl7.org/fhir/StructureDefinition/Medication"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="MedicationKnowledge.productType">
      <path value="MedicationKnowledge.productType"/>
      <short value="Category of the medication or product"/>
      <definition
                  value="Category of the medication or product (e.g. branded product, the
rapeutic moeity, generic product, innovator product, etc.)."/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="MedicationKnowledge.productType"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="CodeableConcept"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="MedicationKnowledge.monograph">
      <path value="MedicationKnowledge.monograph"/>
      <short value="Associated documentation about the medication"/>
      <definition value="Associated documentation about the medication."/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="MedicationKnowledge.monograph"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="BackboneElement"/>
      </type>
```

```xml
        <constraint>
          <key value="ele-1"/>
          <severity value="error"/>
          <human value="All FHIR elements must have a @value or children"/>
          <expression value="hasValue() or (children().count() &gt; id.count())"/>
          <xpath value="@value|f:*|h:div"/>
          <source value="Element"/>
        </constraint>
        <isModifier value="false"/>
        <isSummary value="false"/>
    </element>
    <element id="MedicationKnowledge.monograph.id">
        <path value="MedicationKnowledge.monograph.id"/>
        <representation value="xmlAttr"/>
        <short value="Unique id for inter-element referencing"/>
        <definition
                  value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Element.id"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="string"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
    </element>
    <element id="MedicationKnowledge.monograph.extension">
        <path value="MedicationKnowledge.monograph.extension"/>
        <short value="Additional content defined by implementations"/>
        <definition
                  value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
        <comment
                value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
        <alias value="extensions"/>
        <alias value="user content"/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="Element.extension"/>
          <min value="0"/>
          <max value="*"/>
```

```xml
        </base>
        <type>
          <code value="Extension"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.monograph.modifierExtension">
        <path value="MedicationKnowledge.monograph.modifierExtension"/>
        <short value="Extensions that cannot be ignored even if unrecognized"/>
        <definition
                   value="May be used to represent additional information that is not part
 of the basic definition of the element and that modifies the understanding of the elemen
t in which it is contained and/or the understanding of the containing element&#39;s desce
ndants. Usually modifier elements provide negation or qualification. To make the use of e
xtensions safe and manageable, there is a strict set of governance applied to the definit
ion and use of extensions. Though any implementer can define an extension, there is a set
 of requirements that SHALL be met as part of the definition of the extension. Applicatio
ns processing a resource are required to check for modifier extensions.

Modifier extensions SHALL NOT change the meaning of any elements on Resource or DomainRes
ource (including cannot change the meaning of modifierExtension itself)."/>
        <comment
               value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
        <requirements
                     value="Modifier extensions allow for extensions that *cannot* be safe
ly ignored to be clearly distinguished from the vast majority of extensions which can be
safely ignored.  This promotes interoperability by eliminating the need for implementers
to prohibit the presence of extensions. For further information, see the [definition of m
odifier extensions](http://build.fhir.org/extensibility.html#modifierExtension)."/>
        <alias value="extensions"/>
        <alias value="user content"/>
        <alias value="modifiers"/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="BackboneElement.modifierExtension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
        </type>
        <isModifier value="true"/>
        <isModifierReason
                         value="Modifier extensions are expected to modify the meaning or
interpretation of the element that contains them"/>
        <isSummary value="true"/>
        <mapping>
          <identity value="rim"/>
```

```xml
          <map value="N/A"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.monograph.type">
        <path value="MedicationKnowledge.monograph.type"/>
        <short value="The category of medication document"/>
        <definition
                    value="The category of documentation about the medication. (e.g. profes
sional monograph, patient education monograph)."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="MedicationKnowledge.monograph.type"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="CodeableConcept"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="MedicationKnowledge.monograph.source">
        <path value="MedicationKnowledge.monograph.source"/>
        <short value="Associated documentation about the medication"/>
        <definition value="Associated documentation about the medication."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="MedicationKnowledge.monograph.source"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="Reference"/>
          <targetProfile
                        value="http://hl7.org/fhir/StructureDefinition/DocumentReference"/
>
          <targetProfile value="http://hl7.org/fhir/StructureDefinition/Media"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="MedicationKnowledge.ingredient">
        <path value="MedicationKnowledge.ingredient"/>
        <short value="Active or inactive ingredient"/>
        <definition
                    value="Identifies a particular constituent of interest in the product."
/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="MedicationKnowledge.ingredient"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
```

```xml
          <code value="BackboneElement"/>
        </type>
        <constraint>
          <key value="ele-1"/>
          <severity value="error"/>
          <human value="All FHIR elements must have a @value or children"/>
          <expression value="hasValue() or (children().count() &gt; id.count())"/>
          <xpath value="@value|f:*|h:div"/>
          <source value="Element"/>
        </constraint>
        <isModifier value="false"/>
        <isSummary value="false"/>
    </element>
    <element id="MedicationKnowledge.ingredient.id">
        <path value="MedicationKnowledge.ingredient.id"/>
        <representation value="xmlAttr"/>
        <short value="Unique id for inter-element referencing"/>
        <definition
                   value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Element.id"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="string"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
    </element>
    <element id="MedicationKnowledge.ingredient.extension">
        <path value="MedicationKnowledge.ingredient.extension"/>
        <short value="Additional content defined by implementations"/>
        <definition
                   value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
        <comment
                 value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
        <alias value="extensions"/>
        <alias value="user content"/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="Element.extension"/>
```

```
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.ingredient.modifierExtension">
        <path value="MedicationKnowledge.ingredient.modifierExtension"/>
        <short value="Extensions that cannot be ignored even if unrecognized"/>
        <definition
                  value="May be used to represent additional information that is not part
 of the basic definition of the element and that modifies the understanding of the elemen
t in which it is contained and/or the understanding of the containing element&#39;s desce
ndants. Usually modifier elements provide negation or qualification. To make the use of e
xtensions safe and manageable, there is a strict set of governance applied to the definit
ion and use of extensions. Though any implementer can define an extension, there is a set
 of requirements that SHALL be met as part of the definition of the extension. Applicatio
ns processing a resource are required to check for modifier extensions.

Modifier extensions SHALL NOT change the meaning of any elements on Resource or DomainRes
ource (including cannot change the meaning of modifierExtension itself)."/>
        <comment
                value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
        <requirements
                    value="Modifier extensions allow for extensions that *cannot* be safe
ly ignored to be clearly distinguished from the vast majority of extensions which can be
safely ignored.  This promotes interoperability by eliminating the need for implementers
to prohibit the presence of extensions. For further information, see the [definition of m
odifier extensions](http://build.fhir.org/extensibility.html#modifierExtension)."/>
        <alias value="extensions"/>
        <alias value="user content"/>
        <alias value="modifiers"/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="BackboneElement.modifierExtension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
        </type>
        <isModifier value="true"/>
        <isModifierReason
                        value="Modifier extensions are expected to modify the meaning or
interpretation of the element that contains them"/>
        <isSummary value="true"/>
```

```
      <mapping>
        <identity value="rim"/>
        <map value="N/A"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.ingredient.item[x]">
      <path value="MedicationKnowledge.ingredient.item[x]"/>
      <short value="Medication(s) or substance(s) contained in the medication"/>
      <definition
                 value="The actual ingredient - either a substance (simple ingredient) o
r another medication."/>
      <min value="1"/>
      <max value="1"/>
      <base>
        <path value="MedicationKnowledge.ingredient.item[x]"/>
        <min value="1"/>
        <max value="1"/>
      </base>
      <type>
        <code value="CodeableConcept"/>
      </type>
      <type>
        <code value="Reference"/>
        <targetProfile value="http://hl7.org/fhir/StructureDefinition/Substance"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="script10.6"/>
        <map
             value="coding.code = //element(*,MedicationType)/DrugCoded/ProductCode

coding.system = //element(*,MedicationType)/DrugCoded/ProductCodeQualifier

coding.display = //element(*,MedicationType)/DrugDescription"/>
      </mapping>
      <mapping>
        <identity value="v2"/>
        <map
             value="RXC-2-Component Code  if medication: RXO-1-Requested Give Code / RXE-
2-Give Code / RXD-2-Dispense/Give Code / RXG-4-Give Code / RXA-5-Administered Code"/>
      </mapping>
      <mapping>
        <identity value="rim"/>
        <map value=".player"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.ingredient.isActive">
      <path value="MedicationKnowledge.ingredient.isActive"/>
      <short value="Active ingredient indicator"/>
      <definition
                 value="Indication of whether this ingredient affects the therapeutic ac
tion of the drug."/>
      <requirements
                    value="True indicates that the ingredient affects the therapeutic act
ion of the drug (i.e. active).
False indicates that the ingredient does not affect the therapeutic action of the drug (i
```

```
.e. inactive)."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="MedicationKnowledge.ingredient.isActive"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="boolean"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="NA"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.ingredient.strength">
      <path value="MedicationKnowledge.ingredient.strength"/>
      <short value="Quantity of ingredient present"/>
      <definition
                  value="Specifies how many (or how much) of the items there are in this
Medication.  For example, 250 mg per tablet.  This is expressed as a ratio where the nume
rator is 250mg and the denominator is 1 tablet."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="MedicationKnowledge.ingredient.strength"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="Ratio"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="script10.6"/>
        <map value="//element(*,DrugCodedType)/Strength"/>
      </mapping>
      <mapping>
        <identity value="v2"/>
        <map
            value="RXC-3-Component Amount &amp; RXC-4-Component Units  if medication: RX
O-2-Requested Give Amount - Minimum &amp; RXO-4-Requested Give Units / RXO-3-Requested Gi
ve Amount - Maximum &amp; RXO-4-Requested Give Units / RXO-11-Requested Dispense Amount &
amp; RXO-12-Requested Dispense Units / RXE-3-Give Amount - Minimum &amp; RXE-5-Give Units
 / RXE-4-Give Amount - Maximum &amp; RXE-5-Give Units / RXE-10-Dispense Amount &amp; RXE-
10-Dispense Units"/>
      </mapping>
      <mapping>
        <identity value="rim"/>
        <map value=".quantity"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.preparationInstruction">
```

```xml
      <path value="MedicationKnowledge.preparationInstruction"/>
      <short value="The instructions for preparing the medication"/>
      <definition value="The instructions for preparing the medication."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="MedicationKnowledge.preparationInstruction"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="markdown"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="MedicationKnowledge.intendedRoute">
      <path value="MedicationKnowledge.intendedRoute"/>
      <short value="The intended or approved route of administration"/>
      <definition value="The intended or approved route of administration."/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="MedicationKnowledge.intendedRoute"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="CodeableConcept"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <binding>
        <extension
                  url="http://hl7.org/fhir/StructureDefinition/elementdefinition-binding
Name">
          <valueString value="MedicationRoute"/>
        </extension>
        <strength value="example"/>
        <description
                    value="A coded concept defining the intended route of administration
."/>
        <valueSet value="http://hl7.org/fhir/ValueSet/route-codes"/>
      </binding>
    </element>
    <element id="MedicationKnowledge.cost">
      <path value="MedicationKnowledge.cost"/>
      <short value="The pricing of the medication"/>
      <definition value="The price of the medication."/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="MedicationKnowledge.cost"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
```

```xml
          <code value="BackboneElement"/>
        </type>
        <constraint>
          <key value="ele-1"/>
          <severity value="error"/>
          <human value="All FHIR elements must have a @value or children"/>
          <expression value="hasValue() or (children().count() &gt; id.count())"/>
          <xpath value="@value|f:*|h:div"/>
          <source value="Element"/>
        </constraint>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="MedicationKnowledge.cost.id">
        <path value="MedicationKnowledge.cost.id"/>
        <representation value="xmlAttr"/>
        <short value="Unique id for inter-element referencing"/>
        <definition
                    value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Element.id"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="string"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.cost.extension">
        <path value="MedicationKnowledge.cost.extension"/>
        <short value="Additional content defined by implementations"/>
        <definition
                    value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
        <comment
                value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
        <alias value="extensions"/>
        <alias value="user content"/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="Element.extension"/>
```

```xml
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.cost.modifierExtension">
        <path value="MedicationKnowledge.cost.modifierExtension"/>
        <short value="Extensions that cannot be ignored even if unrecognized"/>
        <definition
                    value="May be used to represent additional information that is not part
 of the basic definition of the element and that modifies the understanding of the elemen
t in which it is contained and/or the understanding of the containing element&#39;s desce
ndants. Usually modifier elements provide negation or qualification. To make the use of e
xtensions safe and manageable, there is a strict set of governance applied to the definit
ion and use of extensions. Though any implementer can define an extension, there is a set
 of requirements that SHALL be met as part of the definition of the extension. Applicatio
ns processing a resource are required to check for modifier extensions.

Modifier extensions SHALL NOT change the meaning of any elements on Resource or DomainRes
ource (including cannot change the meaning of modifierExtension itself)."/>
        <comment
                 value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
        <requirements
                      value="Modifier extensions allow for extensions that *cannot* be safe
ly ignored to be clearly distinguished from the vast majority of extensions which can be
safely ignored.  This promotes interoperability by eliminating the need for implementers
to prohibit the presence of extensions. For further information, see the [definition of m
odifier extensions](http://build.fhir.org/extensibility.html#modifierExtension)."/>
        <alias value="extensions"/>
        <alias value="user content"/>
        <alias value="modifiers"/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="BackboneElement.modifierExtension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
        </type>
        <isModifier value="true"/>
        <isModifierReason
                          value="Modifier extensions are expected to modify the meaning or
interpretation of the element that contains them"/>
        <isSummary value="true"/>
```

```
        <mapping>
          <identity value="rim"/>
          <map value="N/A"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.cost.type">
        <path value="MedicationKnowledge.cost.type"/>
        <short value="The category of the cost information"/>
        <definition
                    value="The category of the cost information.  For example, manufacturer
s&#39; cost, patient cost, claim reimbursement cost, actual acquisition cost."/>
        <min value="1"/>
        <max value="1"/>
        <base>
          <path value="MedicationKnowledge.cost.type"/>
          <min value="1"/>
          <max value="1"/>
        </base>
        <type>
          <code value="CodeableConcept"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="MedicationKnowledge.cost.source">
        <path value="MedicationKnowledge.cost.source"/>
        <short value="The source or owner for the price information"/>
        <definition
                    value="The source or owner that assigns the price to the medication."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="MedicationKnowledge.cost.source"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="string"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="MedicationKnowledge.cost.cost">
        <path value="MedicationKnowledge.cost.cost"/>
        <short value="The price of the medication"/>
        <definition value="The price of the medication."/>
        <min value="1"/>
        <max value="1"/>
        <base>
          <path value="MedicationKnowledge.cost.cost"/>
          <min value="1"/>
          <max value="1"/>
        </base>
        <type>
          <code value="Money"/>
        </type>
        <isModifier value="false"/>
```

```xml
        <isSummary value="false"/>
      </element>
      <element id="MedicationKnowledge.monitoringProgram">
        <path value="MedicationKnowledge.monitoringProgram"/>
        <short value="Program under which a medication is reviewed"/>
        <definition value="The program under which the medication is reviewed."/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="MedicationKnowledge.monitoringProgram"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="BackboneElement"/>
        </type>
        <constraint>
          <key value="ele-1"/>
          <severity value="error"/>
          <human value="All FHIR elements must have a @value or children"/>
          <expression value="hasValue() or (children().count() &gt; id.count())"/>
          <xpath value="@value|f:*|h:div"/>
          <source value="Element"/>
        </constraint>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="MedicationKnowledge.monitoringProgram.id">
        <path value="MedicationKnowledge.monitoringProgram.id"/>
        <representation value="xmlAttr"/>
        <short value="Unique id for inter-element referencing"/>
        <definition
                  value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Element.id"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="string"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.monitoringProgram.extension">
        <path value="MedicationKnowledge.monitoringProgram.extension"/>
        <short value="Additional content defined by implementations"/>
        <definition
                  value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
```

```
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
      <comment
               value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
      <alias value="extensions"/>
      <alias value="user content"/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="Element.extension"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Extension"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="n/a"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.monitoringProgram.modifierExtension">
      <path value="MedicationKnowledge.monitoringProgram.modifierExtension"/>
      <short value="Extensions that cannot be ignored even if unrecognized"/>
      <definition
                 value="May be used to represent additional information that is not part
 of the basic definition of the element and that modifies the understanding of the elemen
t in which it is contained and/or the understanding of the containing element&#39;s desce
ndants. Usually modifier elements provide negation or qualification. To make the use of e
xtensions safe and manageable, there is a strict set of governance applied to the definit
ion and use of extensions. Though any implementer can define an extension, there is a set
 of requirements that SHALL be met as part of the definition of the extension. Applicatio
ns processing a resource are required to check for modifier extensions.

Modifier extensions SHALL NOT change the meaning of any elements on Resource or DomainRes
ource (including cannot change the meaning of modifierExtension itself)."/>
      <comment
               value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
      <requirements
                   value="Modifier extensions allow for extensions that *cannot* be safe
ly ignored to be clearly distinguished from the vast majority of extensions which can be
safely ignored.  This promotes interoperability by eliminating the need for implementers
to prohibit the presence of extensions. For further information, see the [definition of m
odifier extensions](http://build.fhir.org/extensibility.html#modifierExtension)."/>
      <alias value="extensions"/>
      <alias value="user content"/>
      <alias value="modifiers"/>
      <min value="0"/>
```

```xml
        <max value="*"/>
        <base>
          <path value="BackboneElement.modifierExtension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
        </type>
        <isModifier value="true"/>
        <isModifierReason
                       value="Modifier extensions are expected to modify the meaning or
interpretation of the element that contains them"/>
        <isSummary value="true"/>
        <mapping>
          <identity value="rim"/>
          <map value="N/A"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.monitoringProgram.type">
        <path value="MedicationKnowledge.monitoringProgram.type"/>
        <short value="Type of program under which the medication is monitored"/>
        <definition
                   value="Type of program under which the medication is monitored."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="MedicationKnowledge.monitoringProgram.type"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="CodeableConcept"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="MedicationKnowledge.monitoringProgram.name">
        <path value="MedicationKnowledge.monitoringProgram.name"/>
        <short value="Name of the reviewing program"/>
        <definition value="Name of the reviewing program."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="MedicationKnowledge.monitoringProgram.name"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="string"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="MedicationKnowledge.administrationGuidelines">
        <path value="MedicationKnowledge.administrationGuidelines"/>
        <short value="Guidelines for administration of the medication"/>
```

```
              <definition value="Guidelines for the administration of the medication."/>
              <min value="0"/>
              <max value="*"/>
              <base>
                <path value="MedicationKnowledge.administrationGuidelines"/>
                <min value="0"/>
                <max value="*"/>
              </base>
              <type>
                <code value="BackboneElement"/>
              </type>
              <constraint>
                <key value="ele-1"/>
                <severity value="error"/>
                <human value="All FHIR elements must have a @value or children"/>
                <expression value="hasValue() or (children().count() &gt; id.count())"/>
                <xpath value="@value|f:*|h:div"/>
                <source value="Element"/>
              </constraint>
              <isModifier value="false"/>
              <isSummary value="false"/>
            </element>
            <element id="MedicationKnowledge.administrationGuidelines.id">
              <path value="MedicationKnowledge.administrationGuidelines.id"/>
              <representation value="xmlAttr"/>
              <short value="Unique id for inter-element referencing"/>
              <definition
                        value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
              <min value="0"/>
              <max value="1"/>
              <base>
                <path value="Element.id"/>
                <min value="0"/>
                <max value="1"/>
              </base>
              <type>
                <code value="string"/>
              </type>
              <isModifier value="false"/>
              <isSummary value="false"/>
              <mapping>
                <identity value="rim"/>
                <map value="n/a"/>
              </mapping>
            </element>
            <element id="MedicationKnowledge.administrationGuidelines.extension">
              <path value="MedicationKnowledge.administrationGuidelines.extension"/>
              <short value="Additional content defined by implementations"/>
              <definition
                        value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
              <comment
                      value="There can be no stigma associated with the use of extensions by any
```

```
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
      <alias value="extensions"/>
      <alias value="user content"/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="Element.extension"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Extension"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="n/a"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.administrationGuidelines.modifierExtension">
      <path
            value="MedicationKnowledge.administrationGuidelines.modifierExtension"/>
      <short value="Extensions that cannot be ignored even if unrecognized"/>
      <definition
               value="May be used to represent additional information that is not part
 of the basic definition of the element and that modifies the understanding of the elemen
t in which it is contained and/or the understanding of the containing element&#39;s desce
ndants. Usually modifier elements provide negation or qualification. To make the use of e
xtensions safe and manageable, there is a strict set of governance applied to the definit
ion and use of extensions. Though any implementer can define an extension, there is a set
 of requirements that SHALL be met as part of the definition of the extension. Applicatio
ns processing a resource are required to check for modifier extensions.

Modifier extensions SHALL NOT change the meaning of any elements on Resource or DomainRes
ource (including cannot change the meaning of modifierExtension itself)."/>
      <comment
             value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
      <requirements
                  value="Modifier extensions allow for extensions that *cannot* be safe
ly ignored to be clearly distinguished from the vast majority of extensions which can be
safely ignored.  This promotes interoperability by eliminating the need for implementers
to prohibit the presence of extensions. For further information, see the [definition of m
odifier extensions](http://build.fhir.org/extensibility.html#modifierExtension)."/>
      <alias value="extensions"/>
      <alias value="user content"/>
      <alias value="modifiers"/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="BackboneElement.modifierExtension"/>
        <min value="0"/>
```

```xml
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
        </type>
        <isModifier value="true"/>
        <isModifierReason
                          value="Modifier extensions are expected to modify the meaning or
interpretation of the element that contains them"/>
        <isSummary value="true"/>
        <mapping>
          <identity value="rim"/>
          <map value="N/A"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.administrationGuidelines.dosage">
        <path value="MedicationKnowledge.administrationGuidelines.dosage"/>
        <short value="Dosage for the medication for the specific guidelines"/>
        <definition value="Dosage for the medication for the specific guidelines."/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="MedicationKnowledge.administrationGuidelines.dosage"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="BackboneElement"/>
        </type>
        <constraint>
          <key value="ele-1"/>
          <severity value="error"/>
          <human value="All FHIR elements must have a @value or children"/>
          <expression value="hasValue() or (children().count() &gt; id.count())"/>
          <xpath value="@value|f:*|h:div"/>
          <source value="Element"/>
        </constraint>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="MedicationKnowledge.administrationGuidelines.dosage.id">
        <path value="MedicationKnowledge.administrationGuidelines.dosage.id"/>
        <representation value="xmlAttr"/>
        <short value="Unique id for inter-element referencing"/>
        <definition
                  value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Element.id"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="string"/>
        </type>
```

```xml
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.administrationGuidelines.dosage.extension">
        <path
               value="MedicationKnowledge.administrationGuidelines.dosage.extension"/>
        <short value="Additional content defined by implementations"/>
        <definition
                    value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
        <comment
                 value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
        <alias value="extensions"/>
        <alias value="user content"/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="Element.extension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element
               id="MedicationKnowledge.administrationGuidelines.dosage.modifierExtension">
        <path
               value="MedicationKnowledge.administrationGuidelines.dosage.modifierExtension"
/>
        <short value="Extensions that cannot be ignored even if unrecognized"/>
        <definition
                    value="May be used to represent additional information that is not part
 of the basic definition of the element and that modifies the understanding of the elemen
t in which it is contained and/or the understanding of the containing element&#39;s desce
ndants. Usually modifier elements provide negation or qualification. To make the use of e
xtensions safe and manageable, there is a strict set of governance applied to the definit
ion and use of extensions. Though any implementer can define an extension, there is a set
 of requirements that SHALL be met as part of the definition of the extension. Applicatio
ns processing a resource are required to check for modifier extensions.
```

```xml
Modifier extensions SHALL NOT change the meaning of any elements on Resource or DomainRes
ource (including cannot change the meaning of modifierExtension itself)."/>
      <comment
              value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
      <requirements
                   value="Modifier extensions allow for extensions that *cannot* be safe
ly ignored to be clearly distinguished from the vast majority of extensions which can be
safely ignored.  This promotes interoperability by eliminating the need for implementers
to prohibit the presence of extensions. For further information, see the [definition of m
odifier extensions](http://build.fhir.org/extensibility.html#modifierExtension)."/>
      <alias value="extensions"/>
      <alias value="user content"/>
      <alias value="modifiers"/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="BackboneElement.modifierExtension"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Extension"/>
      </type>
      <isModifier value="true"/>
      <isModifierReason
                        value="Modifier extensions are expected to modify the meaning or
interpretation of the element that contains them"/>
      <isSummary value="true"/>
      <mapping>
        <identity value="rim"/>
        <map value="N/A"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.administrationGuidelines.dosage.type">
      <path value="MedicationKnowledge.administrationGuidelines.dosage.type"/>
      <short value="Type of dosage"/>
      <definition
                  value="The type of dosage (for example, prophylaxis, maintenance, thera
peutic, etc.)."/>
      <min value="1"/>
      <max value="1"/>
      <base>
        <path value="MedicationKnowledge.administrationGuidelines.dosage.type"/>
        <min value="1"/>
        <max value="1"/>
      </base>
      <type>
        <code value="CodeableConcept"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="MedicationKnowledge.administrationGuidelines.dosage.dosage">
      <path value="MedicationKnowledge.administrationGuidelines.dosage.dosage"/>
```

```
      <short value="Dosage for the medication for the specific guidelines"/>
      <definition value="Dosage for the medication for the specific guidelines."/>
      <min value="1"/>
      <max value="*"/>
      <base>
        <path value="MedicationKnowledge.administrationGuidelines.dosage.dosage"/>
        <min value="1"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Dosage"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="MedicationKnowledge.administrationGuidelines.indication[x]">
      <path value="MedicationKnowledge.administrationGuidelines.indication[x]"/>
      <short
            value="Indication for use that apply to the specific administration guidelin
es"/>
      <definition
                 value="Indication for use that apply to the specific administration gui
delines."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="MedicationKnowledge.administrationGuidelines.indication[x]"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="CodeableConcept"/>
      </type>
      <type>
        <code value="Reference"/>
        <targetProfile
                       value="http://hl7.org/fhir/StructureDefinition/ObservationDefiniti
on"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element
            id="MedicationKnowledge.administrationGuidelines.patientCharacteristics">
      <path
            value="MedicationKnowledge.administrationGuidelines.patientCharacteristics"/>
      <short
            value="Characteristics of the patient that are relevant to the administratio
n guidelines"/>
      <definition
                 value="Characteristics of the patient that are relevant to the administ
ration guidelines (for example, height, weight, gender, etc.)."/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path
              value="MedicationKnowledge.administrationGuidelines.patientCharacteristics"
```

```
/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="BackboneElement"/>
        </type>
        <constraint>
          <key value="ele-1"/>
          <severity value="error"/>
          <human value="All FHIR elements must have a @value or children"/>
          <expression value="hasValue() or (children().count() &gt; id.count())"/>
          <xpath value="@value|f:*|h:div"/>
          <source value="Element"/>
        </constraint>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element
             id="MedicationKnowledge.administrationGuidelines.patientCharacteristics.id">
        <path
            value="MedicationKnowledge.administrationGuidelines.patientCharacteristics.id
"/>
        <representation value="xmlAttr"/>
        <short value="Unique id for inter-element referencing"/>
        <definition
                   value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Element.id"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="string"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element
             id="MedicationKnowledge.administrationGuidelines.patientCharacteristics.exte
nsion">
        <path
            value="MedicationKnowledge.administrationGuidelines.patientCharacteristics.ex
tension"/>
        <short value="Additional content defined by implementations"/>
        <definition
                   value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
```

```
 be met as part of the definition of the extension."/>
       <comment
               value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
       <alias value="extensions"/>
       <alias value="user content"/>
       <min value="0"/>
       <max value="*"/>
       <base>
         <path value="Element.extension"/>
         <min value="0"/>
         <max value="*"/>
       </base>
       <type>
         <code value="Extension"/>
       </type>
       <isModifier value="false"/>
       <isSummary value="false"/>
       <mapping>
         <identity value="rim"/>
         <map value="n/a"/>
       </mapping>
     </element>
     <element
             id="MedicationKnowledge.administrationGuidelines.patientCharacteristics.modi
fierExtension">
       <path
           value="MedicationKnowledge.administrationGuidelines.patientCharacteristics.mo
difierExtension"/>
       <short value="Extensions that cannot be ignored even if unrecognized"/>
       <definition
                 value="May be used to represent additional information that is not part
 of the basic definition of the element and that modifies the understanding of the elemen
t in which it is contained and/or the understanding of the containing element&#39;s desce
ndants. Usually modifier elements provide negation or qualification. To make the use of e
xtensions safe and manageable, there is a strict set of governance applied to the definit
ion and use of extensions. Though any implementer can define an extension, there is a set
 of requirements that SHALL be met as part of the definition of the extension. Applicatio
ns processing a resource are required to check for modifier extensions.

Modifier extensions SHALL NOT change the meaning of any elements on Resource or DomainRes
ource (including cannot change the meaning of modifierExtension itself)."/>
       <comment
               value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
       <requirements
                   value="Modifier extensions allow for extensions that *cannot* be safe
ly ignored to be clearly distinguished from the vast majority of extensions which can be
safely ignored.  This promotes interoperability by eliminating the need for implementers
to prohibit the presence of extensions. For further information, see the [definition of m
odifier extensions](http://build.fhir.org/extensibility.html#modifierExtension)."/>
       <alias value="extensions"/>
       <alias value="user content"/>
```

```xml
          <alias value="modifiers"/>
          <min value="0"/>
          <max value="*"/>
          <base>
            <path value="BackboneElement.modifierExtension"/>
            <min value="0"/>
            <max value="*"/>
          </base>
          <type>
            <code value="Extension"/>
          </type>
          <isModifier value="true"/>
          <isModifierReason
                          value="Modifier extensions are expected to modify the meaning or
interpretation of the element that contains them"/>
          <isSummary value="true"/>
          <mapping>
            <identity value="rim"/>
            <map value="N/A"/>
          </mapping>
        </element>
        <element
                id="MedicationKnowledge.administrationGuidelines.patientCharacteristics.char
acteristic[x]">
          <path
              value="MedicationKnowledge.administrationGuidelines.patientCharacteristics.ch
aracteristic[x]"/>
          <short
              value="Specific characteristic that is relevant to the administration guidel
ine"/>
          <definition
                    value="Specific characteristic that is relevant to the administration g
uideline (e.g. height, weight, gender)."/>
          <min value="1"/>
          <max value="1"/>
          <base>
            <path
                value="MedicationKnowledge.administrationGuidelines.patientCharacteristics.
characteristic[x]"/>
            <min value="1"/>
            <max value="1"/>
          </base>
          <type>
            <code value="CodeableConcept"/>
          </type>
          <type>
            <code value="Quantity"/>
            <profile value="http://hl7.org/fhir/StructureDefinition/SimpleQuantity"/>
          </type>
          <isModifier value="false"/>
          <isSummary value="false"/>
        </element>
        <element
                id="MedicationKnowledge.administrationGuidelines.patientCharacteristics.valu
e">
          <path
              value="MedicationKnowledge.administrationGuidelines.patientCharacteristics.va
```

```
lue"/>
      <short value="The specific characteristic"/>
      <definition
                  value="The specific characteristic (e.g. height, weight, gender, etc.).
"/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path
              value="MedicationKnowledge.administrationGuidelines.patientCharacteristics.
value"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="string"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="MedicationKnowledge.medicineClassification">
      <path value="MedicationKnowledge.medicineClassification"/>
      <short
              value="Categorization of the medication within a formulary or classification
 system"/>
      <definition
                  value="Categorization of the medication within a formulary or classific
ation system."/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="MedicationKnowledge.medicineClassification"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="BackboneElement"/>
      </type>
      <constraint>
        <key value="ele-1"/>
        <severity value="error"/>
        <human value="All FHIR elements must have a @value or children"/>
        <expression value="hasValue() or (children().count() &gt; id.count())"/>
        <xpath value="@value|f:*|h:div"/>
        <source value="Element"/>
      </constraint>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="MedicationKnowledge.medicineClassification.id">
      <path value="MedicationKnowledge.medicineClassification.id"/>
      <representation value="xmlAttr"/>
      <short value="Unique id for inter-element referencing"/>
      <definition
                  value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
      <min value="0"/>
```

```xml
        <max value="1"/>
        <base>
          <path value="Element.id"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="string"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.medicineClassification.extension">
        <path value="MedicationKnowledge.medicineClassification.extension"/>
        <short value="Additional content defined by implementations"/>
        <definition
                    value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
        <comment
                  value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
        <alias value="extensions"/>
        <alias value="user content"/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="Element.extension"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="Extension"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
        <mapping>
          <identity value="rim"/>
          <map value="n/a"/>
        </mapping>
      </element>
      <element id="MedicationKnowledge.medicineClassification.modifierExtension">
        <path value="MedicationKnowledge.medicineClassification.modifierExtension"/>
        <short value="Extensions that cannot be ignored even if unrecognized"/>
        <definition
                    value="May be used to represent additional information that is not part
 of the basic definition of the element and that modifies the understanding of the elemen
t in which it is contained and/or the understanding of the containing element&#39;s desce
ndants. Usually modifier elements provide negation or qualification. To make the use of e
```

```
xtensions safe and manageable, there is a strict set of governance applied to the definit
ion and use of extensions. Though any implementer can define an extension, there is a set
 of requirements that SHALL be met as part of the definition of the extension. Applicatio
ns processing a resource are required to check for modifier extensions.

Modifier extensions SHALL NOT change the meaning of any elements on Resource or DomainRes
ource (including cannot change the meaning of modifierExtension itself)."/>
      <comment
                value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
      <requirements
                    value="Modifier extensions allow for extensions that *cannot* be safe
ly ignored to be clearly distinguished from the vast majority of extensions which can be
safely ignored.  This promotes interoperability by eliminating the need for implementers
to prohibit the presence of extensions. For further information, see the [definition of m
odifier extensions](http://build.fhir.org/extensibility.html#modifierExtension)."/>
      <alias value="extensions"/>
      <alias value="user content"/>
      <alias value="modifiers"/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="BackboneElement.modifierExtension"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Extension"/>
      </type>
      <isModifier value="true"/>
      <isModifierReason
                        value="Modifier extensions are expected to modify the meaning or
interpretation of the element that contains them"/>
      <isSummary value="true"/>
      <mapping>
        <identity value="rim"/>
        <map value="N/A"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.medicineClassification.type">
      <path value="MedicationKnowledge.medicineClassification.type"/>
      <short
            value="The type of category for the medication (for example, therapeutic cla
ssification, therapeutic sub-classification)"/>
      <definition
                  value="The type of category for the medication (for example, therapeuti
c classification, therapeutic sub-classification)."/>
      <min value="1"/>
      <max value="1"/>
      <base>
        <path value="MedicationKnowledge.medicineClassification.type"/>
        <min value="1"/>
        <max value="1"/>
      </base>
      <type>
```

```xml
        <code value="CodeableConcept"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="MedicationKnowledge.medicineClassification.classification">
      <path value="MedicationKnowledge.medicineClassification.classification"/>
      <short value="Specific category assigned to the medication"/>
      <definition
                  value="Specific category assigned to the medication (e.g. anti-infectiv
e, anti-hypertensive, antibiotic, etc.)."/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="MedicationKnowledge.medicineClassification.classification"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="CodeableConcept"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="MedicationKnowledge.packaging">
      <path value="MedicationKnowledge.packaging"/>
      <short value="Details about packaged medications"/>
      <definition
                  value="Information that only applies to packages (not products)."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="MedicationKnowledge.packaging"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="BackboneElement"/>
      </type>
      <constraint>
        <key value="ele-1"/>
        <severity value="error"/>
        <human value="All FHIR elements must have a @value or children"/>
        <expression value="hasValue() or (children().count() &gt; id.count())"/>
        <xpath value="@value|f:*|h:div"/>
        <source value="Element"/>
      </constraint>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="MedicationKnowledge.packaging.id">
      <path value="MedicationKnowledge.packaging.id"/>
      <representation value="xmlAttr"/>
      <short value="Unique id for inter-element referencing"/>
      <definition
                  value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
```

```xml
          <min value="0"/>
          <max value="1"/>
          <base>
            <path value="Element.id"/>
            <min value="0"/>
            <max value="1"/>
          </base>
          <type>
            <code value="string"/>
          </type>
          <isModifier value="false"/>
          <isSummary value="false"/>
          <mapping>
            <identity value="rim"/>
            <map value="n/a"/>
          </mapping>
        </element>
        <element id="MedicationKnowledge.packaging.extension">
          <path value="MedicationKnowledge.packaging.extension"/>
          <short value="Additional content defined by implementations"/>
          <definition
                     value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
          <comment
                  value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
          <alias value="extensions"/>
          <alias value="user content"/>
          <min value="0"/>
          <max value="*"/>
          <base>
            <path value="Element.extension"/>
            <min value="0"/>
            <max value="*"/>
          </base>
          <type>
            <code value="Extension"/>
          </type>
          <isModifier value="false"/>
          <isSummary value="false"/>
          <mapping>
            <identity value="rim"/>
            <map value="n/a"/>
          </mapping>
        </element>
        <element id="MedicationKnowledge.packaging.modifierExtension">
          <path value="MedicationKnowledge.packaging.modifierExtension"/>
          <short value="Extensions that cannot be ignored even if unrecognized"/>
          <definition
                     value="May be used to represent additional information that is not part
 of the basic definition of the element and that modifies the understanding of the elemen
t in which it is contained and/or the understanding of the containing element&#39;s desce
```

ndants. Usually modifier elements provide negation or qualification. To make the use of e
xtensions safe and manageable, there is a strict set of governance applied to the definit
ion and use of extensions. Though any implementer can define an extension, there is a set
 of requirements that SHALL be met as part of the definition of the extension. Applicatio
ns processing a resource are required to check for modifier extensions.

Modifier extensions SHALL NOT change the meaning of any elements on Resource or DomainRes
ource (including cannot change the meaning of modifierExtension itself)."/>
      <comment
              value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions. The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
      <requirements
                   value="Modifier extensions allow for extensions that *cannot* be safe
ly ignored to be clearly distinguished from the vast majority of extensions which can be
safely ignored. This promotes interoperability by eliminating the need for implementers
to prohibit the presence of extensions. For further information, see the [definition of m
odifier extensions](http://build.fhir.org/extensibility.html#modifierExtension)."/>
      <alias value="extensions"/>
      <alias value="user content"/>
      <alias value="modifiers"/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="BackboneElement.modifierExtension"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Extension"/>
      </type>
      <isModifier value="true"/>
      <isModifierReason
                     value="Modifier extensions are expected to modify the meaning or
interpretation of the element that contains them"/>
      <isSummary value="true"/>
      <mapping>
        <identity value="rim"/>
        <map value="N/A"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.packaging.type">
      <path value="MedicationKnowledge.packaging.type"/>
      <short
           value="A code that defines the specific type of packaging that the medicatio
n can be found in"/>
      <definition
               value="A code that defines the specific type of packaging that the medi
cation can be found in (e.g. blister sleeve, tube, bottle)."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="MedicationKnowledge.packaging.type"/>
        <min value="0"/>
        <max value="1"/>
      </base>

```
    <type>
      <code value="CodeableConcept"/>
    </type>
    <isModifier value="false"/>
    <isSummary value="false"/>
    <binding>
      <extension
                url="http://hl7.org/fhir/StructureDefinition/elementdefinition-binding
Name">
        <valueString value="MedicationPackageType"/>
      </extension>
      <strength value="example"/>
      <description
                 value="A coded concept defining the type of packaging of a medicatio
n."/>
      <valueSet
              value="http://hl7.org/fhir/ValueSet/medicationknowledge-package-type"/>
    </binding>
  </element>
  <element id="MedicationKnowledge.packaging.quantity">
    <path value="MedicationKnowledge.packaging.quantity"/>
    <short
          value="The number of product units the package would contain if fully loaded
"/>
    <definition
               value="The number of product units the package would contain if fully l
oaded."/>
    <min value="0"/>
    <max value="1"/>
    <base>
      <path value="MedicationKnowledge.packaging.quantity"/>
      <min value="0"/>
      <max value="1"/>
    </base>
    <type>
      <code value="Quantity"/>
      <profile value="http://hl7.org/fhir/StructureDefinition/SimpleQuantity"/>
    </type>
    <isModifier value="false"/>
    <isSummary value="false"/>
  </element>
  <element id="MedicationKnowledge.drugCharacteristic">
    <path value="MedicationKnowledge.drugCharacteristic"/>
    <short value="Specifies descriptive properties of the medicine"/>
    <definition
               value="Specifies descriptive properties of the medicine, such as color,
 shape, imprints, etc."/>
    <min value="0"/>
    <max value="*"/>
    <base>
      <path value="MedicationKnowledge.drugCharacteristic"/>
      <min value="0"/>
      <max value="*"/>
    </base>
    <type>
      <code value="BackboneElement"/>
    </type>
```

```xml
      <constraint>
        <key value="ele-1"/>
        <severity value="error"/>
        <human value="All FHIR elements must have a @value or children"/>
        <expression value="hasValue() or (children().count() &gt; id.count())"/>
        <xpath value="@value|f:*|h:div"/>
        <source value="Element"/>
      </constraint>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="MedicationKnowledge.drugCharacteristic.id">
      <path value="MedicationKnowledge.drugCharacteristic.id"/>
      <representation value="xmlAttr"/>
      <short value="Unique id for inter-element referencing"/>
      <definition
                  value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="Element.id"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="string"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="n/a"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.drugCharacteristic.extension">
      <path value="MedicationKnowledge.drugCharacteristic.extension"/>
      <short value="Additional content defined by implementations"/>
      <definition
                  value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
      <comment
                value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
      <alias value="extensions"/>
      <alias value="user content"/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="Element.extension"/>
        <min value="0"/>
        <max value="*"/>
```

```xml
          </base>
          <type>
            <code value="Extension"/>
          </type>
          <isModifier value="false"/>
          <isSummary value="false"/>
          <mapping>
            <identity value="rim"/>
            <map value="n/a"/>
          </mapping>
        </element>
        <element id="MedicationKnowledge.drugCharacteristic.modifierExtension">
          <path value="MedicationKnowledge.drugCharacteristic.modifierExtension"/>
          <short value="Extensions that cannot be ignored even if unrecognized"/>
          <definition
                      value="May be used to represent additional information that is not part
 of the basic definition of the element and that modifies the understanding of the elemen
t in which it is contained and/or the understanding of the containing element&#39;s desce
ndants. Usually modifier elements provide negation or qualification. To make the use of e
xtensions safe and manageable, there is a strict set of governance applied to the definit
ion and use of extensions. Though any implementer can define an extension, there is a set
 of requirements that SHALL be met as part of the definition of the extension. Applicatio
ns processing a resource are required to check for modifier extensions.

Modifier extensions SHALL NOT change the meaning of any elements on Resource or DomainRes
ource (including cannot change the meaning of modifierExtension itself)."/>
          <comment
                   value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
          <requirements
                        value="Modifier extensions allow for extensions that *cannot* be safe
ly ignored to be clearly distinguished from the vast majority of extensions which can be
safely ignored.  This promotes interoperability by eliminating the need for implementers
to prohibit the presence of extensions. For further information, see the [definition of m
odifier extensions](http://build.fhir.org/extensibility.html#modifierExtension)."/>
          <alias value="extensions"/>
          <alias value="user content"/>
          <alias value="modifiers"/>
          <min value="0"/>
          <max value="*"/>
          <base>
            <path value="BackboneElement.modifierExtension"/>
            <min value="0"/>
            <max value="*"/>
          </base>
          <type>
            <code value="Extension"/>
          </type>
          <isModifier value="true"/>
          <isModifierReason
                            value="Modifier extensions are expected to modify the meaning or
interpretation of the element that contains them"/>
          <isSummary value="true"/>
          <mapping>
            <identity value="rim"/>
```

```xml
        <map value="N/A"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.drugCharacteristic.type">
      <path value="MedicationKnowledge.drugCharacteristic.type"/>
      <short value="Code specifying the type of characteristic of medication"/>
      <definition
                  value="A code specifying which characteristic of the medicine is being
described (for example, colour, shape, imprint)."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="MedicationKnowledge.drugCharacteristic.type"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="CodeableConcept"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <binding>
        <extension
                    url="http://hl7.org/fhir/StructureDefinition/elementdefinition-binding
Name">
          <valueString value="MedicationCharacteristic"/>
        </extension>
        <strength value="example"/>
        <description
                      value="A coded concept defining the characteristic types of a medica
tion."/>
        <valueSet
                  value="http://hl7.org/fhir/ValueSet/medicationknowledge-characteristic"
/>
      </binding>
    </element>
    <element id="MedicationKnowledge.drugCharacteristic.value[x]">
      <path value="MedicationKnowledge.drugCharacteristic.value[x]"/>
      <short value="Description of the characteristic"/>
      <definition value="Description of the characteristic."/>
      <comment
                value="The description should be provided as a CodeableConcept, SimpleQuan
tity or an image.  The description can be a string only when these others are availab
le."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="MedicationKnowledge.drugCharacteristic.value[x]"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="CodeableConcept"/>
      </type>
      <type>
        <code value="string"/>
      </type>
```

```xml
      <type>
        <code value="Quantity"/>
        <profile value="http://hl7.org/fhir/StructureDefinition/SimpleQuantity"/>
      </type>
      <type>
        <code value="base64Binary"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="MedicationKnowledge.contraindication">
      <path value="MedicationKnowledge.contraindication"/>
      <short value="Potential clinical issue with or between medication(s)"/>
      <definition
                   value="Potential clinical issue with or between medication(s) (for exam
ple, drug-drug interaction, drug-disease contraindication, drug-allergy interaction, etc.
)."/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="MedicationKnowledge.contraindication"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Reference"/>
        <targetProfile
                        value="http://hl7.org/fhir/StructureDefinition/DetectedIssue"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="MedicationKnowledge.regulatory">
      <path value="MedicationKnowledge.regulatory"/>
      <short value="Regulatory information about a medication"/>
      <definition value="Regulatory information about a medication."/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="MedicationKnowledge.regulatory"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="BackboneElement"/>
      </type>
      <constraint>
        <key value="ele-1"/>
        <severity value="error"/>
        <human value="All FHIR elements must have a @value or children"/>
        <expression value="hasValue() or (children().count() &gt; id.count())"/>
        <xpath value="@value|f:*|h:div"/>
        <source value="Element"/>
      </constraint>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
```

```xml
    <element id="MedicationKnowledge.regulatory.id">
      <path value="MedicationKnowledge.regulatory.id"/>
      <representation value="xmlAttr"/>
      <short value="Unique id for inter-element referencing"/>
      <definition
                  value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="Element.id"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="string"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="n/a"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.regulatory.extension">
      <path value="MedicationKnowledge.regulatory.extension"/>
      <short value="Additional content defined by implementations"/>
      <definition
                  value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
      <comment
               value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
      <alias value="extensions"/>
      <alias value="user content"/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="Element.extension"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Extension"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="n/a"/>
      </mapping>
    </element>
```

```xml
        <element id="MedicationKnowledge.regulatory.modifierExtension">
          <path value="MedicationKnowledge.regulatory.modifierExtension"/>
          <short value="Extensions that cannot be ignored even if unrecognized"/>
          <definition
                    value="May be used to represent additional information that is not part
 of the basic definition of the element and that modifies the understanding of the elemen
t in which it is contained and/or the understanding of the containing element&#39;s desce
ndants. Usually modifier elements provide negation or qualification. To make the use of e
xtensions safe and manageable, there is a strict set of governance applied to the definit
ion and use of extensions. Though any implementer can define an extension, there is a set
 of requirements that SHALL be met as part of the definition of the extension. Applicatio
ns processing a resource are required to check for modifier extensions.

Modifier extensions SHALL NOT change the meaning of any elements on Resource or DomainRes
ource (including cannot change the meaning of modifierExtension itself)."/>
          <comment
                    value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
          <requirements
                    value="Modifier extensions allow for extensions that *cannot* be safe
ly ignored to be clearly distinguished from the vast majority of extensions which can be
safely ignored.  This promotes interoperability by eliminating the need for implementers
to prohibit the presence of extensions. For further information, see the [definition of m
odifier extensions](http://build.fhir.org/extensibility.html#modifierExtension)."/>
          <alias value="extensions"/>
          <alias value="user content"/>
          <alias value="modifiers"/>
          <min value="0"/>
          <max value="*"/>
          <base>
            <path value="BackboneElement.modifierExtension"/>
            <min value="0"/>
            <max value="*"/>
          </base>
          <type>
            <code value="Extension"/>
          </type>
          <isModifier value="true"/>
          <isModifierReason
                        value="Modifier extensions are expected to modify the meaning or
interpretation of the element that contains them"/>
          <isSummary value="true"/>
          <mapping>
            <identity value="rim"/>
            <map value="N/A"/>
          </mapping>
        </element>
        <element id="MedicationKnowledge.regulatory.regulatoryAuthority">
          <path value="MedicationKnowledge.regulatory.regulatoryAuthority"/>
          <short value="Specifies the authority of the regulation"/>
          <definition value="The authority that is specifying the regulations."/>
          <min value="1"/>
          <max value="1"/>
          <base>
            <path value="MedicationKnowledge.regulatory.regulatoryAuthority"/>
```

```
          <min value="1"/>
          <max value="1"/>
        </base>
        <type>
          <code value="Reference"/>
          <targetProfile
                      value="http://hl7.org/fhir/StructureDefinition/Organization"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="MedicationKnowledge.regulatory.substitution">
        <path value="MedicationKnowledge.regulatory.substitution"/>
        <short
              value="Specifies if changes are allowed when dispensing a medication from a
regulatory perspective"/>
        <definition
                    value="Specifies if changes are allowed when dispensing a medication fr
om a regulatory perspective."/>
        <min value="0"/>
        <max value="*"/>
        <base>
          <path value="MedicationKnowledge.regulatory.substitution"/>
          <min value="0"/>
          <max value="*"/>
        </base>
        <type>
          <code value="BackboneElement"/>
        </type>
        <constraint>
          <key value="ele-1"/>
          <severity value="error"/>
          <human value="All FHIR elements must have a @value or children"/>
          <expression value="hasValue() or (children().count() &gt; id.count())"/>
          <xpath value="@value|f:*|h:div"/>
          <source value="Element"/>
        </constraint>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
      <element id="MedicationKnowledge.regulatory.substitution.id">
        <path value="MedicationKnowledge.regulatory.substitution.id"/>
        <representation value="xmlAttr"/>
        <short value="Unique id for inter-element referencing"/>
        <definition
                    value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="Element.id"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="string"/>
        </type>
```

```xml
          <isModifier value="false"/>
          <isSummary value="false"/>
          <mapping>
            <identity value="rim"/>
            <map value="n/a"/>
          </mapping>
        </element>
        <element id="MedicationKnowledge.regulatory.substitution.extension">
          <path value="MedicationKnowledge.regulatory.substitution.extension"/>
          <short value="Additional content defined by implementations"/>
          <definition
                    value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
          <comment
                value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
          <alias value="extensions"/>
          <alias value="user content"/>
          <min value="0"/>
          <max value="*"/>
          <base>
            <path value="Element.extension"/>
            <min value="0"/>
            <max value="*"/>
          </base>
          <type>
            <code value="Extension"/>
          </type>
          <isModifier value="false"/>
          <isSummary value="false"/>
          <mapping>
            <identity value="rim"/>
            <map value="n/a"/>
          </mapping>
        </element>
        <element id="MedicationKnowledge.regulatory.substitution.modifierExtension">
          <path
              value="MedicationKnowledge.regulatory.substitution.modifierExtension"/>
          <short value="Extensions that cannot be ignored even if unrecognized"/>
          <definition
                    value="May be used to represent additional information that is not part
 of the basic definition of the element and that modifies the understanding of the elemen
t in which it is contained and/or the understanding of the containing element&#39;s desce
ndants. Usually modifier elements provide negation or qualification. To make the use of e
xtensions safe and manageable, there is a strict set of governance applied to the definit
ion and use of extensions. Though any implementer can define an extension, there is a set
 of requirements that SHALL be met as part of the definition of the extension. Applicatio
ns processing a resource are required to check for modifier extensions.

Modifier extensions SHALL NOT change the meaning of any elements on Resource or DomainRes
ource (including cannot change the meaning of modifierExtension itself)."/>
          <comment
```

```
                    value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
      <requirements
                    value="Modifier extensions allow for extensions that *cannot* be safe
ly ignored to be clearly distinguished from the vast majority of extensions which can be
safely ignored.  This promotes interoperability by eliminating the need for implementers
to prohibit the presence of extensions. For further information, see the [definition of m
odifier extensions](http://build.fhir.org/extensibility.html#modifierExtension)."/>
      <alias value="extensions"/>
      <alias value="user content"/>
      <alias value="modifiers"/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="BackboneElement.modifierExtension"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Extension"/>
      </type>
      <isModifier value="true"/>
      <isModifierReason
                        value="Modifier extensions are expected to modify the meaning or
interpretation of the element that contains them"/>
      <isSummary value="true"/>
      <mapping>
        <identity value="rim"/>
        <map value="N/A"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.regulatory.substitution.type">
      <path value="MedicationKnowledge.regulatory.substitution.type"/>
      <short value="Specifies the type of substitution allowed"/>
      <definition value="Specifies the type of substitution allowed."/>
      <min value="1"/>
      <max value="1"/>
      <base>
        <path value="MedicationKnowledge.regulatory.substitution.type"/>
        <min value="1"/>
        <max value="1"/>
      </base>
      <type>
        <code value="CodeableConcept"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="MedicationKnowledge.regulatory.substitution.allowed">
      <path value="MedicationKnowledge.regulatory.substitution.allowed"/>
      <short
             value="Specifies if regulation allows for changes in the medication when dis
pensing"/>
      <definition
                  value="Specifies if regulation allows for changes in the medication whe
```

```xml
n dispensing."/>
      <min value="1"/>
      <max value="1"/>
      <base>
        <path value="MedicationKnowledge.regulatory.substitution.allowed"/>
        <min value="1"/>
        <max value="1"/>
      </base>
      <type>
        <code value="boolean"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="MedicationKnowledge.regulatory.schedule">
      <path value="MedicationKnowledge.regulatory.schedule"/>
      <short value="Specifies the schedule of a medication in jurisdiction"/>
      <definition
                  value="Specifies the schedule of a medication in jurisdiction."/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="MedicationKnowledge.regulatory.schedule"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="BackboneElement"/>
      </type>
      <constraint>
        <key value="ele-1"/>
        <severity value="error"/>
        <human value="All FHIR elements must have a @value or children"/>
        <expression value="hasValue() or (children().count() &gt; id.count())"/>
        <xpath value="@value|f:*|h:div"/>
        <source value="Element"/>
      </constraint>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="MedicationKnowledge.regulatory.schedule.id">
      <path value="MedicationKnowledge.regulatory.schedule.id"/>
      <representation value="xmlAttr"/>
      <short value="Unique id for inter-element referencing"/>
      <definition
                  value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="Element.id"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="string"/>
      </type>
```

```xml
            <isModifier value="false"/>
            <isSummary value="false"/>
            <mapping>
              <identity value="rim"/>
              <map value="n/a"/>
            </mapping>
          </element>
          <element id="MedicationKnowledge.regulatory.schedule.extension">
            <path value="MedicationKnowledge.regulatory.schedule.extension"/>
            <short value="Additional content defined by implementations"/>
            <definition
                      value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
            <comment
                    value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
            <alias value="extensions"/>
            <alias value="user content"/>
            <min value="0"/>
            <max value="*"/>
            <base>
              <path value="Element.extension"/>
              <min value="0"/>
              <max value="*"/>
            </base>
            <type>
              <code value="Extension"/>
            </type>
            <isModifier value="false"/>
            <isSummary value="false"/>
            <mapping>
              <identity value="rim"/>
              <map value="n/a"/>
            </mapping>
          </element>
          <element id="MedicationKnowledge.regulatory.schedule.modifierExtension">
            <path value="MedicationKnowledge.regulatory.schedule.modifierExtension"/>
            <short value="Extensions that cannot be ignored even if unrecognized"/>
            <definition
                      value="May be used to represent additional information that is not part
 of the basic definition of the element and that modifies the understanding of the elemen
t in which it is contained and/or the understanding of the containing element&#39;s desce
ndants. Usually modifier elements provide negation or qualification. To make the use of e
xtensions safe and manageable, there is a strict set of governance applied to the definit
ion and use of extensions. Though any implementer can define an extension, there is a set
 of requirements that SHALL be met as part of the definition of the extension. Applicatio
ns processing a resource are required to check for modifier extensions.

Modifier extensions SHALL NOT change the meaning of any elements on Resource or DomainRes
ource (including cannot change the meaning of modifierExtension itself)."/>
            <comment
                    value="There can be no stigma associated with the use of extensions by any
```

```
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
      <requirements
                   value="Modifier extensions allow for extensions that *cannot* be safe
ly ignored to be clearly distinguished from the vast majority of extensions which can be
safely ignored.  This promotes interoperability by eliminating the need for implementers
to prohibit the presence of extensions. For further information, see the [definition of m
odifier extensions](http://build.fhir.org/extensibility.html#modifierExtension)."/>
      <alias value="extensions"/>
      <alias value="user content"/>
      <alias value="modifiers"/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="BackboneElement.modifierExtension"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Extension"/>
      </type>
      <isModifier value="true"/>
      <isModifierReason
                      value="Modifier extensions are expected to modify the meaning or
interpretation of the element that contains them"/>
      <isSummary value="true"/>
      <mapping>
        <identity value="rim"/>
        <map value="N/A"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.regulatory.schedule.schedule">
      <path value="MedicationKnowledge.regulatory.schedule.schedule"/>
      <short value="Specifies the specific drug schedule"/>
      <definition value="Specifies the specific drug schedule."/>
      <min value="1"/>
      <max value="1"/>
      <base>
        <path value="MedicationKnowledge.regulatory.schedule.schedule"/>
        <min value="1"/>
        <max value="1"/>
      </base>
      <type>
        <code value="CodeableConcept"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="MedicationKnowledge.regulatory.maxDispense">
      <path value="MedicationKnowledge.regulatory.maxDispense"/>
      <short
            value="The maximum number of units of the medication that can be dispensed i
n a period"/>
      <definition
                  value="The maximum number of units of the medication that can be dispen
sed in a period."/>
```

```xml
          <min value="0"/>
          <max value="1"/>
          <base>
            <path value="MedicationKnowledge.regulatory.maxDispense"/>
            <min value="0"/>
            <max value="1"/>
          </base>
          <type>
            <code value="BackboneElement"/>
          </type>
          <constraint>
            <key value="ele-1"/>
            <severity value="error"/>
            <human value="All FHIR elements must have a @value or children"/>
            <expression value="hasValue() or (children().count() &gt; id.count())"/>
            <xpath value="@value|f:*|h:div"/>
            <source value="Element"/>
          </constraint>
          <isModifier value="false"/>
          <isSummary value="false"/>
        </element>
        <element id="MedicationKnowledge.regulatory.maxDispense.id">
          <path value="MedicationKnowledge.regulatory.maxDispense.id"/>
          <representation value="xmlAttr"/>
          <short value="Unique id for inter-element referencing"/>
          <definition
                   value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
          <min value="0"/>
          <max value="1"/>
          <base>
            <path value="Element.id"/>
            <min value="0"/>
            <max value="1"/>
          </base>
          <type>
            <code value="string"/>
          </type>
          <isModifier value="false"/>
          <isSummary value="false"/>
          <mapping>
            <identity value="rim"/>
            <map value="n/a"/>
          </mapping>
        </element>
        <element id="MedicationKnowledge.regulatory.maxDispense.extension">
          <path value="MedicationKnowledge.regulatory.maxDispense.extension"/>
          <short value="Additional content defined by implementations"/>
          <definition
                   value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
 be met as part of the definition of the extension."/>
          <comment
                 value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
```

```
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
      <alias value="extensions"/>
      <alias value="user content"/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="Element.extension"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Extension"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="n/a"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.regulatory.maxDispense.modifierExtension">
      <path value="MedicationKnowledge.regulatory.maxDispense.modifierExtension"/>
      <short value="Extensions that cannot be ignored even if unrecognized"/>
      <definition
                 value="May be used to represent additional information that is not part
 of the basic definition of the element and that modifies the understanding of the elemen
t in which it is contained and/or the understanding of the containing element&#39;s desce
ndants. Usually modifier elements provide negation or qualification. To make the use of e
xtensions safe and manageable, there is a strict set of governance applied to the definit
ion and use of extensions. Though any implementer can define an extension, there is a set
 of requirements that SHALL be met as part of the definition of the extension. Applicatio
ns processing a resource are required to check for modifier extensions.

Modifier extensions SHALL NOT change the meaning of any elements on Resource or DomainRes
ource (including cannot change the meaning of modifierExtension itself)."/>
      <comment
               value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
      <requirements
                    value="Modifier extensions allow for extensions that *cannot* be safe
ly ignored to be clearly distinguished from the vast majority of extensions which can be
safely ignored.  This promotes interoperability by eliminating the need for implementers
to prohibit the presence of extensions. For further information, see the [definition of m
odifier extensions](http://build.fhir.org/extensibility.html#modifierExtension)."/>
      <alias value="extensions"/>
      <alias value="user content"/>
      <alias value="modifiers"/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="BackboneElement.modifierExtension"/>
        <min value="0"/>
        <max value="*"/>
      </base>
```

```xml
      <type>
        <code value="Extension"/>
      </type>
      <isModifier value="true"/>
      <isModifierReason
                        value="Modifier extensions are expected to modify the meaning or
interpretation of the element that contains them"/>
      <isSummary value="true"/>
      <mapping>
        <identity value="rim"/>
        <map value="N/A"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.regulatory.maxDispense.quantity">
      <path value="MedicationKnowledge.regulatory.maxDispense.quantity"/>
      <short
              value="The maximum number of units of the medication that can be dispensed"/
>
      <definition
                    value="The maximum number of units of the medication that can be dispen
sed."/>
      <min value="1"/>
      <max value="1"/>
      <base>
        <path value="MedicationKnowledge.regulatory.maxDispense.quantity"/>
        <min value="1"/>
        <max value="1"/>
      </base>
      <type>
        <code value="Quantity"/>
        <profile value="http://hl7.org/fhir/StructureDefinition/SimpleQuantity"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="MedicationKnowledge.regulatory.maxDispense.period">
      <path value="MedicationKnowledge.regulatory.maxDispense.period"/>
      <short value="The period that applies to the maximum number of units"/>
      <definition
                    value="The period that applies to the maximum number of units."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="MedicationKnowledge.regulatory.maxDispense.period"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="Duration"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="MedicationKnowledge.kinetics">
      <path value="MedicationKnowledge.kinetics"/>
      <short
              value="The time course of drug absorption, distribution, metabolism and excr
```

```
etion of a medication from the body"/>
      <definition
                  value="The time course of drug absorption, distribution, metabolism and
 excretion of a medication from the body."/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="MedicationKnowledge.kinetics"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="BackboneElement"/>
      </type>
      <constraint>
        <key value="ele-1"/>
        <severity value="error"/>
        <human value="All FHIR elements must have a @value or children"/>
        <expression value="hasValue() or (children().count() &gt; id.count())"/>
        <xpath value="@value|f:*|h:div"/>
        <source value="Element"/>
      </constraint>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="MedicationKnowledge.kinetics.id">
      <path value="MedicationKnowledge.kinetics.id"/>
      <representation value="xmlAttr"/>
      <short value="Unique id for inter-element referencing"/>
      <definition
                  value="Unique id for the element within a resource (for internal refere
nces). This may be any string value that does not contain spaces."/>
      <min value="0"/>
      <max value="1"/>
      <base>
        <path value="Element.id"/>
        <min value="0"/>
        <max value="1"/>
      </base>
      <type>
        <code value="string"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="n/a"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.kinetics.extension">
      <path value="MedicationKnowledge.kinetics.extension"/>
      <short value="Additional content defined by implementations"/>
      <definition
                  value="May be used to represent additional information that is not part
 of the basic definition of the element. To make the use of extensions safe and manageabl
e, there is a strict set of governance  applied to the definition and use of extensions.
Though any implementer can define an extension, there is a set of requirements that SHALL
```

```
 be met as part of the definition of the extension."/>
      <comment
                value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
      <alias value="extensions"/>
      <alias value="user content"/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="Element.extension"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Extension"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
      <mapping>
        <identity value="rim"/>
        <map value="n/a"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.kinetics.modifierExtension">
      <path value="MedicationKnowledge.kinetics.modifierExtension"/>
      <short value="Extensions that cannot be ignored even if unrecognized"/>
      <definition
                value="May be used to represent additional information that is not part
 of the basic definition of the element and that modifies the understanding of the elemen
t in which it is contained and/or the understanding of the containing element&#39;s desce
ndants. Usually modifier elements provide negation or qualification. To make the use of e
xtensions safe and manageable, there is a strict set of governance applied to the definit
ion and use of extensions. Though any implementer can define an extension, there is a set
 of requirements that SHALL be met as part of the definition of the extension. Applicatio
ns processing a resource are required to check for modifier extensions.

Modifier extensions SHALL NOT change the meaning of any elements on Resource or DomainRes
ource (including cannot change the meaning of modifierExtension itself)."/>
      <comment
                value="There can be no stigma associated with the use of extensions by any
 application, project, or standard - regardless of the institution or jurisdiction that u
ses or defines the extensions.  The use of extensions is what allows the FHIR specificati
on to retain a core level of simplicity for everyone."/>
      <requirements
                    value="Modifier extensions allow for extensions that *cannot* be safe
ly ignored to be clearly distinguished from the vast majority of extensions which can be
safely ignored.  This promotes interoperability by eliminating the need for implementers
to prohibit the presence of extensions. For further information, see the [definition of m
odifier extensions](http://build.fhir.org/extensibility.html#modifierExtension)."/>
      <alias value="extensions"/>
      <alias value="user content"/>
      <alias value="modifiers"/>
      <min value="0"/>
      <max value="*"/>
      <base>
```

```xml
        <path value="BackboneElement.modifierExtension"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Extension"/>
      </type>
      <isModifier value="true"/>
      <isModifierReason
                       value="Modifier extensions are expected to modify the meaning or
interpretation of the element that contains them"/>
      <isSummary value="true"/>
      <mapping>
        <identity value="rim"/>
        <map value="N/A"/>
      </mapping>
    </element>
    <element id="MedicationKnowledge.kinetics.areaUnderCurve">
      <path value="MedicationKnowledge.kinetics.areaUnderCurve"/>
      <short
            value="The drug concentration measured at certain discrete points in time"/>
      <definition
                 value="The drug concentration measured at certain discrete points in ti
me."/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="MedicationKnowledge.kinetics.areaUnderCurve"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Quantity"/>
        <profile value="http://hl7.org/fhir/StructureDefinition/SimpleQuantity"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="MedicationKnowledge.kinetics.lethalDose50">
      <path value="MedicationKnowledge.kinetics.lethalDose50"/>
      <short value="The median lethal dose of a drug"/>
      <definition value="The median lethal dose of a drug."/>
      <min value="0"/>
      <max value="*"/>
      <base>
        <path value="MedicationKnowledge.kinetics.lethalDose50"/>
        <min value="0"/>
        <max value="*"/>
      </base>
      <type>
        <code value="Quantity"/>
        <profile value="http://hl7.org/fhir/StructureDefinition/SimpleQuantity"/>
      </type>
      <isModifier value="false"/>
      <isSummary value="false"/>
    </element>
    <element id="MedicationKnowledge.kinetics.halfLifePeriod">
```

```xml
        <path value="MedicationKnowledge.kinetics.halfLifePeriod"/>
        <short
               value="Time required for concentration in the body to decrease by half"/>
        <definition
                    value="The time required for any specified property (e.g., the concentr
ation of a substance in the body) to decrease by half."/>
        <min value="0"/>
        <max value="1"/>
        <base>
          <path value="MedicationKnowledge.kinetics.halfLifePeriod"/>
          <min value="0"/>
          <max value="1"/>
        </base>
        <type>
          <code value="Duration"/>
        </type>
        <isModifier value="false"/>
        <isSummary value="false"/>
      </element>
    </snapshot>
    <differential>
      <element id="MedicationKnowledge">
        <path value="MedicationKnowledge"/>
        <definition
                    value="Sets minimum expectations for questionnaire support for SDC-conf
ormant systems, including a number of extensions around display and behavior."/>
        <mustSupport value="false"/>
        <isModifier value="false"/>
      </element>
      <element id="MedicationKnowledge.code">
        <path value="MedicationKnowledge.code"/>
        <min value="1"/>
        <max value="*"/>
        <mustSupport value="true"/>
        <isModifier value="false"/>
      </element>
      <element id="MedicationKnowledge.code.coding">
        <path value="MedicationKnowledge.code.coding"/>
        <slicing>
          <discriminator>
            <type value="value"/>
            <path value="system"/>
          </discriminator>
          <rules value="open"/>
        </slicing>
        <mustSupport value="true"/>
        <isModifier value="false"/>
      </element>
      <element id="MedicationKnowledge.code.coding:UNII">
        <path value="MedicationKnowledge.code.coding"/>
        <sliceName value="UNII"/>
        <min value="1"/>
        <max value="1"/>
        <mustSupport value="true"/>
        <isModifier value="false"/>
      </element>
      <element id="MedicationKnowledge.code.coding:UNII.system">
```

```
        <path value="MedicationKnowledge.code.coding.system"/>
        <min value="1"/>
        <max value="1"/>
        <type>
          <code value="uri"/>
        </type>
        <fixedUri value="http://todo.org/CodeSystem/UNII"/>
        <mustSupport value="true"/>
        <isModifier value="false"/>
      </element>
      <element id="MedicationKnowledge.code.coding:UNII.code">
        <path value="MedicationKnowledge.code.coding.code"/>
        <short value="UNII code"/>
        <definition
                    value="The UNII is a non-proprietary, free, unique, unambiguous, non-se
mantic, alphanumeric identifier based on a substance's molecular structure and/or descrip
tive information. [Source: http://www.fda.gov/ForIndustry/DataStandards/SubstanceRegistra
tionSystem-UniqueIngredientIdentifierUNII/]
Example: 362O9ITL9D
Note: If a UNII does not exist, please go to
http://www.fda.gov/ForIndustry/DataStandards/SubstanceRegistrationSystem-UniqueIngredient
IdentifierUNII/."/>
        <min value="1"/>
        <max value="1"/>
        <mustSupport value="true"/>
        <isModifier value="false"/>
      </element>
      <element id="MedicationKnowledge.code.coding:CASNumber">
        <path value="MedicationKnowledge.code.coding"/>
        <sliceName value="CASNumber"/>
        <min value="1"/>
        <max value="1"/>
        <mustSupport value="true"/>
        <isModifier value="false"/>
      </element>
      <element id="MedicationKnowledge.code.coding:CASNumber.system">
        <path value="MedicationKnowledge.code.coding.system"/>
        <min value="1"/>
        <max value="1"/>
        <type>
          <code value="uri"/>
        </type>
        <fixedUri value="http://todo.org/CodeSystem/CASNumber"/>
        <mustSupport value="true"/>
        <isModifier value="false"/>
      </element>
      <element id="MedicationKnowledge.code.coding:CASNumber.code">
        <path value="MedicationKnowledge.code.coding.code"/>
        <short value="CAS number"/>
        <definition
                    value="Chemical Abstract Service (CAS) Registry Numbers (often referred
 to as CAS RNs or CAS Numbers) are used to provide unmistakable identifiers for chemical
substances. A CAS Registry Number itself has no inherent chemical significance but provid
es a way to identify a chemical substance or molecular structure when there are many poss
ible systematic, generic, proprietary or trivial names. [Source: Adapted from CAS.org]
Example: CAS [103-90-2]."/>
        <min value="1"/>
```

```
        <max value="1"/>
        <mustSupport value="true"/>
        <isModifier value="false"/>
    </element>
    <element id="MedicationKnowledge.code.text">
        <path value="MedicationKnowledge.code.text"/>
        <short value="Name"/>
        <definition
                value="Any ingredient intended for use in the manufacture of a drug pro
duct, including those that may not appear in such drug product. [Source: (21 CFR 210.3(b)
(3)) PAC-ATLS 1998]."/>
        <min value="1"/>
        <max value="1"/>
        <mustSupport value="true"/>
        <isModifier value="false"/>
    </element>
  </differential>
</StructureDefinition>
```

<status value="active"/> <subjectReference> <reference value="MedicationKnoweledge/idigwqdhk4lkudoiwttzesqs5lugq0mu2rsd0xqekd1ptktqxadunl"/> </subject...

Proof of Concept PC/CMC Quality Specification

<status value="active"/> <subjectReference> <reference value="MedicationKnoweledge/idb2fkhte2ctyuos5kunitness0j0okowtvcur2kk0rlcbzuk0wcgo"/> </subject...

Proof of Concept PC/CMC Quality Specification

```xml
<?xml version="1.0" encoding="UTF-8"?>

<CodeSystem xmlns="http://hl7.org/fhir">
  <id value="DoseForm"/>
  <text>
    <status value="generated"/><div xmlns="http://www.w3.org/1999/xhtml"><h2>cmcDose</h2><div><p>This is the
physical form of the product as presented to the individual. For example: tablet, capsule, liquid or ointment. NCI
concept code for pharmaceutical dosage form: C42636</p>
</div><p>This code system http://fda.gov/cder/fhir/pqcmc/CodeSystem/DoseForm defines the following codes:</p>
<table class="codes"><tr><td style="white-space:nowrap"><b>Code</b></td><td><b>Display</b></td><td>
<b>Definition</b></td></tr><tr><td style="white-space:nowrap">C42887<a name="DoseForm-C42887"> </a></td>
<td>AEROSOL</td><td/></tr><tr><td style="white-space:nowrap">C42888<a name="DoseForm-C42888"> </a>
</td><td>AEROSOL, FOAM</td><td/></tr><tr><td style="white-space:nowrap">C42960<a name="DoseForm-
C42960"> </a></td><td>AEROSOL, METERED</td><td/></tr><tr><td style="white-space:nowrap">C42971<a
name="DoseForm-C42971"> </a></td><td>AEROSOL, POWDER</td><td/></tr><tr><td style="white-
space:nowrap">C42889<a name="DoseForm-C42889"> </a></td><td>AEROSOL, SPRAY</td><td/></tr><tr><td
style="white-space:nowrap">C42892<a name="DoseForm-C42892"> </a></td><td>BAR, CHEWABLE</td><td/>
</tr><tr><td style="white-space:nowrap">C42890<a name="DoseForm-C42890"> </a></td><td>BEAD</td><td/>
</tr><tr><td style="white-space:nowrap">C25158<a name="DoseForm-C25158"> </a></td><td>CAPSULE</td>
<td/></tr><tr><td style="white-space:nowrap">C42895<a name="DoseForm-C42895"> </a></td><td>CAPSULE,
COATED</td><td/></tr><tr><td style="white-space:nowrap">C42896<a name="DoseForm-C42896"> </a></td>
<td>CAPSULE, COATED PELLETS</td><td/></tr><tr><td style="white-space:nowrap">C42917<a
name="DoseForm-C42917"> </a></td><td>CAPSULE, COATED, EXTENDED RELEASE</td><td/></tr><tr><td
style="white-space:nowrap">C42902<a name="DoseForm-C42902"> </a></td><td>CAPSULE, DELAYED
RELEASE</td><td/></tr><tr><td style="white-space:nowrap">C42904<a name="DoseForm-C42904"> </a></td>
<td>CAPSULE, DELAYED RELEASE PELLETS</td><td/></tr><tr><td style="white-space:nowrap">C42916<a
name="DoseForm-C42916"> </a></td><td>CAPSULE, EXTENDED RELEASE</td><td/></tr><tr><td style="white-
space:nowrap">C42928<a name="DoseForm-C42928"> </a></td><td>CAPSULE, FILM COATED, EXTENDED
RELEASE</td><td/></tr><tr><td style="white-space:nowrap">C42936<a name="DoseForm-C42936"> </a></td>
<td>CAPSULE, GELATIN COATED</td><td/></tr><tr><td style="white-space:nowrap">C42954<a
name="DoseForm-C42954"> </a></td><td>CAPSULE, LIQUID FILLED</td><td/></tr><tr><td style="white-
space:nowrap">C100103<a name="DoseForm-C100103"> </a></td><td>CELLULAR SHEET</td><td/></tr><tr><td
style="white-space:nowrap">C134876<a name="DoseForm-C134876"> </a></td><td>CHEWABLE GEL</td><td/>
</tr><tr><td style="white-space:nowrap">C60884<a name="DoseForm-C60884"> </a></td><td>CLOTH</td><td/>
</tr><tr><td style="white-space:nowrap">C60891<a name="DoseForm-C60891"> </a></td>
<td>CONCENTRATE</td><td/></tr><tr><td style="white-space:nowrap">C28944<a name="DoseForm-C28944">
</a></td><td>CREAM</td><td/></tr><tr><td style="white-space:nowrap">C60897<a name="DoseForm-C60897">
</a></td><td>CREAM, AUGMENTED</td><td/></tr><tr><td style="white-space:nowrap">C42901<a
name="DoseForm-C42901"> </a></td><td>CRYSTAL</td><td/></tr><tr><td style="white-
space:nowrap">C43525<a name="DoseForm-C43525"> </a></td><td>DISC</td><td/></tr><tr><td style="white-
space:nowrap">C42679<a name="DoseForm-C42679"> </a></td><td>DOUCHE</td><td/></tr><tr><td style="white-
space:nowrap">C42763<a name="DoseForm-C42763"> </a></td><td>DRESSING</td><td/></tr><tr><td
style="white-space:nowrap">C42912<a name="DoseForm-C42912"> </a></td><td>ELIXIR</td><td/></tr><tr><td
style="white-space:nowrap">C42913<a name="DoseForm-C42913"> </a></td><td>EMULSION</td><td/></tr><tr>
<td style="white-space:nowrap">C42915<a name="DoseForm-C42915"> </a></td><td>ENEMA</td><td/></tr><tr>
<td style="white-space:nowrap">C42929<a name="DoseForm-C42929"> </a></td><td>EXTRACT</td><td/></tr>
<tr><td style="white-space:nowrap">C60926<a name="DoseForm-C60926"> </a></td><td>FIBER, EXTENDED
RELEASE</td><td/></tr><tr><td style="white-space:nowrap">C42932<a name="DoseForm-C42932"> </a></td>
<td>FILM</td><td/></tr><tr><td style="white-space:nowrap">C42920<a name="DoseForm-C42920"> </a></td>
<td>FILM, EXTENDED RELEASE</td><td/></tr><tr><td style="white-space:nowrap">C42984<a
name="DoseForm-C42984"> </a></td><td>FILM, SOLUBLE</td><td/></tr><tr><td style="white-
space:nowrap">C60927<a name="DoseForm-C60927"> </a></td><td>FOR SOLUTION</td><td/></tr><tr><td
style="white-space:nowrap">C60928<a name="DoseForm-C60928"> </a></td><td>FOR SUSPENSION</td><td/>
```

Code	Dose Form	
C60929	FOR SUSPENSION, EXTENDED RELEASE	
C42933	GAS	
C42934	GEL	
C42906	GEL, DENTIFRICE	
C60930	GEL, METERED	
C42937	GLOBULE	
C42938	GRANULE	
C42903	GRANULE, DELAYED RELEASE	
C42909	GRANULE, EFFERVESCENT	
C42939	GRANULE, FOR SOLUTION	
C42940	GRANULE, FOR SUSPENSION	
C42921	GRANULE, FOR SUSPENSION, EXTENDED RELEASE	
C42894	GUM, CHEWING	
C42942	IMPLANT	
C42944	INHALANT	
C113106	INJECTABLE FOAM	
C60931	INJECTABLE, LIPOSOMAL	
C42946	INJECTION	
C42914	INJECTION, EMULSION	
C42950	INJECTION, LIPID COMPLEX	
C42974	INJECTION, POWDER, FOR SOLUTION	
C42976	INJECTION, POWDER, FOR SUSPENSION	
C42977	INJECTION, POWDER, FOR SUSPENSION, EXTENDED RELEASE	
C42959	INJECTION, POWDER, LYOPHILIZED, FOR LIPOSOMAL SUSPENSION	
C42957	INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION	
C42958	INJECTION, POWDER, LYOPHILIZED, FOR SUSPENSION	
C42956	INJECTION, POWDER, LYOPHILIZED, FOR SUSPENSION, EXTENDED RELEASE	
C42945	INJECTION, SOLUTION	
C42899	INJECTION, SOLUTION, CONCENTRATE	
C42995	INJECTION, SUSPENSION	
C42926	INJECTION, SUSPENSION, EXTENDED RELEASE	
C42951	INJECTION, SUSPENSION, LIPOSOMAL	
C42988	INJECTION, SUSPENSION, SONICATED	
C60933	INSERT	
C42922	INSERT, EXTENDED RELEASE	
C47915	INTRAUTERINE DEVICE	
C42947	IRRIGANT	
C42948	JELLY	
C47916	KIT	
C42949	LINIMENT	
C42952	LIPSTICK	
C42953	LIQUID	
C60934	LIQUID, EXTENDED RELEASE	
C29167	LOTION	
C60957		

Code	Dose Form
	LOTION, AUGMENTED
C60958	LOTION/SHAMPOO
C42955	LOZENGE
C29269	MOUTHWASH
C48624	NOT APPLICABLE
C42965	OIL
C42966	OINTMENT
C60984	OINTMENT, AUGMENTED
C42967	PASTE
C42907	PASTE, DENTIFRICE
C60985	PASTILLE
C42968	PATCH
C42923	PATCH, EXTENDED RELEASE
C42911	PATCH, EXTENDED RELEASE, ELECTRICALLY CONTROLLED
C42969	PELLET
C42943	PELLET, IMPLANTABLE
C42918	PELLETS, COATED, EXTENDED RELEASE
C25394	PILL
C42970	PLASTER
C47913	POULTICE
C42972	POWDER
C42908	POWDER, DENTIFRICE
C42973	POWDER, FOR SOLUTION
C42975	POWDER, FOR SUSPENSION
C42961	POWDER, METERED
C60988	RING
C42979	RINSE
C42980	SALVE
C42981	SHAMPOO
C42982	SHAMPOO, SUSPENSION
C42983	SOAP
C42986	SOLUTION
C42898	SOLUTION, CONCENTRATE
C42987	SOLUTION, FOR SLUSH
C60994	SOLUTION, GEL FORMING / DROPS
C42935	SOLUTION, GEL FORMING, EXTENDED RELEASE
C60992	SOLUTION/ DROPS
C47912	SPONGE
C42989	SPRAY
C42962	SPRAY, METERED
C42990	SPRAY, SUSPENSION
C42991	STICK
C47914	STRIP
C42993	SUPPOSITORY
C42924	SUPPOSITORY, EXTENDED RELEASE
C42994	SUSPENSION
C42925	SUSPENSION, EXTENDED RELEASE
C60995	

```
<td>SUSPENSION/ DROPS</td><td/></tr><tr><td style="white-space:nowrap">C47898<a name="DoseForm-
C47898"> </a></td><td>SWAB</td><td/></tr><tr><td style="white-space:nowrap">C42996<a name="DoseForm-
C42996"> </a></td><td>SYRUP</td><td/></tr><tr><td style="white-space:nowrap">C42998<a name="DoseForm-
C42998"> </a></td><td>TABLET</td><td/></tr><tr><td style="white-space:nowrap">C42893<a name="DoseForm-
C42893"> </a></td><td>TABLET, CHEWABLE</td><td/></tr><tr><td style="white-space:nowrap">C124794<a
name="DoseForm-C124794"> </a></td><td>TABLET, CHEWABLE, EXTENDED RELEASE</td><td/></tr><tr>
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<td/></tr><tr><td style="white-space:nowrap">C60997<a name="DoseForm-C60997"> </a></td><td>TABLET,
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</td><td>TABLET, EXTENDED RELEASE</td><td/></tr><tr><td style="white-space:nowrap">C42931<a
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RELEASE</td><td/></tr><tr><td style="white-space:nowrap">C61004<a name="DoseForm-C61004"> </a></td>
<td>TABLET, FOR SOLUTION</td><td/></tr><tr><td style="white-space:nowrap">C61005<a name="DoseForm-
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DELAYED RELEASE</td><td/></tr><tr><td style="white-space:nowrap">C42985<a name="DoseForm-C42985">
</a></td><td>TABLET, SOLUBLE</td><td/></tr><tr><td style="white-space:nowrap">C42992<a
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<tr><td style="white-space:nowrap">C47892<a name="DoseForm-C47892"> </a></td><td>TAMPON</td><td/></tr>
<tr><td style="white-space:nowrap">C47897<a name="DoseForm-C47897"> </a></td><td>TAPE</td><td/></tr><tr>
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<tr><td style="white-space:nowrap">C43003<a name="DoseForm-C43003"> </a></td><td>WAFER</td><td/></tr>
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  <status value="draft"/>
  <experimental value="false"/>
  <date value="2019-04-18T17:50:12-04:00"/>
  <contact>
   <telecom>
    <system value="url"/>
   </telecom>
   <telecom>
    <system value="email"/>
   </telecom>
  </contact>
  <description value="This is the physical form of the product as presented to the individual. For example: tablet,
capsule, liquid or ointment. NCI concept code for pharmaceutical dosage form: C42636"/>
  <caseSensitive value="true"/>
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    <concept>
      <code value="C42954"/>
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    <concept>
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    </concept>
    <concept>
      <code value="C28944"/>
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      <code value="C60897"/>
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    </concept>
    <concept>
      <code value="C43525"/>
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    <concept>
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```xml
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```xml
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```xml
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```xml
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```xml
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    <concept>
     <code value="C147579"/>
     <display value="TABLET WITH SENSOR"/>
    </concept>
    <concept>
     <code value="C47892"/>
     <display value="TAMPON"/>
    </concept>
    <concept>
     <code value="C47897"/>
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    <concept>
     <code value="C43000"/>
     <display value="TINCTURE"/>
    </concept>
    <concept>
     <code value="C43001"/>
     <display value="TROCHE"/>
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    <concept>
     <code value="C43003"/>
     <display value="WAFER"/>
    </concept>
   </CodeSystem>
```

```xml
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  <id value="methodOrig"/>
  <text>
    <status value="generated"/><div xmlns="http://www.w3.org/1999/xhtml"><h2>MethodOrigin</h2><div><p>Codes
specifying the source of the method.</p>
</div><p>This code system http://fda.gov/cder/fhir/pqcmc/CodeSystem/methodOrig defines the following codes:</p>
<table class="codes"><tr><td style="white-space:nowrap"><b>Code</b></td><td><b>Display</b></td><td>
<b>Definition</b></td></tr><tr><td style="white-space:nowrap">C96102<a name="methodOrig-C96102"> </a></td>
<td>Compendial</td><td>Method defined in any recognized compendium (e.g., USP, PharmEU, JP, etc.).</td></tr>
<tr><td style="white-space:nowrap">C96103<a name="methodOrig-C96103"> </a></td><td>Proprietary</td>
<td>Method defined by the sponsor (not recognized in CFR or any compendium)</td></tr><tr><td style="white-
space:nowrap">C96164<a name="methodOrig-C96164"> </a></td><td>CFR</td><td>Method defined in the Code of
Federal Regulation (CFR)</td></tr></table></div>
  </text>
  <url value="http://fda.gov/cder/fhir/pqcmc/CodeSystem/methodOrig"/>
  <version value="current"/>
  <name value="MethodOrigin"/>
  <status value="draft"/>
  <experimental value="false"/>
  <date value="2019-04-18T17:50:12-04:00"/>
  <contact>
    <telecom>
      <system value="url"/>
    </telecom>
    <telecom>
      <system value="email"/>
    </telecom>
  </contact>
  <description value="Codes  specifying the source of the method."/>
  <caseSensitive value="true"/>
  <valueSet value="http://fda.gov/cder/fhir/pqcmc/ValueSet/methodOrig"/>
  <content value="complete"/>
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    <code value="C96102"/>
    <display value="Compendial"/>
    <definition value="Method defined in any recognized compendium (e.g., USP, PharmEU, JP, etc.)."/>
  </concept>
  <concept>
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    <display value="Proprietary"/>
    <definition value="Method defined by the sponsor (not recognized in CFR or any compendium)"/>
  </concept>
  <concept>
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    <display value="CFR"/>
    <definition value="Method defined in the Code of Federal Regulation (CFR)"/>
  </concept>
</CodeSystem>
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```xml
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  <id value="SpecStat"/>
  <text>
    <status value="generated"/><div xmlns="http://www.w3.org/1999/xhtml"><h2>SpecStatus</h2><div><p>Code
indicating the current FDA regulatory status of the specification</p>
</div><p>This code system http://fda.gov/cder/fhir/pqcmc/CodeSystem/SpecStat defines the following codes:</p>
<table class="codes"><tr><td style="white-space:nowrap"><b>Code</b></td><td><b>Display</b></td><td>
<b>Definition</b></td></tr><tr><td style="white-space:nowrap">C134010<a name="SpecStat-C134010"> </a></td>
<td>Tentatively Approved</td><td>A specification that met the requirements for approval but the application could not
be approved for reasons such as patents and exclusivity.</td></tr><tr><td style="white-space:nowrap">C134011<a
name="SpecStat-C134011"> </a></td><td>Not Approved</td><td>A specification that has not yet been approved.
</td></tr><tr><td style="white-space:nowrap">C134012<a name="SpecStat-C134012"> </a></td><td>Reported in a
CBE or AR</td><td>The specification may be used without prior approval, and was submitted in a changes being
effected (CBE) supplement or an annual report (AR).</td></tr><tr><td style="white-space:nowrap">C25425<a
name="SpecStat-C25425"> </a></td><td>Approved</td><td>A specification that has met the requirements for
approval</td></tr></table></div>
  </text>
  <url value="http://fda.gov/cder/fhir/pqcmc/CodeSystem/SpecStat"/>
  <version value="current"/>
  <name value="SpecStatus"/>
  <status value="draft"/>
  <experimental value="false"/>
  <date value="2019-04-18T17:50:12-04:00"/>
  <contact>
   <telecom>
    <system value="url"/>
   </telecom>
   <telecom>
    <system value="email"/>
   </telecom>
  </contact>
  <description value="Code indicating the current FDA regulatory status of the specification"/>
  <caseSensitive value="true"/>
  <valueSet value="http://fda.gov/cder/fhir/pqcmc/ValueSet/SpecStat"/>
  <content value="complete"/>
  <concept>
   <code value="C134010"/>
   <display value="Tentatively Approved"/>
   <definition value="A specification that met the requirements for approval but the application could not be approved
for reasons such as patents and exclusivity."/>
  </concept>
  <concept>
   <code value="C134011"/>
   <display value="Not Approved"/>
   <definition value="A specification that has not yet been approved."/>
  </concept>
  <concept>
   <code value="C134012"/>
   <display value="Reported in a CBE or AR"/>
   <definition value="The specification may be used without prior approval, and was submitted in a changes being
effected (CBE) supplement or an annual report (AR)."/>
```

```xml
    </concept>
  <concept>
    <code value="C25425"/>
    <display value="Approved"/>
    <definition value="A specification that has met the requirements for approval"/>
  </concept>
 </CodeSystem>
```

```xml
<?xml version="1.0" encoding="UTF-8"?>

<CodeSystem xmlns="http://hl7.org/fhir">
  <id value="testCat"/>
  <text>
    <status value="generated"/><div xmlns="http://www.w3.org/1999/xhtml"><h2>TestCategory</h2><div><p>List of
test categories allowable values for the Test Category data element</p>
</div><p>This code system http://fda.gov/cder/fhir/pqcmc/CodeSystem/testCat defines the following codes:</p><table
class="codes"><tr><td style="white-space:nowrap"><b>Code</b></td><td><b>Display</b></td><td>
<b>Definition</b></td></tr><tr><td style="white-space:nowrap">C60819<a name="testCat-C60819"> </a></td>
<td>Assay</td><td>Tests which measure the content of the active ingredient in the drug substance or drug product.
Synonymous with strength or purity which is commonly used of define the content of the active ingredient in a drug
product. [Source: Adapted from ICH Q6A and Q6B]  Note:  chiral purity, preservative content, Anti-Oxidant
Concentration, Chelate Concentration, isomeric ratio.</td></tr><tr><td style="white-space:nowrap">C138990<a
name="testCat-C138990"> </a></td><td>Description</td><td>An assessment of the physical state (e.g., color, shape,
size) of the drug substance or product. [Source: Adapted from ICH Q6A]</td></tr><tr><td style="white-
space:nowrap">C138993<a name="testCat-C138993"> </a></td><td>Identification</td><td>Tests that establishes the
characteristic and uniqueness  of the substance of interest and should be able to discriminate between compounds of
closely related structures which are likely to be present. [Source: ICH Q6A]</td></tr><tr><td style="white-
space:nowrap">C158424<a name="testCat-C158424"> </a></td><td>Physical Properties</td><td>Assessments of the
characteristics of a material that are not associated with a change in its composition and basic nature, including but not
limited to its texture, smell, freezing point, boiling point, melting point, opacity, viscosity and density.</td></tr><tr><td
style="white-space:nowrap">C158425<a name="testCat-C158425"> </a></td><td>Biological Properties</td><td>Any
effect a given material has on a living organism (e.g., microbial limits, endotoxin).</td></tr><tr><td style="white-
space:nowrap">C17771<a name="testCat-C17771"> </a></td><td>Chemical Properties</td><td>A characteristic of a
material that is observed during a reaction in which the chemical composition or identity of the material is changed
(e.g., combustibility, solubility, acidity/basicity).</td></tr><tr><td style="white-space:nowrap">C158423<a
name="testCat-C158423"> </a></td><td>Impurities</td><td>Analytical procedures that determine the presence of a
component of the material that is not the chemical entity defined as the material.</td></tr></table></div>
  </text>
  <url value="http://fda.gov/cder/fhir/pqcmc/CodeSystem/testCat"/>
  <version value="current"/>
  <name value="TestCategory"/>
  <status value="draft"/>
  <experimental value="false"/>
  <date value="2019-04-18T17:50:12-04:00"/>
  <contact>
    <telecom>
      <system value="url"/>
    </telecom>
    <telecom>
      <system value="email"/>
    </telecom>
  </contact>
  <description value="List of test categories allowable values for the Test Category data element"/>
  <caseSensitive value="true"/>
  <valueSet value="http://fda.gov/cder/fhir/pqcmc/ValueSet/testCat"/>
  <content value="complete"/>
  <concept>
    <code value="C60819"/>
    <display value="Assay"/>
    <definition value="Tests which measure the content of the active ingredient in the drug substance or drug product.
Synonymous with strength or purity which is commonly used of define the content of the active ingredient in a drug
```

product. [Source: Adapted from ICH Q6A and Q6B] Note: chiral purity, preservative content, Anti-Oxidant Concentration, Chelate Concentration, isomeric ratio."/>
  </concept>
  <concept>
   <code value="C138990"/>
   <display value="Description"/>
   <definition value="An assessment of the physical state (e.g., color, shape, size) of the drug substance or product. [Source: Adapted from ICH Q6A]"/>
  </concept>
  <concept>
   <code value="C138993"/>
   <display value="Identification"/>
  </concept>
  <concept>
   <code value="C158424"/>
   <display value="Physical Properties"/>
   <definition value="Assessments of the characteristics of a material that are not associated with a change in its composition and basic nature, including but not limited to its texture, smell, freezing point, boiling point, melting point, opacity, viscosity and density."/>
  </concept>
  <concept>
   <code value="C158425"/>
   <display value="Biological Properties"/>
   <definition value="Any effect a given material has on a living organism (e.g., microbial limits, endotoxin)."/>
  </concept>
  <concept>
   <code value="C17771"/>
   <display value="Chemical Properties"/>
   <definition value="A characteristic of a material that is observed during a reaction in which the chemical composition or identity of the material is changed (e.g., combustibility, solubility, acidity/basicity)."/>
  </concept>
  <concept>
   <code value="C158423"/>
   <display value="Impurities"/>
   <definition value="Analytical procedures that determine the presence of a component of the material that is not the chemical entity defined as the material."/>
  </concept>
</CodeSystem>

```xml
<?xml version="1.0" encoding="UTF-8"?>

<CodeSystem xmlns="http://hl7.org/fhir">
  <id value="pqcmcUsage"/>
  <text>
    <status value="generated"/><div xmlns="http://www.w3.org/1999/xhtml"><h2>TestUsage</h2><div><p>List of
codes specifying the time point during the manufacturing process of a substance or product when a particular analytical
procedure or measurement is being performed</p>
</div><p>This code system http://fda.gov/cder/fhir/pqcmc/CodeSystem/pqcmcUsage defines the following codes:</p>
<table class="codes"><tr><td style="white-space:nowrap"><b>Code</b></td><td><b>Display</b></td><td>
<b>Definition</b></td></tr><tr><td style="white-space:nowrap">C134029<a name="pqcmcUsage-C134029"> </a>
</td><td>Release</td><td>For determination of acceptability for use of a material, drug or a drug substance. NOTE:
The &quot;use&quot; could be for distribution, marketing, further manufacturing stages, etc.</td></tr><tr><td
style="white-space:nowrap">C134030<a name="pqcmcUsage-C134030"> </a></td><td>Stability</td><td>For
determination of maintained performance parameters on storage over time, of a material, drug or a drug substance.</td>
</tr><tr><td style="white-space:nowrap">C134031<a name="pqcmcUsage-C134031"> </a></td><td>Release and
Stability</td><td>For determination at release and on stability when test and acceptance criteria are the same in both
cases.</td></tr></table></div>
  </text>
  <url value="http://fda.gov/cder/fhir/pqcmc/CodeSystem/pqcmcUsage"/>
  <version value="current"/>
  <name value="TestUsage"/>
  <status value="draft"/>
  <experimental value="false"/>
  <date value="2019-04-18T17:50:12-04:00"/>
  <contact>
    <telecom>
      <system value="url"/>
    </telecom>
    <telecom>
      <system value="email"/>
    </telecom>
  </contact>
  <description value="List of codes specifying the time point during the manufacturing process of a substance or product
when a particular analytical procedure or measurement is being performed"/>
  <caseSensitive value="true"/>
  <valueSet value="http://fda.gov/cder/fhir/pqcmc/ValueSet/pqcmcUsage"/>
  <content value="complete"/>
  <concept>
    <code value="C134029"/>
    <display value="Release"/>
    <definition value="For determination of acceptability for use of a material, drug or a drug substance. NOTE: The
&quot;use&quot; could be for distribution, marketing, further manufacturing stages, etc."/>
  </concept>
  <concept>
    <code value="C134030"/>
    <display value="Stability"/>
    <definition value="For determination of maintained performance parameters on storage over time, of a material, drug
or a drug substance."/>
  </concept>
  <concept>
    <code value="C134031"/>
    <display value="Release and Stability"/>
```

```
    <definition value="For determination at release and on stability when test and acceptance criteria are the same in both
cases."/>
  </concept>
</CodeSystem>
```