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1.0.0-ballot - STU 1 - Ballot


[Table of Contents \(toc.html\)](#) > **07 Fhir Representation**

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7 07 Fhir Representation

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The major FHIR elements used are discussed first followed by explanation of the mappings between M11, USDM and FHIR.

[TOC]

7.1 FHIR Elements and Protocol Representation

We assume a basic understanding of FHIR - to get an introduction, see one of the many HL7 training videos.

The elements of FHIR we will refer to are as follows:

Resource - the basic building block defined by the FHIR specification that represents a concept and its key attributes. For our present purposes the key is the **ResearchStudy** resource.

Datatype - each attribute within a resource has a specific data type. In addition to the usual string, integer etc FHIR also defines complex data types for concepts such as Address, Signature and many more. Of particular relevance is the Code and the CodeableConcept

Terminology - Many items are represented by a fixed *Code* which represents a specific concept. The human readable representation of the concept is the *Term* and a code may have multiple different terms to meet conventional wording in a given context but all the terms have the same meaning (concept). Codes can be arranged in a hierarchy and this constitutes a *CodeSystem*. To express meaning we have to know both the Code and the CodeSystem and for human readability we often include the preferred Term. The Code and the CodeableConcept contain attributes for all three of these elements. To determine which codes are allowed for an attribute we specify a *ValueSet* which explicitly or implicitly specifies the codes that are allowed. The codes may come from more than one code system. In addition to binding a ValueSet to an attribute we also specify if that ValueSet is the only one that can be used (*Required* Binding), codes must be used if they cover the concept but new codes can be added for concepts not in the value set (*Extensible* binding) or the value set is optional (*Preferred* and *Example* bindings).

Extensions - FHIR does not attempt to cover all minority concepts but restricts itself to those that are widely used and then provides a mechanism for defining extensions to a resource in a way that existing FHIR servers can handle even though they may never have seen the extension before. To represent the entirety of USDM and M11 concepts we make significant use of extensions.

Profiles - Resources that are defined by the FHIR specification generally have a lot of flexibility in them. For instance:

- attributes may occur zero to many times,

- [FHIR Elements and Protocol Representation](#)
- [Terminology](#)
- [Validation](#)
- [USDM and M11 to FHIR Mapping](#)

- value sets have an Example binding,
- references from one resource to another allow as wide a set of options as possible.

Profiles are about reducing these options to what is relevant for a particular use case. Attributes that were optional can be made mandatory, allowable codes can be restricted to a small set and so on. Extensions can also be subject to profiling.

7.1.1 Protocol Content - Narrative vs Structured

The M11 template details both narrative content and structured content

Implementers will vary in their desired use of M11: some will treat as a document, others will leverage structured content, others will utilize for machine processing

The FHIR implementation must therefore cover both narrative and structured content. The challenge is that some data is purely textual while others is quite granular. We also have to recognize that some implementers will cling to a document paradigm while others will want to use the granular machine readable content as they automate systems.

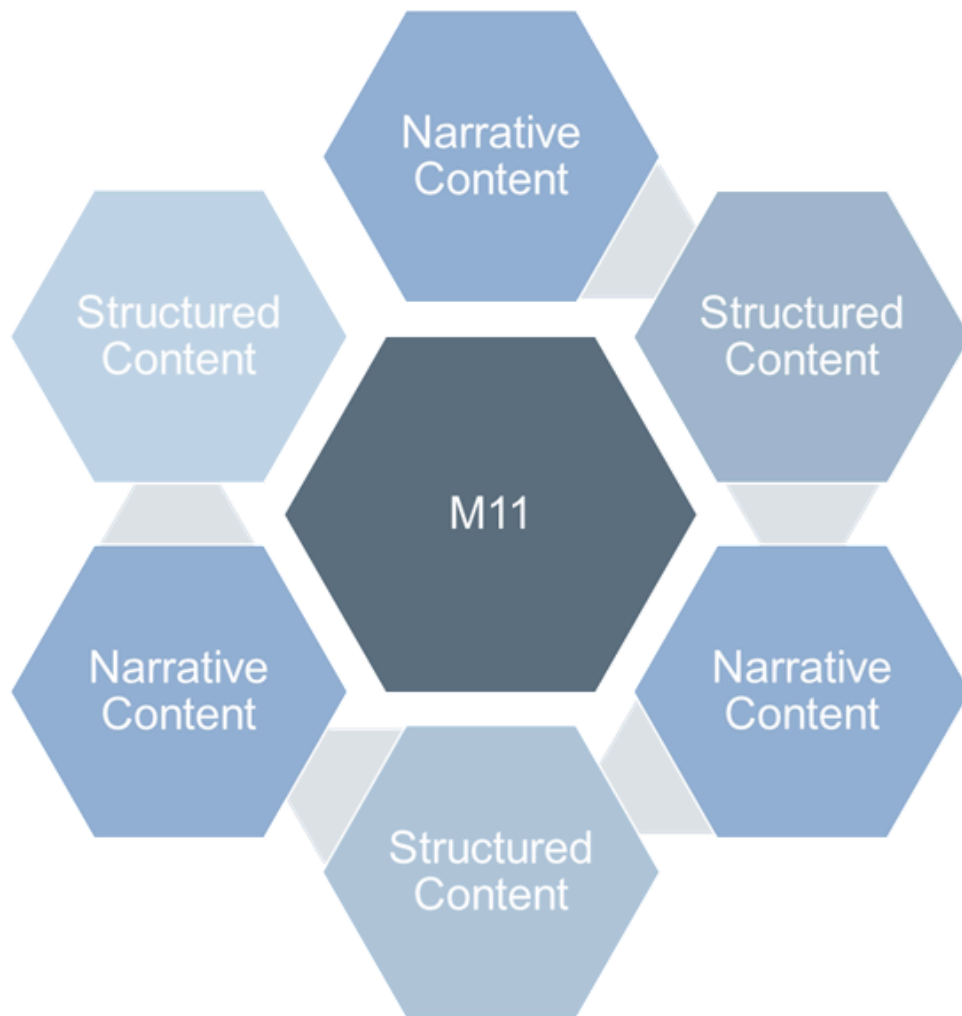


Figure 1: Narrative vs Structured

7.1.1.1 Narrative Representation

In FHIR representation of "documents" is done using a *Composition* resource. This is not immediately accessible from the *ResearchStudy* resource and so we create an extension to attach *Composition* to *ResearchStudy*.



ResearchStudy

ResearchStudy has many structured attributes to describe a protocol and it is the correct starting point to use.
BUT It does not have provision to carry narrative text

Composition

Composition is designed to carry narrative content and the content can have sections, sub-sections, sub-sub-sections etc.

ResearchStudy

+ NarrativeContent

Composition

We created a **NarrativeContent** extension to **ResearchStudy** which is essentially a pointer to a **Composition**.

Figure 2: Narrative Content

To properly reflect the M11 template, the sections and sub-sections in the **Composition** need to match those in the template.

The template sections can be defined in terminology

Code Display

C218514 1 PROTOCOL SUMMARY

C218515 1.1 Protocol Synopsis

C218516 1.1.1 Primary and Secondary Objectives and Estim

C218517 1.1.2 Overall Design

C218518 1.2 Trial Schema

C218519 1.3 Schedule of Activities

C218520 2 INTRODUCTION

C218521 2.1 Purpose of Trial

C218522 2.2 Assessment of Risks and Benefits

Figure 3: Section Code List

Specific narrative instances can then use the codes to specify which parts of the M11 Template they represent.



Figure 4: Narrative Content Example

In the illustration above **ResearchStudy** has two **NarrativeContent** sections attached. One with code *C218517* which is *1.1.2 Overall Design* and one with code *C218520* which is *2 INTRODUCTION* and this would then have all the sub-sections within the *INTRODUCTION*.

7.1.1.2 Structured Representation

The real power of a digital protocol comes from representing the content as a series of distinct attributes. USDM and M11 provide information models that can be represented by FHIR using the same resources used for the narrative representation. While many of the necessary attributes are already present there are inevitably some that have no FHIR equivalent. For this we use the extension mechanism.

ResearchStudy

+ ResearchStudyStudyAmendment

• scope

ResearchStudy already has many attributes to describe a protocol but not everything required by M11 is present.

For example M11 requires a field to describe Amendment Scope.

To accommodate this, we create another extension called **ResearchStudyStudyAmendment** and amongst the attributes present in this extension we have one called scope

Figure 4: Structured Content

Some of these extensions are general purpose and will be relevant beyond USDM and M11 and they can be profiled to tie them to exact requirements.

7.1.1.3 Hierarchy of Resources, Extensions and Profiles Used

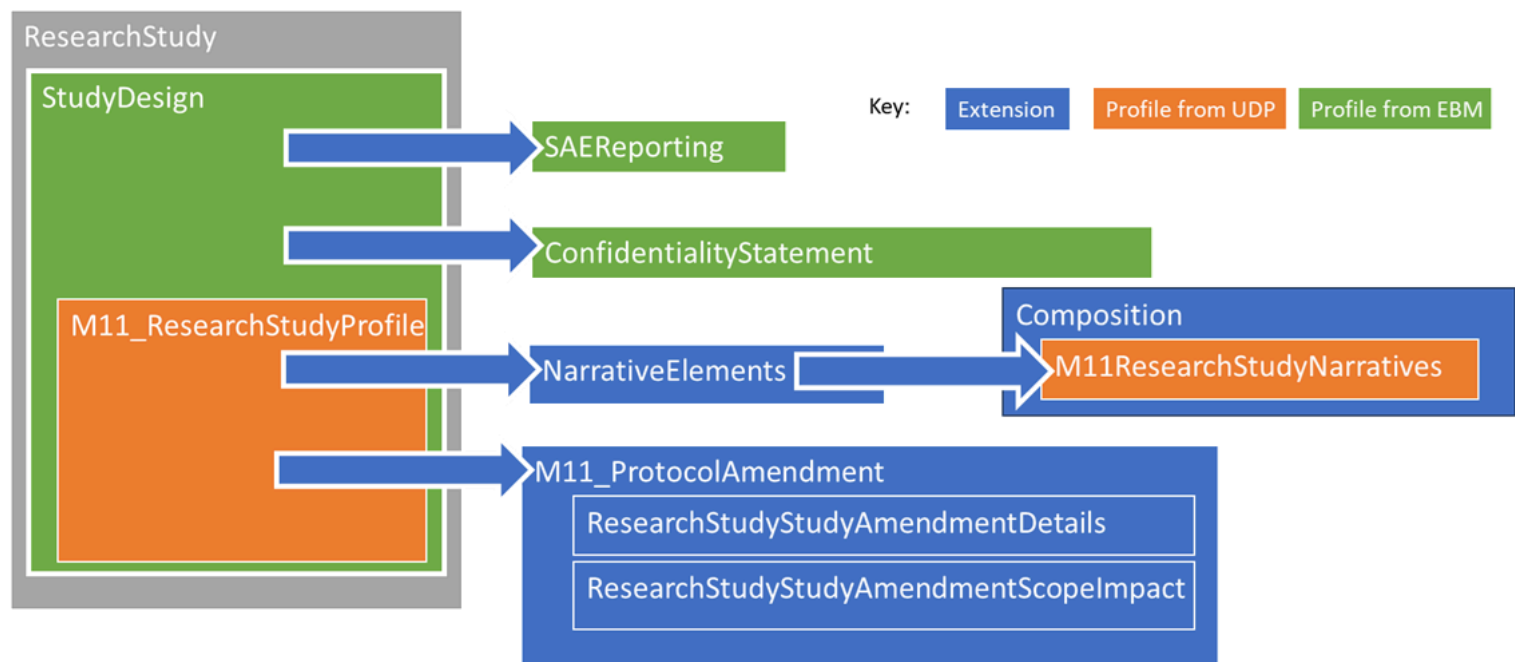


Figure 5: Extensions and Profiles of ResearchStudy

ResearchStudy

- profiled by **StudyDesign** which is part of the EBM IG. This in turn is profiled by **M11_ResearchStudyProfile** which tightens cardinality of some attributes and binds appropriate terminology and connects some extensions.
- extended by **NarrativeElements**
 - which provides a pointer to **M11ResearchStudyNarratives** which is a profile of **Composition**
- **M11_ResearchStudyProfile**
 - contains **ResearchStudyStudyAmendment**
 - which contains **ResearchStudyStudyAmendmentDetails**
 - and **ResearchStudyStudyAmendmentScopeImpact**

7.2 Terminology

The basics of terminology principles are discussed above.

The Value Sets used in this IG are listed on the Artifacts page, in almost every case the value set is composed of terms from the NCI Thesaurus and have been collated by CDISC for ICH and also form part of the USDM work. The values reflect those presented by ICH in the Technical Specification. The exceptions to this are the ISO Country codes and a reference to the one Code System defined here which is for managing the Narrative Element structure.

7.3 Validation

A benefit of FHIR that may not be immediately obvious is that all of the technical content of an FHIR Implementation Guide can be used by a FHIR server to validate content submitted to that server which should comply with the IG. This goes beyond the validation possible for regular JSON or XML content because the IG level validation will only be applied to inputs that say they comply with the IG. This allows a regular FHIR server to perform very targeted validation of incoming content and reject invalid input.

To achieve this level of validation use the Artifact definitions in the Downloads section of this IG and load that content to your server. Your server will have instructions on how to do this.

7.4 USDM and M11 to FHIR Mapping

The relationships between the elements of M11, USDM and FHIR are shown in the Mapping spreadsheet described in the following section. The focus of this is representation of M11 so the mapping does not cover the whole of USDM at this time. There is a useful infographic from CDISC here: [usdm_m11_classes.pdf \(Mappings\usdm_m11_classes.pdf\)](#) that shows the overlap between M11 and USDM and in the bottom right USDM classes not covered by M11.

The spreadsheet for mapping to FHIR is in 3 parts as shown in the illustration. Click on the illustration or click [here](#) (Mappings/M11 to FHIR Mapping 01.xlsx) to download the full spreadsheet

Note: See Read Me sheet for an explanation of the columns and also the FHIR Representation section of the IG.																	
USDM												FHIR					
M11	Section Number	Section Title	ElementName	Short Name	NCIT Code	Definition	CodeList R	Class	Attribute	Path	Status	Notes	Resource	Sample XML	Example Value(s)	Binding (s)	Comment
	Title Page	Sponsor Confidentiality Statement	Sponsor Confidentiality Statement	C181235	A written message within the study protocol that asserts a statement of non-disclosure, such that information contained within the protocol document may only be shared with authorized			StudyDefinitionDocument	type	StudyDefinitionDocument[StudyDefinitionDocument]	Mapped	Use to select the protocol document	ResearchStudy.extension[extension[non-disclosure-statement]]	<extension uri="http://hl7.org/fhir/extension/ncit/C181235" value="non-disclosure-statement" />	Value = "A4: data is confidential"		
5	Title Page	Sponsor Confidentiality Statement	Sponsor Confidentiality Statement	C181235	A written message within the study protocol that asserts a statement of non-disclosure, such that information contained within the protocol document may only be shared with authorized			NarrativeContent	sectionNumber	StudyPerson[StudyPerson] or StudyVersion[StudyVersion]		The section within the document selected by the section Number attribute					USDM mappings
6	Title Page				C181235	A written message within the study protocol that asserts a statement of non-disclosure, such that information contained within the protocol document may only be shared with authorized		NarrativeContentItem	text	StudyPerson[StudyPerson] or NarrativeContentItem[NarrativeContentItem]		The actual section text					USDM mappings
7	Title Page	Full Title	Full Title		C181246	The formal descriptive name for the protocol that contains key elements of the study		StudyTitle	text	StudyPerson[StudyPerson] or StudyTitle[StudyTitle]	Mapped	There are many titles. Select the correct one via the "type" attribute in StudyTitle	ResearchStudy.title	<title value="STUDY-01" />	Value = "A Phase 3 Study of Novel Drug(s) (P00002) Compared to Intravitreal Triamcinolone for Treatment of Macula Induced Neurovascular Disease"		

(Mappings/M11 to FHIR Mapping 01.xlsx)

Figure 6 : M11 / USDM / FHIR Mapping Spreadsheet

The FHIR columns of the spreadsheet are described in detail below together with examples.

FHIR Column Purpose

- Resource

A simple path to the relevant FHIR resource
- Sample XML

A fragment of XML that illustrates the mapping. Uses parameters starting with a \$ or % for conciseness
- Example Value(s)

Elements beginning with % are given a value here - above the dashed line they are fixed, below they are whatever the actual data is. Also uses macro values beginning with \$
- Binding (strength)

FHIR terminology must be bound to a value set and the strength determines whether the value set is fixed or can be extended.

Narrative Content is noted in the mapping sheet but is shown on a separate tab of the spreadsheet. It is discussed further below.

7.4.1 Resource Column

This is the element in FHIR that maps to the M11 element. In many cases there is a simple equivalent in the standard FHIR resource.

M11 FHIR Resource

Trial Phase ResearchStudy.phase

In other cases there is no immediate equivalent and a FHIR extension has to be used. In the example below the extension is a complex one. Extensions are indicated by the word extension followed by the extension name in square brackets. The extension is called \$ext-amd and within that the extension element is called scope.

M11 FHIR Resource

Amendment Scope ResearchStudy.extension[\$ext-amd].extension[scope]

The other pattern found is when the ResearchStudy resource points to an instance of another resource for the necessary link. In the example below Sponsor Name is represented in FHIR using an Organization resource which is pointed to by ResearchStudy using the associatedParty element. The reference from one resource to another is shown using -->

M11 FHIR Resource

Sponsor Name ResearchStudy.associatedParty.party.reference -> Organization.name.value

"FHIR Path" is a specific machine processable representation path through a linked series of FHIR resources. That is NOT what is being used here.

7.4.2 Sample XML and Example Value(s) Columns

For each row the structure is shown in XML. XML has been used in preference to JSON because the XML can be validated with a schema.

ResearchStudy.phase is a coded value in FHIR and uses the CodeableConcept data type which itself has multiple elements. Some of these elements have value that is fixed by the mapping and some are the values for the specific instance. The fixed and variable values are indicated by prefixing the name with a %. The actual values are then shown in the Example Values column - fixed values above the dashed line, variable ones below. Because fixed values occur repeatedly and are often lengthy URLs they are represented by a macro element indicated by the \$ prefix. In the example below \$NCIT has an actual value of <http://ncicb.nci.nih.gov/xml/owl/EVS/Thesaurus.owl>.

7.4.2.0.1 Trial Phase

```
<phase>
  <coding>
    <system value= %SYSTEM />
    <code value= %CODE />
    <display value= %DISPLAY />
  </coding>
</phase>
```

```
%SYSTEM = $NCIT
-----
%CODE = <C15602>
%DISPLAY = <Phase 3>
```

7.4.2.0.2 Amendment Scope

```
<extension url= $ext-amd>
  <extension url="scope">
    <valueCode value= %VALUE />
  </extension>
</extension>
```

```
%VALUE = <C217026>
```

7.4.2.0.3 Sponsor Name

```
<associatedParty>
  <role>
    <coding>
      <system value= %SYSTEM />
      <code value= %CODE />
      <display value= %DISPLAY />
    </coding>
  </role>
  <party>
    <reference value="Organization/%ID" />
  </party>
</associatedParty>

<Organization>
  <id value= %ID />
  ...
  <name value= %VALUE />
  ...
</Organization>
```

XML for Organization is not shown in full - there will be address, contact details etc which are indicated above by ...

```
%SYSTEM = $NCIT
%CODE = C70793
%DISPLAY = Clinical Study Sponsor
-----
%ID = <org-EliLilly>
%VALUE = <Eli Lilly Japan K.K>
```

7.4.3 Binding and Binding Strength Columns

It happens that the three examples shown here all make use of coded elements but this is not always the case. Binding only applies for coded elements.

For a coded element FHIR requires the specification to state the Value Set of allowed codes. This is important for validation and for ensuring that coded elements conform to a set of values that all will understand. A Value Set can be an arbitrary list of codes (and the identity of the code system they belong to), or the Value Set may specify an entire code system (perhaps with some codes excluded).

The FHIR specification will identify a Value Set of each coded element - this is referred to as the *Value Set Binding* and these bindings can vary in the extent to which they must be enforced - this is the *Binding Strength*. Generally a binding on a core FHIR specification can be interpreted quite flexibly and as that core specification is restricted by an Implementation Guide it will become much more rigorously specified. There are 4 Binding Strengths

Binding Strength	Meaning
Example	This value set is for illustration only. It may be useable in practice but no particular effort has been made to ensure that this is so..

Binding Strength	Meaning
Preferred	The bound Value Set is fit for purpose but there may be other equivalent value sets more commonly used in a given context, or there may be different contexts that require a different value set.
Extensible	The bound value set has a values that MUST be used for the specific concept they represent - however if other concepts are required a new value set can be created that contains the previously bound value set plus the additional concepts.
Required	The Value Set bound to the element is the one that MUST be used. It cannot be replaced, extended or modified.

As the table above shows the base FHIR specification will generally provide bindings of Example or Preferred strength while an Implementation Guide should provide bindings that are Extensible or Required. Generally if the Value Set refers to a concept that has a limited number of possible values and where adding a value is likely to result in an update to the processing logic (ie a software update) it should be a Required binding. Where an Extensible binding is used processing system should be able to cope with addition of a value - perhaps through an exception mechanism.

The bindings and binding strengths for the examples above are shown below.

7.4.3.0.4 Trial Phase

\$phase-vs (extensible)

7.4.3.0.5 Amendment Scope

m11-study-amendment-scope-vs (required)

7.4.3.0.6 Sponsor Name

\$study-role-vs (extensible)

7.4.4 Narrative Content

There are multiple sections that can be represented by Narrative content as discussed earlier. Since these all follow the same pattern the example XML for the Composition part is shown here:

```
<composition>
  ...
  <type>
    <coding>
      <system
        value="http://hl7.org/fhir/uv/pharmaceutical-research-protocol/CodeSystem/narrat
      <code value="b001"/>
      <display value="Protocol narrative"/>
    </coding>
  </type>
  ...
  <section>
    <title value=%DISPLAY/>
    <code>
      <coding>
        <system value=$NCIT/>
        <code value=%CODE/>
      </coding>
    </code>
    <text>
      <status value="additional"/>
      <div xmlns="http://www.w3.org/1999/xhtml">%NARRATIVE</div>
    </text>
  </section>
  ...
</composition>
```

The example values here are

```
%CODE = <C218514>
%DISPLAY = <1 PROTOCOL SUMMARY>
-----
%ID= <iiii>
%NARRATIVE = <nnnn>
```

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Links: [Table of Contents \(toc.html\)](#) | [QA Report \(qa.html\)](#) | [Version History](#) |  | [Propose a change](#)