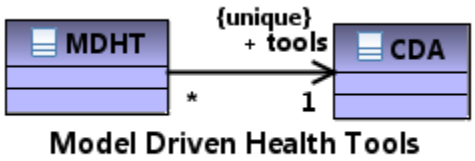
Implementation Guide for CDA Release 2
Human Clinical Study Data



Model Driven Health Tools

Draft Document/Pre-ballot

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Acknowledgments

This document defines the data requirements for using the HL7 Clinical Document Architecture for reporting the experience of subjects within a clinical trial. It has been decisively influenced by the CDISC SDTM Implementation Guide, and draws some descriptive material directly from that document. Code sets defined by CDISC - and managed within the NCI Enterprise vocabulary Services (EVS) will be used whenever possible.

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Revision History

Rev	Date	By Whom	Changes
New	March 2012	Mead Walker	Create a draft document

Chapter 1

INTRODUCTION

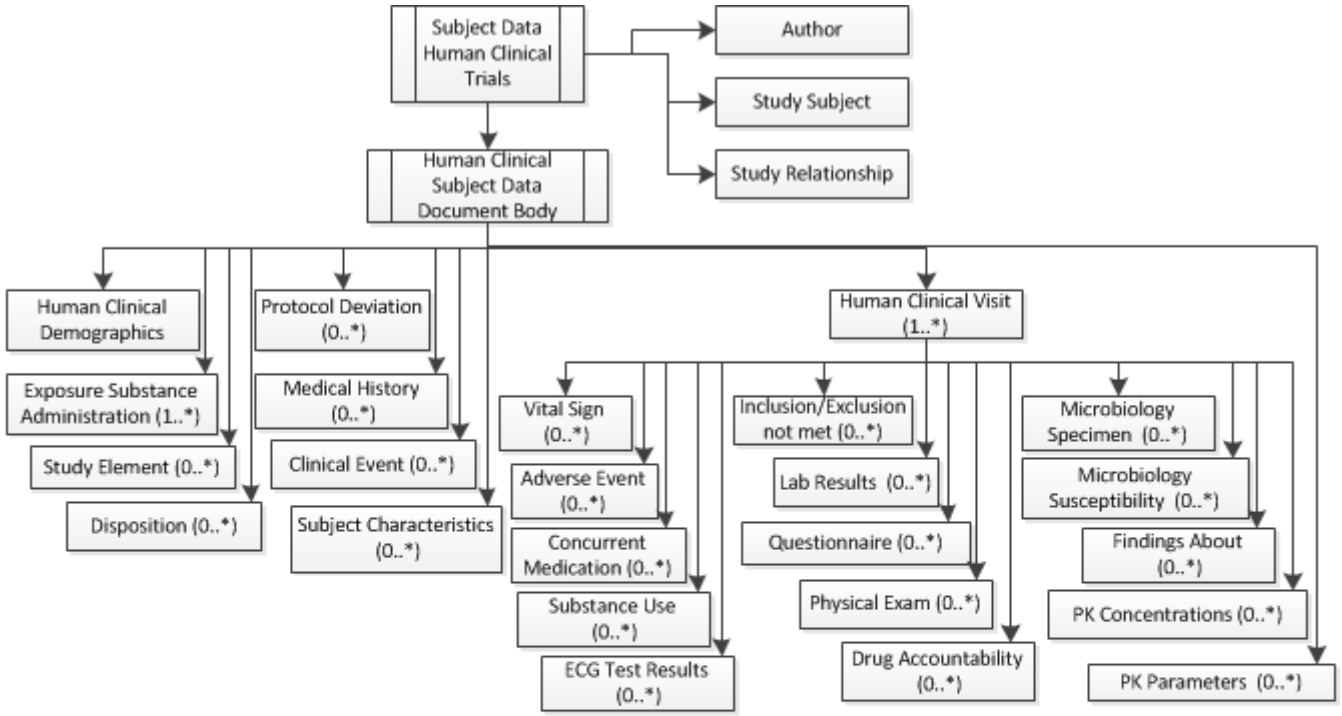
Topics:

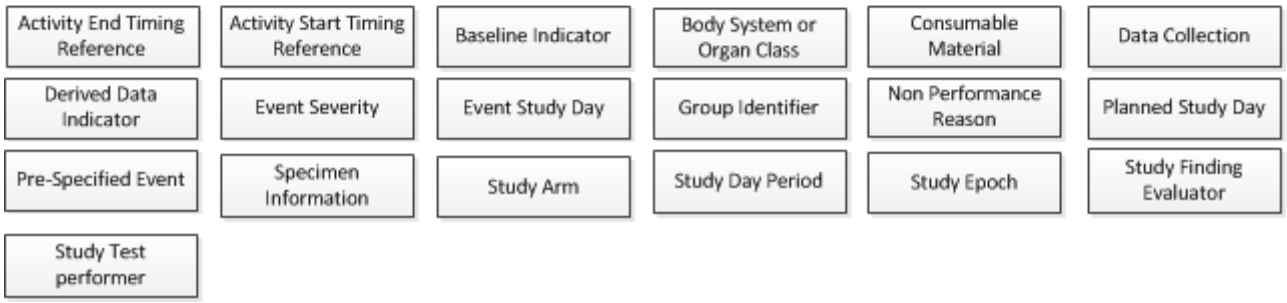
- *Overview*
- *Approach*
- *Implementation Guide Scope*
- *Audience*
- *Organization of This Guide*
- *Use of Templates*
- *Conventions Used in This Guide*

Overview

This implementation guide provides a format for using HL7's Clinical Document Architecture to report on the experience of human subjects within a clinical trial. It is intended that the guide can be used to address the full breadth of the data reporting for clinical trial subjects. In particular, it will cover the functional scope addressed by the CDISC SDTM Implementation Guide

This early draft focuses includes the content defined within theSDTM specification, with the exception of the highly generic Comments, Related Records, and Supplemental Qualifiers domains. The diagram outlines the high level structure of the subject data clinical document. Each of the included boxes underneath the document body represents a template. Those that represent SDTM domains are hierarchically associated to the document body section. The other templates represent repeating structures - these templates have been created to facilitate reuse of data structures within the implementation guide as a whole.





The document is generated from UML models developed in the Open Health Tools (OHT) Model-Driven Health Tools (MDHT) project. The data specifications have been formalized into computational models expressed in UML. These models are used by automated tooling to generate this publication, plus validation tools and Java libraries for implementers.

Approach

Use of the MDHT tool set makes it easier to get the desired Implementation Guide content into a form that can be presented as a document. At the same time, given the development perspective of the tool set, it is also possible to work directly with the set of Java classes that are created by the tooling to assist in implementing the application artifacts that are needed in order to create and receive compliant XML instances. It is expected that the data structures created in the process of building the Implementation Guide will be useful to implementers.

This project supports reusability and ease of data collection through a standard data representation harmonized with work developed by the CDISC Submission Data Standards Team. The content of the Implementation Guide (IG) draws heavily from CDISC's SDTM Implementation Guide. That document was used as a source of data items, and for descriptive material to characterize many of the items. The content is balloted through Health Level Seven (HL7), and will be accepted by FDA as a recognized format for data submissions.

This Implementation Guide specifies a standard for electronic submission of human clinical trial subject data reports in a Clinical Document Architecture (CDA), Release 2 format.

Implementation Guide Scope

TO DO. Use language from project scope statement

Vocabulary considerations

Text needs to be added to address our approach to vocabulary.

Identifier considerations

Text needs to be added to address our approach to managing identifiers.

Audience

The audience for this document includes software developers and implementers who wish to develop specifications for the standards-based and machine processable submission of subject information from human clinical trials.

Organization of This Guide

The requirements as laid out in the body of this document are subject to change per the policy on implementation guides (see section 13.02" Draft Standard for Trial Use Documents" within the HL7 Governance and Operations Manual, *http://www.hl7.org/documentcenter/public/membership/HL7_Governance_and_Operations_Manual.pdf*).

Templates

Templates are organized by document (see Document Templates), by section (see Section Templates), and by clinical statements (see Clinical Statement Templates). Within a section, templates are arranged hierarchically, where a more specific template is nested under the more generic template that it conforms to. See Templates by Containment for a listing of the higher level templates by containment; the appendix Templates Used in This Guide includes a table of all of the templates Organized Hierarchically.

Vocabulary and Value Sets

Vocabularies recommended in this guide are from standard vocabularies. In many cases, these vocabularies are further constrained into value sets for use within this guide. Value set names and OIDs are summarized in the table Summary of Value Sets. Each named value set in this summary table is stored ...(TBD).

Use of Templates

HL7 offers the following definition of a template: "A template is an expression of a set of constraints on the RIM or a RIM derived model that is used to apply additional constraints to a portion of an instance of data which is expressed in terms of some other Static Model. Templates are used to further define and refine these existing models to specify a narrower and more focused scope" Within this Implementation Guide, we have created a template data structure corresponding to each of the domains defined within the SDTM IG. The goal is to make it easier for those familiar with SDTM to recognize data within an instance, and to ease the migration for those who have implemented SDTM IG based reporting. In addition, structures that are repeated have been defined as templates, both to ease eventual implementation, and to simplify creation of this document.

When valued in an instance, the template identifier (`templateId`) signals the imposition of a set of template-defined constraints. The value of this attribute provides a unique identifier for the templates in question.

Originator Responsibilities

An originator can apply a `templateId` to assert conformance with a particular template.

In the most general forms of CDA exchange, an originator need not apply a `templateId` for every template that an object in an instance document conforms to. This implementation guide asserts when `templateId`s are required for conformance.

Recipient Responsibilities

A recipient may reject an instance that does not contain a particular `templateId` (e.g., a recipient looking to receive only CCD documents can reject an instance without the appropriate `templateId`).

A recipient may process objects in an instance document that do not contain a `templateId` (e.g., a recipient can process entries that contain Observation acts within a Problems section, even if the entries do not have `templateId`s).

Conventions Used in This Guide

Conformance Requirements

Conformance statements are grouped and identified by the name of the template, along with the templateId and the context of the template (e.g., ClinicalDocument, section, observation), which specifies the element under constraint. If a template is a specialization of another template, its first constraint indicates the more general template. In all cases where a more specific template conforms to a more general template, asserting the more specific template also implies conformance to the more general template. An example is shown below.

Template name

`[<type of template>: templateId <XXXX.XX.XXX.XXX>]`

Description of the template will be here .....

1. Conforms to <The template name> Template (templateId: XXXX<XX>XXX>YYY).
2. **SHALL** contain [1..1] @classCode = <AAA> <code display name> (CodeSystem: 123.456.789 <XXX> Class) **STATIC** (CONF:<number>).
3. .....

Figure 1: Template name and "conforms to" appearance

The conformance verb keyword at the start of a constraint (**SHALL** , **SHOULD** , **MAY**, etc.) indicates business conformance, whereas the cardinality indicator (0..1, 1..1, 1..*, etc.) specifies the allowable occurrences within an instance. Thus, " **MAY** contain 0..1" and " **SHOULD** contain 0..1" both allow for a document to omit the particular component, but the latter is a stronger recommendation that the component be included if it is known.

The following cardinality indicators may be interpreted as follows:

0..1 as zero to one present
1..1 as one and only one present
2..2 as two must be present
1..* as one or more present
0..* as zero to many present

Value set bindings adhere to HL7 Vocabulary Working Group best practices, and include both a conformance verb (**SHALL** , **SHOULD** , **MAY,** etc.) and an indication of **DYNAMIC** vs. **STATIC** binding. The use of **SHALL** requires that the component be valued with a member from the cited value set; however, in every case any HL7 "null" value such as other (OTH) or unknown (UNK) may be used.

Each constraint is uniquely identified (e.g., "CONF:605") by an identifier placed at or near the end of the constraint. These identifiers are not sequential as they are based on the order of creation of the constraint.

1. **SHALL** contain [1..1] component/structuredBody (CONF:4082).
    a. This component/structuredBody **SHOULD** contain [0..1] component (CONF:4130) such that it
        a. **SHALL** contain [1..1] Reporting Parameters section (templateId:2.16.840.1.113883.10.20.17.2.1) (CONF:4131).
    b. This component/structuredBody **SHALL** contain [1..1] component (CONF:4132) such that it
        a. **SHALL** contain [1..1] Patient data section - NCR (templateId:2.16.840.1.113883.10.20.17.2.5) (CONF:4133).

Figure 2: Template-based conformance statements example

Keywords

The keywords SHALL, SHALL NOT, SHOULD, SHOULD NOT, MAY, and NEED NOT in this document are to be interpreted as described in the *HL7 Version 3 Publishing Facilitator's Guide*:

- **SHALL**: an absolute requirement
- **SHALL NOT**: an absolute prohibition against inclusion
- **SHOULD/SHOULD NOT**: valid reasons to include or ignore a particular item, but must be understood and carefully weighed
- **MAY/NEED NOT**: truly optional; can be included or omitted as the author decides with no implications

XML Examples

XML samples appear in various figures in this document in a fixed-width font. Portions of the XML content may be omitted from the content for brevity, marked by an ellipsis (…) as shown in the example below.

```
<ClinicalDocument xmlns='urn:h17-org:v3'>
  ...
</ClinicalDocument>
```

Figure 3: ClinicalDocument example

XPath expressions are used in the narrative and conformance requirements to identify elements because they are familiar to many XML implementers.

Chapter 2

DOCUMENT TEMPLATES

Topics:

- *Subject Data Human Clinical Trials*

This section contains the document level constraints for CDA documents that are compliant with this implementation guide.

Subject Data Human Clinical Trials

[ClinicalDocument: templateId `2.16.840.1.113883.10.20.23.11`]

This fundamental template contains the core document related information for reporting the experience of a human subject within a clinical trial.

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="DOCCLIN"` (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`)
3. **SHALL** contain exactly one [1..1] **`code/@code`**`="TBD"` (CodeSystem: `2.16.840.1.113883.6.1 LOINC`)
4. **SHOULD** contain exactly one [1..1] **`confidentialityCode`**, where the @code **SHALL** be selected from (CodeSystem: `2.16.840.1.113883.5.25 Confidentiality`)
   - Documents the confidentiality level of the document.
5. **SHALL** contain exactly one [1..1] **`effectiveTime`**
   - The effective date for the contents of the document.
6. **SHALL** contain exactly one [1..1] **`id`**
   - The identifier assigned to the subject data report. It is needed to uniquely identify a particular report of subject data from a study.
7. **MAY** contain zero or one [0..1] **`languageCode`**
   - The language used for the document. The entry may be left out, if the language used is English.
8. **MAY** contain zero or one [0..1] **`realmCode`**
   - Identifies a country or other administrative unit that has defined particular rules for the format or content of the clinical document.
9. **SHALL** contain exactly one [1..1] **`setId`**
   - An identifier that remains consistent across all revisions derived from a common original. In the first version of the document - VersonNumber = 1, setId and id will be identical.
10. **SHALL** contain exactly one [1..1] **`versionNumber`**
    - A unique identifier for a version of a report.
11. **SHALL** contain exactly one [1..1] **`component`**
    a. Contains exactly one [1..1] *Human Clinical Subject Data Document Body* (templateId: `2.16.840.1.113883.10.20.23.13`)
12. **SHALL** contain exactly one [1..1] **`author`**
    a. This author **SHALL** contain exactly one [1..1] **`@typeCode`**`="AUT"`
    b. This author **SHALL** contain exactly one [1..1] **`assignedAuthor`**
       a. This assignedAuthor **SHALL** contain exactly one [1..1] **`@classCode`**`="ASSIGNED"`
       b. This assignedAuthor **SHALL** contain exactly one [1..1] **`id`**

          An identifier for the investigator responsible for the document. [SDTM: INVID]
       c. This assignedAuthor **SHALL** contain exactly one [1..1] **`assignedPerson`**
          a. This assignedPerson **SHALL** contain exactly one [1..1] **`@classCode`**`="PSN"`
          b. This assignedPerson **SHALL** contain exactly one [1..1] **`@determinerCode`**`="INSTANCE"`
          c. This assignedPerson **SHALL** contain zero or one [0..1] **`name`**

             The name of the investigator. [SDTM: INVNAM].
       d. This assignedAuthor **SHALL** contain exactly one [1..1] **`representedOrganization`**
          a. This representedOrganization **SHALL** contain zero or one [0..1] **`@classCode`**`="ORG"`

   b. This representedOrganization **SHALL** contain zero or one [0..1] **`@determinerCode`**`="INSTANCE"`
   c. This representedOrganization **SHALL** contain exactly one [1..1] **`id`**

   Contains the identifier of the study site for the investigator. [SDTM: SITEID].
   d. This representedOrganization **SHALL** contain exactly one [1..1] **`addr`**

   The only part of the address that is required is the country. This records the country of the investigational site associated with the subject's participation in the study. [SDTM: COUNTRY].
   e. This representedOrganization **SHALL** satisfy: Country shall be valued where addressPartType="country".

13. **SHALL** contain exactly one [1..1] **`documentationOf`**

   a. This documentationOf **SHALL** contain exactly one [1..1] **`@typeCode`**`="DOC"`
   b. This documentationOf **SHALL** contain exactly one [1..1] **`serviceEvent`**

      a. This serviceEvent **SHALL** contain zero or one [0..1] **`@classCode`**`="ACT"` *Act* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
      b. This serviceEvent **SHALL** contain zero or one [0..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`)
      c. This serviceEvent **SHALL** contain exactly one [1..1] **`code`**

      The code value indicates the related act refers to the study.
      d. This serviceEvent **SHALL** contain exactly one [1..1] **`id`**

      The identifier of the study. [SDTM: STUDYID]

14. **SHALL** contain exactly one [1..1] **`recordTarget`**

   a. This recordTarget **SHALL** contain exactly one [1..1] **`@typeCode`**`="RCT"`
   b. This recordTarget **SHALL** contain exactly one [1..1] **`patientRole`**

      a. This patientRole **SHALL** contain zero or one [0..1] **`@classCode`**`="PAT"`
      b. This patientRole **SHALL** contain [2..2] **`id`**

      A set of identifiers for the study subject. These include the unique study ID (SDTM: USUBJID) which identifies the subject across all studies for a product, and a study specific ID (SDTM:SUBJID) which identifies the subject within the context of a single study.
      c. This patientRole **SHALL** contain exactly one [1..1] **`patient`**

         a. This patient **SHALL** contain exactly one [1..1] **`@classCode`**`="PSN"`
         b. This patient **SHALL** contain exactly one [1..1] **`@determinerCode`**`="INSTANCE"`
         c. This patient **SHALL** contain exactly one [1..1] **`administrativeGenderCode`**, where the @code **SHALL** be selected from (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`)

         [SDTM: SEX]
         d. This patient **SHOULD** contain zero or one [0..1] **`birthTime`**

         The date of the study subject's birth. [SDTM: BRTHDTC]
         e. This patient **SHOULD** contain zero or one [0..1] **`ethnicGroupCode`**

         [SDTM: ETHNIC
         f. This patient **SHOULD** contain zero or one [0..1] **`raceCode`**

         [SDTM: RACE]
      d. This patientRole **SHALL** satisfy: The unique subject ID shall be present. [SDTM, USUBJID].
      e. This patientRole **SHALL** satisfy: Shall include an identifer for the subject within the study. [SDTM, SUBJID].

sdtm::Subject Data Human Clinical Trials							
cda::clinicaldocument[cda:templateId/@root = 2.16.840.1.113883.10.20.23.1]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
classCode	@classCode	1..1	SHALL	NO	ActClinicalDocument		DOCCLIN
moodCode	@moodCode	1..1	SHALL	NO	ActMood		EVN
nullFlavor	@nullFlavor	0..1		NO	NullFlavor		ASKU
code	code	1..1	SHALL	YES	CE		LOINC 2.16.840.1.113883.6.1 TBD
confidentialityCode	confidentialityCode	1..1	SHOULD	YES	CE		Confidentiality 2.16.840.1.113883.5.25
copyTime	copyTime	0..1		YES	TS		
effectiveTime	effectiveTime	1..1	SHALL	NO	TS		
id	id	1..1	SHALL	NO	II		
languageCode	languageCode	0..1	MAY	YES	CS		
realmCode	realmCode	0..1	MAY	YES	CS		
setId	setId	1..1	SHALL	YES	II		
templateId	templateId	0..*		YES	II		2.16.840.1.113883.10.20.23.1
title	title	0..1		YES	ST		
versionNumber	versionNumber	1..1	SHALL	YES	INT		
authenticator	authenticator	0..*		YES	Authenticator		
author	author	1..*		YES	Author		
authorization	authorization	0..*		YES	Authorization		
authorParticipation	authorParticipation	1..1	SHALL	YES	AuthorParticipation		
component	component	1..1		YES	Component2		
componentOf	componentOf	0..1		YES	Component1		
custodian	custodian	1..1		YES	Custodian		
dataEnterer	dataEnterer	0..1		YES	DataEnterer		
documentationOf	documentationOf	0..*		YES	DocumentationOf		
human Clinical Subject Data Document Body	human Clinical Subject Data Document Body	1..1	SHALL	YES	Human Clinical Subject Data Document Body		
informant	informant	0..*		YES	Informant12		
informationRecipient	informationRecipient	0..*		YES	InformationRecipient		
inFulfillmentOf	inFulfillmentOf	0..*		YES	InFulfillmentOf		
legalAuthenticator	legalAuthenticator	0..1		YES	LegalAuthenticator		
participant	participant	0..*		YES	Participant1		

sdtm::Subject Data Human Clinical Trials							
cda::clinicaldocument[cda:templateId/@root = 2.16.840.1.113883.10.20.23.1]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
recordTarget	recordTarget	1..*		YES	RecordTarget		
relatedDocument	relatedDocument	0..*		YES	RelatedDocument		
studyRelationship	studyRelationship	1..1	SHALL	YES	StudyRelationship		
subjectParticipation	subjectParticipation	1..1	SHALL	YES	SubjectParticipation		
typeId	typeId	1..1		YES	InfrastructureRootTypeId		

Subject Data Human Clinical Trials example

```
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd"
 classCode="DOCCLIN" moodCode="EVN">
  <realmCode code="Code forrealmCode"/>
  <typeId root="2.16.840.1.113883.1.3"/>
  <templateId root="2.16.840.1.113883.10.20.23.1"/>
  <id root="1794006489" extension="MDHT"/>
  <code code="TBD" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
  <title>TEXT FOR TITLE</title>
  <effectiveTime/>
  <confidentialityCode code="1838301416"/>
  <languageCode code="Code forlanguageCode"/>
  <setId root="2a89b894-d42b-4300-a3cd-1c394c928d54" extension="MDHT"/>
  <versionNumber value="1"/>
  <recordTarget typeCode="RCT">
    <patientRole classCode="PAT">
      <id root="86288610" extension="MDHT"/>
      <patient classCode="PSN" determinerCode="INSTANCE">
        <administrativeGenderCode codeSystem="2.16.840.1.113883.3.26.1.1"
 codeSystemName="NCI Thesaurus"/>
      </patient>
    </patientRole>
  </recordTarget>
  <author typeCode="AUT">
    <time/>
    <assignedAuthor classCode="ASSIGNED">
      <id root="242049338" extension="MDHT"/>
      <assignedPerson classCode="PSN" determinerCode="INSTANCE"/>
      <representedOrganization classCode="ORG" determinerCode="INSTANCE"/>
    </assignedAuthor>
  </author>
  <custodian/>
  <documentationOf typeCode="DOC">
    <serviceEvent classCode="ACT" moodCode="EVN">
      <id root="2049806637" extension="MDHT"/>
      <code code="1368023151"/>
    </serviceEvent>
  </documentationOf>
  <component>
    <structuredBody>
      <component>
        <section classCode="DOCSECT" moodCode="EVN">
          <realmCode code="Code forrealmCode"/>
          <templateId root="2.16.840.1.113883.10.20.23.3"/>
          <id root="822356471" extension="MDHT"/>
```

```
          <code code="TBD" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC"/>
          <title>TEXT FOR TITLE</title>
          <confidentialityCode code="33190833"/>
          <languageCode code="Code forlanguageCode"/>
          <entry>
            <organizer classCode="CLUSTER">
              <realmCode code="Code forrealmCode"/>
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</ClinicalDocument>
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Chapter 3

SECTION TEMPLATES

Topics:

- *Human Clinical Subject Data Document Body*

Human Clinical Subject Data Document Body

[Section: templateId `2.16.840.1.113883.10.20.23.13`]

The single section which encompasses the data reported for a subject. Much of the of the content is organized by visit.

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="DOCSECT"` (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
2. **SHALL** contain zero or one [0..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`)
3. **SHALL** contain exactly one [1..1] **`code/@code`**`="TBD"` (CodeSystem: `2.16.840.1.113883.6.1 LOINC`)
4. **SHALL** contain exactly one [1..1] **`entry`**
   a. Contains exactly one [1..1] *Human Clinical Subject Demographics* (templateId: `2.16.840.1.113883.10.20.23.14`)
5. **SHOULD** contain zero or more [0..*] **`entry`**
   a. Contains exactly one [1..1] *Visit* (templateId: `2.16.840.1.113883.10.20.23.17`)
6. **SHALL** contain exactly one [1..1] **`entry`**
   a. Contains exactly one [1..1] *Study Arm* (templateId: `2.16.840.1.113883.10.20.23.66`)
7. **MAY** contain zero or more [0..*] **`exposureAssociation`**
   a. Such exposureAssociations **SHALL** contain exactly one [1..1] **`@typeCode`**`="COMP"`
   b. Such exposureAssociations **SHALL** contain exactly one [1..1] **`substanceAdministration`**, where its type is *Human Clinical Exposure*
      a. Contains exactly one [1..1] *Human Clinical Exposure* (templateId: `2.16.840.1.113883.10.20.23.19`)
8. **SHOULD** contain zero or more [0..*] **`entry`**
   a. Contains exactly one [1..1] *Subject Element* (templateId: `2.16.840.1.113883.10.20.23.16`)
9. **MAY** contain zero or more [0..*] **`entry`**
   a. Contains exactly one [1..1] *Substance Use* (templateId: `2.16.840.1.113883.10.20.23.21`)
10. **SHOULD** contain zero or more [0..*] **`entry`**
    a. Contains exactly one [1..1] *Human Clinical Disposition* (templateId: `2.16.840.1.113883.10.20.23.23`)
11. **SHOULD** contain zero or more [0..*] **`entry`**
    a. Contains exactly one [1..1] *Medical History Item* (templateId: `2.16.840.1.113883.10.20.23.25`)
12. **MAY** contain zero or more [0..*] **`entry`**
    a. Contains exactly one [1..1] *Protocol Deviation* (templateId: `2.16.840.1.113883.10.20.23.26`)
13. **MAY** contain zero or more [0..*] **`entry`**
    a. Contains exactly one [1..1] *Clinical Event* (templateId: `2.16.840.1.113883.10.20.23.27`)
14. **MAY** contain zero or more [0..*] **`entry`**
    a. Contains exactly one [1..1] *ECG Test Result* (templateId: `2.16.840.1.113883.10.20.23.28`)
15. **MAY** contain zero or one [0..1] **`entry`**
    a. Contains exactly one [1..1] *Subject Characteristic* (templateId: `2.16.840.1.113883.10.20.23.34`)
16. **SHOULD** contain zero or one [0..1] **`entry`**
    a. Contains exactly one [1..1] *Pharmacokinetic Parameter Finding* (templateId: `2.16.840.1.113883.10.20.23.40`)

sdtm::Human Clinical Subject Data Document Body							
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moodCode	@moodCode	0..1	SHALL	NO	ActMood		EVN
nullFlavor	@nullFlavor	0..1		NO	NullFlavor		ASKU
sectionId	@sectionId	0..1		NO	String		
code	code	1..1	SHALL	YES	CE		LOINC 2.16.840.1.113883.6.1 TBD
confidentialityCode	confidentialityCode	0..1		YES	CE		
id	id	0..1		YES	II		
languageCode	languageCode	0..1		YES	CS		
realmCode	realmCode	0..*		YES	CS		
templateId	templateId	0..*		YES	II		2.16.840.1.113883.10.20.23.3
title	title	0..1		YES	ST		
author	author	0..*		YES	Author		
clinical Event	cda:entry/ cda:observation[cda:templateId/ @root = 2.16.840.1.113883.10.20.23.33]	0..*	MAY	YES	Clinical Event		
component	component	0..*		YES	Component5		
disposition	disposition	0..*	SHOULD	YES	Human Clinical Disposition		
eCG Test Result	cda:entry/ cda:observation[cda:templateId/ @root = 2.16.840.1.113883.10.20.23.34]	0..*	MAY	YES	ECG Test Result		
entry	entry	0..*		YES	Entry		MISSINGTYPE
exposureAssociation	exposureAssociation	0..*	MAY	YES	exposureAssociation		
human Clinical Study Arm	cda:entry/ cda:act[cda:templateId/ @root = 2.16.840.1.113883.10.20.23.8]	1..1	SHALL	YES	Study Arm		
human Clinical Subject Demographics	cda:entry/ cda:organizer[cda:templateId/ @root = 2.16.840.1.113883.10.20.23.4]	1..1	SHALL	YES	Human Clinical Subject Demographics		
human Clinical Visit	cda:entry/ cda:encounter[cda:templateId/ @root = 2.16.840.1.113883.10.20.23.5]	0..*	SHOULD	YES	Visit		

sdtm::Human Clinical Subject Data Document Body							
/cda:ClinicalDocument/cda:component/cda:structuredBody/cda:component/cda:section[cda:templateId/@root = 2.16.840.1.113883.10.20.23.3]/							
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informant	informant	0..*		YES	Informant12		
medical History	cda:entry/ cda:observation[cda:templateId/ @root = 2.16.840.1.113883.10.20.23.31]	0..*	SHOULD	YES	Medical History Item		
pharmacokinetic Parameter Finding	cda:entry/ cda:observation[cda:templateId/ @root = 2.16.840.1.113883.10.20.23.44]	0..1	SHOULD	YES	Pharmacokinetic Parameter Finding		
protocol Deviation	cda:entry/ cda:observation[cda:templateId/ @root = 2.16.840.1.113883.10.20.23.32]	0..*	MAY	YES	Protocol Deviation		
subject	subject	0..1		YES	Subject		
subject Characteristic	cda:entry/ cda:observation[cda:templateId/ @root = 2.16.840.1.113883.10.20.23.39]	0..1	MAY	YES	Subject Characteristic		
subject Element	cda:entry/ cda:act[cda:templateId/ @root = 2.16.840.1.113883.10.20.23.26]	0..*	SHOULD	YES	Subject Element		
substance Use	cda:entry/ cda:substanceAdministration[cda:templateId/ @root = 2.16.840.1.113883.10.20.23.27]	0..*	MAY	YES	Substance Use		
text	text	0..1		YES	StrucDocText		
typeId	typeId	0..1		YES	InfrastructureRootTypeId		

Human Clinical Subject Data Document Body example

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codeSystemName="NCI Thesaurus"/>
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           <low value="2012"/>
           <high value="2012"/>
         </effectiveTime>
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     <entryRelationship>
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         </effectiveTime>
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       </act>
     </entryRelationship>
     <entryRelationship>
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         <id root="1865244508" extension="MDHT"/>
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Thesaurus"/>
         <effectiveTime>
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         </effectiveTime>
         <entryRelationship>
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codeSystemName="NCI Thesaurus"/>
           </observation>
         </entryRelationship>
       </act>
     </entryRelationship>
   </observation>
 </entry>
```

```
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   <observation>
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Thesaurus"/>
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         </effectiveTime>
       </act>
     </entryRelationship>
   </observation>
 </entry>
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     </effectiveTime>
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     </entryRelationship>
     <entryRelationship>
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codeSystemName="NCI Thesaurus"/>
         <effectiveTime>
           <low value="2012"/>
           <high value="2012"/>
         </effectiveTime>
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     </entryRelationship>
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     <entryRelationship>
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Thesaurus"/>
         <effectiveTime>
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```

```
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codeSystemName="NCI Thesaurus"/>
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        </act>
      </entryRelationship>
      <entryRelationship>
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codeSystemName="NCI Thesaurus"/>
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          </effectiveTime>
        </observation>
      </entryRelationship>
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Thesaurus"/>
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          <entryRelationship typeCode="COMP"/>
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        </act>
      </entryRelationship>
    </observation>
  </entry>
  <entry>
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      </effectiveTime>
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      <entryRelationship typeCode="COMP"/>
      <entryRelationship typeCode="COMP"/>
      <entryRelationship typeCode="COMP"/>
      <entryRelationship>
        <act classCode="ACT" moodCode="EVN">
```

```
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          <code code="TBD" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
          <effectiveTime>
            <low value="2012"/>
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        </act>
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codeSystemName="NCI Thesaurus"/>
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      <entryRelationship>
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Thesaurus"/>
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            <high value="2012"/>
          </effectiveTime>
        </observation>
      </entryRelationship>
      <entryRelationship>
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codeSystemName="NCI Thesaurus"/>
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            <high value="2012"/>
          </effectiveTime>
        </observation>
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          <id root="1616563523" extension="MDHT"/>
          <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus"/>
```

```
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codeSystemName="NCI Thesaurus"/>
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        </act>
      </entryRelationship>
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codeSystemName="NCI Thesaurus"/>
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            <high value="2012"/>
          </effectiveTime>
        </observation>
      </entryRelationship>
      <entryRelationship>
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          <id root="999553431" extension="MDHT"/>
          <code code="TBD" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
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          </effectiveTime>
        </act>
```

```
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 </entry>
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     <code code="554304848"/>
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     </effectiveTime>
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     <entryRelationship typeCode="COMP"/>
     <entryRelationship>
       <act classCode="ACT" moodCode="EVN">
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codeSystemName="NCI Thesaurus"/>
         <effectiveTime>
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           <high value="2012"/>
         </effectiveTime>
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         <id root="1421189234" extension="MDHT"/>
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Thesaurus"/>
         <effectiveTime>
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           <high value="2012"/>
         </effectiveTime>
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         <entryRelationship typeCode="COMP"/>
         <entryRelationship>
           <observation classCode="OBS" moodCode="EVN">
             <templateId root="2.16.840.1.113883.10.20.23.11"/>
             <code code="TBD" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
           </observation>
         </entryRelationship>
         <entryRelationship>
           <act classCode="ACT" moodCode="EVN">
             <templateId root="2.16.840.1.113883.10.20.23.14"/>
             <code codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
           </act>
         </entryRelationship>
       </procedure>
     </entryRelationship>
     <entryRelationship>
       <observation classCode="OBS" moodCode="EVN">
         <templateId root="2.16.840.1.113883.10.20.23.9"/>
         <id root="189234861" extension="MDHT"/>
         <code code="TBD" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
         <effectiveTime>
           <low value="2012"/>
           <high value="2012"/>
         </effectiveTime>
```

```
        </observation>
      </entryRelationship>
      <entryRelationship>
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          <id root="808166231" extension="MDHT"/>
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 Thesaurus"/>
          <effectiveTime>
            <low value="2012"/>
            <high value="2012"/>
          </effectiveTime>
          <entryRelationship typeCode="COMP"/>
        </act>
      </entryRelationship>
    </observation>
  </entry>
</section>
```

Chapter 4

CLINICAL STATEMENT TEMPLATES

Topics:

- *Activity End Timing Reference*
- *Activity Start Timing Reference*
- *Adverse Event*
- *Baseline Indicator*
- *Body System or Organ Class*
- *Clinical Event*
- *Concomitant Medication*
- *Data Collection*
- *Derived Data Indicator*
- *Drug Accountability*
- *ECG Test Result*
- *Event Severity*
- *Event Study Day*
- *Finding About*
- *Group Identifier*
- *Human Clinical Disposition*
- *Human Clinical Exposure*
- *Human Clinical Laboratory Test Result*
- *Human Clinical Subject Demographics*
- *Inclusion or Exclusion Criteria Not Met*
- *Medical History Item*
- *Microbiology Specimen Finding*
- *Microbiology Susceptibility*
- *Non Performance Reason*
- *Pharmacokinetic Concentration Finding*
- *Pharmacokinetic Parameter Finding*
- *Physical Examination Finding*
- *Planned Study Day*
- *Pre-Specified Event*
- *Protocol Deviation*
- *Questionnaire Finding*
- *Specimen Information*

This section of the Implementation Guide details the clinical statement entries referenced in the document section templates. The clinical statement entry templates are arranged alphabetically.

- *Study Arm*
- *Study Day Period*
- *Study Epoch*
- *Subject Characteristic*
- *Subject Element*
- *Substance Use*
- *Timing Reference*
- *Visit*
- *Vital Sign*

Activity End Timing Reference

[Act: templateId `2.16.840.1.113883.10.20.23.51`]

The activity end timing reference makes it possible to indicate the timing of an activity likely to extend over a period of time as an offset from an anchoring event. In particular, it captures the end point of the activity with reference to the anchoring event. Note, in SDTM, the anchoring event is known as the "End Relative to Reference Period'. The reference, described as "an elapsed time relative to a fixed reference point, such as time of last dose", is known as a "Planned Time Point. This structure is captured as a template to facilitate its reuse for different types of data within clinical trial reporting.

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="ACT"` *Act* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`)
3. **SHALL** contain exactly one [1..1] **`code`**, where the @code **SHALL** be selected from (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`)
   - A text description of when the measurement should be taken. This may be captured as an elapsed duration with respect to the anchor time point. [SDTM: VSELTM]
4. **MAY** contain zero or one [0..1] **`effectiveTime`**
   - The planned elapsed time - a duration - at which the event or measurement is to take place with reference to the anchoring time point. [SDTM: VSELTM]

   a. **SHALL** satisfy: The width property of the IVL_TS data type is used.
5. **MAY** contain zero or one [0..1] **`id`**
   - A numeric identifier for the planned time point in order to facilitate sorting of the data content. [SDTM: VSTPTNUM]
6. **MAY** contain zero or one [0..1] **`entryRelationship`**

   Indicates the reference point associated with a timing offset.

   a. This entryRelationship **SHALL** contain exactly one [1..1] **`@typeCode`**`="COMP"`
   b. This entryRelationship **SHALL** contain zero or one [0..1] **`act`**
      a. This act **SHALL** contain exactly one [1..1] **`@classCode`**`="ACT"` *Act* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
      b. This act **SHALL** contain exactly one [1..1] **`@moodCode`**
      c. This act **SHALL** contain exactly one [1..1] **`code`**, where the @code **SHALL** be selected from (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`)

         A code that indicates the nature of the fixed reference point that is referred to by the timing reference. If a suitable value set has not been defined, the original text property of the coded type is used. [SDTM: VSTPTREF]
      d. This act **SHALL** contain zero or one [0..1] **`effectiveTime`**

         The date time of the anchor time point. [SDTM: VSRFTDTC]

sdtm::Activity End Timing Reference							
cda::act[cda:templateId/@root = 2.16.840.1.113883.10.20.23.24]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
classCode	@classCode	1..1	SHALL	NO	x_ActClassDocumentEntryAct		ACCM
moodCode	@moodCode	1..1	SHALL	NO	x_DocumentActMood		APT
negationInd	@negationInd	0..1		NO	Boolean		

sdtm::Activity End Timing Reference							
cda::act[cda:templateId/@root = 2.16.840.1.113883.10.20.23.24]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
nullFlavor	@nullFlavor	0..1		NO	NullFlavor		ASKU
code	code	1..1	SHALL	YES	CD		NCI Thesaurus 2.16.840.1.113883.3.26.1.1 null
effectiveTime	effectiveTime	0..1	MAY	YES	IVL_TS		
id	id	0..1	MAY	YES	II		
languageCode	languageCode	0..1		YES	CS		
priorityCode	priorityCode	0..1		YES	CE		
realmCode	realmCode	0..*		YES	CS		
statusCode	statusCode	0..1		YES	CS		
templateId	templateId	0..*		YES	II		2.16.840.1.113883.10.20.23.24
text	text	0..1		YES	ED		
activityEndAnchorAssociation	activityEndAnchorAssociation	0..1	MAY	YES	ActivityEndAnchorAssociation		
author	author	0..*		YES	Author		
entryRelationship	entryRelationship	0..*		YES	EntryRelationship		
informant	informant	0..*		YES	Informant12		
participant	participant	0..*		YES	Participant2		
performer	performer	0..*		YES	Performer2		
precondition	precondition	0..*		YES	Precondition		
reference	reference	0..*		YES	Reference		
specimen	specimen	0..*		YES	Specimen		
subject	subject	0..1		YES	Subject		
typeId	typeId	0..1		YES	InfrastructureRootTypeId		

Activity End Timing Reference example

```
<?xml version="1.0" encoding="UTF-8"?>
<act xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="urn:hl7-
org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd" classCode="ACT"
 moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.23.24"/>
  <id root="1827917875" extension="MDHT"/>
  <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
 Thesaurus"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <entryRelationship typeCode="COMP">
    <act classCode="ACT">
      <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
 Thesaurus"/>
```

```
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
    </act>
  </entryRelationship>
</act>
```

Activity Start Timing Reference

[Act: templateId `2.16.840.1.113883.10.20.23.52`]

The activity start timing reference makes it possible to indicate the timing of an activity likely to extend over a period of time as an offset from an anchoring event. In particular, it captures the beginning of the activity with reference to the anchoring event. Note, in SDTM, the anchoring event is known as the "Start Relative to Reference Period'. The reference, described as "an elapsed time relative to a fixed reference point, such as time of last dose", is known as a "Planned Time Point. This structure is captured as a template to facilitate its reuse for different types of data within clinical trial reporting.

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="ACT"` *Act* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`)
3. **SHALL** contain exactly one [1..1] **`code`**, where the @code **SHALL** be selected from (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`)
   - A text description of when the measurement should be taken. This may be captured as an elapsed duration with respect to the anchor time point. [SDTM: VSELTM]
4. **MAY** contain zero or one [0..1] **`effectiveTime`**
   - The planned elapsed time - a duration - at which the event or measurement is to take place with reference to the anchoring time point. [SDTM: VSELTM]

   a. **SHALL** satisfy: The width property of the IVL_TS data type is used.
5. **MAY** contain zero or one [0..1] **`id`**
   - A numeric identifier for the planned time point in order to facilitate sorting of the data content. [SDTM: VSTPTNUM]
6. **MAY** contain zero or one [0..1] **`entryRelationship`**

   Indicates the reference point associated with a timing offset.

   a. This entryRelationship **SHALL** contain exactly one [1..1] **`@typeCode`**`="COMP"`
   b. This entryRelationship **SHALL** contain exactly one [1..1] **`act`**

      a. This act **SHALL** contain exactly one [1..1] **`@classCode`**`="ACT"` *Act* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
      b. This act **SHALL** contain exactly one [1..1] **`@moodCode`**
      c. This act **SHALL** contain exactly one [1..1] **`code`**, where the @code **SHALL** be selected from (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`)

         A code that indicates the nature of the fixed reference point that is referred to by the timing reference. If a suitable value set has not been defined, the original text property of the coded type is used. [SDTM: VSTPTREF]
      d. This act **SHALL** contain zero or one [0..1] **`effectiveTime`**

         The date time of the anchor time point. [SDTM: VSRFTDTC]

sdtm::Activity Start Timing Reference							
cda::act[cda:templateId/@root = 2.16.840.1.113883.10.20.23.23]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
classCode	@classCode	1..1	SHALL	NO	x_ActClassDocumentEntryAct		ACCM
moodCode	@moodCode	1..1	SHALL	NO	x_DocumentActMood		APT
negationInd	@negationInd	0..1		NO	Boolean		
nullFlavor	@nullFlavor	0..1		NO	NullFlavor		ASKU
code	code	1..1	SHALL	YES	CD		NCI Thesaurus 2.16.840.1.113883.3.26.1.1 null
effectiveTime	effectiveTime	0..1	MAY	YES	IVL_TS		
id	id	0..1	MAY	YES	II		
languageCode	languageCode	0..1		YES	CS		
priorityCode	priorityCode	0..1		YES	CE		
realmCode	realmCode	0..*		YES	CS		
statusCode	statusCode	0..1		YES	CS		
templateId	templateId	0..*		YES	II		2.16.840.1.113883.10.20.23.23
text	text	0..1		YES	ED		
activityStartAnchorAssociation	activityStartAnchorAssociation	0..1	MAY	YES	ActivityStartAnchorAssociation		
author	author	0..*		YES	Author		
entryRelationship	entryRelationship	0..*		YES	EntryRelationship		
informant	informant	0..*		YES	Informant12		
participant	participant	0..*		YES	Participant2		
performer	performer	0..*		YES	Performer2		
precondition	precondition	0..*		YES	Precondition		
reference	reference	0..*		YES	Reference		
specimen	specimen	0..*		YES	Specimen		
subject	subject	0..1		YES	Subject		
typeId	typeId	0..1		YES	InfrastructureRootTypeId		

Activity Start Timing Reference example

```
<?xml version="1.0" encoding="UTF-8"?>
<act xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="urn:hl7-
org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd" classCode="ACT"
 moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.23.23"/>
  <id root="1655548673" extension="MDHT"/>
  <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
 Thesaurus"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
```

```
  </effectiveTime>
  <entryRelationship typeCode="COMP">
    <act classCode="ACT">
      <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
 Thesaurus"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
    </act>
  </entryRelationship>
</act>
```

Adverse Event

[Observation: templateId `2.16.840.1.113883.10.20.23.22`]

The structure includes information on an adverse event that ocurred to a study subject. It should include clinical data describing "any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have to have a causal relationship with this treatment" (ICH E2A). In consultation with regulatory authorities, sponsors may extend or limit the scope of adverse event collection (e.g., collecting pre-treatment events related to trial conduct, not collecting events that are assessed as efficacy endpoints).

1. Contains exactly one [1..1] **`@classCode="OBS"`** *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
2. **SHALL** contain exactly one [1..1] **`@moodCode="EVN"`** *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`)
3. **SHALL** contain exactly one [1..1] **`code/@code="TBD"`** *Adverse Event - Reported* (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`)
   - The code value indicates that this observation is an adverse event. The verbatim term is captured as original text. A modified term is representated as a translation. [SDTM: AETERM, AEMODIFY, AEDECOD]
4. **SHOULD** contain zero or one [0..1] **`effectiveTime`**
   - Used to capture the start date/time of the adverse event, its end date/time, and/or its duration. [SDTM: AESTDTC, AEENDTC, AEDUR]
5. **SHALL** contain exactly one [1..1] **`value`** with data type CE
   - Identifies the adverse event. [SDTM: AETERM, AEMODIFY, AEDECOD]
   a. **SHALL** satisfy: Capture the verbatim name of the event using the original text property of the CE type.
   b. **SHALL** satisfy: Capture the dictionary derived term for the adverse event using the code and codeSystem properties of the CE data type.
6. **SHALL** contain [1..3] **`id`**
   - An identifier for the adverse event. "An internal or external identifier such as a serial number on an SAE reporting form". [SDTM: AESEQ, AEREFID, AESPID] A sequence number is required.
7. **MAY** contain zero or one [0..1] **`targetSiteCode`**
   - The anatomic location relevant for the adverse event. [SDTM: AELOC]
8. **MAY** contain zero or one [0..1] **`entryRelationship`**
   - Allows capture of a group identifier for the adverse event.
   a. Contains **`@typeCode="COMP"`** *COMP*
   b. Contains exactly one [1..1] *Group Identifier* (templateId: `2.16.840.1.113883.10.20.23.61`)
9. **SHOULD** contain zero or one [0..1] **`entryRelationship`**
   - Allows identification of the relevant body system or organ class.
   a. Contains **`@typeCode="COMP"`** *COMP*

b. Contains exactly one [1..1] *Body System or Organ Class* (templateId: `2.16.840.1.113883.10.20.23.54`)

10. **MAY** contain zero or one [0..1] **`entryRelationship`**

- Carries information about event severity

a. Contains **`@typeCode="COMP"`** *COMP*

b. Contains exactly one [1..1] *Event Severity* (templateId: `2.16.840.1.113883.10.20.23.58`)

11. **SHOULD** contain zero or one [0..1] **`entryRelationship`**

Carries information about event seriousness.

a. This entryRelationship **SHALL** contain zero or one [0..1] **`@typeCode`**`="COMP"`

b. This entryRelationship **SHALL** contain zero or one [0..1] **`observation`**

a. This observation **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)

b. This observation **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`)

c. This observation **SHALL** contain exactly one [1..1] **`code/@code`**`="TBD"` (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`)

d. This observation **SHALL** contain exactly one [1..1] **`value`** with data type BL

A Boolean indicator that shows whether or not the adverse event is considered to be serious. [SDTM: AESER]

e. This observation **MAY** contain zero or more [0..*] **`entryRelationship`**

a. Such entryRelationships **SHALL** contain zero or one [0..1] **`@typeCode`**`="COMP"`

b. Such entryRelationships **SHALL** contain zero or one [0..1] **`observation`**

a. This observation **SHALL** contain exactly one [1..1] **`@classCode`**

b. This observation **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`)

c. This observation **SHALL** contain exactly one [1..1] **`code/@code`**`="TBD"` (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`)

The code value indicates the observation conveys information on the nature of the seriousness of the adverse event.

d. This observation **SHALL** contain zero or more [0..*] **`value`** with data type CE, where the @code **SHALL** be selected from (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`)

The code value indicates the particular feature or effect of the adverse event, e.g., required or prolonged hospitalization, occurred with an overdose, that led it to be considered serious. [SDTM: AESCAN, AESCONG, ASESDISAB, AESDTH, AESHOSP, AESLIFE, AESOD, AESMIE]

12. **SHOULD** contain zero or one [0..1] **`entryRelationship`**

Identifies actions taken that involve changes in the study treatment.

a. This entryRelationship **SHALL** contain zero or one [0..1] **`@typeCode`**`="COMP"`

b. This entryRelationship **SHALL** contain zero or one [0..1] **`observation`**

a. This observation **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)

b. This observation **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`)

c. This observation **SHALL** contain exactly one [1..1] **`code/@code`**`="NCI"` (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`)

d. This observation **SHALL** contain exactly one [1..1] **`value`** with data type CE

Information on an action taken with the study treatment as a result of the event. [SDTM:AEACN]

13. **MAY** contain zero or more [0..*] **entryRelationship**

    Identifies actions taken that are not related to the study treatment.

    a. Such entryRelationships **SHALL** contain exactly one [1..1] **@typeCode**="COMP"
    b. Such entryRelationships **SHALL** contain exactly one [1..1] **observation**

        a. This observation **SHALL** contain exactly one [1..1] **@classCode**="OBS" *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass)
        b. This observation **SHALL** contain exactly one [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
        c. This observation **SHALL** contain exactly one [1..1] **code**

           A code value to indicate information regarding other actions - unrelated to the study treatment - that were taken as a result of the adverse event.
        d. This observation **SHALL** contain exactly one [1..1] **value** with data type ED

           Information on an action taken other than changes to the study treatment as a result of the event. [SDTM:AEACNOTH]

14. **MAY** contain zero or one [0..1] **entryRelationship**

    Indicates a sub-category the adverse event is assigned to.

    a. This entryRelationship **SHALL** contain exactly one [1..1] **@typeCode**="COMP"
    b. This entryRelationship **SHALL** contain exactly one [1..1] **observation**

        a. This observation **SHALL** contain exactly one [1..1] **@classCode**="OBS" *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass)
        b. This observation **SHALL** contain exactly one [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
        c. This observation **SHALL** contain exactly one [1..1] **code/@code**="TBD" (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)
        d. This observation **SHALL** contain exactly one [1..1] **value** with data type CE

           Provide the applicable adverse event sub-category value. [SDTM: AESCAT]

15. **SHOULD** contain zero or one [0..1] **entryRelationship**

    Captures information regarding a causal relationship between the adverse event and the study treatment.

    a. This entryRelationship **SHALL** contain exactly one [1..1] **@typeCode**="COMP"
    b. This entryRelationship **SHALL** contain exactly one [1..1] **observation**

        a. This observation **SHALL** contain exactly one [1..1] **@classCode**="OBS" *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass)
        b. This observation **SHALL** contain exactly one [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
        c. This observation **SHALL** contain exactly one [1..1] **code/@code**="TBD" (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)

           A value to indicate that the observation provides the investigator's opinon regarding the causality of the event to the treatment.
        d. This observation **SHALL** contain exactly one [1..1] **value** with data type CE

           Information on the causal relationship between the adverse event and the study treatment. [SDTM:AEREL]

16. **MAY** contain zero or one [0..1] **entryRelationship**

    Captures information regarding causal relationships between the adverse event and treatments other than the study treatment.

    a. This entryRelationship **SHALL** contain exactly one [1..1] **@typeCode**="COMP"
    b. This entryRelationship **SHALL** contain exactly one [1..1] **observation**

   a. This observation **SHALL** contain exactly one [1..1] **@classCode**="OBS" *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass)
   b. This observation **SHALL** contain exactly one [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
   c. This observation **SHALL** contain exactly one [1..1] **code**

      A value to indicate that the observation provides the investigator's opinon regarding the causality of the event to a non-study treatment.
   d. This observation **SHALL** contain exactly one [1..1] **value** with data type ED

      Information on the causal relationship between the adverse event and a treatment other than the study treatment. [SDTM:AERELNST]

17. **MAY** contain zero or one [0..1] **entryRelationship**

    Captures information regarding the temporal pattern of adverse event occurrence.

    a. This entryRelationship **SHALL** contain exactly one [1..1] **@typeCode**="COMP"
    b. This entryRelationship **SHALL** contain exactly one [1..1] **observation**
       a. This observation **SHALL** contain exactly one [1..1] **@classCode**="OBS" *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass)
       b. This observation **SHALL** contain exactly one [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
       c. This observation **SHALL** contain exactly one [1..1] **code/@code**="TBD" (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)

          A code that indicates the observation contains information regarding the pattern of the adverse event over time.
       d. This observation **SHALL** contain zero or more [0..*] **value** with data type CE

          Provides information on the pattern of the adverse event over time.

18. **MAY** contain zero or one [0..1] **entryRelationship**

    Captures information regarding the outcome of the adverse event.

    a. This entryRelationship **SHALL** contain exactly one [1..1] **@typeCode**="COMP"
    b. This entryRelationship **SHALL** contain exactly one [1..1] **observation**
       a. This observation **SHALL** contain exactly one [1..1] **@classCode**="OBS" *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass)
       b. This observation **SHALL** contain exactly one [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
       c. This observation **SHALL** contain exactly one [1..1] **code/@code**="TBD" (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)

          A code that indicates this observation contains adverse event outcome information.
       d. This observation **SHALL** contain exactly one [1..1] **value** with data type ED

          A description of the outcome of the adverse event. [SDTM: AEOUT]

19. **MAY** contain zero or one [0..1] **entryRelationship**

    Captures information regarding treatments that are concommitant with the adverse event.

    a. This entryRelationship **SHALL** contain exactly one [1..1] **@typeCode**="COMP"
    b. This entryRelationship **SHALL** contain exactly one [1..1] **observation**
       a. This observation **SHALL** contain exactly one [1..1] **@classCode**="OBS" *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass)
       b. This observation **SHALL** contain exactly one [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
       c. This observation **SHALL** contain exactly one [1..1] **code**

The code value indicates the observation contains concomitant or additional treatment information.

d. This observation **SHALL** contain exactly one [1..1] **`value`** with data type BL

Indicate whether or not concomitant or additional treatment was given because of the occurrence of the adverse event. [SDTM: AECONTRT]

20. MAY contain zero or one [0..1] **`entryRelationship`**

Records information for the toxicity of the adverse event. (or could it be the toxicity of the treatment?)

a. This entryRelationship **SHALL** contain exactly one [1..1] **`@typeCode`**="COMP"

b. This entryRelationship **SHALL** contain exactly one [1..1] **`observation`**

a. This observation **SHALL** contain exactly one [1..1] **`@classCode`**="OBS" *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass)

b. This observation **SHALL** contain exactly one [1..1] **`@moodCode`**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)

c. This observation **SHALL** contain exactly one [1..1] **`code/@code`**="TBD" (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)

A code that indicates the observation contains information regarding toxicity grade.

d. This observation **SHALL** contain exactly one [1..1] **`value`** with data type CE, where the @code **SHALL** be selected from (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)

Provides information on the toxicity of the event. A standard toxicity scale is intended to be used. [SDTM: AETOXGR]

21. MAY contain zero or one [0..1] **`entryRelationship`**

Indicates a category the adverse event is assigned to.

a. This entryRelationship **SHALL** contain exactly one [1..1] **`@typeCode`**="COMP"

b. This entryRelationship **SHALL** contain exactly one [1..1] **`observation`**

a. This observation **SHALL** contain exactly one [1..1] **`@classCode`**

b. This observation **SHALL** contain exactly one [1..1] **`@moodCode`**

c. This observation **SHALL** contain exactly one [1..1] **`code/@code`**="TBD" (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)

d. This observation **SHALL** contain exactly one [1..1] **`value`** with data type CE

Provide the adverse event category value. [SDTM: AECAT]

22. MAY contain zero or one [0..1] **`entryRelationship`**

- Indicates whether the adverse event was prespecified on the CRF.

a. Contains **`@typeCode="`**COMP" *COMP*

b. Contains exactly one [1..1] *Pre-Specified Event* (templateId: 2.16.840.1.113883.10.20.23.64)

23. MAY contain zero or one [0..1] **`entryRelationship`**

- Captures information about the study days coincident with the start and stop of the adverse event.

a. Contains **`@typeCode="`**REFR" *REFR*

b. Contains exactly one [1..1] *Study Day Period* (templateId: 2.16.840.1.113883.10.20.23.74)

24. SHALL satisfy: Capture the reported term - the verbatim name - using the original text property of the CE data type within the observation.value element.

25. SHALL satisfy: Effective time information for the adverse event includes start date/time, stop date/time, and duration. Since any two of these determine the value of the third, only two of these properties of time are collected using the IVL_TS data type.

sdtm::Adverse Event							
cda::observation[cda:templateId/@root = 2.16.840.1.113883.10.20.23.6]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
classCode	@classCode	1..1		NO	ActClassObservation		ALRT
moodCode	@moodCode	1..1	SHALL	NO	x_ActMoodDocumentObservation		DEF
negationInd	@negationInd	0..1		NO	Boolean		
nullFlavor	@nullFlavor	0..1		NO	NullFlavor		ASKU
code	code	1..1	SHALL	YES	CD		NCI Thesaurus 2.16.840.1.113883.3.26.1.1 TBD
derivationExpr	derivationExpr	0..1		YES	ST		
effectiveTime	effectiveTime	0..1	SHOULD	YES	IVL_TS		
id	id	1..3	SHALL	YES	II		
interpretationCode	interpretationCode	0..*		YES	CE		
languageCode	languageCode	0..1		YES	CS		
methodCode	methodCode	0..*		YES	CE		
priorityCode	priorityCode	0..1		YES	CE		
realmCode	realmCode	0..*		YES	CS		
repeatNumber	repeatNumber	0..1		YES	IVL_INT		
statusCode	statusCode	0..1		YES	CS		
targetSiteCode	targetSiteCode	0..1	MAY	YES	CD		
templateId	templateId	0..*		YES	II		2.16.840.1.113883.10.20.23.6
text	text	0..1		YES	ED		
value	value	1..1	SHALL	YES	CE		
adverseEventCategoryAssociation	adverseEventCategoryAssociation	0..1	MAY	YES	adverseEventCategoryAssociation		
adverseEventSubCategoryAssociation	adverseEventSubCategoryAssociation	0..1	MAY	YES	adverseEventSubCategoryAssociation		
author	author	0..*		YES	Author		
body System or Organ Class	body System or Organ Class	0..1	SHOULD	YES	Body System or Organ Class		
concomitantTreatmentAssociation	concomitantTreatmentAssociation	0..1	MAY	YES	concomitantTreatmentAssociation		
entryRelationship	entryRelationship	0..*		YES	EntryRelationship		
event Severity	event Severity	0..1	MAY	YES	Event Severity		
groupIdentifier	groupIdentifier	0..1	MAY	YES	Group Identifier		
informant	informant	0..*		YES	Informant12		
nonStudyTreatmentCausalityAssociation	nonStudyTreatmentCausalityAssociation	0..1	MAY	YES	nonStudyTreatmentCausalityAssociation		
otherTreatmentActionTakenAssociation	otherTreatmentActionTakenAssociation	0..*	MAY	YES	otherTreatmentActionTakenAssociation		

sdtm::Adverse Event							
cda::observation[cda:templateId/@root = 2.16.840.1.113883.10.20.23.6]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
outcomeAssociation	outcomeAssociation	0..1	MAY	YES	outcomeAssociation		
participant	participant	0..*		YES	Participant2		
patternAssociation	patternAssociation	0..1	MAY	YES	patternAssociation		
performer	performer	0..*		YES	Performer2		
pre-Specified Event	pre-Specified Event	0..1	MAY	YES	Pre-Specified Event		
precondition	precondition	0..*		YES	Precondition		
reference	reference	0..*		YES	Reference		
referenceRange	referenceRange	0..*		YES	ReferenceRange		
seriousEventAssociation	seriousEventAssociation	0..1	SHOULD	YES	seriousEventAssociation		
specimen	specimen	0..*		YES	Specimen		
study Day Period	study Day Period	0..1	MAY	YES	Study Day Period		
studyTreatmentActionTakenAssociation	studyTreatmentActionTakenAssociation	0..1	SHOULD	YES	studyTreatmentActionTakenAssociation		
studyTreatmentCausalityAssociation	studyTreatmentCausalityAssociation	0..1	SHOULD	YES	studyTreatmentCausalityAssociation		
subject	subject	0..1		YES	Subject		
toxicityAssociation	toxicityAssociation	0..1	MAY	YES	aeToxicityAssociation		
typeId	typeId	0..1		YES	InfrastructureRootTypeId		

Adverse Event example

```
<?xml version="1.0" encoding="UTF-8"?>
<observation xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd"
 classCode="OBS" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.23.6"/>
  <id root="910043831" extension="MDHT"/>
  <code code="TBD" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
 Thesaurus" displayName="Adverse Event - Reported"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <value xsi:type="CE" code="1410498178"/>
  <targetSiteCode code="1102541629"/>
  <entryRelationship>
    <observation>
      <code code="510939129"/>
      <value xsi:type="CE" code="1485225953"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation>
      <code code="207185990"/>
      <value xsi:type="ED">Text Value</value>
    </observation>
```

```
 </entryRelationship>
 <entryRelationship>
   <observation>
     <code code="1930281347"/>
     <value xsi:type="BL"/>
   </observation>
 </entryRelationship>
 <entryRelationship typeCode="COMP">
   <observation classCode="OBS" moodCode="EVN">
     <code code="TBD" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
     <value xsi:type="CE" code="227497987"/>
   </observation>
 </entryRelationship>
 <entryRelationship>
   <observation>
     <code code="1733871883"/>
     <value xsi:type="CE" code="857656037"/>
   </observation>
 </entryRelationship>
 <entryRelationship>
   <observation>
     <code code="14113345"/>
     <value xsi:type="BL"/>
     <entryRelationship/>
   </observation>
 </entryRelationship>
 <entryRelationship>
   <observation>
     <code code="640071052"/>
     <value xsi:type="CE" code="594592282"/>
   </observation>
 </entryRelationship>
 <entryRelationship>
   <observation>
     <code code="1526998965"/>
     <value xsi:type="ED">Text Value</value>
   </observation>
 </entryRelationship>
 <entryRelationship>
   <observation>
     <code code="1718967574"/>
     <value xsi:type="CE" code="874111731"/>
   </observation>
 </entryRelationship>
 <entryRelationship>
   <observation>
     <code code="1077371094"/>
     <value xsi:type="CE" code="221736363"/>
   </observation>
 </entryRelationship>
 <entryRelationship>
   <observation>
     <code code="290530348"/>
     <value xsi:type="ED">Text Value</value>
   </observation>
 </entryRelationship>
 <entryRelationship>
   <observation/>
 </entryRelationship>
 <entryRelationship>
   <observation/>
 </entryRelationship>
 <entryRelationship>
```

```
    <act classCode="ACT" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.15"/>
      <id root="233098973" extension="MDHT"/>
      <code code="TBD" codeSystem="2.16.840.1.113883.3.26.1.1"
 codeSystemName="NCI Thesaurus"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
    </act>
  </entryRelationship>
  <entryRelationship>
    <observation/>
  </entryRelationship>
  <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.17"/>
      <id root="1541729647" extension="MDHT"/>
      <code code="TBD" codeSystem="2.16.840.1.113883.3.26.1.1"
 codeSystemName="NCI Thesaurus"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <value xsi:type="CE" code="1053708556"/>
      <targetSiteCode code="1452072184"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation/>
  </entryRelationship>
</observation>
```

Baseline Indicator

[Observation: templateId `2.16.840.1.113883.10.20.23.53`]

A resusable structure that indicates whether a reported value should be treated as a baseline value.

1. Contains exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
2. Contains exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`)
3. **SHALL** contain exactly one [1..1] **`code`**, where the @code **SHALL** be selected from (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`)
   - A code value that indicates the observation contains baseline information.
4. **SHALL** contain zero or more [0..*] **`value`** with data type BL
   - Indicates whether or not the value is a baseline. [SDTM: EGBLFL, LBBLFL, QSLFL, VSBLFL, MBBLFL, MSBLFL, FABLFL]

sdtm::Baseline Indicator							
cda::observation[cda:templateId/@root = 2.16.840.1.113883.10.20.23.57]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
classCode	@classCode	1..1		NO	ActClassObservation		ALRT
moodCode	@moodCode	1..1		NO	x_ActMoodDocumentObservation		DEF
negationInd	@negationInd	0..1		NO	Boolean		

sdtm::Baseline Indicator							
cda::observation[cda:templateId/@root = 2.16.840.1.113883.10.20.23.57]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
nullFlavor	@nullFlavor	0..1		NO	NullFlavor		ASKU
code	code	1..1	SHALL	YES	CD		NCI Thesaurus 2.16.840.1.113883.3.26.1.1 null
derivationExpr	derivationExpr	0..1		YES	ST		
effectiveTime	effectiveTime	0..1		YES	IVL_TS		
id	id	0..*		YES	II		
interpretationCode	interpretationCode	0..*		YES	CE		
languageCode	languageCode	0..1		YES	CS		
methodCode	methodCode	0..*		YES	CE		
priorityCode	priorityCode	0..1		YES	CE		
realmCode	realmCode	0..*		YES	CS		
repeatNumber	repeatNumber	0..1		YES	IVL_INT		
statusCode	statusCode	0..1		YES	CS		
targetSiteCode	targetSiteCode	0..*		YES	CD		
templateId	templateId	0..*		YES	II		2.16.840.1.113883.10.20.23.57
text	text	0..1		YES	ED		
value	value	0..*	SHALL	YES	BL		
author	author	0..*		YES	Author		
entryRelationship	entryRelationship	0..*		YES	EntryRelationship		
informant	informant	0..*		YES	Informant12		
participant	participant	0..*		YES	Participant2		
performer	performer	0..*		YES	Performer2		
precondition	precondition	0..*		YES	Precondition		
reference	reference	0..*		YES	Reference		
referenceRange	referenceRange	0..*		YES	ReferenceRange		
specimen	specimen	0..*		YES	Specimen		
subject	subject	0..1		YES	Subject		
typeId	typeId	0..1		YES	InfrastructureRootTypeId		

Baseline Indicator example

```
<?xml version="1.0" encoding="UTF-8"?>
<observation xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd"
 classCode="OBS" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.23.57"/>
```

```
  <id root="1824848180" extension="MDHT"/>
  <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
 Thesaurus"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <value xsi:type="BL"/>
</observation>
```

Body System or Organ Class

[Observation: templateId `2.16.840.1.113883.10.20.23.54`]

The resuable structure provides for entry of the body system or organ class that is relevant for a measurement or event. This structure is captured as a template to facilitate its reuse as a characteristic of different types of data within clinical trial reporting.

1. **SHALL** contain exactly one [1..1] **`@classCode`**
2. **SHALL** contain exactly one [1..1] **`@moodCode`**
3. **SHALL** contain exactly one [1..1] **`code`**
4. **SHALL** contain zero or one [0..1] **`value`** with data type CE

    - Provide the Body System or Organ class code. [SDTM: various]

sdtm::Body System or Organ Class							
cda::observation[cda:templateId/@root = 2.16.840.1.113883.10.20.23.16]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
classCode	@classCode	1..1	SHALL	NO	ActClassObservation		ALRT
moodCode	@moodCode	1..1	SHALL	NO	x_ActMoodDocumentObservation		DEF
negationInd	@negationInd	0..1		NO	Boolean		
nullFlavor	@nullFlavor	0..1		NO	NullFlavor		ASKU
code	code	1..1	SHALL	YES	CD		
derivationExpr	derivationExpr	0..1		YES	ST		
effectiveTime	effectiveTime	0..1		YES	IVL_TS		
id	id	0..*		YES	II		
interpretationCode	interpretationCode	0..*		YES	CE		
languageCode	languageCode	0..1		YES	CS		
methodCode	methodCode	0..*		YES	CE		
priorityCode	priorityCode	0..1		YES	CE		
realmCode	realmCode	0..*		YES	CS		
repeatNumber	repeatNumber	0..1		YES	IVL_INT		
statusCode	statusCode	0..1		YES	CS		
targetSiteCode	targetSiteCode	0..*		YES	CD		
templateId	templateId	0..*		YES	II		2.16.840.1.113883.10.20.23.16
text	text	0..1		YES	ED		

sdtm::Body System or Organ Class							
cda::observation[cda:templateId/@root = 2.16.840.1.113883.10.20.23.16]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
value	value	0..1	SHALL	YES	CE		
author	author	0..*		YES	Author		
entryRelationship	entryRelationship	0..*		YES	EntryRelationship		
informant	informant	0..*		YES	Informant12		
participant	participant	0..*		YES	Participant2		
performer	performer	0..*		YES	Performer2		
precondition	precondition	0..*		YES	Precondition		
reference	reference	0..*		YES	Reference		
referenceRange	referenceRange	0..*		YES	ReferenceRange		
specimen	specimen	0..*		YES	Specimen		
subject	subject	0..1		YES	Subject		
typeId	typeId	0..1		YES	InfrastructureRootTypeId		

Body System or Organ Class example

```
<?xml version="1.0" encoding="UTF-8"?>
<observation xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <templateId root="2.16.840.1.113883.10.20.23.16"/>
  <id root="1063565561" extension="MDHT"/>
  <code code="1772578106"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <value xsi:type="CE" code="1059892232"/>
</observation>
```

Clinical Event

[Observation: templateId `2.16.840.1.113883.10.20.23.27`]

The structure captures clinical events of interest that are not classified as adverse events. The data may be data about episodes of symptoms of the disease under study (often known as signs and symptoms), or about events that do not constitute adverse events in themselves, though they might lead to the identification of an adverse event. For example, in a study of an investigational treatment for migraine headaches, migraine headaches may not be considered to be adverse events per protocol. The occurrence of migraines or associated signs and symptoms might be reported as a clinical event. Other studies might track the occurrence of specific events as efficacy endpoints. For example, in a study of an investigational treatment for prevention of ischemic stroke, all occurrences of TIA, stroke and death might be captured as clinical events and assessed as to whether they meet endpoint criteria.

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`)
3. **SHALL** contain exactly one [1..1] **`code`**
   - The value "ASSERTION" must be used.

4. **MAY** contain zero or one [0..1] **`effectiveTime`**
   - The start and stop date/times of the clinical event. [SDTM: CESTDTC, CEENDTC]
5. **SHALL** contain [1..3] **`id`**
   - A value that is provided to ensure the uniqueness of clincal event items. [SDTM: CESEQ, CEREFID, CESPID] A single identifier, the sequence number, is required.
6. **MAY** contain zero or one [0..1] **`statusCode`**, where the @code **SHALL** be selected from (CodeSystem: `2.16.840.1.113883.5.14 HL7ActStatus`)
   - Used to indicate whether the activity - occurrence of the clinical event - did occur. Use statusCode "Completed" if the use occurred. [SDTM: CEOCCUR]
7. **SHALL** contain exactly one [1..1] **`value`**
   - A code value and descriptive text to provide information on the nature of the clinical event. [SDTM: CETERM, CEDECOD]
8. **MAY** contain zero or one [0..1] **`entryRelationship`**

   Indicates a category the clinical event is assigned to.

   a. This entryRelationship **SHALL** contain exactly one [1..1] **`@typeCode`**`="COMP"`
   b. This entryRelationship Contains exactly one [1..1] **`clinicalEventCategory`** with data type *clinical Event Category*
9. **MAY** contain zero or one [0..1] **`entryRelationship`**

   Indicates a sub-category the clinical event is assigned to.

   a. This entryRelationship **SHALL** contain exactly one [1..1] **`@typeCode`**`="COMP"`
   b. This entryRelationship Contains exactly one [1..1] **`clinicalEventSubCategory`** with data type *clinical Event Sub Category*
10. **MAY** contain zero or one [0..1] **`entryRelationship`**
    - Indicates whether or not the event was prespecified on the CRF.

    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Pre-Specified Event* (templateId: `2.16.840.1.113883.10.20.23.64`)
11. **MAY** contain zero or one [0..1] **`entryRelationship`**
    - Provides a reason for not capturing information for the clinical event.

    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Non Performance Reason* (templateId: `2.16.840.1.113883.10.20.23.62`)
12. **MAY** contain zero or one [0..1] **`entryRelationship`**
    - Indicates the body system or organ class associated with the clinical event.

    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Body System or Organ Class* (templateId: `2.16.840.1.113883.10.20.23.54`)
13. **MAY** contain zero or one [0..1] **`entryRelationship`**
    - Carries information regarding the timing of data collection related to the clinical event.

    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Data Collection* (templateId: `2.16.840.1.113883.10.20.23.56`)
14. **MAY** contain zero or one [0..1] **`entryRelationship`**
    - Captures information about the severity of the clinical event.

    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Event Severity* (templateId: `2.16.840.1.113883.10.20.23.58`)
15. **MAY** contain zero or one [0..1] **`entryRelationship`**

- Records the relationship between the start of the clinical event and a reference point defined for the study.

a. Contains **`@typeCode="`**`REFR"` *REFR*

b. Contains exactly one [1..1] *Activity Start Timing Reference* (templateId: `2.16.840.1.113883.10.20.23.52`)

16. **MAY** contain zero or one [0..1] **`entryRelationship`**

- Records the relationship between the end of the clinical event and a reference point defined for the study.

a. Contains **`@typeCode="`**`REFR"` *REFR*

b. Contains exactly one [1..1] *Activity End Timing Reference* (templateId: `2.16.840.1.113883.10.20.23.51`)

sdtm::Clinical Event							
cda::observation[cda:templateId/@root = 2.16.840.1.113883.10.20.23.33]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
classCode	@classCode	1..1	SHALL	NO	ActClassObservation		ALRT
moodCode	@moodCode	1..1	SHALL	NO	x_ActMoodDocumentObservation		DEF
negationInd	@negationInd	0..1		NO	Boolean		
nullFlavor	@nullFlavor	0..1		NO	NullFlavor		ASKU
code	code	1..1	SHALL	YES	CD		
derivationExpr	derivationExpr	0..1		YES	ST		
effectiveTime	effectiveTime	0..1	MAY	YES	IVL_TS		
id	id	1..3	SHALL	YES	II		
interpretationCode	interpretationCode	0..*		YES	CE		
languageCode	languageCode	0..1		YES	CS		
methodCode	methodCode	0..*		YES	CE		
priorityCode	priorityCode	0..1		YES	CE		
realmCode	realmCode	0..*		YES	CS		
repeatNumber	repeatNumber	0..1		YES	IVL_INT		
statusCode	statusCode	0..1	MAY	YES	CS		HL7ActStatus 2.16.840.1.113883.5.14
targetSiteCode	targetSiteCode	0..*		YES	CD		
templateId	templateId	0..*		YES	II		2.16.840.1.113883.10.20.23.33
text	text	0..1		YES	ED		
value	value	1..1	SHALL	YES	ANY		
activity End Timing Reference	activity End Timing Reference	0..1	MAY	YES	Activity End Timing Reference		
activity Start Timing Reference	activity Start Timing Reference	0..1	MAY	YES	Activity Start Timing Reference		
author	author	0..*		YES	Author		

sdtm::Clinical Event							
cda::observation[cda:templateId/@root = 2.16.840.1.113883.10.20.23.33]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
body System or Organ Class	body System or Organ Class	0..1	MAY	YES	Body System or Organ Class		
clinicalEventCategoryAssociation	clinicalEventCategoryAssociation	0..1	MAY	YES	clinicalEventCategoryAssociation		
clinicalEventSubCategoryAssociation	clinicalEventSubCategoryAssociation	0..1	MAY	YES	clinicalEventSubCategoryAssociation		
data Collection	data Collection	0..1	MAY	YES	Data Collection		
entryRelationship	entryRelationship	0..*		YES	EntryRelationship		
event Severity	event Severity	0..1	MAY	YES	Event Severity		
informant	informant	0..*		YES	Informant12		
nonPerformanceReason	nonPerformanceReason	0..1	MAY	YES	Non Performance Reason		
participant	participant	0..*		YES	Participant2		
performer	performer	0..*		YES	Performer2		
pre-Specified Event	pre-Specified Event	0..1	MAY	YES	Pre-Specified Event		
precondition	precondition	0..*		YES	Precondition		
reference	reference	0..*		YES	Reference		
referenceRange	referenceRange	0..*		YES	ReferenceRange		
specimen	specimen	0..*		YES	Specimen		
subject	subject	0..1		YES	Subject		
typeId	typeId	0..1		YES	InfrastructureRootTypeId		

Clinical Event example

```
<?xml version="1.0" encoding="UTF-8"?>
<observation xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd"
 classCode="OBS" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.23.33"/>
  <id root="646974376" extension="MDHT"/>
  <code code="1799884905"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <entryRelationship typeCode="COMP"/>
  <entryRelationship typeCode="COMP"/>
  <entryRelationship>
    <observation/>
  </entryRelationship>
  <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.9"/>
      <id root="1237561627" extension="MDHT"/>
```

```
     <code code="TBD" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
     <statusCode code="completed"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
     <value xsi:type="CE" code="1996844467"/>
   </observation>
 </entryRelationship>
 <entryRelationship>
   <observation/>
 </entryRelationship>
 <entryRelationship>
   <act classCode="ACT" moodCode="EVN">
     <templateId root="2.16.840.1.113883.10.20.23.30"/>
     <id root="143922619" extension="MDHT"/>
     <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus"/>
     <statusCode code="completed"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
     <entryRelationship>
       <observation classCode="OBS" moodCode="EVN">
         <templateId root="2.16.840.1.113883.10.20.23.11"/>
         <id root="228919948" extension="MDHT"/>
         <code code="TBD" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
         <statusCode code="completed"/>
         <effectiveTime>
           <low value="2012"/>
           <high value="2012"/>
         </effectiveTime>
         <value xsi:type="INT" value="1"/>
       </observation>
     </entryRelationship>
   </act>
 </entryRelationship>
 <entryRelationship>
   <observation classCode="OBS" moodCode="EVN">
     <templateId root="2.16.840.1.113883.10.20.23.17"/>
     <id root="929119119" extension="MDHT"/>
     <code code="TBD" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
     <statusCode code="completed"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
     <value xsi:type="CE" code="980099535"/>
   </observation>
 </entryRelationship>
 <entryRelationship>
   <act classCode="ACT" moodCode="EVN">
     <templateId root="2.16.840.1.113883.10.20.23.23"/>
     <id root="1858449650" extension="MDHT"/>
     <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus"/>
     <statusCode code="completed"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
```

```
      </effectiveTime>
      <entryRelationship typeCode="COMP">
        <act classCode="ACT">
          <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
 Thesaurus"/>
        </act>
      </entryRelationship>
    </act>
  </entryRelationship>
  <entryRelationship>
    <act classCode="ACT" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.24"/>
      <id root="1578198038" extension="MDHT"/>
      <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
 Thesaurus"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <entryRelationship typeCode="COMP">
        <act classCode="ACT">
          <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
 Thesaurus"/>
        </act>
      </entryRelationship>
    </act>
  </entryRelationship>
</observation>
```

Concomitant Medication

[SubstanceAdministration: templateId `2.16.840.1.113883.10.20.25.18`]

The structure is used to collect concommitant and prior medications or therapies used by the study subject. Examples are concommitant medications or therapies given on an as-needed basis, and the usual and background medications or therapies given for a condition.

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="SBADM"` (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`)
3. **MAY** contain zero or one [0..1] **`doseQuantity`**
   - The amount of medication taken at a single administration. [SDTM: CMDOSE, CMDOSU]
4. **MAY** contain zero or one [0..1] **`effectiveTime`**
   - Information on when and how ofern the concommitant medication was taken. Possible values include start date, stop date, and duration. Note, only two of these need to be valued, and only two values are supported. [SDTM: CMSTDTC, CMENDTC, CMDUR, CMDOSFRQ]
5. **MAY** contain zero or one [0..1] **`routeCode`**
   - The route by which the medication is administered. [SDTM: CMROUTE]
6. **MAY** contain zero or one [0..1] **`entryRelationship`**
   - Allows capture of a group identifier for the concommitant medication information.

   a. Contains **`@typeCode="`**`COMP"` *COMP*
   b. Contains exactly one [1..1] *Group Identifier* (templateId: `2.16.840.1.113883.10.20.23.61`)
7. **SHALL** contain [1..2] **`id`**

- A sponsor supplied reference number for the concommitant medication. [SDTM: CMSEQ, CMSPID] A sequence number is required.

8. **MAY** contain zero or one [0..1] **`entryRelationship`**

   Indicates a category the concommitant medication substance administration is assigned to.

   a. This entryRelationship **SHALL** contain exactly one [1..1] **`@typeCode`**`="COMP"`
   b. This entryRelationship **SHALL** contain exactly one [1..1] **`observation`**
      a. This observation **SHALL** contain exactly one [1..1] **`@classCode`**
      b. This observation **SHALL** contain exactly one [1..1] **`@moodCode`**
      c. This observation **SHALL** contain exactly one [1..1] **`code`**
      d. This observation **SHALL** contain exactly one [1..1] **`value`** with data type CE

         Provide the concomitant medication category value. [SDTM: CMCAT]

      e. This observation **MAY** contain zero or one [0..1] **`entryRelationship`**
         a. This entryRelationship **SHALL** contain zero or one [0..1] **`@typeCode`**`="COMP"`
         b. This entryRelationship **SHALL** contain zero or one [0..1] **`observation`**
            a. This observation **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
            b. This observation **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`)
            c. This observation **SHALL** contain exactly one [1..1] **`code`**
            d. This observation **SHALL** contain exactly one [1..1] **`value`** with data type CE

               Provide the applicable concomitant medication sub-category value. [SDTM: CMSCAT]

9. **MAY** contain zero or one [0..1] **`entryRelationship`**
   a. Contains **`@typeCode="`**`COMP"` *COMP*
   b. Contains exactly one [1..1] *Non Performance Reason* (templateId: `2.16.840.1.113883.10.20.23.62`)
10. **SHOULD** contain zero or one [0..1] **`statusCode`**
    - Used to indicate whether the activity - use of a particular medication - did occur. Use statusCode "Completed" if the use occurred. [SDTM: CMOCCUR]
11. **MAY** contain zero or one [0..1] **`entryRelationship`**
    a. This entryRelationship **SHALL** contain exactly one [1..1] **`@typeCode`**`="CAUS"`
    b. This entryRelationship **SHALL** contain exactly one [1..1] **`observation`**
       a. This observation **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
       b. This observation **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`)
       c. This observation **SHALL** contain exactly one [1..1] **`code`**
       d. This observation **SHALL** contain zero or more [0..*] **`value`**

          Information about the reason for the medication being taken. [SDTM: CMINDC]

12. **MAY** contain zero or one [0..1] **`text`**
    - A text description of dosing amounts or a range of dosing information. [SDTM: CMDOSTXT]
13. **SHALL** contain exactly one [1..1] **`consumable`**
    a. Contains exactly one [1..1] *Consumable Material* (templateId: `2.16.840.1.113883.10.20.23.55`)
14. **MAY** contain zero or one [0..1] **`entryRelationship`**

    Indicates a subcategory the concommitant medication substance administration is assigned to.

    a. This entryRelationship **SHALL** contain zero or one [0..1] **`@typeCode`**`="COMP"`
    b. This entryRelationship **SHALL** contain zero or one [0..1] **`observation`**

   a. This observation **SHALL** contain exactly one [1..1] **@classCode="OBS"** *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass)
   b. This observation **SHALL** contain exactly one [1..1] **@moodCode="EVN"** *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
   c. This observation **SHALL** contain exactly one [1..1] **code**
   d. This observation **SHALL** contain exactly one [1..1] **value** with data type CE

   Provide the applicable concomitant medication sub-category value. [SDTM: CMSCAT]

15. **MAY** contain zero or one [0..1] **entryRelationship**
   a. Contains **@typeCode="REFR"** *REFR*
   b. Contains exactly one [1..1] *Timing Reference* (templateId: 2.16.840.1.113883.10.20.23.70)
16. **MAY** contain zero or one [0..1] **maxDoseQuantity**
   - Information on the total daily dose of the medication. The structure also accommodates periods other than a day. [SDTM: CMDOSTOT] Note, this attribute can also be used if multiple total dosage amounts need to be reported.
17. **MAY** contain zero or one [0..1] **entryRelationship**
   a. This entryRelationship **SHALL** contain exactly one [1..1] **@typeCode="REFR"**
   b. This entryRelationship **SHALL** contain exactly one [1..1] **observation**
      a. This observation **SHALL** contain exactly one [1..1] **@classCode="OBS"** *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass)
      b. This observation **SHALL** contain exactly one [1..1] **@moodCode="EVN"** *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
      c. This observation **SHALL** contain exactly one [1..1] **code/@code="TBD"** (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)

      The code value indicates that the observation refers to the intended regimen for the substance administration.
      d. This observation **SHALL** contain zero or more [0..*] **value** with data type ED

      The observation value captures the intended regimen for the substance administration. [SDTM: CMDOSRGM]
18. **MAY** contain zero or one [0..1] **entryRelationship**
   - Records the relationship between the start of consumption of the concommitant medication and a reference point defined for the study.
   a. Contains **@typeCode="REFR"** *REFR*
   b. Contains exactly one [1..1] *Activity Start Timing Reference* (templateId: 2.16.840.1.113883.10.20.23.52)
19. **MAY** contain zero or one [0..1] **entryRelationship**
   - Records the relationship between the end of consumption of the concommitant medication and a reference point defined for the study.
   a. Contains **@typeCode="REFR"** *REFR*
   b. Contains exactly one [1..1] *Activity End Timing Reference* (templateId: 2.16.840.1.113883.10.20.23.51)
20. **MAY** contain zero or one [0..1] **entryRelationship**
   a. Contains **@typeCode="COMP"** *COMP*
   b. Contains exactly one [1..1] *Pre-Specified Event* (templateId: 2.16.840.1.113883.10.20.23.64)
21. **MAY** contain zero or one [0..1] **entryRelationship**
   a. Contains **@typeCode="COMP"** *COMP*
   b. Contains exactly one [1..1] *Data Collection* (templateId: 2.16.840.1.113883.10.20.23.56)
22. **MAY** contain zero or one [0..1] **entryRelationship**

a. Contains `@typeCode="REFR"` *REFR*

b. Contains exactly one [1..1] *Study Day Period* (templateId: `2.16.840.1.113883.10.20.23.74`)

23. **SHALL** satisfy: The efective time attribute is used to capture information regarding the start, stop, duration and frequency of use for the concommitant medication. There shall be Two SXPR components created. The first will be an interval of time stamps (IVL_TS) to addres stop and start dates. Note, when duration is included, it is associated with either the stop or the start date. That is to say, only two of the three interval parameters may be instantiated, since, with two known, the third can be derived. The second SXPR component addresses the frequency of use. It uses the periodic interval (PIVL) type. Note, that this HL7 type tends to invert the usual expression. I.e. BID is expressed as every 12 hours.

sdtm::Concomitant Medication							
cda::substanceadministration[cda:templateId/@root = 2.16.840.1.113883.10.20.25.19]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
classCode	@classCode	1..1	SHALL	NO	ActClass		SBADM
moodCode	@moodCode	1..1	SHALL	NO	x_DocumentSubstanceMood		EVN
negationInd	@negationInd	0..1		NO	Boolean		
nullFlavor	@nullFlavor	0..1		NO	NullFlavor		ASKU
administrationUnitCode	administrationUnitCode	0..1		YES	CE		
approachSiteCode	approachSiteCode	0..*		YES	CD		
code	code	0..1		YES	CD		
doseQuantity	doseQuantity	0..1	MAY	YES	IVL_PQ		
effectiveTime	effectiveTime	0..1	MAY	YES	SXCM_TS		
id	id	1..2	SHALL	YES	II		
maxDoseQuantity	maxDoseQuantity	0..1	MAY	YES	RTO_PQ_PQ		
priorityCode	priorityCode	0..1		YES	CE		
rateQuantity	rateQuantity	0..1		YES	IVL_PQ		
realmCode	realmCode	0..*		YES	CS		
repeatNumber	repeatNumber	0..1		YES	IVL_INT		
routeCode	routeCode	0..1	MAY	YES	CE		
statusCode	statusCode	0..1	SHOULD	YES	CS		
templateId	templateId	0..*		YES	II		2.16.840.1.113883.10.20.25.19
text	text	0..1	MAY	YES	ED		
indicationAssociation	indicationAssociation	0..1	MAY	YES	concomitantMedicationIndicationAssociation		
activity Start Timing Reference	activity Start Timing Reference	0..1	MAY	YES	Activity Start Timing Reference		
activty End Timing Reference	activty End Timing Reference	0..1	MAY	YES	Activity End Timing Reference		
author	author	0..*		YES	Author		
concomitantMedicationCategoryAssociation	concomitantMedicationCategoryAssociation	0..1	MAY	YES	concomitantMedicationCategoryAssociation		

sdtm::Concomitant Medication							
cda::substanceadministration[cda:templateId/@root = 2.16.840.1.113883.10.20.25.19]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
concomitantMedicationSubCategoryAssociation	concomitantMedicationSubCategoryAssociation	0..1	MAY	YES	concomitantMedicationSubCategoryAssociation		
consumable	consumable	1..1		YES	Consumable		
consumableMaterial	consumableMaterial	1..1	SHALL	YES	Consumable Material		
data Collection	data Collection	0..1	MAY	YES	Data Collection		
entryRelationship	entryRelationship	0..*		YES	EntryRelationship		
group Identifier	group Identifier	0..1	MAY	YES	Group Identifier		
informant	informant	0..*		YES	Informant12		
intendedRegimenAssociation	intendedRegimenAssociation	0..1	MAY	YES	IntendedRegimenAssociation		
nonPerformanceReason	nonPerformanceReason	0..1	MAY	YES	Non Performance Reason		
participant	participant	0..*		YES	Participant2		
performer	performer	0..*		YES	Performer2		
pre-Specified Event	pre-Specified Event	0..1	MAY	YES	Pre-Specified Event		
precondition	precondition	0..*		YES	Precondition		
reference	reference	0..*		YES	Reference		
specimen	specimen	0..*		YES	Specimen		
study Day Period	study Day Period	0..1	MAY	YES	Study Day Period		
subject	subject	0..1		YES	Subject		
timingReference	timingReference	0..1	MAY	YES	Timing Reference		
typeId	typeId	0..1		YES	InfrastructureRootTypeId		

Concomitant Medication example

```
<?xml version="1.0" encoding="UTF-8"?>
<substanceadministration xmlns:xsi="http://www.w3.org/2001/XMLSchema-
instance" xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd"
 classCode="SBADM" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.25.19"/>
  <id root="716159128" extension="MDHT"/>
  <text>Text Value</text>
  <statusCode code="completed"/>
  <effectiveTime value="20120508"/>
  <routeCode code="2028827248"/>
  <doseQuantity/>
  <maxDoseQuantity/>
  <consumable>
    <manufacturedProduct classCode="MANU">
      <manufacturedMaterial classCode="MMAT" determinerCode="KIND"/>
```

```
    </manufacturedProduct>
  </consumable>
  <entryRelationship typeCode="COMP">
    <observation>
      <code code="194561355"/>
      <value xsi:type="CE" code="54206585"/>
      <entryRelationship typeCode="COMP"/>
    </observation>
  </entryRelationship>
  <entryRelationship typeCode="CAUS">
    <observation classCode="OBS" moodCode="EVN">
      <code code="490486278"/>
    </observation>
  </entryRelationship>
  <entryRelationship typeCode="COMP">
    <observation classCode="OBS" moodCode="EVN">
      <code code="931320455"/>
      <value xsi:type="CE" code="1318105145"/>
    </observation>
  </entryRelationship>
  <entryRelationship typeCode="REFR">
    <observation classCode="OBS" moodCode="EVN">
      <code code="TBD" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
      <value xsi:type="ED">Text Value</value>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <act classCode="ACT" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.15"/>
      <id root="747327618" extension="MDHT"/>
      <code code="TBD" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
      <text>Text Value</text>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
    </act>
  </entryRelationship>
  <entryRelationship>
    <observation/>
  </entryRelationship>
  <entryRelationship>
    <observation/>
  </entryRelationship>
  <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.9"/>
      <id root="1910582935" extension="MDHT"/>
      <code code="TBD" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
      <text>Text Value</text>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <act classCode="ACT" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.14"/>
```

```
      <id root="1043794013" extension="MDHT"/>
      <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus"/>
      <text>Text Value</text>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <entryRelationship typeCode="COMP">
        <act classCode="ACT"/>
      </entryRelationship>
    </act>
 </entryRelationship>
 <entryRelationship>
    <act classCode="ACT" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.23"/>
      <id root="1397836539" extension="MDHT"/>
      <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus"/>
      <text>Text Value</text>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <entryRelationship typeCode="COMP">
        <act classCode="ACT">
          <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus"/>
        </act>
      </entryRelationship>
    </act>
 </entryRelationship>
 <entryRelationship>
    <act classCode="ACT" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.24"/>
      <id root="1535537014" extension="MDHT"/>
      <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus"/>
      <text>Text Value</text>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <entryRelationship typeCode="COMP">
        <act classCode="ACT">
          <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus"/>
        </act>
      </entryRelationship>
    </act>
 </entryRelationship>
 <entryRelationship>
    <observation/>
 </entryRelationship>
 <entryRelationship>
    <act classCode="ACT" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.30"/>
      <id root="446515615" extension="MDHT"/>
      <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus"/>
      <text>Text Value</text>
```

```
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <entryRelationship>
        <observation classCode="OBS" moodCode="EVN">
          <templateId root="2.16.840.1.113883.10.20.23.11"/>
          <id root="453557541" extension="MDHT"/>
          <code code="TBD" codeSystem="2.16.840.1.113883.3.26.1.1"
 codeSystemName="NCI Thesaurus"/>
          <text>Text Value</text>
          <statusCode code="completed"/>
          <effectiveTime>
            <low value="2012"/>
            <high value="2012"/>
          </effectiveTime>
        </observation>
      </entryRelationship>
    </act>
  </entryRelationship>
</substanceadministration>
```

Data Collection

[Act: templateId `2.16.840.1.113883.10.20.23.56`]

Information regarding the collection of data or the completion of a question with regard to an activity or other event. This structure is captured as a template to facilitate its reuse as a characteristic of different types of data within clinical trial reporting.

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="ACT"` *Act* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`)
3. **MAY** contain zero or one [0..1] **`@negationInd`**
   - When information about an event or activity is pre-specified, the negation indicator may be used to state that the information was not collected. Value the indicator as TRUE if the information item was not elicited. [SDTM: CMSTAT, SUSTAT, MHSTAT, CESTAT, MSSTAT]
4. **SHALL** contain exactly one [1..1] **`code`**, where the @code **SHALL** be selected from (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`)
   - The code value indicates the information relates to the collection of data regarding an event or activity.
5. **MAY** contain zero or one [0..1] **`effectiveTime`** with data type TS
   - The date/time of data collection: [SDTM: DMDTC, SUDTC, DSDTC, MHDTC, CEDTC, IEDTC, QSDTC, SCDTC, MSDTC]
6. **MAY** contain zero or one [0..1] **`entryRelationship`**
   a. Contains **`@typeCode="`**`REFR"` *REFR*
   b. Contains exactly one [1..1] *Event Study Day* (templateId: `2.16.840.1.113883.10.20.23.59`)

sdtm::Data Collection							
cda::act[cda:templateId/@root = 2.16.840.1.113883.10.20.23.30]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
classCode	@classCode	1..1	SHALL	NO	x_ActClassDocumentEntryAct		ACCM
moodCode	@moodCode	1..1	SHALL	NO	x_DocumentActMood		APT

sdtm::Data Collection							
cda::act[cda:templateId/@root = 2.16.840.1.113883.10.20.23.30]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
negationInd	@negationInd	0..1	MAY	NO	Boolean		
nullFlavor	@nullFlavor	0..1		NO	NullFlavor		ASKU
code	code	1..1	SHALL	YES	CD		NCI Thesaurus 2.16.840.1.113883.3.26.1.1 null
effectiveTime	effectiveTime	0..1	MAY	YES	TS		
id	id	0..*		YES	II		
languageCode	languageCode	0..1		YES	CS		
priorityCode	priorityCode	0..1		YES	CE		
realmCode	realmCode	0..*		YES	CS		
statusCode	statusCode	0..1		YES	CS		
templateId	templateId	0..*		YES	II		2.16.840.1.113883.10.20.23.30
text	text	0..1		YES	ED		
author	author	0..*		YES	Author		
entryRelationship	entryRelationship	0..*		YES	EntryRelationship		
event Study Day	event Study Day	0..1	MAY	YES	Event Study Day		
informant	informant	0..*		YES	Informant12		
participant	participant	0..*		YES	Participant2		
performer	performer	0..*		YES	Performer2		
precondition	precondition	0..*		YES	Precondition		
reference	reference	0..*		YES	Reference		
specimen	specimen	0..*		YES	Specimen		
subject	subject	0..1		YES	Subject		
typeId	typeId	0..1		YES	InfrastructureRootTypeId		

Data Collection example

```
<?xml version="1.0" encoding="UTF-8"?>
<act xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="urn:hl7-
org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd" classCode="ACT"
 moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.23.30"/>
  <id root="1344346292" extension="MDHT"/>
  <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
 Thesaurus"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
```

```
      <templateId root="2.16.840.1.113883.10.20.23.11"/>
      <id root="829715679" extension="MDHT"/>
      <code code="TBD" codeSystem="2.16.840.1.113883.3.26.1.1"
 codeSystemName="NCI Thesaurus"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
    </observation>
  </entryRelationship>
</act>
```

Derived Data Indicator

[Observation: templateId `2.16.840.1.113883.10.20.23.57`]

A resusable structure that indicates whether a reported value contains derived data.

1. Contains exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
2. Contains exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`)
3. **SHALL** contain exactly one [1..1] **`code`**, where the @code **SHALL** be selected from (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`)
   - A code value that indicates the observation indicates whether or not the related observation contains derived data.
4. **SHALL** contain zero or more [0..*] **`value`** with data type BL
   - Indicates whether or not the assocated data is derived. [SDTM: EGDRVFL, LBDRVFL, QSDRVFL, VSDRVFL, MBDRVFL, MSDRVFL, PCDRVFL]

sdtm::Derived Data Indicator							
cda::observation[cda:templateId/@root = 2.16.840.1.113883.10.20.23.58]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
classCode	@classCode	1..1		NO	ActClassObservation		ALRT
moodCode	@moodCode	1..1		NO	x_ActMoodDocumentObservation		DEF
negationInd	@negationInd	0..1		NO	Boolean		
nullFlavor	@nullFlavor	0..1		NO	NullFlavor		ASKU
code	code	1..1	SHALL	YES	CD		NCI Thesaurus 2.16.840.1.113883.3.26.1.1 null
derivationExpr	derivationExpr	0..1		YES	ST		
effectiveTime	effectiveTime	0..1		YES	IVL_TS		
id	id	0..*		YES	II		
interpretationCode	interpretationCode	0..*		YES	CE		
languageCode	languageCode	0..1		YES	CS		
methodCode	methodCode	0..*		YES	CE		
priorityCode	priorityCode	0..1		YES	CE		
realmCode	realmCode	0..*		YES	CS		

sdtm::Derived Data Indicator							
cda::observation[cda:templateId/@root = 2.16.840.1.113883.10.20.23.58]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
repeatNumber	repeatNumber	0..1		YES	IVL_INT		
statusCode	statusCode	0..1		YES	CS		
targetSiteCode	targetSiteCode	0..*		YES	CD		
templateId	templateId	0..*		YES	II		2.16.840.1.113883.10.20.23.58
text	text	0..1		YES	ED		
value	value	0..*	SHALL	YES	BL		
author	author	0..*		YES	Author		
entryRelationship	entryRelationship	0..*		YES	EntryRelationship		
informant	informant	0..*		YES	Informant12		
participant	participant	0..*		YES	Participant2		
performer	performer	0..*		YES	Performer2		
precondition	precondition	0..*		YES	Precondition		
reference	reference	0..*		YES	Reference		
referenceRange	referenceRange	0..*		YES	ReferenceRange		
specimen	specimen	0..*		YES	Specimen		
subject	subject	0..1		YES	Subject		
typeId	typeId	0..1		YES	InfrastructureRootTypeId		

Derived Data Indicator example

```
<?xml version="1.0" encoding="UTF-8"?>
<observation xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd"
 classCode="OBS" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.23.58"/>
  <id root="1811428834" extension="MDHT"/>
  <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
 Thesaurus"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <value xsi:type="BL"/>
</observation>
```

Drug Accountability

[Observation: templateId `2.16.840.1.113883.10.20.23.36`]

The structure allows entry of a wide range of data related to the drugs used in a study. It is intended for use in tracking the receipt, dispensing, return, and packaging of the study drug. However, the SDTM IG notes that a) one way a sponsor may choose to distinguish between different types of medications (e.g., study medication, rescue medication, run-in medication) is to use DACAT, and b) DAREFID and DASPID are both available for capturing label information.

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`)
3. **SHALL** contain exactly one [1..1] **`code`**
   - A coded value that indentifies the drug accountability item whose value is being conveyed. The verbatim text is placed within the original text property of the CD data type. [SDTM: DATESTCD, DATEST]
4. **SHALL** contain [1..3] **`id`**
   - A value that is provided to ensure the uniqueness of drug accountability items. [SDTM: DASEQ, DAREFID, DASPID] A single identifier, the sequence number, is required.
5. **SHOULD** contain zero or more [0..*] **`value`**
   - Captures the drug accountability value. The finding may be recorded as a coded value - if the result is character based - or as a physical quantity - if the result is numeric. [SDTM: DAORRES, DAORRESU, DASTRESC, DASTRESN, DASTRESU]
6. **MAY** contain zero or one [0..1] **`entryRelationship`**
   - Allows capture of a group identifier for the drug accountability item.
   a. Contains **`@typeCode="`**`COMP"` *COMP*
   b. Contains exactly one [1..1] *Group Identifier* (templateId: `2.16.840.1.113883.10.20.23.61`)
7. **MAY** contain zero or one [0..1] **`entryRelationship`**

   Indicates a category the drug accountability item is assigned to.
   a. This entryRelationship **SHALL** contain exactly one [1..1] **`@typeCode`**`="COMP"`
   b. This entryRelationship Contains exactly one [1..1] **`drugAccountabilityCategory`** with data type *drug Accountability Category*
8. **MAY** contain zero or one [0..1] **`entryRelationship`**

   Indicates a subcategory the drug accountability item is assigned to.
   a. This entryRelationship **SHALL** contain exactly one [1..1] **`@typeCode`**`="COMP"`
   b. This entryRelationship Contains exactly one [1..1] **`drugAccountabilitySubCategory`** with data type *drug Accountability Sub Category*
9. **MAY** contain zero or one [0..1] **`statusCode`**
   - Used to indicate whether the activity - recording the drug accountability value - did occur. Use statusCode "Completed" if the use occurred. [SDTM: DASTAT]
10. **MAY** contain zero or one [0..1] **`entryRelationship`**
    a. Contains **`@typeCode="`**`COMP"` *COMP*
    b. Contains exactly one [1..1] *Non Performance Reason* (templateId: `2.16.840.1.113883.10.20.23.62`)
11. **SHOULD** contain zero or one [0..1] **`effectiveTime`**
    - The date/time of the accountability assessment. [SDTM: DADTC]
12. **MAY** contain zero or one [0..1] **`entryRelationship`**
    a. Contains exactly one [1..1] *Event Study Day* (templateId: `2.16.840.1.113883.10.20.23.59`)

Drug Accountability example

ECG Test Result

[Observation: templateId `2.16.840.1.113883.10.20.23.28`]

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)

2. **SHALL** contain exactly one [1..1] **@moodCode="EVN"** *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **code**
   - A coded value that indentifies the measurement, test, or examination whose result is being conveyed. The verbatim text is placed within the original text property of the CD data type. [SDTM: EGTESTCD, EGTEST]
4. **SHOULD** contain zero or one [0..1] **effectiveTime**
   - The performance date of the ECG test. [SDTM: EGDTC]
5. **SHALL** contain [1..3] **id**
   - A value that is provided to ensure the uniqueness of ECG test result items. [SDTM: EGSEQ, EGREFID, EGSPID] A single identifier, the sequence number, is required.
6. **SHOULD** contain zero or one [0..1] **value**
   - Captures the ECG measurement or finding. The finding may be recorded as a coded value - if the result is character based - or as a physical quantity - if the result is numeric. [SDTM: EGORRES, EGORRESU, EGSTRESC, EGSTRESN, EGSTRESU]
7. **MAY** contain zero or one [0..1] **entryRelationship**
   - Allows capture of a group identifier for the ECG result.
   a. Contains **@typeCode="COMP"** *COMP*
   b. Contains exactly one [1..1] *Group Identifier* (templateId: 2.16.840.1.113883.10.20.23.61)
8. **MAY** contain zero or one [0..1] **entryRelationship**

   Indicates a category the ECG test result is assigned to.
   a. This entryRelationship **SHALL** contain exactly one [1..1] **@typeCode="COMP"**
   b. This entryRelationship Contains exactly one [1..1] **ecgTestResultCategory** with data type *ecg Test Result Category*
9. **MAY** contain zero or one [0..1] **entryRelationship**

   Indicates a subcategory the ECG test result is assigned to.
   a. This entryRelationship **SHALL** contain exactly one [1..1] **@typeCode="COMP"**
   b. This entryRelationship Contains exactly one [1..1] **ecgTestResultSubCategory** with data type *ecg Test Result Sub Category*
10. **MAY** contain zero or one [0..1] **entryRelationship**
    a. This entryRelationship **SHALL** contain exactly one [1..1] **@typeCode="COMP"**
    b. This entryRelationship **SHALL** contain exactly one [1..1] **position** with data type *position*
11. **MAY** contain zero or one [0..1] **statusCode**
    - Used to indicate whether the activity - performance of the ECG - did occur. Use statusCode "Completed" if the use occurred. [SDTM: EGSTAT]
12. **MAY** contain zero or one [0..1] **entryRelationship**
    a. Contains exactly one [1..1] *Non Performance Reason* (templateId: 2.16.840.1.113883.10.20.23.62)
13. **MAY** contain zero or one [0..1] **methodCode**
    - Capture the method of the ECG test. [SDTM: EGMETHOD]
14. **MAY** contain zero or one [0..1] **text**
    - The reference property of the ED data type is used to capture the file name and path for the external ECG waveform file. [SDTM: EGXFN]
15. **SHOULD** contain zero or one [0..1] **entryRelationship**
    a. This entryRelationship **SHALL** contain zero or one [0..1] **@typeCode="COMP"**
    b. This entryRelationship **SHALL** contain exactly one [1..1] **ecgLeadLocation** with data type *ecg Lead Location*
16. **SHOULD** contain zero or one [0..1] **entryRelationship**

   a. Contains **`@typeCode="COMP"`** *COMP*
   b. Contains exactly one [1..1] *Baseline Indicator* (templateId: `2.16.840.1.113883.10.20.23.53`)
17. **MAY** contain zero or one [0..1] **`entryRelationship`**
   a. Contains **`@typeCode="COMP"`** *COMP*
   b. Contains exactly one [1..1] *Derived Data Indicator* (templateId: `2.16.840.1.113883.10.20.23.57`)
18. **MAY** contain zero or one [0..1] **`entryRelationship`**
   a. Contains **`@typeCode="REFR"`** *REFR*
   b. Contains exactly one [1..1] *Event Study Day* (templateId: `2.16.840.1.113883.10.20.23.59`)
19. **MAY** contain zero or one [0..1] **`entryRelationship`**
   a. Contains **`@typeCode="REFR"`** *REFR*
   b. Contains exactly one [1..1] *Timing Reference* (templateId: `2.16.840.1.113883.10.20.23.70`)
20. **MAY** contain zero or one [0..1] **`study Test Performer`**
   a. Contains exactly one [1..1] *Study Test Performer* (templateId: `2.16.840.1.113883.10.20.23.72`)
21. **MAY** contain zero or one [0..1] **`study Finding Evaluator`**
   a. Contains exactly one [1..1] *Study Finding Evaluator* (templateId: `2.16.840.1.113883.10.20.23.73`)
22. **SHALL** satisfy: Use the PQR type. Capture the numeric result in standard units as value and unit, capture the numeric result in the orginal units as a translation. Note, this is only necessary if the original result does not use the standard units.
23. **SHALL** satisfy: Use the CE type. Capture the character result in standard units as code and code system, capture the character result in the orginal units as a translation. Note, this is only necessary if the original result does not use the standard format.

sdtm::ECG Test Result							
cda::observation[cda:templateId/@root = 2.16.840.1.113883.10.20.23.34]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
classCode	@classCode	1..1	SHALL	NO	ActClassObservation		ALRT
moodCode	@moodCode	1..1	SHALL	NO	x_ActMoodDocumentObservation		DEF
negationInd	@negationInd	0..1		NO	Boolean		
nullFlavor	@nullFlavor	0..1		NO	NullFlavor		ASKU
code	code	1..1	SHALL	YES	CD		
derivationExpr	derivationExpr	0..1		YES	ST		
effectiveTime	effectiveTime	0..1	SHOULD	YES	IVL_TS		
id	id	1..3	SHALL	YES	II		
interpretationCode	interpretationCode	0..*		YES	CE		
languageCode	languageCode	0..1		YES	CS		
methodCode	methodCode	0..1	MAY	YES	CE		
priorityCode	priorityCode	0..1		YES	CE		
realmCode	realmCode	0..*		YES	CS		
repeatNumber	repeatNumber	0..1		YES	IVL_INT		
statusCode	statusCode	0..1	MAY	YES	CS		
targetSiteCode	targetSiteCode	0..*		YES	CD		

sdtm::ECG Test Result							
cda::observation[cda:templateId/@root = 2.16.840.1.113883.10.20.23.34]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
templateId	templateId	0..*		YES	II		2.16.840.1.113883.10.20.23.34
text	text	0..1	MAY	YES	ED		
value	value	0..1	SHOULD	YES	ANY		
associatedPosition	associatedPosition	0..1	MAY	YES	associatedPosition		
author	author	0..*		YES	Author		
baseline Indicator	baseline Indicator	0..1	SHOULD	YES	Baseline Indicator		
derived Data Indicator	derived Data Indicator	0..1	MAY	YES	Derived Data Indicator		
ecgTestResultCategoryAssociation	ecgTestResultCategoryAssociation	0..1	MAY	YES	ecgTestResultCategoryAssociation		
ecgTestResultSubCategoryAssociation	ecgTestResultSubCategoryAssociation	0..1	MAY	YES	ecgTestResultSubCategoryAssociation		
entryRelationship	entryRelationship	0..*		YES	EntryRelationship		
event Study Day	event Study Day	0..1	MAY	YES	Event Study Day		
group Identifier	group Identifier	0..1	MAY	YES	Group Identifier		
informant	informant	0..*		YES	Informant12		
leadLocationAssociation	leadLocationAssociation	0..1	SHOULD	YES	leadLocationAssociation		
nonPerformanceReason	nonPerformanceReason	0..1	MAY	YES	Non Performance Reason		
participant	participant	0..*		YES	Participant2		
performer	performer	0..*		YES	Performer2		
precondition	precondition	0..*		YES	Precondition		
reference	reference	0..*		YES	Reference		
referenceRange	referenceRange	0..*		YES	ReferenceRange		
specimen	specimen	0..*		YES	Specimen		
study Finding Evaluator	study Finding Evaluator	0..1	MAY	YES	Study Finding Evaluator		
study Test Performer	study Test Performer	0..1	MAY	YES	Study Test Performer		
subject	subject	0..1		YES	Subject		
timing Reference	timing Reference	0..1	MAY	YES	Timing Reference		
typeId	typeId	0..1		YES	InfrastructureRootTypeId		

ECG Test Result example

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

```
<observation xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd"
 classCode="OBS" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.23.34"/>
  <id root="1650042740" extension="MDHT"/>
  <code code="559868413"/>
  <text>Text Value</text>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <methodCode code="915539928"/>
  <entryRelationship typeCode="COMP"/>
  <entryRelationship typeCode="COMP"/>
  <entryRelationship typeCode="COMP"/>
  <entryRelationship typeCode="COMP"/>
  <entryRelationship>
    <act classCode="ACT" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.15"/>
      <id root="583892174" extension="MDHT"/>
      <code code="TBD" codeSystem="2.16.840.1.113883.3.26.1.1"
 codeSystemName="NCI Thesaurus"/>
      <text>Text Value</text>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
    </act>
  </entryRelationship>
  <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.9"/>
      <id root="53175585" extension="MDHT"/>
      <code code="TBD" codeSystem="2.16.840.1.113883.3.26.1.1"
 codeSystemName="NCI Thesaurus"/>
      <text>Text Value</text>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <value xsi:type="CE" code="1222418855"/>
      <methodCode code="807308232"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.57"/>
      <id root="1249834971" extension="MDHT"/>
      <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
 Thesaurus"/>
      <text>Text Value</text>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <value xsi:type="BL"/>
      <methodCode code="96589015"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
```

```
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.58"/>
      <id root="990355016" extension="MDHT"/>
      <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
 Thesaurus"/>
      <text>Text Value</text>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <value xsi:type="BL"/>
      <methodCode code="1858701256"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.11"/>
      <id root="484011862" extension="MDHT"/>
      <code code="TBD" codeSystem="2.16.840.1.113883.3.26.1.1"
 codeSystemName="NCI Thesaurus"/>
      <text>Text Value</text>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <value xsi:type="INT" value="1"/>
      <methodCode code="1625178797"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <act classCode="ACT" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.14"/>
      <id root="34713401" extension="MDHT"/>
      <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
 Thesaurus"/>
      <text>Text Value</text>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <entryRelationship typeCode="COMP">
        <act classCode="ACT"/>
      </entryRelationship>
    </act>
  </entryRelationship>
</observation>
```

Event Severity

[Observation: templateId `2.16.840.1.113883.10.20.23.58`]

The reusable stucture is used to record information regarding the severity or intensity of an observed event. This structure is captured as a template to facilitate its reuse as a characteristic of different types of data within clinical trial reporting.

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`)

3. **SHALL** contain exactly one [1..1] **`code/@code`**`="TBD"` (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`)
4. **SHALL** contain exactly one [1..1] **`value`** with data type CE, where the @code **SHALL** be selected from (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`)
   - Provide the severity or intensity of the event.

sdtm::Event Severity							
cda::observation[cda:templateId/@root = 2.16.840.1.113883.10.20.23.17]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
classCode	@classCode	1..1	SHALL	NO	ActClassObservation		ALRT
moodCode	@moodCode	1..1	SHALL	NO	x_ActMoodDocumentObservation		DEF
negationInd	@negationInd	0..1		NO	Boolean		
nullFlavor	@nullFlavor	0..1		NO	NullFlavor		ASKU
code	code	1..1	SHALL	YES	CD		NCI Thesaurus 2.16.840.1.113883.3.26.1.1 TBD
derivationExpr	derivationExpr	0..1		YES	ST		
effectiveTime	effectiveTime	0..1		YES	IVL_TS		
id	id	0..*		YES	II		
interpretationCode	interpretationCode	0..*		YES	CE		
languageCode	languageCode	0..1		YES	CS		
methodCode	methodCode	0..*		YES	CE		
priorityCode	priorityCode	0..1		YES	CE		
realmCode	realmCode	0..*		YES	CS		
repeatNumber	repeatNumber	0..1		YES	IVL_INT		
statusCode	statusCode	0..1		YES	CS		
targetSiteCode	targetSiteCode	0..*		YES	CD		
templateId	templateId	0..*		YES	II		2.16.840.1.113883.10.20.23.17
text	text	0..1		YES	ED		
value	value	1..1	SHALL	YES	CE		NCI Thesaurus 2.16.840.1.113883.3.26.1.1
author	author	0..*		YES	Author		
entryRelationship	entryRelationship	0..*		YES	EntryRelationship		
informant	informant	0..*		YES	Informant12		
participant	participant	0..*		YES	Participant2		
performer	performer	0..*		YES	Performer2		
precondition	precondition	0..*		YES	Precondition		
reference	reference	0..*		YES	Reference		
referenceRange	referenceRange	0..*		YES	ReferenceRange		

sdtm::Event Severity							
cda::observation[cda:templateId/@root = 2.16.840.1.113883.10.20.23.17]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
specimen	specimen	0..*		YES	Specimen		
subject	subject	0..1		YES	Subject		
typeId	typeId	0..1		YES	InfrastructureRootTypeId		

Event Severity example

```
<?xml version="1.0" encoding="UTF-8"?>
<observation xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd"
 classCode="OBS" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.23.17"/>
  <id root="734300173" extension="MDHT"/>
  <code code="TBD" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
 Thesaurus"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <value xsi:type="CE" code="1742479724"/>
</observation>
```

Event Study Day

[Observation: templateId `2.16.840.1.113883.10.20.23.59`]

The resusable structure contains information to identify the study day on which the event it is related to occurred. "Study Day" refers to the relative day of an observation or other event with respect the the designated reference day for the study - which is labled as "Day 1". Note, dates prior to the reference data are decremented by 1, with the day preceeding the reference day designated as "Study Day -1". This structure is captured as a template to facilitate its reuse as a characteristic of different types of data within clinical trial reporting.

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`)
3. **SHALL** contain exactly one [1..1] **`code/@code`**`="TBD"` (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`)
   - A fixed value that indicates the observation captures the actual study day for an event.
4. **SHALL** contain exactly one [1..1] **`value`** with data type INT
   - The applicable study day value. [SDTM: DMDY, MHDY, CEDY, EGDY, IEDY, LBDY, PEDY, QSDY, SCDY, VSDY, DADY, MBDY, MSDY, PCDY, FADY]

sdtm::Event Study Day							
cda::observation[cda:templateId/@root = 2.16.840.1.113883.10.20.23.11]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
classCode	@classCode	1..1	SHALL	NO	ActClassObservation		ALRT
moodCode	@moodCode	1..1	SHALL	NO	x_ActMoodDocumentObservation		DEF
negationInd	@negationInd	0..1		NO	Boolean		

sdtm::Event Study Day							
cda::observation[cda:templateId/@root = 2.16.840.1.113883.10.20.23.11]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
nullFlavor	@nullFlavor	0..1		NO	NullFlavor		ASKU
code	code	1..1	SHALL	YES	CD		NCI Thesaurus 2.16.840.1.113883.3.26.1.1 TBD
derivationExpr	derivationExpr	0..1		YES	ST		
effectiveTime	effectiveTime	0..1		YES	IVL_TS		
id	id	0..*		YES	II		
interpretationCode	interpretationCode	0..*		YES	CE		
languageCode	languageCode	0..1		YES	CS		
methodCode	methodCode	0..*		YES	CE		
priorityCode	priorityCode	0..1		YES	CE		
realmCode	realmCode	0..*		YES	CS		
repeatNumber	repeatNumber	0..1		YES	IVL_INT		
statusCode	statusCode	0..1		YES	CS		
targetSiteCode	targetSiteCode	0..*		YES	CD		
templateId	templateId	0..*		YES	II		2.16.840.1.113883.10.20.23.11
text	text	0..1		YES	ED		
value	value	1..1	SHALL	YES	INT		
author	author	0..*		YES	Author		
entryRelationship	entryRelationship	0..*		YES	EntryRelationship		
informant	informant	0..*		YES	Informant12		
participant	participant	0..*		YES	Participant2		
performer	performer	0..*		YES	Performer2		
precondition	precondition	0..*		YES	Precondition		
reference	reference	0..*		YES	Reference		
referenceRange	referenceRange	0..*		YES	ReferenceRange		
specimen	specimen	0..*		YES	Specimen		
subject	subject	0..1		YES	Subject		
typeId	typeId	0..1		YES	InfrastructureRootTypeId		

Event Study Day example

```
<?xml version="1.0" encoding="UTF-8"?>
<observation xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd"
 classCode="OBS" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.23.11"/>
```

```
  <id root="292897361" extension="MDHT"/>
  <code code="TBD" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
 Thesaurus"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <value xsi:type="INT" value="1"/>
</observation>
```

Finding About

[Observation: templateId `2.16.840.1.113883.10.20.23.40`]

The Findings About strucuture is used to capture information about an event or intervention that is cannot be included within the data structures directly associated with the event or intervention type.

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`)
3. **SHALL** contain exactly one [1..1] **`code`**
   - A coded value that identifies the findings about result. The verbatim text is placed within the original text property of the CD data type. [SDTM: FATESTCD, FATEST]
4. Contains zero or one [0..1] **`effectiveTime`**
5. **SHALL** contain [1..2] **`id`**
   - A value that is provided to ensure the uniqueness of the findings about result. [SDTM: FASEQ, FASPID] A single identifier, the sequence number, is required.
6. **MAY** contain zero or one [0..1] **`statusCode`**
   - Used to indicate whether or not a measurement has been performed. [SDTM: FASTAT]
7. **MAY** contain zero or more [0..*] **`targetSiteCode`**
   - Used to specify the location of a clinical evaluation. [SDTM: FALOC]
8. **SHALL** contain exactly one [1..1] **`value`**
   - The findings about result, using both original units and a standard format or set of units. [SDTM: FAORRES, FAORRESU, FASTRESC, FASTRESN, FASTRESU]
9. **SHALL** contain zero or one [0..1] **`entryRelationship`**
   - Allows capture of a group identifier for the finding.
   a. Contains **`@typeCode="`**`COMP"` *COMP*
   b. Contains exactly one [1..1] *Group Identifier* (templateId: `2.16.840.1.113883.10.20.23.61`)
10. **SHALL** contain zero or one [0..1] **`entryRelationship`**
    a. This entryRelationship **SHALL** contain exactly one [1..1] **`@typeCode`**`="REFR"`
    b. This entryRelationship **SHALL** contain zero or one [0..1] **`observation`**
       a. This observation **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
       b. This observation **SHALL** contain exactly one [1..1] **`@moodCode`**`="DEF"` (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`)
       c. This observation **SHALL** contain exactly one [1..1] **`code`**, where the @code **SHALL** be selected from (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`)
       d. This observation **SHALL** contain zero or more [0..*] **`value`** with data type CE

          A coded value to identify the concept which is considered to be the object of the finding about observation. [SDTM: FAOBJ]

11. **MAY** contain zero or one [0..1] **`entryRelationship`**

    Indicates a category the finding is assigned to.
    a. This entryRelationship **SHALL** contain exactly one [1..1] **`@typeCode`**="COMP"
    b. This entryRelationship **SHALL** contain exactly one [1..1] **`findingAboutCategory`** with data type *finding About Category*
12. **MAY** contain zero or one [0..1] **`entryRelationship`**

    Indicates a subcategory the finding is assigned to.
    a. This entryRelationship **SHALL** contain exactly one [1..1] **`@typeCode`**="COMP"
    b. This entryRelationship **SHALL** contain exactly one [1..1] **`findingAboutSubCategory`** with data type *finding About Sub Category*
13. **MAY** contain zero or one [0..1] **`entryRelationship`**
    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Non Performance Reason* (templateId: 2.16.840.1.113883.10.20.23.62)
14. **MAY** contain zero or one [0..1] **`entryRelationship`**
    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Baseline Indicator* (templateId: 2.16.840.1.113883.10.20.23.53)
15. **MAY** contain zero or one [0..1] **`entryRelationship`**
    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Data Collection* (templateId: 2.16.840.1.113883.10.20.23.56)
16. **MAY** contain zero or one [0..1] **`study Finding Evaluator`**
    a. Contains exactly one [1..1] *Study Finding Evaluator* (templateId: 2.16.840.1.113883.10.20.23.73)

sdtm::Finding About							
cda::observation[cda:templateId/@root = 2.16.840.1.113883.10.20.23.45]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
classCode	@classCode	1..1	SHALL	NO	ActClassObservation		ALRT
moodCode	@moodCode	1..1	SHALL	NO	x_ActMoodDocumentObservation		DEF
negationInd	@negationInd	0..1		NO	Boolean		
nullFlavor	@nullFlavor	0..1		NO	NullFlavor		ASKU
code	code	1..1	SHALL	YES	CD		
derivationExpr	derivationExpr	0..1		YES	ST		
effectiveTime	effectiveTime	0..1		YES	IVL_TS		
id	id	1..2	SHALL	YES	II		
interpretationCode	interpretationCode	0..*		YES	CE		
languageCode	languageCode	0..1		YES	CS		
methodCode	methodCode	0..*		YES	CE		
priorityCode	priorityCode	0..1		YES	CE		
realmCode	realmCode	0..*		YES	CS		
repeatNumber	repeatNumber	0..1		YES	IVL_INT		
statusCode	statusCode	0..1	MAY	YES	CS		
targetSiteCode	targetSiteCode	0..*	MAY	YES	CD		

sdtm::Finding About							
cda::observation[cda:templateId/@root = 2.16.840.1.113883.10.20.23.45]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
templateId	templateId	0..*		YES	II		2.16.840.1.113883.10.20.23.45
text	text	0..1		YES	ED		
value	value	1..1	SHALL	YES	ANY		
author	author	0..*		YES	Author		
baseline Indicator	baseline Indicator	0..1	MAY	YES	Baseline Indicator		
data Collection	data Collection	0..1	MAY	YES	Data Collection		
entryRelationship	entryRelationship	0..*		YES	EntryRelationship		
findingAboutCategoryAssociation	findingAboutCategoryAssociation	0..1	MAY	YES	findingAboutCategoryAssociation		
findingAboutSubCategoryAssociation	findingAboutSubCategoryAssociation	0..1	MAY	YES	findingAboutSubCategoryAssociation		
findingObservationObjectAssociation	findingObservationObjectAssociation	0..1	SHALL	YES	findingObservationObjectAssociation		
group Identifier	group Identifier	0..1	SHALL	YES	Group Identifier		
informant	informant	0..*		YES	Informant12		
non Performance Reason	non Performance Reason	0..1	MAY	YES	Non Performance Reason		
participant	participant	0..*		YES	Participant2		
performer	performer	0..*		YES	Performer2		
precondition	precondition	0..*		YES	Precondition		
reference	reference	0..*		YES	Reference		
referenceRange	referenceRange	0..*		YES	ReferenceRange		
specimen	specimen	0..*		YES	Specimen		
study Finding Evaluator	study Finding Evaluator	0..1	MAY	YES	Study Finding Evaluator		
subject	subject	0..1		YES	Subject		
typeId	typeId	0..1		YES	InfrastructureRootTypeId		

Finding About example

```
<?xml version="1.0" encoding="UTF-8"?>
<observation xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd"
 classCode="OBS" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.23.45"/>
  <id root="1968199858" extension="MDHT"/>
  <code code="1411634683"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
```

```
 <targetSiteCode code="991033221"/>
 <entryRelationship typeCode="REFR">
   <observation classCode="OBS" moodCode="DEF">
     <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus"/>
     <value xsi:type="CE" code="123080439"/>
   </observation>
 </entryRelationship>
 <entryRelationship typeCode="COMP"/>
 <entryRelationship typeCode="COMP"/>
 <entryRelationship>
   <act classCode="ACT" moodCode="EVN">
     <templateId root="2.16.840.1.113883.10.20.23.15"/>
     <id root="785297180" extension="MDHT"/>
     <code code="TBD" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
     <statusCode code="completed"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
   </act>
 </entryRelationship>
 <entryRelationship>
   <observation classCode="OBS" moodCode="EVN">
     <templateId root="2.16.840.1.113883.10.20.23.9"/>
     <id root="144288714" extension="MDHT"/>
     <code code="TBD" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
     <statusCode code="completed"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
     <value xsi:type="CE" code="1004940233"/>
     <targetSiteCode code="960582234"/>
   </observation>
 </entryRelationship>
 <entryRelationship>
   <observation classCode="OBS" moodCode="EVN">
     <templateId root="2.16.840.1.113883.10.20.23.57"/>
     <id root="1345004285" extension="MDHT"/>
     <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus"/>
     <statusCode code="completed"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
     <value xsi:type="BL"/>
     <targetSiteCode code="884234140"/>
   </observation>
 </entryRelationship>
 <entryRelationship>
   <act classCode="ACT" moodCode="EVN">
     <templateId root="2.16.840.1.113883.10.20.23.30"/>
     <id root="269688425" extension="MDHT"/>
     <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus"/>
     <statusCode code="completed"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
```

```
      <entryRelationship>
        <observation classCode="OBS" moodCode="EVN">
          <templateId root="2.16.840.1.113883.10.20.23.11"/>
          <id root="423309418" extension="MDHT"/>
          <code code="TBD" codeSystem="2.16.840.1.113883.3.26.1.1"
 codeSystemName="NCI Thesaurus"/>
          <statusCode code="completed"/>
          <effectiveTime>
            <low value="2012"/>
            <high value="2012"/>
          </effectiveTime>
          <value xsi:type="INT" value="1"/>
          <targetSiteCode code="1571438072"/>
        </observation>
      </entryRelationship>
    </act>
  </entryRelationship>
</observation>
```

Group Identifier

[Act: templateId `2.16.840.1.113883.10.20.23.61`]

The reusable structure contains information on an identifier that can be assigned to a concommitant medication, adverse event or other event, and that is used as a grouping mechanism. This structure is captured as a template to facilitate its reuse as a characteristic of different types of data within clinical trial reporting.

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="ACT"` *Act* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`)
3. **SHALL** contain exactly one [1..1] **`code/@code`**`="TBD"` (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`)
   - The code value indicates that the act contains group identifier information.
4. **SHALL** contain exactly one [1..1] **`id`**
   - The group code value. [SDTM: CMGRPID, EXGRPID, SUGRPID, AEGRPID, DSGRPID, MHGRPID, CEGRPID, EGGRPID, LBGRPID, PEGRPID, QSGRPID, SCGRPID, VSGRPID, DAGRPID, MBGRPID, MSGRPID, PCGRPID, PPGRPID, FAGRPID,]

sdtm::Group Identifier							
cda::act[cda:templateId/@root = 2.16.840.1.113883.10.20.23.15]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
classCode	@classCode	1..1	SHALL	NO	x_ActClassDocumentEntryAct		ACCM
moodCode	@moodCode	1..1	SHALL	NO	x_DocumentActMood		APT
negationInd	@negationInd	0..1		NO	Boolean		
nullFlavor	@nullFlavor	0..1		NO	NullFlavor		ASKU
code	code	1..1	SHALL	YES	CD		NCI Thesaurus 2.16.840.1.113883.3.26.1.1 TBD
effectiveTime	effectiveTime	0..1		YES	IVL_TS		
id	id	1..1	SHALL	YES	II		
languageCode	languageCode	0..1		YES	CS		

sdtm::Group Identifier							
cda::act[cda:templateId/@root = 2.16.840.1.113883.10.20.23.15]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
priorityCode	priorityCode	0..1		YES	CE		
realmCode	realmCode	0..*		YES	CS		
statusCode	statusCode	0..1		YES	CS		
templateId	templateId	0..*		YES	II		2.16.840.1.113883.10.20.23.15
text	text	0..1		YES	ED		
author	author	0..*		YES	Author		
entryRelationship	entryRelationship	0..*		YES	EntryRelationship		
informant	informant	0..*		YES	Informant12		
participant	participant	0..*		YES	Participant2		
performer	performer	0..*		YES	Performer2		
precondition	precondition	0..*		YES	Precondition		
reference	reference	0..*		YES	Reference		
specimen	specimen	0..*		YES	Specimen		
subject	subject	0..1		YES	Subject		
typeId	typeId	0..1		YES	InfrastructureRootTypeId		

Group Identifier example

```
<?xml version="1.0" encoding="UTF-8"?>
<act xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="urn:hl7-
org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd" classCode="ACT"
 moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.23.15"/>
  <id root="297186539" extension="MDHT"/>
  <code code="TBD" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
 Thesaurus"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
</act>
```

Human Clinical Disposition

[Act: templateId `2.16.840.1.113883.10.20.23.23`]

Disposition information provides an accounting for all subjects who entered the study and may include protocol milestones, such as randomization, as well as the subject's completion status or reason for discontinuation for the entire study or each phase or segment of the study, including screening and post-treatment follow-up.

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="ACT"` *Act* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`)
3. **SHALL** contain exactly one [1..1] **`code`**

- A code drawn from a controlled terminology for the event or protocol milestone. The verbatim name for the term must be captured as well. [SDTM:DSTERM; DSDECOD]

4. **SHOULD** contain zero or one [0..1] **`effectiveTime`**
   - The start date/time of the disposition event. [SDTM: DSSTDTC]
5. **SHALL** contain [1..2] **`id`**
   - An identifier that is used to ensure the uniqueness of subject records within the substance use domain. [SDTM: DSSEQ, DSREFID] Note, the Sequence Number is required.
6. **SHOULD** contain zero or one [0..1] **`entryRelationship`**

   Indicates a category the disposition item is assigned to.
   a. This entryRelationship **SHALL** contain exactly one [1..1] **`@typeCode`**`="COMP"`
   b. This entryRelationship **SHALL** contain exactly one [1..1] **`dispositionCategory`** with data type *disposition Category*
7. **SHOULD** contain zero or one [0..1] **`entryRelationship`**

   Indicates a subcategory the disposition item is assigned to.
   a. This entryRelationship **SHALL** contain exactly one [1..1] **`@typeCode`**`="COMP"`
   b. This entryRelationship **SHALL** contain exactly one [1..1] **`dispositionSubCategory`** with data type *disposition Sub Category*
8. **MAY** contain zero or one [0..1] **`entryRelationship`**
   a. Contains **`@typeCode="`**`COMP"` *COMP*
   b. Contains exactly one [1..1] *Study Epoch* (templateId: `2.16.840.1.113883.10.20.23.71`)
9. **SHOULD** contain zero or one [0..1] **`entryRelationship`**
   a. Contains **`@typeCode="`**`COMP"` *COMP*
   b. Contains exactly one [1..1] *Data Collection* (templateId: `2.16.840.1.113883.10.20.23.56`)
10. **MAY** contain zero or one [0..1] **`entryRelationship`**
    - Allows capture of a group identifier for the disposition item.

    a. Contains **`@typeCode="`**`COMP"` *COMP*
    b. Contains exactly one [1..1] *Group Identifier* (templateId: `2.16.840.1.113883.10.20.23.61`)
11. **MAY** contain zero or one [0..1] **`entryRelationship`**
    a. Contains **`@typeCode="`**`REFR"` *REFR*
    b. Contains exactly one [1..1] *Study Day Period* (templateId: `2.16.840.1.113883.10.20.23.74`)

Human Clinical Disposition example

Human Clinical Exposure

[SubstanceAdministration: templateId `2.16.840.1.113883.10.20.23.19`]

The template captures details of a subject's exposure to protocol-specified study treatment. Study treatment may be any intervention that is prospectively defined as a test material within a study, and is typically but not always supplied to the subject.

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="SBADM"` (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`)
3. **SHOULD** contain zero or one [0..1] **`doseQuantity`**
   - The amount of study treatment taken at a single administration. [SDTM: EXDOSE, EXDOSU]
4. **MAY** contain zero or one [0..1] **`effectiveTime`**

- Information on when and how ofter the study treatment was taken. Possible values include start date, stop date, and duration. Note, only two of these need to be valued, and only two values are supported. [SDTM: EXSTDTC, EXENDTC, EXDUR, EXDOSFRQ]

5. **SHALL** contain [1..2] **`id`**
   - A sponsor supplied reference number for the study treatment. [SDTM: EXSEQ, EXSPID] A sequence number is required.
6. **MAY** contain zero or one [0..1] **`routeCode`**
   - The route by which the treatment is administered. [SDTM: EXROUTE]
7. **MAY** contain zero or one [0..1] **`maxDoseQuantity`**
   - Information on the total daily dose of the medication. The structure also accommodates periods other than a day. [SDTM: EXDOSTOT] Note, this attribute can also be used if multiple total dosage amounts need to be reported.
8. **MAY** contain zero or one [0..1] **`entryRelationship`**
   - Allows capture of a group identifier for the exposure information.
   a. Contains **`@typeCode="COMP"`** *COMP*
   b. Contains exactly one [1..1] *Group Identifier* (templateId: `2.16.840.1.113883.10.20.23.61`)
9. **SHALL** contain exactly one [1..1] **`consumable`**
   a. Contains exactly one [1..1] *Consumable Material* (templateId: `2.16.840.1.113883.10.20.23.55`)
10. **MAY** contain zero or one [0..1] **`entryRelationship`**

    Indicates a category the exposure information is assigned to.

    a. This entryRelationship **SHALL** contain exactly one [1..1] **`@typeCode`**`="COMP"`
    b. This entryRelationship **SHALL** contain exactly one [1..1] **`exposureCategory`** with data type *exposure Event Category*
11. **MAY** contain zero or one [0..1] **`entryRelationship`**

    Indicates a subcategory the exposure information is assigned to.

    a. This entryRelationship **SHALL** contain exactly one [1..1] **`@typeCode`**`="COMP"`
    b. This entryRelationship **SHALL** contain exactly one [1..1] **`exposureEventSubCategory`** with data type *exposure Event Sub Category*
12. **MAY** contain zero or one [0..1] **`text`**
    - A text description of the dosing. [SDTM: EXDOSTXT]
13. **MAY** contain zero or one [0..1] **`approachSiteCode`** with data type CE
    - An indication of the location, e.g. left arm, where the substance was administered. [SDTM: EXLOC]
14. **MAY** contain zero or one [0..1] **`entryRelationship`**
    a. This entryRelationship **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
    b. This entryRelationship **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`)
    c. This entryRelationship **SHALL** contain exactly one [1..1] **`code`**
    d. This entryRelationship **SHALL** contain exactly one [1..1] **`value`** with data type ED

    Text description of the intended schedule or regimen for the intervention [SDTM: EXDOSRGM]

    a. Contains **`@typeCode="REFR"`** *REFR*
15. **MAY** contain zero or one [0..1] **`entryRelationship`**
    a. This entryRelationship **SHALL** contain exactly one [1..1] **`@typeCode`**`="CAUS"`
    b. This entryRelationship Contains exactly one [1..1] **`doseAdjustmentReason`** with data type *dose Adjustment Reason*

16. **MAY** contain zero or one [0..1] **entryRelationship**
    a. Contains **@typeCode="COMP"** *COMP*
    b. Contains exactly one [1..1] *Study Epoch* (templateId: 2.16.840.1.113883.10.20.23.71)
17. **MAY** contain zero or one [0..1] **entryRelationship**
    a. This entryRelationship **SHALL** contain exactly one [1..1] **@typeCode**="COMP"
    b. This entryRelationship **SHALL** contain zero or one [0..1] **observation**
        a. This observation **SHALL** contain exactly one [1..1] **@classCode**="OBS" *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass)
        b. This observation **SHALL** contain exactly one [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
        c. This observation **SHALL** contain exactly one [1..1] **code**, where the @code **SHALL** be selected from (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)

           The code value indicates the observation captures an element's order within a trial arm.
        d. This observation **SHALL** contain zero or more [0..*] **value** with data type INT

           A value that gives the order of an element within the trial arm. [SDTM: TAETORD]
18. **MAY** contain zero or one [0..1] **entryRelationship**
    a. Contains **@typeCode="REFR"** *REFR*
    b. Contains exactly one [1..1] *Timing Reference* (templateId: 2.16.840.1.113883.10.20.23.70)
19. **MAY** contain zero or one [0..1] **entryRelationship**
    a. Contains **@typeCode="REFR"** *REFR*
    b. Contains exactly one [1..1] *Study Day Period* (templateId: 2.16.840.1.113883.10.20.23.74)

Human Clinical Exposure example

Human Clinical Laboratory Test Result

[Observation: templateId 2.16.840.1.113883.10.20.23.30]

Information on laboratory data collected on a reporting form or received from a central provider or vendor.

1. **SHALL** contain exactly one [1..1] **@classCode**="OBS" *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass)
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **code**
    - A coded value that identifies the laboratory test result. The verbatim text is placed within the original text property of the CD data type. [SDTM: LBTESTCD, LBTEST. LBLOINC] If the LOINC code is available it should be used as the base code within the CD type.
4. **SHALL** contain [1..2] **id**
    - A value that is provided to ensure the uniqueness of the laboratory result. [SDTM: LBSEQ, LBSPID] A single identifier, the sequence number, is required.
5. **MAY** contain zero or one [0..1] **statusCode**
    - Used to indicate whether or not an exam has been performed. [SDTM: LBSTAT]
6. **SHOULD** contain zero or one [0..1] **value** with data type CD
    - The laboratory result, using both original units and a standard format or set of units. [SDTM: LBORRES, LBORRESU, LBSTRESC, LBSTRESN, LBSTRESU]
7. **MAY** contain zero or one [0..1] **entryRelationship**
    - Allows capture of a group identifier for the laboratory result.

   a. Contains **@typeCode="COMP"** *COMP*
   b. Contains exactly one [1..1] *Group Identifier* (templateId: 2.16.840.1.113883.10.20.23.61)
8. **MAY** contain zero or one [0..1] **methodCode**
   - Indicates the method of the test or examination. [SDTM: LBMETHOD]
9. **SHOULD** contain zero or one [0..1] **entryRelationship**
   a. Contains **@typeCode="COMP"** *COMP*
   b. Contains exactly one [1..1] *Specimen Information* (templateId: 2.16.840.1.113883.10.20.23.59)
10. **MAY** contain zero or one [0..1] **entryRelationship**

    Indicates a category the laboratory test result is assigned to.

   a. This entryRelationship **SHALL** contain exactly one [1..1] **@typeCode**="COMP"
   b. This entryRelationship **SHALL** contain exactly one [1..1] **laboratoryTestResultCategory** with data type *laboratory Test Result Category*
11. **MAY** contain zero or one [0..1] **entryRelationship**

    Indicates a subcategory the laboratory test result is assigned to.

   a. This entryRelationship **SHALL** contain exactly one [1..1] **@typeCode**="COMP"
   b. This entryRelationship **SHALL** contain exactly one [1..1] **laboratoryTestResultSubCategory** with data type *laboratory Test Result Sub Category*
12. **SHOULD** contain zero or one [0..1] **referenceRange**
   a. This referenceRange **SHALL** contain exactly one [1..1] **@typeCode**="REFV"
   b. This referenceRange **SHALL** contain exactly one [1..1] **observationRange**
      a. This observationRange **SHALL** contain exactly one [1..1] **@classCode**="OBS" *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass)
      b. This observationRange **SHALL** contain exactly one [1..1] **@moodCode**="EVN.CRT" (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
      c. This observationRange **SHALL** contain exactly one [1..1] **code**, where the @code **SHALL** be selected from (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)
      d. This observationRange **SHALL** contain zero or one [0..1] **interpretationCode**, where the @code **SHALL** be selected from (CodeSystem: 2.16.840.1.113883.5.83 ObservationInterpretation)

         The value is used to interpret the meaning of the range information.
      e. This observationRange **SHALL** contain exactly one [1..1] **value** with data type PQR

         Contains the actual reference range value as an interval of physical quantities. Note, the predetermined value of interpretation code indicates that the normal range is being reported. [SDTM: LBORNRLO, LBORNHRHI, LBSTTNLO, LBSTNRLO, LBSTRNHI, LBSTNRC, LBNRIND] Standard referemce ramge values go into the base value and unt, while the orginal values use the translation property of the PQR type.
13. **MAY** contain zero or one [0..1] **entryRelationship**
   a. Contains exactly one [1..1] *Non Performance Reason* (templateId: 2.16.840.1.113883.10.20.23.62)
14. **MAY** contain zero or one [0..1] **study Test Performer**
   a. Contains exactly one [1..1] *Study Test Performer* (templateId: 2.16.840.1.113883.10.20.23.72)
15. **MAY** contain zero or one [0..1] **entryRelationship**
   a. Contains **@typeCode="COMP"** *COMP*
   b. Contains exactly one [1..1] *Baseline Indicator* (templateId: 2.16.840.1.113883.10.20.23.53)
16. **MAY** contain zero or one [0..1] **entryRelationship**
   a. Contains **@typeCode="COMP"** *COMP*
   b. Contains exactly one [1..1] *Derived Data Indicator* (templateId: 2.16.840.1.113883.10.20.23.57)

17. **MAY** contain zero or one [0..1] **entryRelationship**
    a. This entryRelationship **SHALL** contain exactly one [1..1] **@typeCode**="COMP"
    b. This entryRelationship **SHALL** contain zero or one [0..1] **observation**
        a. This observation **SHALL** contain exactly one [1..1] **@classCode**="OBS" *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass)
        b. This observation **SHALL** contain exactly one [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
        c. This observation **SHALL** contain exactly one [1..1] **code**, where the @code **SHALL** be selected from (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)

           The code value indicates the observation concerns the subject's fasting status.
        d. This observation **SHALL** contain exactly one [1..1] **value** with data type BN

           Information on whether the person was fasting at the time the specimen was collected. [SDTM: LBFAST]
18. **MAY** contain zero or one [0..1] **entryRelationship**
    a. This entryRelationship **SHALL** contain zero or one [0..1] **@typeCode**="COMP"
    b. This entryRelationship Contains zero or one [0..1] **LabtoxicityGrade** with data type *lab Toxicity Grade*

Human Clinical Laboratory Test Result example

Human Clinical Subject Demographics

[Organizer: templateId 2.16.840.1.113883.10.20.23.14]

The demographic information for a study subject which is not accommodated within the recordTarget structure. Currently, for human clinical trial reporting, age of the subject is the only contained item.

1. **SHALL** contain exactly one [1..1] **@classCode**="CLUSTER" (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass)
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **code/@code**="TBD" (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)
   - Indicates that the contained information includes subject demographic data that is not acommodated by the record target participation.
4. **MAY** contain zero or one [0..1] **ageAssociation**
    a. This ageAssociation **SHALL** contain exactly one [1..1] **@typeCode**="COMP"
    b. This ageAssociation **SHALL** contain exactly one [1..1] **subjectAge**
        a. This subjectAge **SHALL** contain exactly one [1..1] **@classCode**="OBS" *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass)
        b. This subjectAge **SHALL** contain exactly one [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
        c. This subjectAge **SHALL** contain exactly one [1..1] **code/@code**="TBD" *Reported Age* (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)

           The code value indicates this is an age observation.
        d. This subjectAge **SHALL** contain exactly one [1..1] **value** with data type PQ

           The recorded age of the study subject. Note, in some cases age will be available while date of birth is either not known or withheld. [SDTM: AGE, AGEU]
5. **MAY** contain zero or one [0..1] **component**
    a. Contains exactly one [1..1] *Data Collection* (templateId: 2.16.840.1.113883.10.20.23.56)
6. **SHALL** contain exactly one [1..1] **component**

   a. Contains exactly one [1..1] *Study Arm* (templateId: `2.16.840.1.113883.10.20.23.66`)
7. Contains zero or more [0..*] **`templateId`**

sdtm::Human Clinical Subject Demographics							
cda::organizer[cda:templateId/@root = 2.16.840.1.113883.10.20.23.4]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
classCode	@classCode	1..1	SHALL	NO	x_ActClassDocumentEntryOrganizer		BATTERY
moodCode	@moodCode	1..1	SHALL	NO	ActMood		APT
nullFlavor	@nullFlavor	0..1		NO	NullFlavor		ASKU
code	code	1..1	SHALL	YES	CD		NCI Thesaurus 2.16.840.1.113883.3.26.1.1 TBD
effectiveTime	effectiveTime	0..1		YES	IVL_TS		
id	id	0..*		YES	II		
realmCode	realmCode	0..*		YES	CS		
statusCode	statusCode	1..1		YES	CS		
templateId	templateId	0..*		YES	II		2.16.840.1.113883.10.20.23.4
ageAssociation	ageAssociation	0..1	MAY	YES	AgeAssociation		
author	author	0..*		YES	Author		
component	component	0..*		YES	Component4		
data Collection	data Collection	0..1	MAY	YES	Data Collection		
informant	informant	0..*		YES	Informant12		
participant	participant	0..*		YES	Participant2		
performer	performer	0..*		YES	Performer2		
precondition	precondition	0..*		YES	Precondition		
reference	reference	0..*		YES	Reference		
specimen	specimen	0..*		YES	Specimen		
study Arm	study Arm	1..1	SHALL	YES	Study Arm		
subject	subject	0..1		YES	Subject		
typeId	typeId	0..1		YES	InfrastructureRootTypeId		

Human Clinical Subject Demographics example

```
<?xml version="1.0" encoding="UTF-8"?>
<organizer xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd"
 classCode="CLUSTER">
  <templateId root="2.16.840.1.113883.10.20.23.4"/>
  <id root="115453018" extension="MDHT"/>
  <code code="TBD" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
 Thesaurus"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2012"/>
```

```
    <high value="2012"/>
  </effectiveTime>
  <component>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.11"/>
      <id root="581580161" extension="MDHT"/>
      <code code="TBD" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
    </observation>
  </component>
  <component>
    <act classCode="ACT" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.30"/>
      <id root="506252307" extension="MDHT"/>
      <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <entryRelationship>
        <observation classCode="OBS" moodCode="EVN">
          <templateId root="2.16.840.1.113883.10.20.23.11"/>
          <id root="1610155753" extension="MDHT"/>
          <code code="TBD" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
          <effectiveTime>
            <low value="2012"/>
            <high value="2012"/>
          </effectiveTime>
        </observation>
      </entryRelationship>
    </act>
  </component>
</organizer>
```

Inclusion or Exclusion Criteria Not Met

[Observation: templateId `2.16.840.1.113883.10.20.23.29`]

The structure includes inclusion and exclusion criteria exceptions. It should be used to record any criteria violations, even if a sponsor has granted a waiver or the subject was admitted by mistake. The intent is to only include information relating to criteria the subject did not meet. It should include exceptions to inclusion or exclusion cretieria at the time that eligibility for study entry is determined - at the end of a run in period or immediately before randmization.

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`)
3. **SHALL** contain exactly one [1..1] **`code`**, where the @code **SHALL** be selected from (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`)
   - A coded value that indentifies the inclusion or exclusion criteria that was not met. The verbatim text is placed within the original text property of the CD data type. [SDTM: IETESTCD, IETEST]
4. **SHALL** contain [1..2] **`id`**

- A value that is provided to ensure the uniqueness of the inclusion/exclusion exception. [SDTM: IESEQ, IESPID] A single identifier, the sequence number, is required.

5. **SHALL** contain exactly one [1..1] **`value`** with data type BL
   - The response to the question - was the inclusion or exclusion criteria met? [SDTM: IEORRES, IESTRESC]
6. **SHALL** contain exactly one [1..1] **`entryRelationship`**

   Indicates a category the inclusion or exclusion item is assigned to.

   a. This entryRelationship **SHALL** contain exactly one [1..1] **`@typeCode`**`="COMP"`
   b. This entryRelationship **SHALL** contain exactly one [1..1] **`inclusionExclusionCategory`** with data type *inclusion Exclusion Category*
7. **MAY** contain zero or one [0..1] **`entryRelationship`**

   Indicates a subcategory the inclusion or exclusion item is assigned to.

   a. This entryRelationship **SHALL** contain exactly one [1..1] **`@typeCode`**`="COMP"`
   b. This entryRelationship **SHALL** contain exactly one [1..1] **`inclusionExclusionSubCategory`** with data type *inclusion Exclusion Sub Category*
8. **MAY** contain zero or one [0..1] **`entryRelationship`**

   a. Contains **`@typeCode="COMP"`** *COMP*
   b. Contains exactly one [1..1] *Data Collection* (templateId: `2.16.840.1.113883.10.20.23.56`)

sdtm::Inclusion or Exclusion Criteria Not Met							
cda::observation[cda:templateId/@root = 2.16.840.1.113883.10.20.23.35]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
classCode	@classCode	1..1	SHALL	NO	ActClassObservation		ALRT
moodCode	@moodCode	1..1	SHALL	NO	x_ActMoodDocumentObservation		DEF
negationInd	@negationInd	0..1		NO	Boolean		
nullFlavor	@nullFlavor	0..1		NO	NullFlavor		ASKU
code	code	1..1	SHALL	YES	CD		NCI Thesaurus 2.16.840.1.113883.3.26.1.1 null
derivationExpr	derivationExpr	0..1		YES	ST		
effectiveTime	effectiveTime	0..1		YES	IVL_TS		
id	id	1..2	SHALL	YES	II		
interpretationCode	interpretationCode	0..*		YES	CE		
languageCode	languageCode	0..1		YES	CS		
methodCode	methodCode	0..*		YES	CE		
priorityCode	priorityCode	0..1		YES	CE		
realmCode	realmCode	0..*		YES	CS		
repeatNumber	repeatNumber	0..1		YES	IVL_INT		
statusCode	statusCode	0..1		YES	CS		
targetSiteCode	targetSiteCode	0..*		YES	CD		
templateId	templateId	0..*		YES	II		2.16.840.1.113883.10.20.23.35

sdtm::Inclusion or Exclusion Criteria Not Met							
cda::observation[cda:templateId/@root = 2.16.840.1.113883.10.20.23.35]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
text	text	0..1		YES	ED		
value	value	1..1	SHALL	YES	BL		
author	author	0..*		YES	Author		
data Collection	data Collection	0..1	MAY	YES	Data Collection		
entryRelationship	entryRelationship	0..*		YES	EntryRelationship		
inclusionExclusionCategoryAssociation	CategoryAssociation	1	SHALL	YES	inclusionExclusion	CategoryAssociation	
inclusionExclusionSubCategoryAssociation	SubCategoryAssociation	0..1	MAY	YES	inclusionExclusion	SubCategoryAssociation	
informant	informant	0..*		YES	Informant12		
participant	participant	0..*		YES	Participant2		
performer	performer	0..*		YES	Performer2		
precondition	precondition	0..*		YES	Precondition		
reference	reference	0..*		YES	Reference		
referenceRange	referenceRange	0..*		YES	ReferenceRange		
specimen	specimen	0..*		YES	Specimen		
subject	subject	0..1		YES	Subject		
typeId	typeId	0..1		YES	InfrastructureRoot	TypeId	

Inclusion or Exclusion Criteria Not Met example

```
<?xml version="1.0" encoding="UTF-8"?>
<observation xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd"
 classCode="OBS" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.23.35"/>
  <id root="1180078644" extension="MDHT"/>
  <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
 Thesaurus"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <value xsi:type="BL"/>
  <entryRelationship typeCode="COMP"/>
  <entryRelationship typeCode="COMP"/>
  <entryRelationship>
    <act classCode="ACT" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.30"/>
      <id root="1651886627" extension="MDHT"/>
      <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
 Thesaurus"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <entryRelationship>
        <observation classCode="OBS" moodCode="EVN">
```

```
          <templateId root="2.16.840.1.113883.10.20.23.11"/>
          <id root="1478905109" extension="MDHT"/>
          <code code="TBD" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
          <effectiveTime>
            <low value="2012"/>
            <high value="2012"/>
          </effectiveTime>
          <value xsi:type="INT" value="1"/>
        </observation>
      </entryRelationship>
    </act>
  </entryRelationship>
</observation>
```

Medical History Item

[Observation: templateId `2.16.840.1.113883.10.20.23.25`]

The Medical History dataset generally includes the subject's prior and concomitant conditions at the start of the trial. Examples of subject medical history information could include general medical history and gynecological history.

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`)
3. **SHALL** contain exactly one [1..1] **`code`**
   - The code value = ASSERTION
4. **MAY** contain zero or one [0..1] **`effectiveTime`**
   - The start and stop date/times of the medical history event. [SDTM: MHSTDTC, MHENDTC]
5. **SHALL** contain [1..3] **`id`**
   - A value that is provided to ensure the uniqueness of medical history items. [SDTM: MHSEQ, MHREFID, MHSPID] A single identifier, the sequence number, is required.
6. **MAY** contain zero or one [0..1] **`statusCode`**, where the @code **SHALL** be selected from (CodeSystem: `2.16.840.1.113883.5.14 HL7ActStatus`)
   - Used to indicate whether the activity - occurrence of the medical history event - did occur. Use statusCode "Completed" if the use occurred. [SDTM: MHOCCUR]
7. **SHALL** contain exactly one [1..1] **`value`** with data type CE
   - A code value and descriptive text to provide information on the nature of the mdical condition or event. [SDTM: MHTERM, MHMODIFY, MHDECOD]
8. **MAY** contain zero or one [0..1] **`entryRelationship`**
   - Allows capture of a group identifier for the medical history item.

   a. Contains exactly one [1..1] *Group Identifier* (templateId: `2.16.840.1.113883.10.20.23.61`)
9. **MAY** contain zero or one [0..1] **`entryRelationship`**

   Indicates a subcategory the medical history item is assigned to.

   a. This entryRelationship **SHALL** contain exactly one [1..1] **`@typeCode`**`="COMP"`
   b. This entryRelationship Contains exactly one [1..1] **`medicalHistoryCategory`** with data type *medical History Category*
10. **MAY** contain zero or one [0..1] **`entryRelationship`**

    Indicates a subcategory the medical history item is assigned to.

    a. This entryRelationship **SHALL** contain exactly one [1..1] **`@typeCode`**`="COMP"`

   b. This entryRelationship Contains exactly one [1..1] **`medicalHistorySubCategory`** with data type *medical History Sub Category*

11. **SHALL** contain zero or one [0..1] **`entryRelationship`**
    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Pre-Specified Event* (templateId: `2.16.840.1.113883.10.20.23.64`)
12. **MAY** contain zero or one [0..1] **`entryRelationship`**
    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Non Performance Reason* (templateId: `2.16.840.1.113883.10.20.23.62`)
13. **MAY** contain zero or one [0..1] **`entryRelationship`**
    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Body System or Organ Class* (templateId: `2.16.840.1.113883.10.20.23.54`)
14. **MAY** contain zero or one [0..1] **`entryRelationship`**
    a. Contains **`@typeCode="REFR"`** *REFR*
    b. Contains exactly one [1..1] *Event Study Day* (templateId: `2.16.840.1.113883.10.20.23.59`)
15. **MAY** contain zero or one [0..1] **`entryRelationship`**
    a. Contains **`@typeCode="REFR"`** *REFR*
    b. Contains exactly one [1..1] *Activity End Timing Reference* (templateId: `2.16.840.1.113883.10.20.23.51`)
16. **MAY** contain zero or one [0..1] **`entryRelationship`**
    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Data Collection* (templateId: `2.16.840.1.113883.10.20.23.56`)

sdtm::Medical History Item							
cda::observation[cda:templateId/@root = 2.16.840.1.113883.10.20.23.31]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
classCode	@classCode	1..1	SHALL	NO	ActClassObservation		ALRT
moodCode	@moodCode	1..1	SHALL	NO	x_ActMoodDocumentObservation		DEF
negationInd	@negationInd	0..1		NO	Boolean		
nullFlavor	@nullFlavor	0..1		NO	NullFlavor		ASKU
code	code	1..1	SHALL	YES	CD		
derivationExpr	derivationExpr	0..1		YES	ST		
effectiveTime	effectiveTime	0..1	MAY	YES	IVL_TS		
id	id	1..3	SHALL	YES	II		
interpretationCode	interpretationCode	0..*		YES	CE		
languageCode	languageCode	0..1		YES	CS		
methodCode	methodCode	0..*		YES	CE		
priorityCode	priorityCode	0..1		YES	CE		
realmCode	realmCode	0..*		YES	CS		
repeatNumber	repeatNumber	0..1		YES	IVL_INT		
statusCode	statusCode	0..1	MAY	YES	CS		HL7ActStatus 2.16.840.1.113883.5.14

sdtm::Medical History Item							
cda::observation[cda:templateId/@root = 2.16.840.1.113883.10.20.23.31]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
targetSiteCode	targetSiteCode	0..*		YES	CD		
templateId	templateId	0..*		YES	II		2.16.840.1.113883.10.20.23.31
text	text	0..1		YES	ED		
value	value	1..1	SHALL	YES	CE		
activity End Timing Reference	activity End Timing Reference	0..1	MAY	YES	Activity End Timing Reference		
author	author	0..*		YES	Author		
body System or Organ Class	body System or Organ Class	0..1	MAY	YES	Body System or Organ Class		
data Collection	data Collection	0..1	MAY	YES	Data Collection		
entryRelationship	entryRelationship	0..*		YES	EntryRelationship		
event Study Day	event Study Day	0..1	MAY	YES	Event Study Day		
group Identifier	group Identifier	0..1	MAY	YES	Group Identifier		
informant	informant	0..*		YES	Informant12		
medicalHistoryCategoryAssociation	medicalHistoryCategoryAssociation	0..1	MAY	YES	medicalHistoryCategoryAssociation		
medicalHistorySubCategoryAssociation	medicalHistorySubCategoryAssociation	0..1	MAY	YES	medicalHistorySubCategoryAssociation		
nonPerformanceReason	nonPerformanceReason	0..1	MAY	YES	Non Performance Reason		
participant	participant	0..*		YES	Participant2		
performer	performer	0..*		YES	Performer2		
pre-Specified Event	pre-Specified Event	0..1	SHALL	YES	Pre-Specified Event		
precondition	precondition	0..*		YES	Precondition		
reference	reference	0..*		YES	Reference		
referenceRange	referenceRange	0..*		YES	ReferenceRange		
specimen	specimen	0..*		YES	Specimen		
subject	subject	0..1		YES	Subject		
typeId	typeId	0..1		YES	InfrastructureRootTypeId		

Medical History Item example

```
<?xml version="1.0" encoding="UTF-8"?>
<observation xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd"
 classCode="OBS" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.23.31"/>
  <id root="1391642009" extension="MDHT"/>
```

```
 <code code="1173445964"/>
 <statusCode code="completed"/>
 <effectiveTime>
   <low value="2012"/>
   <high value="2012"/>
 </effectiveTime>
 <value xsi:type="CE" code="448467332"/>
 <entryRelationship typeCode="COMP"/>
 <entryRelationship typeCode="COMP"/>
 <entryRelationship>
   <act classCode="ACT" moodCode="EVN">
     <templateId root="2.16.840.1.113883.10.20.23.15"/>
     <id root="1474893697" extension="MDHT"/>
     <code code="TBD" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
     <statusCode code="completed"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
   </act>
 </entryRelationship>
 <entryRelationship>
   <observation/>
 </entryRelationship>
 <entryRelationship>
   <observation classCode="OBS" moodCode="EVN">
     <templateId root="2.16.840.1.113883.10.20.23.9"/>
     <id root="1555421542" extension="MDHT"/>
     <code code="TBD" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
     <statusCode code="completed"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
     <value xsi:type="CE" code="1547909146"/>
   </observation>
 </entryRelationship>
 <entryRelationship>
   <observation/>
 </entryRelationship>
 <entryRelationship>
   <observation classCode="OBS" moodCode="EVN">
     <templateId root="2.16.840.1.113883.10.20.23.11"/>
     <id root="426676819" extension="MDHT"/>
     <code code="TBD" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
     <statusCode code="completed"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
     <value xsi:type="INT" value="1"/>
   </observation>
 </entryRelationship>
 <entryRelationship>
   <act classCode="ACT" moodCode="EVN">
     <templateId root="2.16.840.1.113883.10.20.23.24"/>
     <id root="299533417" extension="MDHT"/>
     <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus"/>
     <statusCode code="completed"/>
     <effectiveTime>
```

```
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <entryRelationship typeCode="COMP">
        <act classCode="ACT">
          <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus"/>
        </act>
      </entryRelationship>
    </act>
  </entryRelationship>
  <entryRelationship>
    <act classCode="ACT" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.30"/>
      <id root="1996548596" extension="MDHT"/>
      <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <entryRelationship>
        <observation classCode="OBS" moodCode="EVN">
          <templateId root="2.16.840.1.113883.10.20.23.11"/>
          <id root="1217025933" extension="MDHT"/>
          <code code="TBD" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
          <statusCode code="completed"/>
          <effectiveTime>
            <low value="2012"/>
            <high value="2012"/>
          </effectiveTime>
          <value xsi:type="INT" value="1"/>
        </observation>
      </entryRelationship>
    </act>
  </entryRelationship>
</observation>
```

Microbiology Specimen Finding

[Observation: templateId `2.16.840.1.113883.10.20.23.37`]

The structure is used to store microbiololgy findings that include organisms found, gram stain results, and organism growth status.

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`)
3. **SHALL** contain exactly one [1..1] **`code`**
   - A coded value that identifies the microbiology finding. The verbatim text is placed within the original text property of the CD data type. [SDTM: MBTESTCD, MBTEST. MBLOINC] If the LOINC code is available it should be used as the base code within the CD type.
4. **SHALL** contain [1..3] **`id`**
   - A value that is provided to ensure the uniqueness of the microbiology finding. [SDTM: MBSEQ, MBREFID, MBSPID] A single identifier, the sequence number, is required.
5. **SHOULD** contain zero or more [0..*] **`methodCode`**

- Indicates the method of the test or examination. [SDTM: MBMETHOD]

6. **MAY** contain zero or one [0..1] **`statusCode`**
   - Used to indicate whether or not an exam has been performed. [SDTM: MBSTAT]
7. **SHOULD** contain zero or more [0..*] **`value`**
   - The microbiology specimen result, using both original units and a standard format or set of units. [SDTM: MBORRES, MBORRESU, MBSTRESC, MBSTRESN, MBSTRESU]
8. **SHOULD** contain zero or one [0..1] **`entryRelationship`**
   - Allows capture of a group identifier for the finding.

   a. Contains **`@typeCode="COMP"`** *COMP*
   b. Contains exactly one [1..1] *Group Identifier* (templateId: `2.16.840.1.113883.10.20.23.61`)
9. **MAY** contain zero or one [0..1] **`entryRelationship`**

   Indicates a category the finding is assigned to.

   a. This entryRelationship **SHALL** contain exactly one [1..1] **`@typeCode`**`="COMP"`
   b. This entryRelationship **SHALL** contain exactly one [1..1] **`microbiologySpecimenFindingCategory`** with data type *microbiology Specimen Finding Category*
10. **MAY** contain zero or one [0..1] **`entryRelationship`**

    Indicates a subcategory the finding is assigned to.

    a. This entryRelationship **SHALL** contain exactly one [1..1] **`@typeCode`**`="COMP"`
    b. This entryRelationship **SHALL** contain exactly one [1..1] **`microbiologySpecimenFindingSubCategory`** with data type *microbiology Specimen Finding Sub Category*
11. **MAY** contain zero or one [0..1] **`study Test Performer`**

    a. Contains exactly one [1..1] *Study Test Performer* (templateId: `2.16.840.1.113883.10.20.23.72`)
12. **SHALL** contain zero or one [0..1] **`entryRelationship`**

    a. Contains exactly one [1..1] *Non Performance Reason* (templateId: `2.16.840.1.113883.10.20.23.62`)
13. **MAY** contain zero or one [0..1] **`entryRelationship`**

    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Specimen Information* (templateId: `2.16.840.1.113883.10.20.23.59`)
14. **MAY** contain zero or one [0..1] **`entryRelationship`**

    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Baseline Indicator* (templateId: `2.16.840.1.113883.10.20.23.53`)
15. **MAY** contain zero or one [0..1] **`entryRelationship`**

    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Derived Data Indicator* (templateId: `2.16.840.1.113883.10.20.23.57`)
16. Contains zero or one [0..1] **`entryRelationship`**

    a. This entryRelationship **SHALL** contain exactly one [1..1] **`@typeCode`**`="COMP"`
    b. This entryRelationship **SHALL** contain exactly one [1..1] **`microbiologyResultCategory`** with data type *microbiology Result Category*

Microbiology Specimen Finding example

Microbiology Susceptibility

[Observation: templateId `2.16.840.1.113883.10.20.23.38`]

The structure is used to store any findings related to the organisms found and submitted under the heading of microbiology specimen. This will usually consist of susceptibility testing results, but can also be other organism-related findings such as extent of growth of an organism.

1. **SHALL** contain exactly one [1..1] **`@classCode="OBS"`** *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
2. **SHALL** contain exactly one [1..1] **`@moodCode="EVN"`** *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`)
3. **SHALL** contain exactly one [1..1] **`code`**
   - A coded value that identifies the microbiology susceptibility result. The verbatim text is placed within the original text property of the CD data type. [SDTM: MSTESTCD, MSTEST. MSLOINC] If the LOINC code is available it should be used as the base code within the CD type.
4. **SHALL** contain [1..3] **`id`**
   - A value that is provided to ensure the uniqueness of the microbiology finding. [SDTM: MSSEQ, MSREFID, MSSPID] A single identifier, the sequence number, is required.
5. **SHOULD** contain zero or more [0..*] **`methodCode`**
   - Indicates the method of the test or examination. [SDTM: MSMETHOD]
6. **MAY** contain zero or one [0..1] **`statusCode`**
   - Used to indicate whether or not an exam has been performed. [SDTM: MSSTAT]
7. **SHOULD** contain zero or more [0..*] **`value`**
   - The microbiology specimen result, using both original units and a standard format or set of units. [SDTM: MSORRES, MSORRESU, MSSTRESC, MSSTRESN, MSSTRESU]
8. **SHALL** contain exactly one [1..1] **`group Identifier`** with data type *Group Identifier*
   - Allows capture of a group identifier for the finding.
9. **SHALL** contain zero or one [0..1] **`microbiologySusceptibilityResultCategoryAssociation`** with data type *microbiology Susceptibility Finding Category Association*
10. **MAY** contain zero or one [0..1] **`microbiologySpecimenResultSubCategoryAssociation`** with data type *microbiology Susceptibility Finding Sub Category Association*
11. **MAY** contain zero or one [0..1] **`study Test Performer`** with data type *Study Test Performer*
12. **MAY** contain zero or one [0..1] **`nonPerformanceReason`** with data type *Non Performance Reason*
13. **MAY** contain zero or one [0..1] **`baseline Indicator`** with data type *Baseline Indicator*
14. **MAY** contain zero or one [0..1] **`derived Data Indicator`** with data type *Derived Data Indicator*
15. **SHOULD** contain zero or one [0..1] **`microbiologySusceptibilityResultCategoryAssociation`** with data type *microbiology Susceptibility Result Category Association*
16. **MAY** contain zero or one [0..1] **`effectiveTime`** with data type TS
    - The date/time that the test was performed. [SDTM: MSDTC]
17. **MAY** contain zero or one [0..1] **`entryRelationship`**
    a. Contains **`@typeCode="REFR"`** *REFR*
    b. Contains exactly one [1..1] *Event Study Day* (templateId: `2.16.840.1.113883.10.20.23.59`)
18. **MAY** contain zero or one [0..1] **`entryRelationship`**
    a. Contains **`@typeCode="REFR"`** *REFR*
    b. Contains exactly one [1..1] *Timing Reference* (templateId: `2.16.840.1.113883.10.20.23.70`)

sdtm::Microbiology Susceptibility							
cda::observation[cda:templateId/@root = 2.16.840.1.113883.10.20.23.42]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
classCode	@classCode	1..1	SHALL	NO	ActClassObservation		ALRT
moodCode	@moodCode	1..1	SHALL	NO	x_ActMoodDocumentObservation		DEF
negationInd	@negationInd	0..1		NO	Boolean		
nullFlavor	@nullFlavor	0..1		NO	NullFlavor		ASKU
code	code	1..1	SHALL	YES	CD		
derivationExpr	derivationExpr	0..1		YES	ST		
effectiveTime	effectiveTime	0..1	MAY	YES	TS		
id	id	1..3	SHALL	YES	II		
interpretationCode	interpretationCode	0..*		YES	CE		
languageCode	languageCode	0..1		YES	CS		
methodCode	methodCode	0..*	SHOULD	YES	CE		
priorityCode	priorityCode	0..1		YES	CE		
realmCode	realmCode	0..*		YES	CS		
repeatNumber	repeatNumber	0..1		YES	IVL_INT		
statusCode	statusCode	0..1	MAY	YES	CS		
targetSiteCode	targetSiteCode	0..*		YES	CD		
templateId	templateId	0..*		YES	II		2.16.840.1.113883.10.20.23.42
text	text	0..1		YES	ED		
value	value	0..*	SHOULD	YES	ANY		
author	author	0..*		YES	Author		
baseline Indicator	baseline Indicator	0..1	MAY	YES	Baseline Indicator		
derived Data Indicator	derived Data Indicator	0..1	MAY	YES	Derived Data Indicator		
entryRelationship	entryRelationship	0..*		YES	EntryRelationship		
event Study Day	event Study Day	0..1	MAY	YES	Event Study Day		
group Identifier	group Identifier	1..1	SHALL	YES	Group Identifier		
informant	informant	0..*		YES	Informant12		
microbiologySpecimenResultSubCategoryAssociation	microbiologySpecimenResultSubCategoryAssociation	0..1	MAY	YES	microbiologySusceptibilityFindingSubCategoryAssociation		
microbiologySusceptibilityFindingCategoryAssociation	microbiologySusceptibilityFindingCategoryAssociation	0..1	SHALL	YES	microbiologySusceptibilityFindingCategoryAssociation		
nonPerformanceReason	nonPerformanceReason	0..1	MAY	YES	Non Performance Reason		
participant	participant	0..*		YES	Participant2		

sdtm::Microbiology Susceptibility							
cda::observation[cda:templateId/@root = 2.16.840.1.113883.10.20.23.42]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
performer	performer	0..*		YES	Performer2		
precondition	precondition	0..*		YES	Precondition		
reference	reference	0..*		YES	Reference		
referenceRange	referenceRange	0..*		YES	ReferenceRange		
specimen	specimen	0..*		YES	Specimen		
study Test Performer	study Test Performer	0..1	MAY	YES	Study Test Performer		
subject	subject	0..1		YES	Subject		
timing Reference	timing Reference	0..1	MAY	YES	Timing Reference		
typeId	typeId	0..1		YES	InfrastructureRootTypeId		

Microbiology Susceptibility example

```
<?xml version="1.0" encoding="UTF-8"?>
<observation xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd"
 classCode="OBS" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.23.42"/>
  <id root="635851328" extension="MDHT"/>
  <code code="917969682"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <methodCode code="715664887"/>
  <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.11"/>
      <id root="1248044344" extension="MDHT"/>
      <code code="TBD" codeSystem="2.16.840.1.113883.3.26.1.1"
 codeSystemName="NCI Thesaurus"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <value xsi:type="INT" value="1"/>
      <methodCode code="181807434"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <act classCode="ACT" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.14"/>
      <id root="1057554133" extension="MDHT"/>
      <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
 Thesaurus"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
```

```
        <high value="2012"/>
      </effectiveTime>
      <entryRelationship typeCode="COMP">
        <act classCode="ACT"/>
      </entryRelationship>
    </act>
  </entryRelationship>
</observation>
```

Non Performance Reason

[Observation: templateId `2.16.840.1.113883.10.20.23.62`]

The reusable structure contains information on the reason that information relating to an intended measure or other activity was not collected.

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`)
3. **SHALL** contain exactly one [1..1] **`code/@code`**`="TBD"` (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`)
   - The code value identifies this observation as a non-performance reason.
4. **SHALL** contain exactly one [1..1] **`value`** with data type CE
   - A coded indication of the reason that information relating to the intended activity or measure was not collected. [SDTM: CMREASND, SUREASND, MHREASND, CEREASND, EGREASND, LBREASND, PEREASND, QSREASND, SCREASND, VSREASND, DAREASND, MBREASND, MSREASND, PCREASND, PRREASND, FAREASND]

sdtm::Non Performance Reason							
cda::observation[cda:templateId/@root = 2.16.840.1.113883.10.20.23.9]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
classCode	@classCode	1..1	SHALL	NO	ActClassObservation		ALRT
moodCode	@moodCode	1..1	SHALL	NO	x_ActMoodDocumentObservation		DEF
negationInd	@negationInd	0..1		NO	Boolean		
nullFlavor	@nullFlavor	0..1		NO	NullFlavor		ASKU
code	code	1..1	SHALL	YES	CD		NCI Thesaurus 2.16.840.1.113883.3.26.1.1 TBD
derivationExpr	derivationExpr	0..1		YES	ST		
effectiveTime	effectiveTime	0..1		YES	IVL_TS		
id	id	0..*		YES	II		
interpretationCode	interpretationCode	0..*		YES	CE		
languageCode	languageCode	0..1		YES	CS		
methodCode	methodCode	0..*		YES	CE		
priorityCode	priorityCode	0..1		YES	CE		
realmCode	realmCode	0..*		YES	CS		

sdtm::Non Performance Reason							
cda::observation[cda:templateId/@root = 2.16.840.1.113883.10.20.23.9]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
repeatNumber	repeatNumber	0..1		YES	IVL_INT		
statusCode	statusCode	0..1		YES	CS		
targetSiteCode	targetSiteCode	0..*		YES	CD		
templateId	templateId	0..*		YES	II		2.16.840.1.113883.10.20.23.9
text	text	0..1		YES	ED		
value	value	1..1	SHALL	YES	CE		
author	author	0..*		YES	Author		
entryRelationship	entryRelationship	0..*		YES	EntryRelationship		
informant	informant	0..*		YES	Informant12		
participant	participant	0..*		YES	Participant2		
performer	performer	0..*		YES	Performer2		
precondition	precondition	0..*		YES	Precondition		
reference	reference	0..*		YES	Reference		
referenceRange	referenceRange	0..*		YES	ReferenceRange		
specimen	specimen	0..*		YES	Specimen		
subject	subject	0..1		YES	Subject		
typeId	typeId	0..1		YES	InfrastructureRootTypeId		

Non Performance Reason example

```
<?xml version="1.0" encoding="UTF-8"?>
<observation xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd"
 classCode="OBS" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.23.9"/>
  <id root="480203745" extension="MDHT"/>
  <code code="TBD" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
 Thesaurus"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <value xsi:type="CE" code="949955277"/>
</observation>
```

Pharmacokinetic Concentration Finding

[Observation: templateId `2.16.840.1.113883.10.20.23.39`]

Data collected about tissue concentrations of anylytes(usually study drugs and/or their metabolites) as a function of time after dosing the study drug.

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)

2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **code**
   - A coded value that identifies the pharmacokinetics result. The verbatim text is placed within the original text property of the CD data type. [SDTM: PCTESTCD, PCTEST]
4. **SHALL** contain [1..3] **id**
   - A value that is provided to ensure the uniqueness of the pharacokinetics result. [SDTM: PCSEQ, PCREFID, PCSPID] A single identifier, the sequence number, is required.
5. **MAY** contain zero or one [0..1] **statusCode**
   - Used to indicate whether or not an exam has been performed. [SDTM: PCSTAT]
6. **SHOULD** contain zero or one [0..1] **value** with data type CD
   - The pharmacokinetics result, using both original units and a standard format or set of units. [SDTM: PCORRES, PCORRESU, PCSTRESC, PCSTRESN, PCSTRESU]
7. **MAY** contain zero or one [0..1] **methodCode**
   - Indicates the method of the test or examination. [SDTM: PCMETHOD]
8. **MAY** contain zero or one [0..1] **entryRelationship**
   - Allows capture of a group identifier for the finding.
   a. Contains **@typeCode="**COMP" *COMP*
   b. Contains exactly one [1..1] *Group Identifier* (templateId: 2.16.840.1.113883.10.20.23.61)
9. **MAY** contain zero or one [0..1] **entryRelationship**

   Indicates a category the finding is assigned to.
   a. This entryRelationship **SHALL** contain exactly one [1..1] **@typeCode**="COMP"
   b. This entryRelationship **SHALL** contain exactly one [1..1] **pharmacokineticsTestResultCategory** with data type *pharmacokinetics Test Result Category*
10. **MAY** contain zero or one [0..1] **entryRelationship**

    Indicates a subcategory the finding is assigned to.
    a. This entryRelationship **SHALL** contain exactly one [1..1] **@typeCode**="COMP"
    b. This entryRelationship **SHALL** contain exactly one [1..1] **pharmacokineticsTestResultSubCategory** with data type *pharmacokinetics Test Result Sub Category*
11. **MAY** contain zero or one [0..1] **entryRelationship**
    a. This entryRelationship **SHALL** contain exactly one [1..1] **@typeCode**="COMP"
    b. This entryRelationship **SHALL** contain zero or one [0..1] **observation**
       a. This observation **SHALL** contain exactly one [1..1] **@classCode**="OBS" *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass)
       b. This observation **SHALL** contain exactly one [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
       c. This observation **SHALL** contain exactly one [1..1] **code**, where the @code **SHALL** be selected from (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)

          The code value indicates the observation concerns the subject's fasting status.
       d. This observation **SHALL** contain exactly one [1..1] **value** with data type BN

          Information on whether the person was fasting at the time the specimen was collected. [SDTM: LBFAST]
12. **SHALL** contain zero or one [0..1] **entryRelationship**
    a. Contains **@typeCode="**COMP" *COMP*
    b. Contains exactly one [1..1] *Specimen Information* (templateId: 2.16.840.1.113883.10.20.23.59)
13. **MAY** contain zero or one [0..1] **entryRelationship**

   a. Contains **`@typeCode="COMP"`** *COMP*
   b. Contains exactly one [1..1] *Non Performance Reason* (templateId: `2.16.840.1.113883.10.20.23.62`)
14. **MAY** contain zero or one [0..1] **`study Test Performer`**
   a. Contains exactly one [1..1] *Study Test Performer* (templateId: `2.16.840.1.113883.10.20.23.72`)
15. **MAY** contain zero or one [0..1] **`entryRelationship`**
   a. Contains **`@typeCode="COMP"`** *COMP*
   b. Contains exactly one [1..1] *Derived Data Indicator* (templateId: `2.16.840.1.113883.10.20.23.57`)
16. **SHOULD** contain zero or one [0..1] **`entryRelationship`**
   a. This entryRelationship **SHALL** contain zero or one [0..1] **`typeId`**
   b. This entryRelationship **SHALL** contain zero or one [0..1] **`observation`**
      a. This observation **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
      b. This observation **SHALL** contain exactly one [1..1] **`@moodCode`**`="DEF"` (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`)
      c. This observation **SHALL** contain exactly one [1..1] **`code`**, where the @code **SHALL** be selected from (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`)

         The code value identifies this as an asssay quantitation observation.
      d. This observation **SHALL** contain zero or more [0..*] **`value`** with data type IVL_PQ

         Captures the lower limit of assay quantitation. Value as the low property of the IVL data type. The units of measure are expected to match those designated as the standard units for the result. [SDTM: PCLLOQ]

sdtm::Pharmacokinetic Concentration Finding							
cda::observation[cda:templateId/@root = 2.16.840.1.113883.10.20.23.43]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
classCode	@classCode	1..1	SHALL	NO	ActClassObservation		ALRT
moodCode	@moodCode	1..1	SHALL	NO	x_ActMoodDocumentObservation		DEF
negationInd	@negationInd	0..1		NO	Boolean		
nullFlavor	@nullFlavor	0..1		NO	NullFlavor		ASKU
code	code	1..1	SHALL	YES	CD		
derivationExpr	derivationExpr	0..1		YES	ST		
effectiveTime	effectiveTime	0..1		YES	IVL_TS		
id	id	1..3	SHALL	YES	II		
interpretationCode	interpretationCode	0..*		YES	CE		
languageCode	languageCode	0..1		YES	CS		
methodCode	methodCode	0..1	MAY	YES	CE		
priorityCode	priorityCode	0..1		YES	CE		
realmCode	realmCode	0..*		YES	CS		
repeatNumber	repeatNumber	0..1		YES	IVL_INT		
statusCode	statusCode	0..1	MAY	YES	CS		
targetSiteCode	targetSiteCode	0..*		YES	CD		
templateId	templateId	0..*		YES	II		2.16.840.1.113883.10.20.23.43

sdtm::Pharmacokinetic Concentration Finding							
cda::observation[cda:templateId/@root = 2.16.840.1.113883.10.20.23.43]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
text	text	0..1		YES	ED		
value	value	0..1	SHOULD	YES	CD		
assayQuantitationAssociation	assayQuantitationAssociation	0..1	SHOULD	YES	assayQuantitationAssociation		
author	author	0..*		YES	Author		
derived Data Indicator	derived Data Indicator	0..1	MAY	YES	Derived Data Indicator		
entryRelationship	entryRelationship	0..*		YES	EntryRelationship		
fastingAssociation	fastingAssociation	0..1	MAY	YES	fastingAssociation		
group Identifier	group Identifier	0..1	MAY	YES	Group Identifier		
informant	informant	0..*		YES	Informant12		
non Performance Reason	non Performance Reason	0..1	MAY	YES	Non Performance Reason		
participant	participant	0..*		YES	Participant2		
performer	performer	0..*		YES	Performer2		
pharmacokineticsTestResultCategoryAssociation	pharmacokineticsTestResultCategoryAssociation	0..1	MAY	YES	pharmacokineticsTestResultCategoryAssociation		
pharmacokineticsTestResultSubCategoryAssociation	pharmacokineticsTestResultSubCategoryAssociation	0..1	MAY	YES	pharmacokineticsTestResultSubCategoryAssociation		
precondition	precondition	0..*		YES	Precondition		
reference	reference	0..*		YES	Reference		
referenceRange	referenceRange	0..*		YES	ReferenceRange		
specimen	specimen	0..*		YES	Specimen		
specimen Information	specimen Information	0..1	SHALL	YES	Specimen Information		
study Test Performer	study Test Performer	0..1	MAY	YES	Study Test Performer		
subject	subject	0..1		YES	Subject		
typeId	typeId	0..1		YES	InfrastructureRootTypeId		

Pharmacokinetic Concentration Finding example

```
<?xml version="1.0" encoding="UTF-8"?>
<observation xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd"
 classCode="OBS" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.23.43"/>
  <id root="378259949" extension="MDHT"/>
  <code code="465601347"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
```

```
 </effectiveTime>
 <value xsi:type="CD" code="1565649929"/>
 <methodCode code="1815865795"/>
 <entryRelationship typeCode="COMP"/>
 <entryRelationship typeCode="COMP"/>
 <entryRelationship>
   <observation>
     <code code="157464281"/>
     <value xsi:type="BN"/>
   </observation>
 </entryRelationship>
 <entryRelationship>
   <typeId/>
   <observation classCode="OBS" moodCode="DEF">
     <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus"/>
     <value xsi:type="IVL_PQ"/>
   </observation>
 </entryRelationship>
 <entryRelationship>
   <act classCode="ACT" moodCode="EVN">
     <templateId root="2.16.840.1.113883.10.20.23.15"/>
     <id root="512494406" extension="MDHT"/>
     <code code="TBD" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
     <statusCode code="completed"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
   </act>
 </entryRelationship>
 <entryRelationship>
   <procedure classCode="ACT" moodCode="EVN">
     <templateId root="2.16.840.1.113883.10.20.23.59"/>
     <id root="1973712066" extension="MDHT"/>
     <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus"/>
     <statusCode code="completed"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
     <methodCode code="1985423375"/>
     <specimen typeCode="SPC">
       <specimenRole classCode="SPEC"/>
     </specimen>
     <entryRelationship typeCode="COMP">
       <observation classCode="OBS" moodCode="EVN">
         <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus"/>
       </observation>
     </entryRelationship>
     <entryRelationship>
       <observation classCode="OBS" moodCode="EVN">
         <templateId root="2.16.840.1.113883.10.20.23.11"/>
         <id root="1817107169" extension="MDHT"/>
         <code code="TBD" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
         <statusCode code="completed"/>
         <effectiveTime>
           <low value="2012"/>
           <high value="2012"/>
         </effectiveTime>
```

```
          <value xsi:type="INT" value="1"/>
          <methodCode code="822379089"/>
        </observation>
      </entryRelationship>
      <entryRelationship>
        <act classCode="ACT" moodCode="EVN">
          <templateId root="2.16.840.1.113883.10.20.23.14"/>
          <id root="1850670195" extension="MDHT"/>
          <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
 Thesaurus"/>
          <statusCode code="completed"/>
          <effectiveTime>
            <low value="2012"/>
            <high value="2012"/>
          </effectiveTime>
          <entryRelationship typeCode="COMP"/>
        </act>
      </entryRelationship>
    </procedure>
  </entryRelationship>
  <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.9"/>
      <id root="2120424368" extension="MDHT"/>
      <code code="TBD" codeSystem="2.16.840.1.113883.3.26.1.1"
 codeSystemName="NCI Thesaurus"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <value xsi:type="CE" code="1698977411"/>
      <methodCode code="804875736"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.58"/>
      <id root="523176530" extension="MDHT"/>
      <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
 Thesaurus"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <value xsi:type="BL"/>
      <methodCode code="1946740475"/>
    </observation>
  </entryRelationship>
</observation>
```

Pharmacokinetic Parameter Finding

[Observation: templateId `2.16.840.1.113883.10.20.23.40`]

Data collected for relevant parameters of tissue concentrations of anylytes.

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`)
3. **SHALL** contain exactly one [1..1] **`code`**

- A coded value that identifies the pharmacokinetics parameter result. The verbatim text is placed within the original text property of the CD data type. [SDTM: PPTESTCD, PPTEST]

4. **SHALL** contain exactly one [1..1] **`id`**
   - A value that is provided to ensure the uniqueness of the pharacokinetics parameter result. [SDTM: PPSEQ] A single identifier, the sequence number, is required.
5. **MAY** contain zero or one [0..1] **`statusCode`**
   - Used to indicate whether or not an exam has been performed. [SDTM: PPSTAT]
6. **SHOULD** contain zero or one [0..1] **`value`** with data type CD
   - The pharmacokinetics parameter result, using both original units and a standard format or set of units. [SDTM: PPORRES, PPORRESU, PPSTRESC, PPSTRESN, PPSTRESU]
7. **MAY** contain zero or one [0..1] **`entryRelationship`**
   - Allows capture of a group identifier for the finding.

   a. Contains **`@typeCode="COMP"`** *COMP*
   b. Contains exactly one [1..1] *Group Identifier* (templateId: `2.16.840.1.113883.10.20.23.61`)
8. **MAY** contain zero or one [0..1] **`entryRelationship`**

   a. Contains **`@typeCode="COMP"`** *COMP*
   b. Contains exactly one [1..1] *Specimen Information* (templateId: `2.16.840.1.113883.10.20.23.59`)
9. **MAY** contain zero or one [0..1] **`entryRelationship`**

   Indicates a subcategory the finding is assigned to.

   a. This entryRelationship **SHALL** contain exactly one [1..1] **`@typeCode`**`="COMP"`
   b. This entryRelationship **SHALL** contain exactly one [1..1] **`pharmacokineticsParameterCategory`** with data type *pharmacokinetics Parameter Category*
10. **MAY** contain zero or one [0..1] **`entryRelationship`**

    Indicates a subcategory the finding is assigned to.

    a. This entryRelationship **SHALL** contain exactly one [1..1] **`@typeCode`**`="COMP"`
    b. This entryRelationship **SHALL** contain exactly one [1..1] **`pharmacokineticsParameterSubCategory`** with data type *pharmacokinetics Parameter Sub Category*
11. **MAY** contain zero or one [0..1] **`entryRelationship`**

    a. Contains exactly one [1..1] *Non Performance Reason* (templateId: `2.16.840.1.113883.10.20.23.62`)
12. **SHOULD** contain zero or one [0..1] **`entryRelationship`**

    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Timing Reference* (templateId: `2.16.840.1.113883.10.20.23.70`)

sdtm::Pharmacokinetic Parameter Finding							
cda::observation[cda:templateId/@root = 2.16.840.1.113883.10.20.23.44]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
classCode	@classCode	1..1	SHALL	NO	ActClassObservation		ALRT
moodCode	@moodCode	1..1	SHALL	NO	x_ActMoodDocumentObservation		DEF
negationInd	@negationInd	0..1		NO	Boolean		
nullFlavor	@nullFlavor	0..1		NO	NullFlavor		ASKU
code	code	1..1	SHALL	YES	CD		
derivationExpr	derivationExpr	0..1		YES	ST		

sdtm::Pharmacokinetic Parameter Finding							
cda::observation[cda:templateId/@root = 2.16.840.1.113883.10.20.23.44]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
effectiveTime	effectiveTime	0..1		YES	IVL_TS		
id	id	1..1	SHALL	YES	II		
interpretationCode	interpretationCode	0..*		YES	CE		
languageCode	languageCode	0..1		YES	CS		
methodCode	methodCode	0..*		YES	CE		
priorityCode	priorityCode	0..1		YES	CE		
realmCode	realmCode	0..*		YES	CS		
repeatNumber	repeatNumber	0..1		YES	IVL_INT		
statusCode	statusCode	0..1	MAY	YES	CS		
targetSiteCode	targetSiteCode	0..*		YES	CD		
templateId	templateId	0..*		YES	II		2.16.840.1.113883.10.20.23.44
text	text	0..1		YES	ED		
value	value	0..1	SHOULD	YES	CD		
author	author	0..*		YES	Author		
entryRelationship	entryRelationship	0..*		YES	EntryRelationship		
group Identifier	group Identifier	0..1	MAY	YES	Group Identifier		
informant	informant	0..*		YES	Informant12		
non Performance Reason	non Performance Reason	0..1	MAY	YES	Non Performance Reason		
participant	participant	0..*		YES	Participant2		
performer	performer	0..*		YES	Performer2		
pharmacokineticsParameterCategoryAssociation	pharmacokineticsParameterCategoryAssociation	0..1	MAY	YES	pharmacokineticsParameterCategoryAssociation		
pharmacokineticsParameterSubCategoryAssociation	pharmacokineticsParameterSubCategoryAssociation	0..1	MAY	YES	pharmacokineticsParameterSubCategoryAssociation		
precondition	precondition	0..*		YES	Precondition		
reference	reference	0..*		YES	Reference		
referenceRange	referenceRange	0..*		YES	ReferenceRange		
specimen	specimen	0..*		YES	Specimen		
specimen Information	specimen Information	0..1	MAY	YES	Specimen Information		
subject	subject	0..1		YES	Subject		
timing Reference	timing Reference	0..1	SHOULD	YES	Timing Reference		
typeId	typeId	0..1		YES	InfrastructureRootTypeId		

Pharmacokinetic Parameter Finding example

```
<?xml version="1.0" encoding="UTF-8"?>
<observation xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd"
 classCode="OBS" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.23.44"/>
  <id root="1760504936" extension="MDHT"/>
  <code code="2138282087"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <value xsi:type="CD" code="202920179"/>
  <entryRelationship typeCode="COMP"/>
  <entryRelationship typeCode="COMP"/>
  <entryRelationship>
    <act classCode="ACT" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.15"/>
      <id root="333195465" extension="MDHT"/>
      <code code="TBD" codeSystem="2.16.840.1.113883.3.26.1.1"
 codeSystemName="NCI Thesaurus"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
    </act>
  </entryRelationship>
  <entryRelationship>
    <procedure classCode="ACT" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.59"/>
      <id root="1347577749" extension="MDHT"/>
      <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
 Thesaurus"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <specimen typeCode="SPC">
        <specimenRole classCode="SPEC"/>
      </specimen>
      <entryRelationship typeCode="COMP">
        <observation classCode="OBS" moodCode="EVN">
          <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
 Thesaurus"/>
        </observation>
      </entryRelationship>
      <entryRelationship>
        <observation classCode="OBS" moodCode="EVN">
          <templateId root="2.16.840.1.113883.10.20.23.11"/>
          <id root="2078051315" extension="MDHT"/>
          <code code="TBD" codeSystem="2.16.840.1.113883.3.26.1.1"
 codeSystemName="NCI Thesaurus"/>
          <statusCode code="completed"/>
          <effectiveTime>
            <low value="2012"/>
            <high value="2012"/>
          </effectiveTime>
          <value xsi:type="INT" value="1"/>
        </observation>
      </entryRelationship>
```

```
      <entryRelationship>
        <act classCode="ACT" moodCode="EVN">
          <templateId root="2.16.840.1.113883.10.20.23.14"/>
          <id root="1961098614" extension="MDHT"/>
          <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
 Thesaurus"/>
          <statusCode code="completed"/>
          <effectiveTime>
            <low value="2012"/>
            <high value="2012"/>
          </effectiveTime>
          <entryRelationship typeCode="COMP"/>
        </act>
      </entryRelationship>
    </procedure>
  </entryRelationship>
  <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.9"/>
      <id root="1747726076" extension="MDHT"/>
      <code code="TBD" codeSystem="2.16.840.1.113883.3.26.1.1"
 codeSystemName="NCI Thesaurus"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <value xsi:type="CE" code="586467866"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <act classCode="ACT" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.14"/>
      <id root="486269686" extension="MDHT"/>
      <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
 Thesaurus"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <entryRelationship typeCode="COMP">
        <act classCode="ACT"/>
      </entryRelationship>
    </act>
  </entryRelationship>
</observation>
```

Physical Examination Finding

[Observation: templateId `2.16.840.1.113883.10.20.23.32`]

A structure for collecting findings derived from physical exams.

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`)
3. **SHALL** contain exactly one [1..1] **`code`**
   - A coded value that identifies the physical exam finding. The verbatim text is placed within the original text property of the CD data type. [SDTM: PETESTCD, PETEST]
4. **MAY** contain zero or one [0..1] **`effectiveTime`**

- The date time of the phsyical exam. [SDTM: PEDC]

5. **SHALL** contain [1..2] **`id`**
   - A value that is provided to ensure the uniqueness of the physical exam finding. [SDTM: PESEQ, PESPID] A single identifier, the sequence number, is required.
6. **SHOULD** contain zero or one [0..1] **`value`**
   - The result of the component of the physical exam indicated by the code value. Verbatim findings are captured in orginal text. A result or finding in standard format should be recorded as a base value - either code or physical quantity. A modified reported term is included as a translation. [SDTM: PEMODIFY, PEORRES, PEORESU, PESTRESC]
7. **MAY** contain zero or one [0..1] **`entryRelationship`**
   - Allows capture of a group identifier for the finding.

   a. Contains **`@typeCode="COMP"`** *COMP*
   b. Contains exactly one [1..1] *Group Identifier* (templateId: `2.16.840.1.113883.10.20.23.61`)
8. **MAY** contain zero or one [0..1] **`statusCode`**
   - Used to indicate whether or not the specified physical exam has been performed. [SDTM: PESTAT]
9. **MAY** contain zero or one [0..1] **`targetSiteCode`**
   - Can be used to specify where a physical exam finding occurred. [SDTM: PELOC]
10. **MAY** contain zero or one [0..1] **`entryRelationship`**

    Indicates a subcategory the finding is assigned to.

    a. This entryRelationship **SHALL** contain exactly one [1..1] **`@typeCode`**`="COMP"`
    b. This entryRelationship **SHALL** contain exactly one [1..1] **`physicalExamResultCategory`** with data type *physical Exam Result Category*
11. **MAY** contain zero or one [0..1] **`entryRelationship`**

    Indicates a subcategory the finding is assigned to.

    a. This entryRelationship **SHALL** contain exactly one [1..1] **`@typeCode`**`="COMP"`
    b. This entryRelationship **SHALL** contain exactly one [1..1] **`physicalExamResultSubCategory`** with data type *physical Exam Result Sub Category*
12. **MAY** contain zero or one [0..1] **`entryRelationship`**

    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Body System or Organ Class* (templateId: `2.16.840.1.113883.10.20.23.54`)
13. **MAY** contain zero or one [0..1] **`entryRelationship`**

    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Non Performance Reason* (templateId: `2.16.840.1.113883.10.20.23.62`)
14. **MAY** contain zero or one [0..1] **`methodCode`**
    - The method used for conducting the test or examination. [SDTM: PEMETHOD]
15. **MAY** contain zero or one [0..1] **`study Finding Evaluator`**

    a. Contains exactly one [1..1] *Study Finding Evaluator* (templateId: `2.16.840.1.113883.10.20.23.73`)

sdtm::Physical Examination Finding							
cda::observation[cda:templateId/@root = 2.16.840.1.113883.10.20.23.37]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
classCode	@classCode	1..1	SHALL	NO	ActClassObservation		ALRT
moodCode	@moodCode	1..1	SHALL	NO	x_ActMoodDocumentObservation		DEF

sdtm::Physical Examination Finding							
cda::observation[cda:templateId/@root = 2.16.840.1.113883.10.20.23.37]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
negationInd	@negationInd	0..1		NO	Boolean		
nullFlavor	@nullFlavor	0..1		NO	NullFlavor		ASKU
code	code	1..1	SHALL	YES	CD		
derivationExpr	derivationExpr	0..1		YES	ST		
effectiveTime	effectiveTime	0..1	MAY	YES	IVL_TS		
id	id	1..2	SHALL	YES	II		
interpretationCode	interpretationCode	0..*		YES	CE		
languageCode	languageCode	0..1		YES	CS		
methodCode	methodCode	0..1	MAY	YES	CE		
priorityCode	priorityCode	0..1		YES	CE		
realmCode	realmCode	0..*		YES	CS		
repeatNumber	repeatNumber	0..1		YES	IVL_INT		
statusCode	statusCode	0..1	MAY	YES	CS		
targetSiteCode	targetSiteCode	0..1	MAY	YES	CD		
templateId	templateId	0..*		YES	II		2.16.840.1.113883.10.20.23.37
text	text	0..1		YES	ED		
value	value	0..1	SHOULD	YES	ANY		
author	author	0..*		YES	Author		
body System or Organ Class	body System or Organ Class	0..1	MAY	YES	Body System or Organ Class		
entryRelationship	entryRelationship	0..*		YES	EntryRelationship		
group Identifier	group Identifier	0..1	MAY	YES	Group Identifier		
informant	informant	0..*		YES	Informant12		
nonPerformanceReason	nonPerformanceReason	0..1	MAY	YES	Non Performance Reason		
participant	participant	0..*		YES	Participant2		
performer	performer	0..*		YES	Performer2		
physicalExamResultCategoryAssociation	physicalExamResultCategoryAssociation	0..1	MAY	YES	physicalExamResultCategoryAssociation		
physicalExamResultSubCategoryAssociation	physicalExamResultSubCategoryAssociation	0..1	MAY	YES	physicalExamResultSubCategoryAssociation		
precondition	precondition	0..*		YES	Precondition		
reference	reference	0..*		YES	Reference		
referenceRange	referenceRange	0..*		YES	ReferenceRange		

sdtm::Physical Examination Finding							
cda::observation[cda:templateId/@root = 2.16.840.1.113883.10.20.23.37]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
specimen	specimen	0..*		YES	Specimen		
study Finding Evaluator	study Finding Evaluator	0..1	MAY	YES	Study Finding Evaluator		
subject	subject	0..1		YES	Subject		
typeId	typeId	0..1		YES	InfrastructureRootTypeId		

Physical Examination Finding example

```
<?xml version="1.0" encoding="UTF-8"?>
<observation xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd"
 classCode="OBS" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.23.37"/>
  <id root="1230687781" extension="MDHT"/>
  <code code="2003700728"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <methodCode code="2046255925"/>
  <targetSiteCode code="2052731480"/>
  <entryRelationship typeCode="COMP"/>
  <entryRelationship typeCode="COMP"/>
  <entryRelationship>
    <act classCode="ACT" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.15"/>
      <id root="843225326" extension="MDHT"/>
      <code code="TBD" codeSystem="2.16.840.1.113883.3.26.1.1"
 codeSystemName="NCI Thesaurus"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
    </act>
  </entryRelationship>
  <entryRelationship>
    <observation/>
  </entryRelationship>
  <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.9"/>
      <id root="2111063783" extension="MDHT"/>
      <code code="TBD" codeSystem="2.16.840.1.113883.3.26.1.1"
 codeSystemName="NCI Thesaurus"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <value xsi:type="CE" code="195751620"/>
      <methodCode code="286827094"/>
      <targetSiteCode code="419721918"/>
    </observation>
  </entryRelationship>
```

```
</observation>
```

Planned Study Day

[Observation: templateId `2.16.840.1.113883.10.20.23.63`]

The resusable structure contains information that is used to identify the study day on which the event it is related was planned to occurr. "Study Day" refers to the relative day of an observation or other event with respect the the designated reference day for the study - which is labled as "Day 1". Note, dates prior to the reference data are decremented by 1, with the day preceeding the reference day designated as "Study Day -1". This structure is captured as a template to facilitate its reuse for different types of data within clinical trial reporting.

1. **SHALL** contain exactly one [1..1] **`@classCode="OBS"`** *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
2. **SHALL** contain exactly one [1..1] **`@moodCode="INT"`** (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`)
3. **SHALL** contain exactly one [1..1] **`code`**, where the @code **SHALL** be selected from (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`)
   - A fixed value that indicates the observation captures the planned study day for an event.
4. **SHALL** contain zero or more [0..*] **`value`** with data type INT
   - The applicable study day value. [SDTM: various]

sdtm::Planned Study Day							
cda::observation[cda:templateId/@root = 2.16.840.1.113883.10.20.23.10]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
classCode	@classCode	1..1	SHALL	NO	ActClassObservation		ALRT
moodCode	@moodCode	1..1	SHALL	NO	x_ActMoodDocumentObservation		DEF
negationInd	@negationInd	0..1		NO	Boolean		
nullFlavor	@nullFlavor	0..1		NO	NullFlavor		ASKU
code	code	1..1	SHALL	YES	CD		NCI Thesaurus 2.16.840.1.113883.3.26.1.1 null
derivationExpr	derivationExpr	0..1		YES	ST		
effectiveTime	effectiveTime	0..1		YES	IVL_TS		
id	id	0..*		YES	II		
interpretationCode	interpretationCode	0..*		YES	CE		
languageCode	languageCode	0..1		YES	CS		
methodCode	methodCode	0..*		YES	CE		
priorityCode	priorityCode	0..1		YES	CE		
realmCode	realmCode	0..*		YES	CS		
repeatNumber	repeatNumber	0..1		YES	IVL_INT		
statusCode	statusCode	0..1		YES	CS		
targetSiteCode	targetSiteCode	0..*		YES	CD		
templateId	templateId	0..*		YES	II		2.16.840.1.113883.10.20.23.10

sdtm::Planned Study Day							
cda::observation[cda:templateId/@root = 2.16.840.1.113883.10.20.23.10]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
text	text	0..1		YES	ED		
value	value	0..*	SHALL	YES	INT		
author	author	0..*		YES	Author		
entryRelationship	entryRelationship	0..*		YES	EntryRelationship		
informant	informant	0..*		YES	Informant12		
participant	participant	0..*		YES	Participant2		
performer	performer	0..*		YES	Performer2		
precondition	precondition	0..*		YES	Precondition		
reference	reference	0..*		YES	Reference		
referenceRange	referenceRange	0..*		YES	ReferenceRange		
specimen	specimen	0..*		YES	Specimen		
subject	subject	0..1		YES	Subject		
typeId	typeId	0..1		YES	InfrastructureRootTypeId		

Planned Study Day example

```
<?xml version="1.0" encoding="UTF-8"?>
<observation xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd"
 classCode="OBS" moodCode="INT">
  <templateId root="2.16.840.1.113883.10.20.23.10"/>
  <id root="1927048882" extension="MDHT"/>
  <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
 Thesaurus"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <value xsi:type="INT" value="1"/>
</observation>
```

Pre-Specified Event

[Observation: templateId `2.16.840.1.113883.10.20.23.64`]

An observation that indicates whther a pre-speicified event occurred or not. This structure is captured as a template to facilitate its reuse as a characteristic of different types of data within clinical trial reporting.

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`)
3. **SHALL** contain exactly one [1..1] **`code`**, where the @code **SHALL** be selected from (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`)
   - The code value indicates that the observation refers to occurrence of a pre-specified event.
4. **SHALL** contain exactly one [1..1] **`value`** with data type BL

- Indicate whether or not the the indicated activity or event was prespecified on the CRF. [SDTM: CMPRESP. SUPRESP, AEPRESP, MHPRESP, CEPRESP]

sdtm::Pre-Specified Event							
cda::observation[cda:templateId/@root = 2.16.840.1.113883.10.20.23.28]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
classCode	@classCode	1..1	SHALL	NO	ActClassObservation		ALRT
moodCode	@moodCode	1..1	SHALL	NO	x_ActMoodDocumentObservation		DEF
negationInd	@negationInd	0..1		NO	Boolean		
nullFlavor	@nullFlavor	0..1		NO	NullFlavor		ASKU
code	code	1..1	SHALL	YES	CD		NCI Thesaurus 2.16.840.1.113883.3.26.1.1 null
derivationExpr	derivationExpr	0..1		YES	ST		
effectiveTime	effectiveTime	0..1		YES	IVL_TS		
id	id	0..*		YES	II		
interpretationCode	interpretationCode	0..*		YES	CE		
languageCode	languageCode	0..1		YES	CS		
methodCode	methodCode	0..*		YES	CE		
priorityCode	priorityCode	0..1		YES	CE		
realmCode	realmCode	0..*		YES	CS		
repeatNumber	repeatNumber	0..1		YES	IVL_INT		
statusCode	statusCode	0..1		YES	CS		
targetSiteCode	targetSiteCode	0..*		YES	CD		
templateId	templateId	0..*		YES	II		2.16.840.1.113883.10.20.23.28
text	text	0..1		YES	ED		
value	value	1..1	SHALL	YES	BL		
author	author	0..*		YES	Author		
entryRelationship	entryRelationship	0..*		YES	EntryRelationship		
informant	informant	0..*		YES	Informant12		
participant	participant	0..*		YES	Participant2		
performer	performer	0..*		YES	Performer2		
precondition	precondition	0..*		YES	Precondition		
reference	reference	0..*		YES	Reference		
referenceRange	referenceRange	0..*		YES	ReferenceRange		
specimen	specimen	0..*		YES	Specimen		
subject	subject	0..1		YES	Subject		

sdtm::Pre-Specified Event							
cda::observation[cda:templateId/@root = 2.16.840.1.113883.10.20.23.28]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
typeId	typeId	0..1		YES	InfrastructureRootTypeId		

Pre-Specified Event example

```
<?xml version="1.0" encoding="UTF-8"?>
<observation xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd"
 classCode="OBS" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.23.28"/>
  <id root="1940387094" extension="MDHT"/>
  <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
 Thesaurus"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <value xsi:type="BL"/>
</observation>
```

Protocol Deviation

[Observation: templateId `2.16.840.1.113883.10.20.23.26`]

Used to capture events that are considered to be deviations from the protocol that has been established for the study subject.

1. **SHALL** contain exactly one [1..1] **`@classCode`**
2. **SHALL** contain exactly one [1..1] **`@moodCode`**
3. **SHALL** contain exactly one [1..1] **`code`**
   - Use the code value ASSERTION
4. **MAY** contain zero or one [0..1] **`effectiveTime`**
   - Used to record the start and stop date/times of the protocol deviation. [SDTM: DVSTDTC, DVENDTC]
5. **SHALL** contain [1..3] **`id`**
   - A value that is provided to ensure the uniqueness of protocol deviation items. [SDTM: DVSEQ, DVREFID, DVSPID] A single identifier, the sequence number, is required.
6. **SHALL** contain exactly one [1..1] **`value`** with data type CE
   - A code value and descriptive text to provide information on the nature of the protocol deviation. [SDTM: DVTERM, DVDECOD]
7. **MAY** contain zero or one [0..1] **`entryRelationship`**

   Indicates a category the protocol deviation is assigned to.

   a. This entryRelationship **SHALL** contain exactly one [1..1] **`@typeCode`**`="COMP"`
   b. This entryRelationship Contains exactly one [1..1] **`protocolDeviationCategory`** with data type *protocol Deviation Category*
8. **SHOULD** contain zero or one [0..1] **`entryRelationship`**

   Indicates a subcategory the protocol deviation is assigned to.

   a. This entryRelationship **SHALL** contain exactly one [1..1] **`@typeCode`**`="COMP"`
   b. This entryRelationship Contains exactly one [1..1] **`protocolDeviationSubCategory`** with data type *protocol Deviation Sub Category*

9. **MAY** contain zero or one [0..1] **`entryRelationship`**
   a. Contains exactly one [1..1] *Study Epoch* (templateId: `2.16.840.1.113883.10.20.23.71`)

sdtm::Protocol Deviation							
cda::observation[cda:templateId/@root = 2.16.840.1.113883.10.20.23.32]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
classCode	@classCode	1..1	SHALL	NO	ActClassObservation		ALRT
moodCode	@moodCode	1..1	SHALL	NO	x_ActMoodDocumentObservation		DEF
negationInd	@negationInd	0..1		NO	Boolean		
nullFlavor	@nullFlavor	0..1		NO	NullFlavor		ASKU
code	code	1..1	SHALL	YES	CD		
derivationExpr	derivationExpr	0..1		YES	ST		
effectiveTime	effectiveTime	0..1	MAY	YES	IVL_TS		
id	id	1..3	SHALL	YES	II		
interpretationCode	interpretationCode	0..*		YES	CE		
languageCode	languageCode	0..1		YES	CS		
methodCode	methodCode	0..*		YES	CE		
priorityCode	priorityCode	0..1		YES	CE		
realmCode	realmCode	0..*		YES	CS		
repeatNumber	repeatNumber	0..1		YES	IVL_INT		
statusCode	statusCode	0..1		YES	CS		
targetSiteCode	targetSiteCode	0..*		YES	CD		
templateId	templateId	0..*		YES	II		2.16.840.1.113883.10.20.23.32
text	text	0..1		YES	ED		
value	value	1..1	SHALL	YES	CE		
author	author	0..*		YES	Author		
entryRelationship	entryRelationship	0..*		YES	EntryRelationship		
informant	informant	0..*		YES	Informant12		
participant	participant	0..*		YES	Participant2		
performer	performer	0..*		YES	Performer2		
precondition	precondition	0..*		YES	Precondition		
protocolDeviationCategoryAssociation	protocolDeviationCategoryAssociation	0..1	MAY	YES	protocolDeviationCategoryAssociation		
protocolDeviationSubCategoryAssociation	protocolDeviationSubCategoryAssociation	0..1	SHOULD	YES	protocolDeviationSubCategoryAssociation		
reference	reference	0..*		YES	Reference		
referenceRange	referenceRange	0..*		YES	ReferenceRange		
specimen	specimen	0..*		YES	Specimen		
study Epoch	study Epoch	0..1	MAY	YES	Study Epoch		

sdtm::Protocol Deviation							
cda::observation[cda:templateId/@root = 2.16.840.1.113883.10.20.23.32]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
subject	subject	0..1		YES	Subject		
typeId	typeId	0..1		YES	InfrastructureRootTypeId		

Protocol Deviation example

```
<?xml version="1.0" encoding="UTF-8"?>
<observation xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <templateId root="2.16.840.1.113883.10.20.23.32"/>
  <id root="1674164126" extension="MDHT"/>
  <code code="1510592376"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <value xsi:type="CE" code="498621963"/>
  <entryRelationship typeCode="COMP"/>
  <entryRelationship typeCode="COMP"/>
  <entryRelationship>
    <act classCode="ACT" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.25"/>
      <id root="606037162" extension="MDHT"/>
      <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
 Thesaurus"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
    </act>
  </entryRelationship>
</observation>
```

Questionnaire Finding

[Observation: templateId `2.16.840.1.113883.10.20.23.33`]

A questionnaire is a written or electronic survey instrument comprised of a series of questions, designed to measure a specific item or set of items. Questionnaire data may include, but are not limited to subject reported outcomes and validated or non-validated questionnaires. The QS domain is not intended for use in submitting a set of questions grouped on the CRF for convenience of data capture.

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`)
3. **SHALL** contain exactly one [1..1] **`code`**
   - A coded value that identifies the questionnaire finding. The verbatim text is placed within the original text property of the CD data type. [SDTM: QSTESTCD, QSTEST]
4. **MAY** contain zero or one [0..1] **`effectiveTime`**
   - Used to capture the evaluation interval associated with the questionnaire finding. E.g., "Have you experienced any episodes in the last two years?" [SDTM: QSEVLINT]
5. **SHALL** contain [1..2] **`id`**

- A value that is provided to ensure the uniqueness of the questionnaire finding. [SDTM: QSSEQ, QSSPID] A single identifier, the sequence number, is required.

6. **SHOULD** contain zero or one [0..1] **`value`**
   - The response to the questionnaire item indicated by the code value. A result or finding in standard format should be recorded as a base value - either code or physical quantity. A modified reported term is included as a translation. [SDTM: QSORRES, QSORRESU, QSSTRESC, QSSTRESN, QSSTRESU]
7. **MAY** contain zero or one [0..1] **`entryRelationship`**
   - Allows capture of a group identifier for the response to the question.
   a. Contains exactly one [1..1] *Group Identifier* (templateId: `2.16.840.1.113883.10.20.23.61`)
8. **SHALL** contain exactly one [1..1] **`entryRelationship`**

   Indicates a category the question is assigned to.
   a. This entryRelationship **SHALL** contain exactly one [1..1] **`@typeCode`**`="COMP"`
   b. This entryRelationship **SHALL** contain exactly one [1..1] **`questionnaireCategory`** with data type *questionnaire Category*
9. **MAY** contain zero or one [0..1] **`entryRelationship`**

   Indicates a subcategory the question is assigned to.
   a. This entryRelationship **SHALL** contain exactly one [1..1] **`@typeCode`**`="COMP"`
   b. This entryRelationship **SHALL** contain exactly one [1..1] **`questionnaireSubCategory`** with data type *questionnaire Sub Category*
10. **MAY** contain zero or one [0..1] **`statusCode`**
    - Used to indicate whether or not the specified questionnaire response was elicited. [SDTM: QSSTAT]
11. **MAY** contain zero or one [0..1] **`entryRelationship`**
    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Non Performance Reason* (templateId: `2.16.840.1.113883.10.20.23.62`)
12. **SHALL** contain zero or one [0..1] **`entryRelationship`**
    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Baseline Indicator* (templateId: `2.16.840.1.113883.10.20.23.53`)
13. **MAY** contain zero or one [0..1] **`entryRelationship`**
    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Derived Data Indicator* (templateId: `2.16.840.1.113883.10.20.23.57`)
14. **MAY** contain zero or one [0..1] **`entryRelationship`**
    a. Contains **`@typeCode="REFR"`** *REFR*
    b. Contains exactly one [1..1] *Timing Reference* (templateId: `2.16.840.1.113883.10.20.23.70`)
15. **SHOULD** contain zero or one [0..1] **`entryRelationship`**
    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Data Collection* (templateId: `2.16.840.1.113883.10.20.23.56`)

sdtm::Questionnaire Finding							
cda::observation[cda:templateId/@root = 2.16.840.1.113883.10.20.23.38]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
classCode	@classCode	1..1	SHALL	NO	ActClassObservation		ALRT
moodCode	@moodCode	1..1	SHALL	NO	x_ActMoodDocumentObservation		DEF
negationInd	@negationInd	0..1		NO	Boolean		
nullFlavor	@nullFlavor	0..1		NO	NullFlavor		ASKU

sdtm::Questionnaire Finding							
cda::observation[cda:templateId/@root = 2.16.840.1.113883.10.20.23.38]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
code	code	1..1	SHALL	YES	CD		
derivationExpr	derivationExpr	0..1		YES	ST		
effectiveTime	effectiveTime	0..1	MAY	YES	IVL_TS		
id	id	1..2	SHALL	YES	II		
interpretationCode	interpretationCode	0..*		YES	CE		
languageCode	languageCode	0..1		YES	CS		
methodCode	methodCode	0..*		YES	CE		
priorityCode	priorityCode	0..1		YES	CE		
realmCode	realmCode	0..*		YES	CS		
repeatNumber	repeatNumber	0..1		YES	IVL_INT		
statusCode	statusCode	0..1	MAY	YES	CS		
targetSiteCode	targetSiteCode	0..*		YES	CD		
templateId	templateId	0..*		YES	II		2.16.840.1.113883.10.20.23.38
text	text	0..1		YES	ED		
value	value	0..1	SHOULD	YES	ANY		
author	author	0..*		YES	Author		
baseline Indicator	baseline Indicator	0..1	SHALL	YES	Baseline Indicator		
data Collection	data Collection	0..1	SHOULD	YES	Data Collection		
derived Data Indicator	derived Data Indicator	0..1	MAY	YES	Derived Data Indicator		
entryRelationship	entryRelationship	0..*		YES	EntryRelationship		
group Identifier	group Identifier	0..1	MAY	YES	Group Identifier		
informant	informant	0..*		YES	Informant12		
nonPerformanceReason	nonPerformanceReason	0..1	MAY	YES	Non Performance Reason		
participant	participant	0..*		YES	Participant2		
performer	performer	0..*		YES	Performer2		
precondition	precondition	0..*		YES	Precondition		
questionnaireCategoryAssociation	questionnaireCategoryAssociation	1..1	SHALL	YES	questionnaireCategoryAssociation		
questionnaireSubCategoryAssociation	questionnaireSubCategoryAssociation	0..1	MAY	YES	questionnaireSubCategoryAssociation		
reference	reference	0..*		YES	Reference		
referenceRange	referenceRange	0..*		YES	ReferenceRange		

sdtm::Questionnaire Finding							
cda::observation[cda:templateId/@root = 2.16.840.1.113883.10.20.23.38]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
specimen	specimen	0..*		YES	Specimen		
subject	subject	0..1		YES	Subject		
timing Reference	timing Reference	0..1	MAY	YES	Timing Reference		
typeId	typeId	0..1		YES	InfrastructureRootTypeId		

Questionnaire Finding example

```
<?xml version="1.0" encoding="UTF-8"?>
<observation xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd"
 classCode="OBS" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.23.38"/>
  <id root="1156798224" extension="MDHT"/>
  <code code="1224419792"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <entryRelationship typeCode="COMP"/>
  <entryRelationship typeCode="COMP"/>
  <entryRelationship>
    <act classCode="ACT" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.15"/>
      <id root="230534665" extension="MDHT"/>
      <code code="TBD" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
    </act>
  </entryRelationship>
  <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.9"/>
      <id root="186875080" extension="MDHT"/>
      <code code="TBD" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <value xsi:type="CE" code="1987030253"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.57"/>
      <id root="122552356" extension="MDHT"/>
      <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus"/>
      <statusCode code="completed"/>
```

```
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <value xsi:type="BL"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.58"/>
      <id root="1064201635" extension="MDHT"/>
      <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <value xsi:type="BL"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <act classCode="ACT" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.14"/>
      <id root="654258135" extension="MDHT"/>
      <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <entryRelationship typeCode="COMP">
        <act classCode="ACT"/>
      </entryRelationship>
    </act>
  </entryRelationship>
  <entryRelationship>
    <act classCode="ACT" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.30"/>
      <id root="523259731" extension="MDHT"/>
      <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <entryRelationship>
        <observation classCode="OBS" moodCode="EVN">
          <templateId root="2.16.840.1.113883.10.20.23.11"/>
          <id root="1904660998" extension="MDHT"/>
          <code code="TBD" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
          <statusCode code="completed"/>
          <effectiveTime>
            <low value="2012"/>
            <high value="2012"/>
          </effectiveTime>
          <value xsi:type="INT" value="1"/>
        </observation>
      </entryRelationship>
    </act>
  </entryRelationship>
```

```
</observation>
```

Specimen Information

[Procedure: templateId `2.16.840.1.113883.10.20.23.59`]

The reusable structure carrying specimen information is has, as its starting point, the act of specimen collection. Specimen information is captured as characteristics of the entity playing the specimen role, while specimen condition is recorded as a component act.

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="ACT"` *Act* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`)
3. **SHOULD** contain zero or one [0..1] **`effectiveTime`**
   - The point in time at which the specimen on which the test is based was collected. This may also be a time interval with a start point and a stopping point. [SDTM: LBDTC, LBENDTC, MBDTC, PCDTC, PCENDTC] Note the point in time, or the start of the specimen collection interval is expected data, while the end point of a collection interval is optional.
4. **SHALL** contain exactly one [1..1] **`code`**, where the @code **SHALL** be selected from (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`)
5. **SHOULD** contain zero or one [0..1] **`specimen`**
   a. This specimen **SHALL** contain zero or one [0..1] **`@typeCode`**`="SPC"`
   b. This specimen **SHOULD** contain zero or one [0..1] **`specimenRole`**
      a. This specimenRole **SHALL** contain zero or one [0..1] **`@classCode`**`="SPEC"`
      b. This specimenRole **MAY** contain zero or one [0..1] **`id`**

         An identifier for the specimen on which the test result is based. [SDTM: LBREFID, MBREFID, MSREFID, PCREFID]
      c. This specimenRole **SHOULD** contain zero or one [0..1] **`specimenEntity`**
         a. This specimenEntity **SHALL** contain zero or one [0..1] **`@classCode`**`="ENT"`
         b. This specimenEntity **SHALL** contain zero or one [0..1] **`@determinerCode`**`="INSTANCE"`
         c. This specimenEntity **SHALL** contain zero or one [0..1] **`code`**

            Used to indicate the specimen type. [SDTM: LBSPEC, PCSPEC, PPSPEC]
6. **MAY** contain zero or one [0..1] **`entryRelationship`**
   a. This entryRelationship **SHALL** contain exactly one [1..1] **`@typeCode`**`="COMP"`
   b. This entryRelationship **SHALL** contain exactly one [1..1] **`observation`**
      a. This observation Contains exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
      b. This observation **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`)
      c. This observation **SHALL** contain exactly one [1..1] **`code`**, where the @code **SHALL** be selected from (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`)

         The value indicates the nature of the observation. It provides information on the specimen condition.
      d. This observation **SHALL** contain exactly one [1..1] **`value`** with data type CE

         Information on the condition of a specimen used for testing. [SDTM: LBSPCCND, MBSPCCND, PCSPCCND]
7. **MAY** contain zero or one [0..1] **`entryRelationship`**
   a. Contains **`@typeCode="`**`REFR"` *REFR*
   b. Contains exactly one [1..1] *Event Study Day* (templateId: `2.16.840.1.113883.10.20.23.59`)

8. **MAY** contain zero or one [0..1] **`entryRelationship`**
   a. Contains **`@typeCode="`**`REFR"` *REFR*
   b. Contains exactly one [1..1] *Timing Reference* (templateId: `2.16.840.1.113883.10.20.23.70`)
9. **MAY** contain zero or more [0..*] **`targetSiteCode`**
   - The body site from which a specimen was collected. {SDTM: MBLOC]

sdtm::Specimen Information							
cda::procedure[cda:templateId/@root = 2.16.840.1.113883.10.20.23.59]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
classCode	@classCode	1..1	SHALL	NO	ActClass		ACCM
moodCode	@moodCode	1..1	SHALL	NO	x_ActMoodDocumentObservation		APT
negationInd	@negationInd	0..1		NO	Boolean		
nullFlavor	@nullFlavor	0..1		NO	NullFlavor		ASKU
approachSiteCode	approachSiteCode	0..*		YES	CD		
code	code	1..1	SHALL	YES	CD		NCI Thesaurus 2.16.840.1.113883.3.26.1.1 null
effectiveTime	effectiveTime	0..1	SHOULD	YES	IVL_TS		
id	id	0..*		YES	II		
languageCode	languageCode	0..1		YES	CS		
methodCode	methodCode	0..*		YES	CE		
priorityCode	priorityCode	0..1		YES	CE		
realmCode	realmCode	0..*		YES	CS		
statusCode	statusCode	0..1		YES	CS		
targetSiteCode	targetSiteCode	0..*	MAY	YES	CD		
templateId	templateId	0..*		YES	II		2.16.840.1.113883.10.20.23.59
text	text	0..1		YES	ED		
author	author	0..*		YES	Author		
conditionAssociation	conditionAssociation	0..1	MAY	YES	conditionAssociation		
entryRelationship	entryRelationship	0..*		YES	EntryRelationship		
event Study Day	event Study Day	0..1	MAY	YES	Event Study Day		
informant	informant	0..*		YES	Informant12		
participant	participant	0..*		YES	Participant2		
participatingSpecimen	participatingSpecimen	0..1	SHOULD	YES	participatingSpecimen		
performer	performer	0..*		YES	Performer2		
precondition	precondition	0..*		YES	Precondition		
reference	reference	0..*		YES	Reference		
specimen	specimen	0..*		YES	Specimen		

sdtm::Specimen Information							
cda::procedure[cda:templateId/@root = 2.16.840.1.113883.10.20.23.59]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
subject	subject	0..1		YES	Subject		
timing Reference	timing Reference	0..1	MAY	YES	Timing Reference		
typeId	typeId	0..1		YES	InfrastructureRootTypeId		

Specimen Information example

```
<?xml version="1.0" encoding="UTF-8"?>
<procedure xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd"
 classCode="ACT" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.23.59"/>
  <id root="2033322728" extension="MDHT"/>
  <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
 Thesaurus"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <targetSiteCode code="1170128511"/>
  <specimen typeCode="SPC">
    <specimenRole classCode="SPEC">
      <id root="159419632" extension="MDHT"/>
    </specimenRole>
  </specimen>
  <entryRelationship typeCode="COMP">
    <observation classCode="OBS" moodCode="EVN">
      <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
 Thesaurus"/>
      <value xsi:type="CE" code="56629193"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.11"/>
      <id root="631962111" extension="MDHT"/>
      <code code="TBD" codeSystem="2.16.840.1.113883.3.26.1.1"
 codeSystemName="NCI Thesaurus"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <targetSiteCode code="46569631"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <act classCode="ACT" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.14"/>
      <id root="1813946039" extension="MDHT"/>
      <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
 Thesaurus"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <entryRelationship typeCode="COMP">
```

```
        <act classCode="ACT"/>
      </entryRelationship>
    </act>
  </entryRelationship>
</procedure>
```

Study Arm

[Act: templateId `2.16.840.1.113883.10.20.23.66`]

The template contains information on the study arm to which the subject was assigned, the planned study arm. Patients in clinical trials are assigned to on part or segment of a study- a study "arm." One arm receives a different treatment from another. This structure is captured as a template to facilitate its reuse as a characteristic of different types of data within clinical trial reporting.

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="ACT"` *Act* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`)
3. **SHALL** contain exactly one [1..1] **`code`**, where the @code **SHALL** be selected from (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`)
   - Provide the code for the planned arm. [SDTM: ARMCD]
4. **SHALL** contain zero or one [0..1] **`text`**
   - Provide the description of the planned arm for the subject. [SDTM, ARM].
5. **SHOULD** contain zero or one [0..1] **`effectiveTime`**
   - The reference period for the subject's participation in the study. It is usually equivalent to an interval that begins on the date/time when the person was first exposed to study treatment, and ends when the subject was determined to have ended the trial. The end date is often equivalent to the date/time of last exposure to study treatment. [SDTM: RFSTDTC, RFENDTC].

sdtm::Study Arm							
cda::act[cda:templateId/@root = 2.16.840.1.113883.10.20.23.8]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
classCode	@classCode	1..1	SHALL	NO	x_ActClassDocumentEntryAct		ACCM
moodCode	@moodCode	1..1	SHALL	NO	x_DocumentActMood		APT
negationInd	@negationInd	0..1		NO	Boolean		
nullFlavor	@nullFlavor	0..1		NO	NullFlavor		ASKU
code	code	1..1	SHALL	YES	CD		NCI Thesaurus 2.16.840.1.113883.3.26.1.1 null
effectiveTime	effectiveTime	0..1	SHOULD	YES	IVL_TS		
id	id	0..*		YES	II		
languageCode	languageCode	0..1		YES	CS		
priorityCode	priorityCode	0..1		YES	CE		
realmCode	realmCode	0..*		YES	CS		
statusCode	statusCode	0..1		YES	CS		
templateId	templateId	0..*		YES	II		2.16.840.1.113883.10.20.23.8

sdtm::Study Arm							
cda::act[cda:templateId/@root = 2.16.840.1.113883.10.20.23.8]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
text	text	0..1	SHALL	YES	ED		
author	author	0..*		YES	Author		
entryRelationship	entryRelationship	0..*		YES	EntryRelationship		
informant	informant	0..*		YES	Informant12		
participant	participant	0..*		YES	Participant2		
performer	performer	0..*		YES	Performer2		
precondition	precondition	0..*		YES	Precondition		
reference	reference	0..*		YES	Reference		
specimen	specimen	0..*		YES	Specimen		
subject	subject	0..1		YES	Subject		
typeId	typeId	0..1		YES	InfrastructureRootTypeId		

Study Arm example

```
<?xml version="1.0" encoding="UTF-8"?>
<act xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="urn:hl7-
org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd" classCode="ACT"
 moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.23.8"/>
  <id root="798016984" extension="MDHT"/>
  <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
 Thesaurus"/>
  <text>Text Value</text>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
</act>
```

Study Day Period

[Observation: templateId `2.16.840.1.113883.10.20.23.74`]

The resusable structure contains information to identify the beginning and end study days on which the prolonged event it is related to occurred. "Study Day" refers to the relative day of an observation or other event with respect the the designated reference day for the study - which is labled as "Day 1". Note, dates prior to the reference data are decremented by 1, with the day preceeding the reference day designated as "Study Day -1". This structure is captured as a template to facilitate its reuse as a characteristic of different types of data within clinical trial reporting.

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`)
3. **SHALL** contain exactly one [1..1] **`code/@code`**`="TBD"` (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`)
   - A fixed value that indicates the observation captures the actual study day for an event.
4. **SHALL** contain exactly one [1..1] **`value`** with data type IVL_INT

- The applicable study day value. [SDTM: SVSTDY, SVENDY, CMSTDY, CMENDY, EXSTDY, EXENDY, SUSTDY, SUENDY, AESTDY, AEENDY, DSSTDY,]

Study Day Period example

Study Epoch

[Act: templateId `2.16.840.1.113883.10.20.23.71`]

As part of the design of a trial, the planned period of subjects' participation in the trial is divided into Epochs. Each Epoch is a period of time that serves a purpose in the trial as a whole. That purpose will be at the level of the primary objectives of the trial. Typically, the purpose of an Epoch will be to expose subjects to a treatment, or to prepare for such a treatment period (e.g., determine subject eligibility, wash out previous treatments) or to gather data on subjects after a treatment has ended. This structure is captured as a template in order to facilitate its reuse as a characteristic of different types of data within clinical trial reporting.

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="ACT"` , where the @code **SHALL** be selected from (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`)
3. **SHALL** contain exactly one [1..1] **`code`**, where the @code **SHALL** be selected from (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`)
   - The code value indicates that the act information relates to an epoch.
4. **SHALL** contain zero or one [0..1] **`text`**
   - The text name or title of the epoch.

sdtm::Study Epoch							
cda::act[cda:templateId/@root = 2.16.840.1.113883.10.20.23.25]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
classCode	@classCode	1..1	SHALL	NO	x_ActClassDocumentEntryAct		NCI Thesaurus 2.16.840.1.113883.3.26.1.1 ACCM
moodCode	@moodCode	1..1	SHALL	NO	x_DocumentActMood		APT
negationInd	@negationInd	0..1		NO	Boolean		
nullFlavor	@nullFlavor	0..1		NO	NullFlavor		ASKU
code	code	1..1	SHALL	YES	CD		NCI Thesaurus 2.16.840.1.113883.3.26.1.1 null
effectiveTime	effectiveTime	0..1		YES	IVL_TS		
id	id	0..*		YES	II		
languageCode	languageCode	0..1		YES	CS		
priorityCode	priorityCode	0..1		YES	CE		
realmCode	realmCode	0..*		YES	CS		
statusCode	statusCode	0..1		YES	CS		
templateId	templateId	0..*		YES	II		2.16.840.1.113883.10.20.23.25
text	text	0..1	SHALL	YES	ED		

sdtm::Study Epoch							
cda::act[cda:templateId/@root = 2.16.840.1.113883.10.20.23.25]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
author	author	0..*		YES	Author		
entryRelationship	entryRelationship	0..*		YES	EntryRelationship		
informant	informant	0..*		YES	Informant12		
participant	participant	0..*		YES	Participant2		
performer	performer	0..*		YES	Performer2		
precondition	precondition	0..*		YES	Precondition		
reference	reference	0..*		YES	Reference		
specimen	specimen	0..*		YES	Specimen		
subject	subject	0..1		YES	Subject		
typeId	typeId	0..1		YES	InfrastructureRootTypeId		

Study Epoch example

```
<?xml version="1.0" encoding="UTF-8"?>
<act xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="urn:hl7-
org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd" classCode="ACT"
 moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.23.25"/>
  <id root="860964948" extension="MDHT"/>
  <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
 Thesaurus"/>
  <text>Text Value</text>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
</act>
```

Subject Characteristic

[Observation: templateId `2.16.840.1.113883.10.20.23.34`]

Used to capture subject related data that is does not fit within the other SDTM domains.

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`)
3. **SHALL** contain exactly one [1..1] **`code`**
   - A coded value that identifies the subject charateristic. The verbatim text is placed within the original text property of the CD data type. [SDTM: SCTESTCD, SCTEST]
4. **SHALL** contain [1..2] **`id`**
   - A value that is provided to ensure the uniqueness of the subject characteristic item. [SDTM: SCSEQ, SCSPID] A single identifier, the sequence number, is required.
5. **SHOULD** contain zero or one [0..1] **`value`**

- The response to the study characteristic item indicated by the code value. A result or finding in standard format should be recorded as a base value - either code or physical quantity. A modified reported term is included as a translation. [SDTM: SCORRES, SCORRESU, QSSTRESC, SCSTRESN, SCSTRESU]

6. **MAY** contain zero or one [0..1] **`entryRelationship`**
   a. Contains **`@typeCode="REFR"`** *REFR*
   b. Contains exactly one [1..1] *Data Collection* (templateId: `2.16.840.1.113883.10.20.23.56`)
7. **MAY** contain zero or one [0..1] **`entryRelationship`**
   a. Contains **`@typeCode="COMP"`** *COMP*
   b. Contains exactly one [1..1] *Non Performance Reason* (templateId: `2.16.840.1.113883.10.20.23.62`)
8. **MAY** contain zero or one [0..1] **`entryRelationship`**
   - Allows capture of a group identifier for the subject characteristic.

   a. Contains **`@typeCode="COMP"`** *COMP*
   b. Contains exactly one [1..1] *Group Identifier* (templateId: `2.16.840.1.113883.10.20.23.61`)
9. **SHALL** contain zero or one [0..1] **`entryRelationship`**
   Indicates a subcategory the subject characteristic is assigned to.
   a. This entryRelationship **SHALL** contain exactly one [1..1] **`@typeCode`**`="COMP"`
   b. This entryRelationship **SHALL** contain exactly one [1..1] **`subjectCharateristicCategory`** with data type *questionnaire Category*
10. Contains zero or one [0..1] **`entryRelationship`**
    Indicates a subcategory the subject characteristic is assigned to.
    a. This entryRelationship **SHALL** contain exactly one [1..1] **`@typeCode`**`="COMP"`
    b. This entryRelationship **SHALL** contain exactly one [1..1] **`subjectCharateristicSubCategory`** with data type *subject Charateristic Sub Category*
11. **MAY** contain zero or one [0..1] **`statusCode`**
    - Used to indicate whether or not the specified study characteristic response was elicited. [SDTM: SCSTAT]

sdtm::Subject Characteristic							
cda::observation[cda:templateId/@root = 2.16.840.1.113883.10.20.23.39]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
classCode	@classCode	1..1	SHALL	NO	ActClassObservation		ALRT
moodCode	@moodCode	1..1	SHALL	NO	x_ActMoodDocumentObservation		DEF
negationInd	@negationInd	0..1		NO	Boolean		
nullFlavor	@nullFlavor	0..1		NO	NullFlavor		ASKU
code	code	1..1	SHALL	YES	CD		
derivationExpr	derivationExpr	0..1		YES	ST		
effectiveTime	effectiveTime	0..1		YES	IVL_TS		
id	id	1..2	SHALL	YES	II		
interpretationCode	interpretationCode	0..*		YES	CE		
languageCode	languageCode	0..1		YES	CS		
methodCode	methodCode	0..*		YES	CE		
priorityCode	priorityCode	0..1		YES	CE		

sdtm::Subject Characteristic							
cda::observation[cda:templateId/@root = 2.16.840.1.113883.10.20.23.39]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
realmCode	realmCode	0..*		YES	CS		
repeatNumber	repeatNumber	0..1		YES	IVL_INT		
statusCode	statusCode	0..1	MAY	YES	CS		
targetSiteCode	targetSiteCode	0..*		YES	CD		
templateId	templateId	0..*		YES	II		2.16.840.1.113883.10.20.23.39
text	text	0..1		YES	ED		
value	value	0..1	SHOULD	YES	ANY		
author	author	0..*		YES	Author		
data Collection	data Collection	0..1	MAY	YES	Data Collection		
entryRelationship	entryRelationship	0..*		YES	EntryRelationship		
group Identifier	group Identifier	0..1	MAY	YES	Group Identifier		
informant	informant	0..*		YES	Informant12		
nonPerformanceReason	nonPerformanceReason	0..1	MAY	YES	Non Performance Reason		
participant	participant	0..*		YES	Participant2		
performer	performer	0..*		YES	Performer2		
precondition	precondition	0..*		YES	Precondition		
reference	reference	0..*		YES	Reference		
referenceRange	referenceRange	0..*		YES	ReferenceRange		
specimen	specimen	0..*		YES	Specimen		
subject	subject	0..1		YES	Subject		
subjectCharateristicCategoryAssociation	subjectCharateristicCategoryAssociation	0..1	SHALL	YES	subjectCharateristicCategoryAssociation		
subjectCharateristicSubCategoryAssociation	subjectCharateristicSubCategoryAssociation	0..1		YES	subjectCharateristicSubCategoryAssociation		
typeId	typeId	0..1		YES	InfrastructureRootTypeId		

Subject Characteristic example

```
<?xml version="1.0" encoding="UTF-8"?>
<observation xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd"
 classCode="OBS" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.23.39"/>
  <id root="730099075" extension="MDHT"/>
  <code code="1250069213"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
```

```
 <entryRelationship typeCode="COMP">
   <templateId root="null"/>
 </entryRelationship>
 <entryRelationship typeCode="COMP"/>
 <entryRelationship>
   <act classCode="ACT" moodCode="EVN">
     <templateId root="2.16.840.1.113883.10.20.23.30"/>
     <id root="583898129" extension="MDHT"/>
     <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus"/>
     <statusCode code="completed"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
     <entryRelationship>
       <observation classCode="OBS" moodCode="EVN">
         <templateId root="2.16.840.1.113883.10.20.23.11"/>
         <id root="1847312336" extension="MDHT"/>
         <code code="TBD" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
         <statusCode code="completed"/>
         <effectiveTime>
           <low value="2012"/>
           <high value="2012"/>
         </effectiveTime>
         <value xsi:type="INT" value="1"/>
       </observation>
     </entryRelationship>
   </act>
 </entryRelationship>
 <entryRelationship>
   <observation classCode="OBS" moodCode="EVN">
     <templateId root="2.16.840.1.113883.10.20.23.9"/>
     <id root="1501923149" extension="MDHT"/>
     <code code="TBD" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
     <statusCode code="completed"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
     <value xsi:type="CE" code="632011240"/>
   </observation>
 </entryRelationship>
 <entryRelationship>
   <act classCode="ACT" moodCode="EVN">
     <templateId root="2.16.840.1.113883.10.20.23.15"/>
     <id root="2034278172" extension="MDHT"/>
     <code code="TBD" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
     <statusCode code="completed"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
   </act>
 </entryRelationship>
</observation>
```

Subject Element

[Act: templateId `2.16.840.1.113883.10.20.23.16`]

The Subject Element content consolidates information about the timing of each subjects progress through the epochs and elements of the trial.

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="ACT"` *Act* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`)
3. **SHALL** contain exactly one [1..1] **`code`**, where the @code **SHALL** be selected from (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`)
   - The code value indicates the nature of the element. If the element is unplanned, the code value should indicate this. Uose original text to provide the verbatim content of the element - whether planned or unplanned. [SDTM: ETCD, ELEMENT, SEUPDES]
4. **SHALL** contain exactly one [1..1] **`effectiveTime`**
   - Information that records the start and stop dates of the element. A value for the start date - interval lower bound is required. [SDTM: SESDTC, SEENDTC]
5. **SHALL** contain exactly one [1..1] **`id`**
   - The identifier is assigned to ensure uniqueness of the subject records within the domain. [SDTM: SESEQ]
6. **MAY** contain zero or one [0..1] **`entryRelationship`**
   a. Contains **`@typeCode="COMP"`** *COMP*
   b. Contains exactly one [1..1] *Study Epoch* (templateId: `2.16.840.1.113883.10.20.23.71`)
7. **MAY** contain zero or one [0..1] **`entryRelationship`**
   a. This entryRelationship **SHALL** contain exactly one [1..1] **`@typeCode`**`="COMP"`
   b. This entryRelationship **SHALL** contain zero or one [0..1] **`observation`**
      a. This observation **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
      b. This observation **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`)
      c. This observation **SHALL** contain exactly one [1..1] **`code`**, where the @code **SHALL** be selected from (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`)

         The code value indicates the observation captures an element's order within a trial arm.
      d. This observation **SHALL** contain zero or more [0..*] **`value`** with data type INT

         A value that gives the order of an element within the trial arm. [SDTM: TAETORD]

sdtm::Subject Element							
cda::act[cda:templateId/@root = 2.16.840.1.113883.10.20.23.26]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
classCode	@classCode	1..1	SHALL	NO	x_ActClassDocumentEntryAct		ACCM
moodCode	@moodCode	1..1	SHALL	NO	x_DocumentActMood		APT
negationInd	@negationInd	0..1		NO	Boolean		
nullFlavor	@nullFlavor	0..1		NO	NullFlavor		ASKU
code	code	1..1	SHALL	YES	CD		NCI Thesaurus 2.16.840.1.113883.3.26.1.1 null

sdtm::Subject Element							
cda::act[cda:templateId/@root = 2.16.840.1.113883.10.20.23.26]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
effectiveTime	effectiveTime	1..1	SHALL	YES	IVL_TS		
id	id	1..1	SHALL	YES	II		
languageCode	languageCode	0..1		YES	CS		
priorityCode	priorityCode	0..1		YES	CE		
realmCode	realmCode	0..*		YES	CS		
statusCode	statusCode	0..1		YES	CS		
templateId	templateId	0..*		YES	II		2.16.840.1.113883.10.20.23.26
text	text	0..1		YES	ED		
author	author	0..*		YES	Author		
elementOrderAssociation	elementOrderAssociation	0..1	MAY	YES	elementOrderAssociation		
entryRelationship	entryRelationship	0..*		YES	EntryRelationship		
informant	informant	0..*		YES	Informant12		
participant	participant	0..*		YES	Participant2		
performer	performer	0..*		YES	Performer2		
precondition	precondition	0..*		YES	Precondition		
reference	reference	0..*		YES	Reference		
specimen	specimen	0..*		YES	Specimen		
study Epoch	study Epoch	0..1	MAY	YES	Study Epoch		
subject	subject	0..1		YES	Subject		
typeId	typeId	0..1		YES	InfrastructureRootTypeId		

Subject Element example

```
<?xml version="1.0" encoding="UTF-8"?>
<act xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="urn:hl7-
org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd" classCode="ACT"
 moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.23.26"/>
  <id root="505727430" extension="MDHT"/>
  <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
 Thesaurus"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <entryRelationship>
    <observation>
      <code code="1180829289"/>
      <value xsi:type="INT" value="1"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <act classCode="ACT" moodCode="EVN">
```

```
      <templateId root="2.16.840.1.113883.10.20.23.25"/>
      <id root="2039233586" extension="MDHT"/>
      <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
 Thesaurus"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
    </act>
  </entryRelationship>
</act>
```

Substance Use

[SubstanceAdministration: templateId `2.16.840.1.113883.10.20.23.21`]

The structure is used to capture substance use information that may be used to assess the efficacy and/or safety of therapies that look to mitigate the effects of chronic substance use, or that could be used as covariates in other efficacy and/or safety analyses. This information may be independent of planned study evaluations, or may be a key outcome (e.g., planned evaluation) of a clinical trial. In many clinical trials, detailed substance use information as provided for in the domain model above may not be required (e.g., the only information collected may be a response to the question ?Have you ever smoked tobacco??); in such cases, many of the Qualifier variables would not be submitted. This content may contain responses to questions about use of pre-specified substances as well as records of substance use collected as free text.

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="SBADM"` (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`)
3. **MAY** contain zero or one [0..1] **`doseQuantity`**
   - Information on the dosage of the substance that was consumed. [SDTM: SUDOSE, SUDOSU]
4. **MAY** contain zero or one [0..1] **`effectiveTime`**
   - Information on when and how ofern the substance was taken. Possible values include start date, stop date, and duration. Note, only two of these need to be valued, and only two values are supported. [SDTM: SUSTDTC, SUENDTC, SUDUR, SUDOSFRQ]
5. **SHALL** contain [1..2] **`id`**
   - An identifier that is used to ensure the uniqueness of subject records within the substance use domain. [SDTM: SUSEQ, SUSPID] The sequence number is required.
6. **MAY** contain zero or one [0..1] **`maxDoseQuantity`**
   - Information on the total daily dose of the substance. The structure also accommodates periods other than a day. [SDTM: SUDOSTOT] Note, this attribute can also be used if multiple total dosage amounts need to be reported.
7. **MAY** contain zero or one [0..1] **`routeCode`**
   - The route by which the substance is administered, applied or ingested. [SDTM: SUROUTE]
8. **MAY** contain zero or one [0..1] **`statusCode`**, where the @code **SHALL** be selected from (CodeSystem: `2.16.840.1.113883.5.14 HL7ActStatus`)
   - Used to indicate whether the activity - use of a particular substance - did occur. Use statusCode "Completed" if the use occurred. [SDTM: SUOCCUR]
9. **SHALL** contain exactly one [1..1] **`consumable`**
   a. Contains exactly one [1..1] *Consumable Material* (templateId: `2.16.840.1.113883.10.20.23.55`)
10. **MAY** contain zero or one [0..1] **`text`**
    - Used to capture textual information about the use of the substance. [SDTM: SUDOSTXT]
11. **MAY** contain zero or one [0..1] **`entryRelationship`**

Indicates a category the substance use is assigned to.

a. This entryRelationship **SHALL** contain exactly one [1..1] **`@typeCode="COMP"`**

b. This entryRelationship **SHALL** contain exactly one [1..1] **`substanceUseCategory`** with data type *substance Use Category*

12. **MAY** contain zero or one [0..1] **`entryRelationship`**

Indicates a subcategory the substance use is assigned to.

a. This entryRelationship **SHALL** contain exactly one [1..1] **`@typeCode="COMP"`**

b. This entryRelationship **SHALL** contain exactly one [1..1] **`substanceUseSubCategory`** with data type *substance Use Sub Category*

13. **MAY** contain zero or one [0..1] **`entryRelationship`**

a. Contains **`@typeCode="COMP"`** *COMP*

b. Contains exactly one [1..1] *Pre-Specified Event* (templateId: `2.16.840.1.113883.10.20.23.64`)

14. **MAY** contain zero or one [0..1] **`entryRelationship`**

a. Contains **`@typeCode="COMP"`** *COMP*

b. Contains exactly one [1..1] *Non Performance Reason* (templateId: `2.16.840.1.113883.10.20.23.62`)

15. **MAY** contain zero or one [0..1] **`entryRelationship`**

- Records the relationship between the start of consumption of the substance use and a reference point defined for the study.

a. Contains **`@typeCode="REFR"`** *REFR*

b. Contains exactly one [1..1] *Activity Start Timing Reference* (templateId: `2.16.840.1.113883.10.20.23.52`)

16. **MAY** contain zero or one [0..1] **`entryRelationship`**

- Records the relationship between the end of consumption of the substance use and a reference point defined for the study.

a. Contains **`@typeCode="REFR"`** *REFR*

b. Contains exactly one [1..1] *Activity End Timing Reference* (templateId: `2.16.840.1.113883.10.20.23.51`)

17. **MAY** contain zero or one [0..1] **`entryRelationship`**

a. Contains **`@typeCode="COMP"`** *COMP*

b. Contains exactly one [1..1] *Data Collection* (templateId: `2.16.840.1.113883.10.20.23.56`)

18. **MAY** contain zero or one [0..1] **`entryRelationship`**

a. Contains **`@typeCode="REFR"`** *REFR*

b. Contains exactly one [1..1] *Study Day Period* (templateId: `2.16.840.1.113883.10.20.23.74`)

19. **SHALL** satisfy: The efective time attribute is used to capture information regarding the start, stop, duration and frequency of use for the concommitant medication. There shall be Two SXPR components created. The first will be an interval of time stamps (IVL_TS) to addres stop and start dates. Note, when duration is included, it is associated with either the stop or the start date. That is to say, only two of the three interval parameters may be instantiated, since, with two known, the third can be derived. The second SXPR component addresses the frequency of use. It uses the periodic interval (PIVL) type. Note, that this HL7 type tends to invert the usual expression. I.e. BID is expressed as every 12 hours.

sdtm::Substance Use							
cda::substanceadministration[cda:templateId/@root = 2.16.840.1.113883.10.20.23.27]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
classCode	@classCode	1..1	SHALL	NO	ActClass		SBADM
moodCode	@moodCode	1..1	SHALL	NO	x_DocumentSubstanceMood		EVN

sdtm::Substance Use							
cda::substanceadministration[cda:templateId/@root = 2.16.840.1.113883.10.20.23.27]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
negationInd	@negationInd	0..1		NO	Boolean		
nullFlavor	@nullFlavor	0..1		NO	NullFlavor		ASKU
administrationUnitCode	administrationUnitCode	0..1		YES	CE		
approachSiteCode	approachSiteCode	0..*		YES	CD		
code	code	0..1		YES	CD		
doseQuantity	doseQuantity	0..1	MAY	YES	IVL_PQ		
effectiveTime	effectiveTime	0..1	MAY	YES	SXCM_TS		
id	id	1..2	SHALL	YES	II		
maxDoseQuantity	maxDoseQuantity	0..1	MAY	YES	RTO_PQ_PQ		
priorityCode	priorityCode	0..1		YES	CE		
rateQuantity	rateQuantity	0..1		YES	IVL_PQ		
realmCode	realmCode	0..*		YES	CS		
repeatNumber	repeatNumber	0..1		YES	IVL_INT		
routeCode	routeCode	0..1	MAY	YES	CE		
statusCode	statusCode	0..1	MAY	YES	CS		HL7ActStatus 2.16.840.1.113883.5.14
templateId	templateId	0..*		YES	II		2.16.840.1.113883.10.20.23.27
text	text	0..1	MAY	YES	ED		
activity End Timing Reference	activity End Timing Reference	0..1	MAY	YES	Activity End Timing Reference		
activity Start Timing Reference	activity Start Timing Reference	0..1	MAY	YES	Activity Start Timing Reference		
author	author	0..*		YES	Author		
consumable	consumable	1..1		YES	Consumable		
consumable Material	consumable Material	1..1	SHALL	YES	Consumable Material		
data Collection	data Collection	0..1	MAY	YES	Data Collection		
entryRelationship	entryRelationship	0..*		YES	EntryRelationship		
informant	informant	0..*		YES	Informant12		
nonPerformanceReason	nonPerformanceReason	0..1	MAY	YES	Non Performance Reason		
participant	participant	0..*		YES	Participant2		

sdtm::Substance Use							
cda::substanceadministration[cda:templateId/@root = 2.16.840.1.113883.10.20.23.27]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
performer	performer	0..*		YES	Performer2		
pre-Specified Event	pre-Specified Event	0..1	MAY	YES	Pre-Specified Event		
precondition	precondition	0..*		YES	Precondition		
reference	reference	0..*		YES	Reference		
specimen	specimen	0..*		YES	Specimen		
study Day Period	study Day Period	0..1	MAY	YES	Study Day Period		
subject	subject	0..1		YES	Subject		
substanceUseCategoryAssociation	substanceUseCategoryAssociation	0..1	MAY	YES	substanceUseCategoryAssociation		
substanceUseSubCategoryAssociation	substanceUseSubCategoryAssociation	0..1	MAY	YES	substanceUseSubCategoryAssociation		
typeId	typeId	0..1		YES	InfrastructureRootTypeId		

Substance Use example

```
<?xml version="1.0" encoding="UTF-8"?>
<substanceadministration xmlns:xsi="http://www.w3.org/2001/XMLSchema-
instance" xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd"
 classCode="SBADM" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.23.27"/>
  <id root="1624574451" extension="MDHT"/>
  <text>Text Value</text>
  <statusCode code="completed"/>
  <effectiveTime value="20120508"/>
  <routeCode code="121518996"/>
  <doseQuantity/>
  <maxDoseQuantity/>
  <consumable>
    <manufacturedProduct classCode="MANU">
      <manufacturedMaterial classCode="MMAT" determinerCode="KIND"/>
    </manufacturedProduct>
  </consumable>
  <entryRelationship typeCode="COMP"/>
  <entryRelationship typeCode="COMP"/>
  <entryRelationship>
    <observation/>
  </entryRelationship>
  <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.9"/>
      <id root="178035519" extension="MDHT"/>
      <code code="TBD" codeSystem="2.16.840.1.113883.3.26.1.1"
 codeSystemName="NCI Thesaurus"/>
      <text>Text Value</text>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
    </observation>
  </entryRelationship>
```

```
 <entryRelationship>
   <observation/>
 </entryRelationship>
 <entryRelationship>
   <observation/>
 </entryRelationship>
 <entryRelationship>
   <act classCode="ACT" moodCode="EVN">
     <templateId root="2.16.840.1.113883.10.20.23.23"/>
     <id root="283818578" extension="MDHT"/>
     <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus"/>
     <text>Text Value</text>
     <statusCode code="completed"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
     <entryRelationship typeCode="COMP">
       <act classCode="ACT">
         <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus"/>
       </act>
     </entryRelationship>
   </act>
 </entryRelationship>
 <entryRelationship>
   <act classCode="ACT" moodCode="EVN">
     <templateId root="2.16.840.1.113883.10.20.23.24"/>
     <id root="311349737" extension="MDHT"/>
     <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus"/>
     <text>Text Value</text>
     <statusCode code="completed"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
     <entryRelationship typeCode="COMP">
       <act classCode="ACT">
         <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus"/>
       </act>
     </entryRelationship>
   </act>
 </entryRelationship>
 <entryRelationship>
   <act classCode="ACT" moodCode="EVN">
     <templateId root="2.16.840.1.113883.10.20.23.30"/>
     <id root="1542178664" extension="MDHT"/>
     <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus"/>
     <text>Text Value</text>
     <statusCode code="completed"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
     <entryRelationship>
       <observation classCode="OBS" moodCode="EVN">
         <templateId root="2.16.840.1.113883.10.20.23.11"/>
         <id root="2128266040" extension="MDHT"/>
         <code code="TBD" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
```

```
          <text>Text Value</text>
          <statusCode code="completed"/>
          <effectiveTime>
            <low value="2012"/>
            <high value="2012"/>
          </effectiveTime>
        </observation>
      </entryRelationship>
    </act>
  </entryRelationship>
</substanceadministration>
```

Timing Reference

[Act: templateId `2.16.840.1.113883.10.20.23.70`]

The timing reference makes it possible to indicate the timing of a measurement or activity as an offset from an anchoring event. Note, in SDTM, the anchoring event is known as a "Time Point Reference'. The reference, described as "an elapsed time relative to a fixed reference point, such as time of last dose", is known as a "Planned Time Point. This structure is captured as a template to facilitate its reuse for different types of data within clinical trial reporting.

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="ACT"` *Act* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`)
3. **SHALL** contain exactly one [1..1] **`code`**, where the @code **SHALL** be selected from (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`)
   - A text description of when the measurement should be taken. This may be captured as an elapsed duration with respect to the anchor time point. [SDTM: VSELTM]
4. **MAY** contain zero or one [0..1] **`effectiveTime`**
   - The planned elapsed time - a duration - at which the event or measurement is to take place with reference to the anchoring time point. [SDTM: VSELTM]

   a. **SHALL** satisfy: The width property of the IVL_TS data type is used.
5. **MAY** contain zero or one [0..1] **`id`**
   - A numeric identifier for the planned time point in order to facilitate sorting of the data content. [SDTM: VSTPTNUM]
6. **MAY** contain zero or one [0..1] **`entryRelationship`**

   Indicates the reference point associated with a timing offset.

   a. This entryRelationship **SHALL** contain exactly one [1..1] **`@typeCode`**`="COMP"`
   b. This entryRelationship **SHALL** contain exactly one [1..1] **`act`**

      Information on a fixed reference point that acts as an anchor for indicating when a measurement, observation, or other event is expected to happen. The event timeing is indicated as an offset from the time point reference.

      a. This act **SHALL** contain exactly one [1..1] **`@classCode`**`="ACT"` *Act* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
      b. This act **SHALL** contain exactly one [1..1] **`@moodCode`**
      c. This act **SHALL** contain exactly one [1..1] **`code`**

         A code that indicates the nature of the fixed reference point that is referred to by the timing reference. If a suitable value set has not been defined, the original text property of the coded type is used. [SDTM: VSTPTREF]
      d. This act **MAY** contain zero or one [0..1] **`effectiveTime`**

         The date time of the anchor time point. [SDTM: VSRFTDTC]

Information on a fixed reference point that acts as an anchor for indicating when a measurement, observation, or other event is expected to happen. The event timeing is indicated as an offset from the time point reference.

sdtm::Timing Reference							
cda::act[cda:templateId/@root = 2.16.840.1.113883.10.20.23.14]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
classCode	@classCode	1..1	SHALL	NO	x_ActClassDocumentEntryAct		ACCM
moodCode	@moodCode	1..1	SHALL	NO	x_DocumentActMood		APT
negationInd	@negationInd	0..1		NO	Boolean		
nullFlavor	@nullFlavor	0..1		NO	NullFlavor		ASKU
code	code	1..1	SHALL	YES	CD		NCI Thesaurus 2.16.840.1.113883.3.26.1.1 null
effectiveTime	effectiveTime	0..1	MAY	YES	IVL_TS		
id	id	0..1	MAY	YES	II		
languageCode	languageCode	0..1		YES	CS		
priorityCode	priorityCode	0..1		YES	CE		
realmCode	realmCode	0..*		YES	CS		
statusCode	statusCode	0..1		YES	CS		
templateId	templateId	0..*		YES	II		2.16.840.1.113883.10.20.23.14
text	text	0..1		YES	ED		
anchorAssociation	anchorAssociation	0..1	MAY	YES	AnchorAssociation		
author	author	0..*		YES	Author		
entryRelationship	entryRelationship	0..*		YES	EntryRelationship		
informant	informant	0..*		YES	Informant12		
participant	participant	0..*		YES	Participant2		
performer	performer	0..*		YES	Performer2		
precondition	precondition	0..*		YES	Precondition		
reference	reference	0..*		YES	Reference		
specimen	specimen	0..*		YES	Specimen		
subject	subject	0..1		YES	Subject		
typeId	typeId	0..1		YES	InfrastructureRootTypeId		

Timing Reference example

```
<?xml version="1.0" encoding="UTF-8"?>
<act xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="urn:hl7-
org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd" classCode="ACT"
 moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.23.14"/>
  <id root="1950787968" extension="MDHT"/>
  <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
 Thesaurus"/>
```

```
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <entryRelationship typeCode="COMP">
    <act classCode="ACT">
      <code code="1059063649"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
    </act>
  </entryRelationship>
</act>
```

Visit

[Encounter: templateId `2.16.840.1.113883.10.20.23.17`]

The activity that is captured within the data report of a subject's experience is organized by visit, by the subject's encounter with a study clinician. The encounter may be face to face, or it may be indirect, such as over the phone. All reported activity either takes place within the context of a study, or is associated with the visit (encounter) in which it is reported to the investigator.

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="ENC"` (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`)
3. **SHALL** contain exactly one [1..1] **`code`**
   - A coded value that indicates the type or name of the vist. If this information is not formally condified, the value may be placed in the original text property of the coded data type. [SDTM: VISIT].
4. **SHOULD** contain exactly one [1..1] **`effectiveTime`**
   - The interval data type allows entry of the start date/time of the visit and of the end/date time. [SDTM: SVSTDTC, SVENDTC]
5. **MAY** contain zero or more [0..*] **`entryRelationship`**
   a. Contains **`@typeCode="`**`COMP`**`"` *COMP*
   b. Contains exactly one [1..1] *Adverse Event* (templateId: `2.16.840.1.113883.10.20.23.22`)
6. **MAY** contain zero or more [0..*] **`entryRelationship`**
   a. Contains **`@typeCode="`**`COMP`**`"` *COMP*
   b. Contains exactly one [1..1] *Vital Sign* (templateId: `2.16.840.1.113883.10.20.23.35`)
7. **MAY** contain zero or one [0..1] **`text`**
   - A text block to be used for description of an unplanned visit. [SDTM: SVUPDES]
8. **SHALL** contain exactly one [1..1] **`id`**
   - The clinical encounter number. It is a numeric value that is used for sorting. [SDTM, VISITNUM].
9. **MAY** contain zero or one [0..1] **`entryRelationship`**
   a. Contains **`@typeCode="`**`REFR`**`"` *REFR*
   b. Contains exactly one [1..1] *Planned Study Day* (templateId: `2.16.840.1.113883.10.20.23.63`)
10. **MAY** contain zero or more [0..*] **`entryRelationship`**
    a. Such entryRelationships **SHALL** contain exactly one [1..1] **`@typeCode`**`="COMP"`
    b. Such entryRelationships **SHALL** contain exactly one [1..1] **`substanceAdministration`**, where its type is *Concomitant Medication*
       a. Contains exactly one [1..1] *Concomitant Medication* (templateId: `2.16.840.1.113883.10.20.25.18`)

11. **MAY** contain zero or more [0..*] **entryRelationship**
    a. Contains **@typeCode="COMP"** *COMP*
    b. Contains exactly one [1..1] *ECG Test Result* (templateId: 2.16.840.1.113883.10.20.23.28)
12. **MAY** contain zero or more [0..*] **entryRelationship**
    a. Contains **@typeCode="COMP"** *COMP*
    b. Contains exactly one [1..1] *Inclusion or Exclusion Criteria Not Met* (templateId: 2.16.840.1.113883.10.20.23.29)
13. **MAY** contain zero or more [0..*] **entryRelationship**
    a. Contains **@typeCode="COMP"** *COMP*
    b. Contains exactly one [1..1] *Human Clinical Laboratory Test Result* (templateId: 2.16.840.1.113883.10.20.23.30)
14. **MAY** contain zero or more [0..*] **entryRelationship**
    a. Contains **@typeCode="COMP"** *COMP*
    b. Contains exactly one [1..1] *Physical Examination Finding* (templateId: 2.16.840.1.113883.10.20.23.32)
15. **MAY** contain zero or one [0..1] **entryRelationship**
    a. This entryRelationship **SHALL** contain exactly one [1..1] **@typeCode**="COMP"
    b. This entryRelationship Contains zero or one [0..1] **substanceAdministration**, where its type is *Substance Use*
        a. Contains exactly one [1..1] *Substance Use* (templateId: 2.16.840.1.113883.10.20.23.21)
16. **MAY** contain zero or one [0..1] **entryRelationship**
    a. Contains exactly one [1..1] *Microbiology Specimen Finding* (templateId: 2.16.840.1.113883.10.20.23.37)
17. **MAY** contain zero or one [0..1] **entryRelationship**
    a. Contains exactly one [1..1] *Microbiology Susceptibility* (templateId: 2.16.840.1.113883.10.20.23.38)
18. **MAY** contain zero or one [0..1] **entryRelationship**
    a. Contains exactly one [1..1] *Pharmacokinetic Concentration Finding* (templateId: 2.16.840.1.113883.10.20.23.39)
19. **MAY** contain zero or one [0..1] **entryRelationship**
    a. Contains exactly one [1..1] *Finding About* (templateId: 2.16.840.1.113883.10.20.23.40)
20. **MAY** contain zero or one [0..1] **entryRelationship**
    a. Contains **@typeCode="COMP"** *COMP*
    b. Contains exactly one [1..1] *Drug Accountability* (templateId: 2.16.840.1.113883.10.20.23.36)
21. **MAY** contain zero or one [0..1] **entryRelationship**
    a. Contains **@typeCode="REFR"** *REFR*
    b. Contains exactly one [1..1] *Study Day Period* (templateId: 2.16.840.1.113883.10.20.23.74)

sdtm::Visit							
cda::encounter[cda:templateId/@root = 2.16.840.1.113883.10.20.23.5]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
classCode	@classCode	1..1	SHALL	NO	ActClass		ACCM
moodCode	@moodCode	1..1	SHALL	NO	x_DocumentEncounterMood		APT
nullFlavor	@nullFlavor	0..1		NO	NullFlavor		ASKU
code	code	1..1	SHALL	YES	CD		

sdtm::Visit							
cda::encounter[cda:templateId/@root = 2.16.840.1.113883.10.20.23.5]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
effectiveTime	effectiveTime	1..1	SHOULD	YES	IVL_TS		
id	id	1..1	SHALL	YES	II		
priorityCode	priorityCode	0..1		YES	CE		
realmCode	realmCode	0..*		YES	CS		
statusCode	statusCode	0..1		YES	CS		
templateId	templateId	0..*		YES	II		2.16.840.1.113883.10.20.23.5
text	text	0..1	MAY	YES	ED		
author	author	0..*		YES	Author		
concommitantMedicationAssociation	concommitantMedicationAssociation	0..*	MAY	YES	concommitantMedicationAssociation		
drug Accountability	drug Accountability	0..1	MAY	YES	Drug Accountability		
eCG Test Result	eCG Test Result	0..*	MAY	YES	ECG Test Result		
entryRelationship	entryRelationship	0..*		YES	EntryRelationship		
finding About	finding About	0..1	MAY	YES	Finding About		
human Clinical Adverse Event	human Clinical Adverse Event	0..*	MAY	YES	Adverse Event		
human Clinical Vital Sign	human Clinical Vital Sign	0..*	MAY	YES	Vital Sign		
inclusion or Exclusion Criteria Not Met	inclusion or Exclusion Criteria Not Met	0..*	MAY	YES	Inclusion or Exclusion Criteria Not Met		
informant	informant	0..*		YES	Informant12		
laboratory Test Result	laboratory Test Result	0..*	MAY	YES	Human Clinical Laboratory Test Result		
microbiology Specimen	microbiology Specimen	0..1	MAY	YES	Microbiology Specimen Finding		
microbiology Susceptibility	microbiology Susceptibility	0..1	MAY	YES	Microbiology Susceptibility		
participant	participant	0..*		YES	Participant2		
performer	performer	0..*		YES	Performer2		
pharmacokinetic Concentration Finding	pharmacokinetic Concentration Finding	0..1	MAY	YES	Pharmacokinetic Concentration Finding		

sdtm::Visit							
cda::encounter[cda:templateId/@root = 2.16.840.1.113883.10.20.23.5]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
physical Examination	physical Examination	0..*	MAY	YES	Physical Examination Finding		
planned Study Day	planned Study Day	0..1	MAY	YES	Planned Study Day		
precondition	precondition	0..*		YES	Precondition		
reference	reference	0..*		YES	Reference		
specimen	specimen	0..*		YES	Specimen		
study Day Period	study Day Period	0..1	MAY	YES	Study Day Period		
subject	subject	0..1		YES	Subject		
substanceUseAssociation	substanceUseAssociation	0..1	MAY	YES	substanceUseAssociation		
typeId	typeId	0..1		YES	InfrastructureRootTypeId		

Visit example

```
<?xml version="1.0" encoding="UTF-8"?>
<encounter xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd"
 classCode="ENC" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.23.5"/>
  <id root="114279004" extension="MDHT"/>
  <code code="826610762"/>
  <text>Text Value</text>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <entryRelationship typeCode="COMP">
    <substanceAdministration>
      <id root="1176499472" extension="MDHT"/>
      <text>Text Value</text>
      <statusCode code="completed"/>
      <effectiveTime value="20120508"/>
      <routeCode code="1317397785"/>
      <doseQuantity/>
      <maxDoseQuantity/>
      <consumable/>
      <entryRelationship typeCode="COMP"/>
      <entryRelationship typeCode="CAUS"/>
      <entryRelationship typeCode="COMP"/>
      <entryRelationship typeCode="REFR"/>
    </substanceAdministration>
  </entryRelationship>
  <entryRelationship typeCode="COMP">
    <substanceAdministration>
      <id root="2112044060" extension="MDHT"/>
      <text>Text Value</text>
      <statusCode code="completed"/>
      <effectiveTime value="20120508"/>
      <routeCode code="123676513"/>
```

```
      <doseQuantity/>
      <maxDoseQuantity/>
      <consumable/>
      <entryRelationship typeCode="COMP"/>
      <entryRelationship typeCode="COMP"/>
    </substanceAdministration>
  </entryRelationship>
  <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.6"/>
      <id root="523114685" extension="MDHT"/>
      <code code="TBD" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus" displayName="Adverse Event - Reported"/>
      <text>Text Value</text>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <entryRelationship>
        <observation/>
      </entryRelationship>
      <entryRelationship>
        <observation/>
      </entryRelationship>
      <entryRelationship>
        <observation/>
      </entryRelationship>
      <entryRelationship typeCode="COMP">
        <observation classCode="OBS" moodCode="EVN">
          <code code="TBD" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
        </observation>
      </entryRelationship>
      <entryRelationship>
        <observation/>
      </entryRelationship>
      <entryRelationship>
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      <entryRelationship>
        <observation/>
      </entryRelationship>
      <entryRelationship>
        <observation/>
      </entryRelationship>
      <entryRelationship>
        <act classCode="ACT" moodCode="EVN">
          <templateId root="2.16.840.1.113883.10.20.23.15"/>
          <id root="527136794" extension="MDHT"/>
```

```
          <code code="TBD" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
          <text>Text Value</text>
          <effectiveTime>
            <low value="2012"/>
            <high value="2012"/>
          </effectiveTime>
        </act>
      </entryRelationship>
      <entryRelationship>
        <observation/>
      </entryRelationship>
      <entryRelationship>
        <observation classCode="OBS" moodCode="EVN">
          <templateId root="2.16.840.1.113883.10.20.23.17"/>
          <id root="390672148" extension="MDHT"/>
          <code code="TBD" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
          <text>Text Value</text>
          <effectiveTime>
            <low value="2012"/>
            <high value="2012"/>
          </effectiveTime>
        </observation>
      </entryRelationship>
      <entryRelationship>
        <observation/>
      </entryRelationship>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.7"/>
      <id root="1047813187" extension="MDHT"/>
      <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus"/>
      <text>Text Value</text>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <interpretationCode codeSystemName="TrialDataIntepretations"/>
      <entryRelationship typeCode="COMP">
        <observation>
          <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus"/>
        </observation>
      </entryRelationship>
      <entryRelationship>
        <observation classCode="OBS" moodCode="EVN">
          <templateId root="2.16.840.1.113883.10.20.23.11"/>
          <id root="754537267" extension="MDHT"/>
          <code code="TBD" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
          <text>Text Value</text>
          <effectiveTime>
            <low value="2012"/>
            <high value="2012"/>
          </effectiveTime>
        </observation>
      </entryRelationship>
      <entryRelationship>
        <observation classCode="OBS" moodCode="INT">
          <templateId root="2.16.840.1.113883.10.20.23.10"/>
```

```
          <id root="638674400" extension="MDHT"/>
          <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus"/>
          <text>Text Value</text>
          <effectiveTime>
            <low value="2012"/>
            <high value="2012"/>
          </effectiveTime>
        </observation>
      </entryRelationship>
      <entryRelationship>
        <act classCode="ACT" moodCode="EVN">
          <templateId root="2.16.840.1.113883.10.20.23.14"/>
          <id root="1737896183" extension="MDHT"/>
          <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus"/>
          <text>Text Value</text>
          <effectiveTime>
            <low value="2012"/>
            <high value="2012"/>
          </effectiveTime>
          <entryRelationship typeCode="COMP"/>
        </act>
      </entryRelationship>
      <entryRelationship>
        <observation classCode="OBS" moodCode="EVN">
          <templateId root="2.16.840.1.113883.10.20.23.9"/>
          <id root="1603686429" extension="MDHT"/>
          <code code="TBD" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
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```

```
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codeSystemName="NCI Thesaurus"/>
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codeSystemName="NCI Thesaurus"/>
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```

```
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codeSystemName="NCI Thesaurus"/>
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codeSystemName="NCI Thesaurus"/>
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        </procedure>
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codeSystemName="NCI Thesaurus"/>
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```

```
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  </observation>
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     <code code="1667140218"/>
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     </effectiveTime>
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Thesaurus"/>
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codeSystemName="NCI Thesaurus"/>
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codeSystemName="NCI Thesaurus"/>
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         </effectiveTime>
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```

```
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          </effectiveTime>
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      <entryRelationship>
        <act classCode="ACT" moodCode="EVN">
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          <text>Text Value</text>
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          </effectiveTime>
          <entryRelationship>
            <observation classCode="OBS" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.23.11"/>
              <code code="TBD" codeSystem="2.16.840.1.113883.3.26.1.1"
 codeSystemName="NCI Thesaurus"/>
            </observation>
          </entryRelationship>
        </act>
      </entryRelationship>
    </observation>
  </entryRelationship>
</encounter>
```

Vital Sign

[Observation: templateId `2.16.840.1.113883.10.20.23.35`]

A vital sign measurement that is collected for the study subject. A vital sign is a measure of a particular physiological statistic, often taken by a health professional, that is intended to assess a basic body function.

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`)
3. **SHALL** contain exactly one [1..1] **`code`**, where the @code **SHALL** be selected from (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`)
   - A coded indication of the nature of the vital sign. [SDTM, VSTESTCD, VSTEST] - the descriptive text associated with the code.
4. **MAY** contain [0..2] **`value`**
   - The result of the observation. Note, if the observation was not performed, the value will not be present. Observation values may be provided as text, as coded data, or as physical quanitities. A second observation value may be provided to include the content in standard format or units. The second observation may be a coded element to provide information using a standard code set. It may be a numeric value to provide the information using the standard unit of measure. [SDTM: VSORRES, VSORRESU, VSSTRESN, VSSTRESU].
5. **SHALL** contain exactly one [1..1] **`statusCode`**, where the @code **SHALL** be selected from (CodeSystem: `2.16.840.1.113883.5.14 HL7ActStatus`)

- Use the value "completed" to indicate a desired observation was performed. If no observation was performed, provide the null flavor "NI"

6. **SHALL** contain [2..2] **`interpretationCode`**, where the @code **SHALL** be selected from (CodeSystem: `TrialDataIntepretations`)
   - Used to indicate whether a value represents a baseline value, and whether or not the value was derived. [SDTM: VSBLFL, VSDRVFL].
7. **MAY** contain zero or one [0..1] **`targetSiteCode`**
   - The body locatin relevant to the vital sign measurement. [SDTM: VSLOC]
8. **MAY** contain zero or one [0..1] **`entryRelationship`**
   a. This entryRelationship **SHALL** contain exactly one [1..1] **`@typeCode`**`="COMP"`
   b. This entryRelationship **SHALL** contain zero or one [0..1] **`observation`**

   INLINE

   a. This observation **SHALL** contain exactly one [1..1] **`@classCode`**
   b. This observation **SHALL** contain exactly one [1..1] **`@moodCode`**
   c. This observation **SHALL** contain exactly one [1..1] **`code`**, where the @code **SHALL** be selected from (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`)

      A code value that indicates that the observation is that of body position.
   d. This observation **SHALL** contain zero or more [0..*] **`value`** with data type CE

      A coded value that indicates the body position for the subject when the vital sign measurement was recorded.

   INLINE

9. **MAY** contain zero or one [0..1] **`entryRelationship`**
   a. Contains **`@typeCode="`**`REFR"` *REFR*
   b. Contains exactly one [1..1] *Event Study Day* (templateId: `2.16.840.1.113883.10.20.23.59`)
10. **SHOULD** contain zero or one [0..1] **`effectiveTime`** with data type TS
    - The date time on which the measurement was taken.
11. **MAY** contain zero or one [0..1] **`entryRelationship`**
    a. Contains **`@typeCode="`**`REFR"` *REFR*
    b. Contains exactly one [1..1] *Planned Study Day* (templateId: `2.16.840.1.113883.10.20.23.63`)
12. **MAY** contain zero or one [0..1] **`entryRelationship`**
    a. Contains **`@typeCode="`**`REFR"` *REFR*
    b. Contains exactly one [1..1] *Timing Reference* (templateId: `2.16.840.1.113883.10.20.23.70`)
13. **MAY** contain zero or one [0..1] **`entryRelationship`**
    a. Contains **`@typeCode="`**`COMP"` *COMP*
    b. Contains exactly one [1..1] *Non Performance Reason* (templateId: `2.16.840.1.113883.10.20.23.62`)

sdtm::Vital Sign							
cda::observation[cda:templateId/@root = 2.16.840.1.113883.10.20.23.7]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
classCode	@classCode	1..1	SHALL	NO	ActClassObservation		ALRT
moodCode	@moodCode	1..1	SHALL	NO	x_ActMoodDocumentObservation		DEF
negationInd	@negationInd	0..1		NO	Boolean		
nullFlavor	@nullFlavor	0..1		NO	NullFlavor		ASKU

sdtm::Vital Sign							
cda::observation[cda:templateId/@root = 2.16.840.1.113883.10.20.23.7]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
code	code	1..1	SHALL	YES	CD		NCI Thesaurus 2.16.840.1.113883.3.26.1.1 null
derivationExpr	derivationExpr	0..1		YES	ST		
effectiveTime	effectiveTime	0..1	SHOULD	YES	TS		
id	id	0..*		YES	II		
interpretationCode	interpretationCode	2..2	SHALL	YES	CE		TrialDataIntepretations null null
languageCode	languageCode	0..1		YES	CS		
methodCode	methodCode	0..*		YES	CE		
priorityCode	priorityCode	0..1		YES	CE		
realmCode	realmCode	0..*		YES	CS		
repeatNumber	repeatNumber	0..1		YES	IVL_INT		
statusCode	statusCode	1..1	SHALL	YES	CS		HL7ActStatus 2.16.840.1.113883.5.14
targetSiteCode	targetSiteCode	0..1	MAY	YES	CD		
templateId	templateId	0..*		YES	II		2.16.840.1.113883.10.20.23.7
text	text	0..1		YES	ED		
value	value	0..2	MAY	YES	ANY		
associatedPosition	associatedPosition	0..1	MAY	YES	associatedPosition		
author	author	0..*		YES	Author		
entryRelationship	entryRelationship	0..*		YES	EntryRelationship		
event Study Day	event Study Day	0..1	MAY	YES	Event Study Day		
informant	informant	0..*		YES	Informant12		
nonPerformanceReason	nonPerformanceReason	0..1	MAY	YES	Non Performance Reason		
participant	participant	0..*		YES	Participant2		
performer	performer	0..*		YES	Performer2		
planned Study Day	planned Study Day	0..1	MAY	YES	Planned Study Day		
precondition	precondition	0..*		YES	Precondition		
reference	reference	0..*		YES	Reference		
referenceRange	referenceRange	0..*		YES	ReferenceRange		
specimen	specimen	0..*		YES	Specimen		

sdtm::Vital Sign							
cda::observation[cda:templateId/@root = 2.16.840.1.113883.10.20.23.7]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
subject	subject	0..1		YES	Subject		
timingReference	timingReference	0..1	MAY	YES	Timing Reference		
typeId	typeId	0..1		YES	InfrastructureRootTypeId		

Vital Sign example

```
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 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd"
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 Thesaurus"/>
  <statusCode code="completed"/>
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  <targetSiteCode code="831757648"/>
  <entryRelationship typeCode="COMP">
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 codeSystemName="NCI Thesaurus"/>
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      <targetSiteCode code="1732866087"/>
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```

```
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      <targetSiteCode code="483772432"/>
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      <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
 Thesaurus"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <entryRelationship typeCode="COMP">
        <act classCode="ACT"/>
      </entryRelationship>
    </act>
  </entryRelationship>
  <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.9"/>
      <id root="501748383" extension="MDHT"/>
      <code code="TBD" codeSystem="2.16.840.1.113883.3.26.1.1"
 codeSystemName="NCI Thesaurus"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <value xsi:type="CE" code="444544132"/>
      <interpretationCode code="651471208"/>
      <targetSiteCode code="175848644"/>
    </observation>
  </entryRelationship>
</observation>
```

Chapter 5

OTHER CLASSES

Topics:

- *Consumable Material*
- *Study Finding Evaluator*
- *Study Test Performer*

This section of the Implementation Guide describes other classes that are not CDA Clinical Documents, Sections, or Clinical Statements.

Consumable Material

[Consumable: templateId `2.16.840.1.113883.10.20.23.55`]

This resusable structure captures information for medicinal substances tested in trials and/or substances consumed by trial subjects.

1. **SHALL** contain zero or one [0..1] **`@typeCode`**="CSM"
2. **SHALL** contain zero or one [0..1] **`manufacturedProduct`**
   a. This manufacturedProduct **SHALL** contain exactly one [1..1] **`@classCode`**="MANU"
   b. This manufacturedProduct Contains exactly one [1..1] **`manufacturedMaterial`**
      a. This manufacturedMaterial **SHALL** contain exactly one [1..1] **`@classCode`**="MMAT"
      b. This manufacturedMaterial Contains exactly one [1..1] **`@determinerCode`**="KIND"
      c. This manufacturedMaterial **SHALL** contain exactly one [1..1] **`code`**

         The code attribute captures information about the nature of the drug, medication or therapy. Within SDMT, medication information can appear as a concommitant medication, as the study medication within the exposure domain, or as a substance that is used. {SDTM: CMTRT, CMMODIFY, CMDECOD, EXTRT, SUTRT, SUMODIFY, SUDECOD]
      d. This manufacturedMaterial **MAY** contain zero or one [0..1] **`lotNumberText`**

         The lot number is relevant when information regarding the study treatment is provided. [SDTM: EXLOT]
      e. This manufacturedMaterial **SHALL** satisfy: The vebatim medication name is captured as the original text property within the material.code attribute.
      f. This manufacturedMaterial **SHALL** satisfy: The standardized or dictionary-derived text description of the medication is captured as the code property of the translation within the material.code attribute. Code system OID must be valued as well.
      g. This manufacturedMaterial **SHALL** satisfy: If the text description is modified to facilitate coding, the modified name is captured as the original text property of the translation within the material.code attribute.

sdtm::Consumable Material							
cda::consumable[cda:templateId/@root = 2.16.840.1.113883.10.20.23.20]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
nullFlavor	@nullFlavor	0..1		NO	NullFlavor		ASKU
typeCode	@typeCode	0..1	SHALL	NO	ParticipationType		CSM
realmCode	realmCode	0..*		YES	CS		
templateId	templateId	0..*		YES	II		2.16.840.1.113883.10.20.23.20
manufacturedProduct	manufacturedProduct	1..1		YES	ManufacturedProduct		
medication	medication	0..1	SHALL	YES	Medication		
typeId	typeId	0..1		YES	InfrastructureRootTypeId		

Consumable Material example

```
<?xml version="1.0" encoding="UTF-8"?>
<consumable xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd"
 typeCode="CSM">
  <templateId root="2.16.840.1.113883.10.20.23.20"/>
  <manufacturedProduct classCode="MANU">
    <manufacturedMaterial classCode="MMAT" determinerCode="KIND">
```

```
      <code code="1603200371"/>
      <lotNumberText>TEXT FOR LOT NUMBER TEXT</lotNumberText>
    </manufacturedMaterial>
  </manufacturedProduct>
</consumable>
```

Study Finding Evaluator

[Participant1: templateId `2.16.840.1.113883.10.20.23.73`]

Information on the performer of a test or other activity within the context of the study. Within SDTM, this is captured as vendor information.

1. **SHALL** contain exactly one [1..1] **`@typeCode`**`="PRF"`
2. Contains zero or one [0..1] **`roleOfEvaluator`** with data type *role Of Evaluator*

sdtm::Study Finding Evaluator							
cda::participant1[cda:templateId/@root = 2.16.840.1.113883.10.20.23.61]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
contextControlCode	@contextControlCode	0..1		NO	ContextControl		OP
nullFlavor	@nullFlavor	0..1		NO	NullFlavor		ASKU
typeCode	@typeCode	1..1	SHALL	NO	ParticipationType		ADM
functionCode	functionCode	0..1		YES	CE		
realmCode	realmCode	0..*		YES	CS		
templateId	templateId	0..*		YES	II		2.16.840.1.113883.10.20.23.61
time	time	0..1		YES	IVL_TS		
associatedEntity	associatedEntity	1..1		YES	AssociatedEntity		
roleOfEvaluator	roleOfEvaluator	0..1		YES	roleOfEvaluator		
typeId	typeId	0..1		YES	InfrastructureRootTypeId		

Study Finding Evaluator example

```
<?xml version="1.0" encoding="UTF-8"?>
<participant1 xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd"
 typeCode="PRF">
  <templateId root="2.16.840.1.113883.10.20.23.61"/>
  <time>
    <low value="2012"/>
    <high value="2012"/>
  </time>
  <associatedEntity/>
</participant1>
```

Study Test Performer

[Participant1: templateId `2.16.840.1.113883.10.20.23.72`]

Information on the performer of a test or other activity within the context of the study. Within SDTM, this is captured as vendor information.

1. **SHALL** contain exactly one [1..1] **`@typeCode`**`="AUT"`

2. **SHALL** contain zero or one [0..1] **`roleOfPerformer`**
   a. This roleOfPerformer **SHALL** contain zero or one [0..1] **`@classCode`**="ASSIGNED"
   b. This roleOfPerformer **SHALL** contain zero or one [0..1] **`performer`**
      a. This performer **SHALL** contain zero or one [0..1] **`@classCode`**="ORG"
      b. This performer **SHALL** contain zero or one [0..1] **`@determinerCode`**="INSTANCE"
      c. This performer **SHALL** contain zero or more [0..*] **`name`**

      The name of the "vendor" that performed the test. [SDTM: LBNAM]

sdtm::Study Test Performer							
cda::participant1[cda:templateId/@root = 2.16.840.1.113883.10.20.23.60]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
contextControlCode	@contextControlCode	0..1		NO	ContextControl		OP
nullFlavor	@nullFlavor	0..1		NO	NullFlavor		ASKU
typeCode	@typeCode	1..1	SHALL	NO	ParticipationType		ADM
functionCode	functionCode	0..1		YES	CE		
realmCode	realmCode	0..*		YES	CS		
templateId	templateId	0..*		YES	II		2.16.840.1.113883.10.20.23.60
time	time	0..1		YES	IVL_TS		
associatedEntity	associatedEntity	1..1		YES	AssociatedEntity		
roleOfPerformer	roleOfPerformer	0..1	SHALL	YES	roleOfPerformer		
typeId	typeId	0..1		YES	InfrastructureRootTypeId		

Study Test Performer example

```
<?xml version="1.0" encoding="UTF-8"?>
<participant1 xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd"
 typeCode="AUT">
  <templateId root="2.16.840.1.113883.10.20.23.60"/>
  <time>
    <low value="2012"/>
    <high value="2012"/>
  </time>
  <associatedEntity/>
</participant1>
```

Chapter 6

VALUE SETS

Topics:

- *Administrative Gender Type*
- *Adverse Event Category*
- *Adverse Event Pattern Type*
- *Adverse Event Sub-Category*
- *Adverse Event Type*
- *Body Position Type*
- *Body Site Type*
- *Body System/Organ Class Type*
- *Concurrent Medication Category*
- *Concurrent Medication Indication Tyhpe*
- *Concurrent Medication Sub-Category*
- *Disposition Category*
- *Disposition Item Type*
- *Disposition Sub-Category*
- *Drug Accountability Category*
- *Drug Accountability Finding Type*
- *Drug Accountability Sub-Category*
- *ECG Lead Location*
- *ECG Test Result Category*
- *ECG Test Result Sub-Category*
- *ECG Test Result Type*
- *Ethnic Group*
- *Evaluator Role Type*
- *Event Severity Type*
- *Exposure Category*
- *Exposure Sub-Category*
- *Finding About Category*
- *Finding About Finding Type*
- *Finding About Object Type*
- *Finding About Sub-Category*
- *Inclusion/Exclusion Criteria Category*

The following tables summarize the value sets used in this Implementation Guide.

- *Inclusion/Exclusion Criteria Sub-Category*
- *Inclusion/Exclusion Criteria Type*
- *Laboratory Test Result Category*
- *Laboratory Test Result Sub-Category*
- *Laboratory Test Result Toxicity Scale*
- *Laboratory Test Type*
- *Medical History Category*
- *Medical History Item Type*
- *Medical History Sub-Category*
- *Medication Item Type*
- *Microbiology Finding Category*
- *Microbiology Finding Sub-Category*
- *Microbiology Finding Type*
- *Microbiology Result Finding Category*
- *Microbiology Susceptibility Finding Category*
- *Microbiology Susceptibility Finding Sub-Category*
- *Microbiology Susceptibility Finding Type*
- *Microbiology Susceptibility Result Category*
- *Non Performance Type*
- *Pharmacokinetics Concentration Category*
- *Pharmacokinetics Concentration Finding Type*
- *Pharmacokinetics Concentration Sub-Category*
- *Pharmacokinetics Parameter Category*
- *Pharmacokinetics Parameter Finding Type*
- *Pharmacokinetics Parameter Sub-Category*
- *Physical Exam Finding Category*
- *Physical Exam Finding Sub-Category*
- *Physical Exam Finding Type*
- *Question Type*
- *Questionnaire Category*
- *Questionnaire Sub-Category*

- *Race*
- *Route Type*
- *Serious Event*
- *Specimen Condition Type*
- *Specimen Type*
- *Study Arm Type*
- *Subject Characteristic Category*
- *Subject Characteristic Sub-Category*
- *Subject Characteristic Type*
- *Substance Use Category*
- *Substance Use Sub-Category*
- *Test Method Type*
- *Toxicity Grade Type*
- *Toxicity Measure Type*
- *Vital Sign Type*

Administrative Gender Type

Value Set	Administrative Gender Type
Description	The different relevant values for capturing a study subject's gender.

Adverse Event Category

Value Set	Adverse Event Category
Description	Captures the list of categories for adverse events.

Adverse Event Pattern Type

Value Set	Adverse Event Pattern Type
Description	A list of different patterns that can be assigned to an adverse event.

Adverse Event Sub-Category

Value Set	Adverse Event Sub-Category
Description	Captures the list of sub-categories for adverse events.

Adverse Event Type

Value Set	Adverse Event Type
Description	A list of adverse event types. Use MeDRA as the code system for adverse events.

Body Position Type

Value Set	Body Position Type
Description	A list of relevant body positions.

Body Site Type

Value Set	Body Site Type
Description	Captures the list of relevant body sites.

Body System/Organ Class Type

Value Set	Body System/Organ Class Type
Description	Captures the list of body systems and organ types.

Concurrent Medication Category

Value Set	Concurrent Medication Category
Description	A list of categories used for organizing concurrent medications.

Concurrent Medication Indication Tyhpe

Value Set	Concurrent Medication Indication Tyhpe
Description	A list of possible reasons for a subject's use of a medication item.

Concurrent Medication Sub-Category

Value Set	Concurrent Medication Sub-Category
Description	A list of sub-categories used for organizing concurrent medications.

Disposition Category

Value Set	Disposition Category
Description	A list of categories used for organizing dispositions.

Disposition Item Type

Value Set	Disposition Item Type
Description	A list of possible types of study subject disposition.

Disposition Sub-Category

Value Set	Disposition Sub-Category
Description	A list of sub-categories used for organizing dispositions.

Drug Accountability Category

Value Set	Drug Accountability Category
Description	A list of categories used to organize drug accountability information.

Drug Accountability Finding Type

Value Set	Drug Accountability Finding Type
Description	A list of the different valid drug accountability findings.

Drug Accountability Sub-Category

Value Set	Drug Accountability Sub-Category
Description	A list of categories used to organize drug accountability information.

ECG Lead Location

Value Set	ECG Lead Location
Description	A list of possible location types used for ECG leads.

ECG Test Result Category

Value Set	ECG Test Result Category
Description	A list of possible categories used to organize ECT test results.

ECG Test Result Sub-Category

Value Set	ECG Test Result Sub-Category
Description	A list of sub-possible categories used to organize ECT test results.

ECG Test Result Type

Value Set	ECG Test Result Type
Description	A list of possible test results generated by an ECG.

Ethnic Group

Value Set	Ethnic Group
Description	A list of the valid ethnic groups to be used when categorizing study subjects.

Evaluator Role Type

Value Set	Evaluator Role Type
Description	A list of possible study roles played by the evaluator of a result.

Event Severity Type

Value Set	Event Severity Type
Description	A list of possible values for event severity.

Exposure Category

Value Set	Exposure Category
Description	A list of categories used for organizing exposures.

Exposure Sub-Category

Value Set	Exposure Sub-Category
Description	A list of sub-categories used for organizing exposures.

Finding About Category

Value Set	Finding About Category
Description	A list of categories used for organizing finding about results.

Finding About Finding Type

Value Set	Finding About Finding Type
Description	A list of the different types of findings that may be captured within the SDTM Findings About domain.

Finding About Object Type

Value Set	Finding About Object Type
Description	A list of possible types of object of a findings about observation. SDTM offers the following examples: the term (such as Acne) describing a clinical sign or symptom that is being measured by a Severity test, or an event such as VOMIT where the volume of Vomit is being measured by a VOLUME test.

Finding About Sub-Category

Value Set	Finding About Sub-Category
Description	A list of sub-categories used for organizing finding about results.

Inclusion/Exclusion Criteria Category

Value Set	Inclusion/Exclusion Criteria Category
Description	A list of categories used for organizing Inclusion/Exclusion criteria.

Inclusion/Exclusion Criteria Sub-Category

Value Set	Inclusion/Exclusion Criteria Sub-Category
Description	A list of sub-categories used for organizing Inclusion/Exclusion criteria.

Inclusion/Exclusion Criteria Type

Value Set	Inclusion/Exclusion Criteria Type
Description	A list of the possible types of inclusion or exclusion criteria for a subject's participation in a study.

Laboratory Test Result Category

Value Set	Laboratory Test Result Category
Description	A list of categories used for organizing laboratory tests.

Laboratory Test Result Sub-Category

Value Set	Laboratory Test Result Sub-Category
Description	A list of sub-categories used for organizing laboratory tests.

Laboratory Test Result Toxicity Scale

Value Set	Laboratory Test Result Toxicity Scale
Description	A list of the types of toxicity scale that can be used as the scale for measuring the toxicity of a laboratory result.

Laboratory Test Type

Value Set	Laboratory Test Type
Description	A list of the different types of lab tests that can be recorded. These test codes are used when the proper LOINC code is not know.

Medical History Category

Value Set	Medical History Category
Description	A list of categories used for organizing medical history items.

Medical History Item Type

Value Set	Medical History Item Type
Description	A list of possible items recorded as part of a study subject's medical history

Medical History Sub-Category

Value Set	Medical History Sub-Category
Description	A list of sub-categories used for organizing medical history items.

Medication Item Type

Value Set	Medication Item Type
Description	A list of possible substances that are used and/or referred to in the concurrent medication, exposure, and substance use domains.

Microbiology Finding Category

Value Set	Microbiology Finding Category
Description	A list of categories used for organizing microbiology specimen related tests.

Microbiology Finding Sub-Category

Value Set	Microbiology Finding Sub-Category
Description	A list of sub-categories used for organizing microbiology specimen related tests.

Microbiology Finding Type

Value Set	Microbiology Finding Type
Description	A list of types of microbiology specimen related finding.

Microbiology Result Finding Category

Value Set	Microbiology Result Finding Category
Description	A list of categories used to organize specimen related microbiology results.

Microbiology Susceptibility Finding Category

Value Set	Microbiology Susceptibility Finding Category

Description	A list of categories used for organizing microbiology susceptibility tests.

Microbiology Susceptibility Finding Sub-Category

Value Set	Microbiology Susceptibility Finding Sub-Category
Description	A list of sub-categories used for organizing microbiology susceptibility tests.

Microbiology Susceptibility Finding Type

Value Set	Microbiology Susceptibility Finding Type
Description	A list of types of microbiology susceptibility related finding.

Microbiology Susceptibility Result Category

Value Set	Microbiology Susceptibility Result Category
Description	A list of categories used for organizing microbiology susceptibility results.

Non Performance Type

Value Set	Non Performance Type
Description	A list of the possible reasons for not performing an obseration or collecting a pre-defined information item.

Pharmacokinetics Concentration Category

Value Set	Pharmacokinetics Concentration Category
Description	A list of categories used for organizing pharmacokinetic concentration findings.

Pharmacokinetics Concentration Finding Type

Value Set	Pharmacokinetics Concentration Finding Type
Description	A list of the different types of pharmacokinetics concentration findings.

Pharmacokinetics Concentration Sub-Category

Value Set	Pharmacokinetics Concentration Sub-Category
Description	A list of sub-categories used for organizing pharmacokinetic concentration findings.

Pharmacokinetics Parameter Category

Value Set	Pharmacokinetics Parameter Category
Description	A list of the different types of pharmacokinetics parameter findings.

Pharmacokinetics Parameter Finding Type

Value Set	Pharmacokinetics Parameter Finding Type
Description	A list of categories used for organizing pharmacokinetic parameter findings.

Pharmacokinetics Parameter Sub-Category

Value Set	Pharmacokinetics Parameter Sub-Category
Description	A list of sub-categories used for organizing pharmacokinetic parameter findings.

Physical Exam Finding Category

Value Set	Physical Exam Finding Category
Description	A list of categories used for organizing physical exam findings.

Physical Exam Finding Sub-Category

Value Set	Physical Exam Finding Sub-Category
Description	A list of sub-categories used for organizing physical exam findings.

Physical Exam Finding Type

Value Set	Physical Exam Finding Type
Description	A list of the different types of physical exam finding.

Question Type

Value Set	Question Type
Description	A list of the different questions that may be included on a questionnaire.

Questionnaire Category

Value Set	Questionnaire Category
Description	A list of categories used for organizing questionnaire results.

Questionnaire Sub-Category

Value Set	Questionnaire Sub-Category
Description	A list of sub-categories used for organizing questionnaire results.

Race

Value Set	Race
Description	A list of the valid race codes to be used when categorizing study subjects.

Route Type

Value Set	Route Type
Description	A list of the possible routes of adminstration for a substance.

Serious Event

Value Set	Serious Event
Description	A listing of different types of event that are considered to be serious.

Specimen Condition Type

Value Set	Specimen Condition Type
Description	A list of different possible values for specimen condition.

Specimen Type

Value Set	Specimen Type
Description	A list of different specimen types.

Study Arm Type

Value Set	Study Arm Type
Description	A list of valid values to be used for categorizing study arms.

Subject Characteristic Category

Value Set	Subject Characteristic Category
Description	A list of categories used for organizing subject characteristic findings.

Subject Characteristic Sub-Category

Value Set	Subject Characteristic Sub-Category
Description	A list of sub-categories used for organizing subject characteristic findings.

Subject Characteristic Type

Value Set	Subject Characteristic Type
Description	A list of different types of subject characteristic.

Substance Use Category

Value Set	Substance Use Category
Description	A list of categories used for organizing substance uses.

Substance Use Sub-Category

Value Set	Substance Use Sub-Category
Description	A list of sub-categories used for organizing substance uses.

Test Method Type

Value Set	Test Method Type
Description	A list of valid types of test method. Within SDTM, the code system is used within the ECG Test, Lab Test, Physical Exam, microbiology specimen, microbiology susceptibility, and pharmacokinetics domains.

Toxicity Grade Type

Value Set	Toxicity Grade Type
Description	A list of possible values for toxicity grade.

Toxicity Measure Type

Value Set	Toxicity Measure Type
Description	A list of the different toxicity scales, e.g., Common Terminology Criteria for Adverse Events (CTCAE), that could be used to record the toxicity of an event.

Vital Sign Type

Value Set	Vital Sign Type
Description	A list of supported types of vital sign.

REFERENCES

- CDISC Submission Data Standards Team. Study Data Tabulation Model Implementation Guide: Human Clinical Trials Available at: *www.CDISC.org*
- Dolin RH, Alschuler L, Boyer S, Beebe C, Behlen FM, Biron PV, Shabo A, (Editors). HL7 Clinical Document Architecture, Release 2.0. ANSI-approved HL7 Standard; May 2005. Ann Arbor, Mich.: Health Level Seven, Inc. Available through *HL7* or if an HL7 member with the following link: *CDA Release 2 Normative Web Edition.*
- *LOINC®* : Logical Observation Identifiers Names and Codes, Regenstrief Institute.
- Extensible Markup Language, *www.w3.org/XML* .
- Dolin RH, Alschuler L, Boyer S, Beebe C, Behlen FM, Biron PV, Shabo A., HL7 Clinical Document Architecture, Release 2. J Am Med Inform Assoc. 2006;13:30-39. Available at: *http://www.jamia.org/cgi/reprint/13/1/30* .