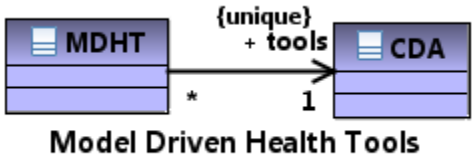
Implementation Guide for CDA Release 2

Subject Study Data

Human Clinical



Model Driven Health Tools

FDA Draft Document

Contents

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.

Revision History

Rev	Date	By Whom	Changes
New	March 2012	Mead Walker	Create a draft document.
Revise	July 2012	Mead Walker	Update draft to include SDTM and SEND content in a single document.
Revise	August 2012	Mead Walker	Create independent SDTM and SEND documents. Update the content.
Revise	September 2012	Mead Walker	Update the SDTM and SEND documents based on review. Improve explanatory sections, QA template content, create more consistent and correct vocabulary references.

Chapter 1

INTRODUCTION

Topics:

Overview

A subject data report captures information regarding the experience of a subject within a study or trial. 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 this 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. The goal is to provide a common format, and a common set of semantics for reporting trial data. Achievement of this goal will make it easier to evaluate the success of an individual study, and will greatly increase reviewer's and researcher's ability to compare data across multiple studies.

The reader should note that reporting on clinical trial subjects is structured through creation of a individual CDA compliant document instance for each trial subject's experience. This outcome is conditioned by the basic principal of CDA that an individual document normally reports on the experience of a single record target (aka patient.) A corollary of this principle is that the report on a clinical trial will consist of a series of clinical documents, one for each study subject.

This Implementation Guide focuses includes the content defined within the SDTM specification. However, it has been constructed within a model driven environment including the data structures needed for reporting the results of both human and non-human studies. Working within a single environment has reduced the overall effort since many data structures are shared across the two reporting traditions. It is also expected that, use of a model driven development tool will ease the task of implementation through use of tooling products beyond this guide.

Implementation Guide Scope

The scope of this Implementation Guide, which relies on the Clinical Document Architecture, is intended to allow communication of the relevant information captured for a study subject during the conduct of the study. Although this specification can be used for company-to-company communication, the initial intent is for communication from applicant to regulatory authority.

Approach

HL7's Clinical Document Architecture (CDA) has been chosen to define the format and structure of the subject data report. The goal is to use a widely accepted approach to supporting clinical data that is sufficiently expressive to support the wide range of data requirements seen in the study setting. However, there are data requirements of subject data reporting that require adding extensions to CDA. The process for accomplishing this is discussed below.

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 will be accepted by FDA as a recognized format for data submissions. It is under consideration for balloting as a Draft Standard for Trial Use through Health Level Seven (HL7).

Coded concepts used within this guide are managed by the National Cancer Institute using its Enterprise Vocabulary Services (EVS).

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. CDA is an Health Level 7 Version 3 specification. It uses a schema and data structure defined by the CDA specification and by the HL7 Reference Information Model.

The formatting of data within the structure rests on the HL7 Data Types Release 1 specification. Refer to the HL7 Normative Edition for more information on these topics.

Implementation Guide Structure

The Human Subject Data Report is a typical CDA implementation guide, and its content can be divided into three categories:

- **Document Header**: Information about the document being transmitted, the document subject, and the parties taking responsibility for it. The guide includes document identification, specification of the responsible party for the document – its author, specification of a custodian for the document – the study sponsor, the study subject the report refers to, and identification of the study that subject activity occurs within.
- **Document Body**: The document body defines the section or sections a document is divided into. The sections of the document are based on the domains defined by CDISC in the SDTM Implementation Guide. Each section is rooted in a single SDTM domain. The section will **only** contain content associated with other domains if that domain's data is nested within the domain primary domain - this is defined within the template for that domain. Note, locally defined or new domains can be created by using the generic Study Subject Event, Study Subject Finding or Study Subject Intervention domain templates. The content provided for this single domain is captured as one or more document entries. The section is also expected to contain a text representation of the structured content contained in the document entries.
- **Document Entries**:The functional content of the Subject Data Report consists of the document entries. Within the CDA model, the content of an entry is defined using an HL7 structure known as “clinical statement”. A clinical statement consists of a base specialization of the Act class, e.g., observation, substance administration, procedure, in the HL7 RIM, but may also include additional associated acts in order to fill out needed slots for data. Entry types – templates – have been defined for each domain within SDTM. There are also entry types that represent data structures within SDTM that are reused across the various domains.

Note: In addition to supporting the domains that have been defined for SDTM, the Implementation Guide includes 3 generic domains: Findings, Events, and Interventions. When submitters need to provide material that goes beyond the currently defined scope, these structures can be used to create "custom" domains.

Within the context of the implementation guide, every conformant document will consist of a single header, and will normally contain several sections. A section will contain several entries, some of which are directly tied to the section, others which are used by a containing entry.

All of the structures discussed above are defined as templates within the Implementation Guide. The use of templates – also discussed below – is virtually mandated by the design of the MDHT tooling. In addition, identifying templates within document instances is relied upon by some implementation techniques.

The content of the document sections within the report comprise the heart of the document. These sections – listed below are based, for the most part, on the domains defined within the SDTM Implementation Guide. The reader will note that, while the SDTM and SEND implementation guides share a number of domains, this document creates specialized templates, e.g., Non-human Disposition, for some of them. That has been done because the content of domains with the same name differs between the SDTM and SEND documents. Specialized templates were created when those differences seemed particularly large.

- **Demographics Section**: Additional information on the study subject. The section contains a template based on the Demographics domain.
- **Subject Element Section**: The section draws on the named domain within SDTM.
- **Visit Section**: The section draws on the study visits domain. It also supports the notion that much human clinical subject data is collected during a visit, and organized in terms of that visit. Therefore, those SDTM domains in which visit number is collected are recorded within the context of a containing visit. That is, their templates are nested within the visit template, and do not have their own sections. The following templates are nested within the visit template: ECG Test, Human Clinical Laboratory, Physical Examination, Questionnaire Finding, Vital Sign, Pharmacokinetic Concentration, Pharmacokinetic Parameter, Drug Accountability. For the data in these SDTM domains, we assume that a visit number will always be present.
- **Concurrent Medication Section**: The section contains a template based on the Concurrent Medication domain.

- **Exposure Section**: Information on use of the study substance. The section contains a template based on the Exposure domain.
- **Substance Use Section**: The section contains a template based on the Substance Use domain. It records information about relevant substances the subject is consuming.
- **Adverse Event Section**: The section draws on the named domain. It records information for any adverse events suffered by the study subject.
- **Disposition Section**: The section draws on the named domain.
- **Medical History Section**: The section draws on the named domain.
- **Protocol Deviation Section**: The section draws on the named domain.
- **Clinical Event Section**: The section draws on the named domain.
- **Inclusion/Exclusion Criteria**: The section draws on the named domain.
- **Subject Characteristics Section**: The section draws on the named domain.
- **Comment Section**: The section draws on the named domain. The section contains comments related generally to the subject's participation in the study. More specific comments may be added – based on the defined template used in the particular section.
- **Custom Domain Section**: The custom domain section is provided to allow data to be provided within domains that have not been included within the SDTM Implementation Guide. This implementation supports that requirement by providing a set of generic templates based directly on the Study Data Tabulation Model. These templates: Study Subject Event, Study Subject Finding, and Study Subject Intervention are to be used for the supplying any data that is not supported by one of the existing domains.

Review of the Implementation Guide will show a number of templates not based on SDTM domains. These templates represent data structures that are reused across several domains. They can also be used when a general section is used with a custom domain. The content of each template is discussed within the Templates Sections.

Relevant HL7 Version 3 Material

This implementation guide - as with any CDA product makes use of data structures defined in the HL7 RIM and in the HL7 data type specifications. It also makes use of the vocabulary principles defined by HL7.

Working with the HL7 data structures

Implementing and working with HL7 data structures is not always intuitive, and some of the types are used in particular ways for this Implementation Guide. These issues are discussed below.

- **Working with Act Identifier**: Identifiers – the attribute "id" – are implemented with the instance identifier (II) data type. This type has two properties: root – which identifies the namespace from which an identifier value is drawn, and extension – which carries the identifier itself. Most of the identifiers used within this guide are identified as "sequence numbers" they are used within an SDTM or SEND domain to keep track of individual records, and are only meaningful within the context of a single report. It would be both burdensome and unnecessary to attempt to identify the name space (Wikipedia: A namespace (sometimes also called a name scope) is an abstract container or environment created to hold a logical grouping of unique identifiers or symbols (i.e., names). An identifier defined in a namespace is associated only with that namespace. The same identifier can be independently defined in multiple namespaces.) for the identifier. In such cases, the HL7 null indicator should be valued as "NI" – No information. Note, the subject data report also includes unique subject identifiers as well as identifiers for the study and the study sponsor. If reporters are, practically speaking, unable to manage the assignment of object identifiers to these namespaces, it is possible to make use of a GUID, or to use a generic OID that indicates the type of identifier being provided.

  For example:

```
<id root=”1.9.9.9” extension=”12348899B”/>
```

Note that the id element may appear in a number of different contexts, e.g., within observation, within role.

- **Working with Act Code**: A great number of the important concepts within subject data reporting, e.g., adverse event, subject age, whether an item was predefined on a CRF, a body weight observation are modeled as acts or as specializations of act, e.g., observation, within CDA. In such cases, the attribute act.code (observation.code) is evaluated to discover what kind of information is being passed. In SEND and SDTM, these items often occur as records within a domain with data items identified as –TESTCD = an identifying code, -TEST = a text or verbatim description, -MODIFY = a modified term for the item. These concepts should be supported within the CD data type by using the CD code property for the code value. Text values which are simply descriptive text for a code use the display Name property, while verbatim text uses the original Text property. Modified terms – whether code or text should use the translation property of the CD type. Note, any time a code value is used within the CD or CE data types, the code system the code is drawn from should be identified. If the code system is centrally managed, within NCI EVS, the OID to be used can be looked up within this document.

  For example:

```
<code code="C66734" displayName="Domain Abbreviation"
 codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus"/>
```

```
<code code="-TESTCD" displayName="TESTCD Description" codeSystem="2.9.9.9">
<originalText mediaType="text/plan">-TEST</originalText>
<translation code="-MODIFY" codeSystem="2.9.9.10"/>
</code>
```

  Note that the code element will appear within an act - observation, or procedure - or within an entity - person, organization, or manufactured material, e.g., within observation, within role.

- **Working with Physical Quantity**: HL7 defines a physical quantity as “A dimensioned quantity expressing the result of measuring.” There is a general expectation that all such quantities will use a single scheme for expressing units of measure – the Unified Code for Units of Measure. However, it is possible to refer to alternate representations of the units using the Physical Quantity Representation (PQR) data type. Physical quantities in this guide will use the PQR type, so that it is possible to distinguish between the use of standard and localized units of measure.

  HL7 recommends the use of the UCUM (Unified Codes of Measure) specification for use in physical quantities. Within this guide, UCUM items are represented using the unit concept IDs provided by the NCI EVS.

  For example:

```
<value xsi:type="PQR" value="64.4625" code="C49670" displayName="MMHG"
codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus"/>
<!-- A quantity using CDISC Units of measure  -->
```

  Note that quantities can be passed using either CDISC or local units of measure. The physical quantity usually, but not always, appears as an observation value.

- **Working with Observation Value**: The HL7 Reference Information Model uses a single attribute – observation.value – to capture the result of any observation. In order to implement this attribute within an XML schema, it is necessary to use the xs:type property to designate the particular data type to be used. Within SDTM and SEND, findings and event descriptions are provided as either numeric values (what HL7 would treat as a physical quantity given the presence of units of measure)or as character (text) values. In addition, the data is

characterized as original – with original units or locally controlled text values – or as normalized – with standard units of measure or "normalized" character based content. Within the subject data report, multiple expressions of a result should be managed as multiple instances of the value attribute. The type, numeric, physical quantity, coded, or text is given by the xsi:type property. The use of standard or local units of measure is expressed by the OID the code system within the unit of measure – see below. Similarly, the use of local or standard codes is indicated by the OID for the code system of the code being passed. Note, all the standard codes are supported as concepts within NCI EVS. The OID for the EVS can be used, without exception, when NCI EVS concept IDs are being provided to identify the concept in question.

For example:

```
<value xsi:type="PQR" value="64.4625" code="MMHG"   codeSystem="1.22.115"/>
<!-- Result using original units of measure.  -->
<value xsi:type="PQR" value="64.4625" code="C49670" displayName="MMHG"
codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus"/>
<!-- Result using CDISC Units of measure  -->
<value xsi:type="ED" mediaType="text/plain">64.4625</value>
```

Note that not all of the different representations of the result are required. Also, the result may be a coded value as opposed to a physical quantity.

- **Working with Effective Time**: The HL7 effective time attribute is used for all varieties of acts to express the time or times of either relevance or occurrence. The attribute can be used to express a time point, a time interval or a collection of time points (i.e., a frequency). The implementation guide defines how to use this attribute to capture the different timing expressions currently used in subject data reporting (as defined for SEND and SDTM).

  Here is an example of a point in time.

```
<effectiveTime value="20120704"/>
```

  Here is an example of a time interval.

```
<effectiveTime>
 <low value="19990517"/>
 <high value="19990524"/>
</effectiveTime>
```

  Here is an example of a intervention frequency in which both the periodicity of the intervention and its start and stop time points are shown..

```
<effectiveTime xsi:type="SXPR_TS">
 <comp xsi:type="IVL_TS">
  <low value="1990517"/>
  <high value="1990523"/>
 </comp>
 <comp xsi:type="PIVL_TS" operator="A">
  <period value="24" unit="h"/>
 </comp>
</effectiveTime>
```

  These details are also where applicable for a data element.

- **Working with Interpretation Code**: In the HL7 RIM, the interpretation code "provides a qualitative interpretation of the observation". The code is used, for example, with laboratory results to express the relationship of a result to the normal values. However, it also used more broadly within subject data reporting to express the notions of baseline flag, derived value flag, and exclusion flag that are seen in SDTM and SEND.

HL7 Vocabulary Concepts

The HL7 approach to organizing vocabulary is oriented around three concepts:

- **Concept Domain**: A named category of like concepts (a semantic type) that will be bound to one or more attributes in a static model whose data types are coded. HL7 specifications define concept domains for each coded attribute - in CDA these assignmens are extremely general. The implementation guide has to get more specific in order to guide implementation.
- **Code System**: A collection of coded concepts. each having associated designations and meanings. Code systems assign definite codes to individual, useful concepts. Two key points are: 1) Effective and useful interoperability requires sharing of codes for important concepts. 2(Code systems are managed by a sponsoring party. Having a unified code system managed by a single, agreed upon source is a key goal for integrating subject data from studies.
- **Value Set**: A uniquely identifiable set of valid concept representations (AKA code), where any concept representation can be tested to determine whether or not it is a member of the value set. The value set lists those codes which are relevant to a particular purpose, it provides the specification for implementation.

The Implementation Guide lists the collection of value sets needed to support subject data reporting. Many of these - in fact wherever feasible - are drawn from the NCI Enterprise Vocabulary Services. However, others are listed as defined by the study sponsor. In these cases, it is best to think of the study sponsor as creating their own local code system for some need, perhaps a set of exposure categories. The value set that is used will simply be the content of that code system. Given this double identity, it is not necessary to define both code system and value set in cases where the collection of contained codes is identical.

Additional Vocabulary considerations

HL7's Clinical Document Architecture takes a very general approach to vocabulary issues. It encourages the development of templates to express structures for which definite conformance rules are defined, and which may repeat both across documents and within a single document. The CDA also identifies coded attributes - those attributes whose value is expected to be drawn from a defined vocabulary or code set. In addition, the CDA schema includes a special feature - the observation (a class drawn from the HL7 information model)- which can be used to convey virtually any type of information. Within the observation, the content of *observation code* tells you what kind of information is included, and the content of *observation value* gives you the information itself. CDA does not, and cannot, define the types of observation which are relevant.

A key role of the implementation guide is to provide the additional detail that is needed. It defines:

- the set of requirements, the list of observation types that are needed. Each needed observation or act type will be supported within NCI EVS, and its content will be expressed as an EVS concept code within the subject data document.
- the collection of value sets(code tables) needed to properly define allowable values for the coded attributes used for conveying study subject. Some of the value sets that are used are centrally managed, and are housed – or to be housed – within the NCI EVS. Others are supplied by the study sponsor data.

The vocabulary section of the guide is designed to meet these two requirements. The vocabulary items not left to study sponsors are managed by NCI within the EVS Thesaurus. NCI EVS will provide a file for the Subject Data Report user community to be located at: *http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/fda.* Material at this site will contain all pertinent CDISC terminology subsets as well as additional value sets as needed. This material is available for download 24/7 and updates to terminology will be completed by the NCI EVS team. NC EVS currently provides terminology in Excel and Text formats.

The consistent use of vocabularies - of code systems and value sets - by study data submitters greatly improves the usefulness of the data, and makes it possible to compare data across submissions. However, there are situations in which the defined value set does not contain all the needed concepts. For this reason, the value sets used within this guide have been defined as extensible value sets. This means that data submitters are expected to use the given value set wherever possible. However the value set can be extended - additional code values may be provided when needed.

Supporting CDISC data structures

Building a CDA Implementation Guide that supports the content of an SDTM or SEND based submission involves the definition of translations or mappings between the data structures defined within the CDISC implementation guides and those supported by HL7's Clinical Document Architecture. This section focuses on areas where the relationships between the two sets of specifications are potentially unclear, and discusses the conventions used in the mapping

- **Subject Identifiers**: Each SEND and SDTM domain contains information to identify the subject of the data being provided. In CDA, a document has a single subject identified in the header. The identifier appears as a feature of the "patient" which is associated with the clinical document as its record target.

  For example:

```
<recordTarget typeCode="RCT">
  <patientRole classCode="PAT">
   <id root="1.11.1121" extension="COMPOUNDA_STUDY1_11951"/>
   <!-- We need an OID that says Unique Subject ID -->
   <id root="1.11.1122" extension="11951"/>
   <!-- We need an OID that says  Subject ID -->
   <patient classCode="PSN" determinerCode="INSTANCE">
   </patient>
  </patientRole>
 </recordTarget>
```

  Note, the root attribute within the id element is used to distinguish between the unique subject id and a study specific identifier.

- **Pool Identifier**: A pool, which only appears in SEND, is a group of subjects about which data is collected. In other words, a CDA instance will have either a single subject or a subject pool as its subject - as the record target. The pool id is treated in the same way as the subject id in the example above.

- **Collection Date/Time**: A finding can refer to a physical process or condition that takes place over a period of time, and the start and stop dates for a fact related to a subject, e.g., a disease or pattern of behavior, may be recorded as the effectiveTime for that act. It may also be relevant to capture the date/time on which this information was collected. The Implementation Guide handles this situation by defining a template - "Data Collection" - for capturing this information. This template also supports capturing the study day of data collection by including a "Study Day" observation which may be associated with the data collection one.

  For example:

```
<entryRelationship typeCode="COMP">
 <observation classCode="OBS" moodCode="EVN">
  <code code="CXXXXXX" codeSystem="2.16.840.1.113883.3.26.1.1"
 codeSystemName="NCI Thesaurus"/>
  <!-- Indicate data collection -->
  <effectiveTime value="1990508"/>
  <entryRelationship typeCode="REFR">
   <observation classCode="OBS" moodCode="EVN">
    <code code="ESDtbd" codeSystem="2.16.840.1.113883.3.26.1.1"
 codeSystemName="NCI Thesaurus"/>
    <!-- Indicate study day  -->
    <value xsi:type="INT" value="-16"/>
   </observation>
  </entryRelationship>
 </observation>
</entryRelationship>
```

Note, it may be relevant to capture both the start and stop dates of data collection and, consequently, the start and stop study days. In this case, an interval of effectiveTimes or of integer values may be used.

- **Test or Observation Names**:Virtually all SEND and SDTM domains contain information about something, be it a measurement, a test, a particular type of observation. The implementation guides make it possible to capture the name of an item, as well as short name, reported name, modified name and standardized name. Each of these is treated differently within CDA as discussed above in the section on Observation code.
- **Category and Sub-Category**: Many domains include the notion of category and sub-category. In each case, there is a domain specific value set(vocabulary)that contains the list of valid categories or sub-categories. For the most part these are sponsor defined. A single template has been defined for category, and an analogous one for sub-category. In this template, unlike many of the others, the value of observation code is not fixed, it indicates the domain that a category value is drawn from. In other words, the value set used to constrain observation value is based on the content of observation code.

  For example:

```
<entryRelationship typeCode="COMP">
 <observation classCode="OBS" moodCode="EVN">
  <code code="CXXXXX" codeSystem="2.16.840.1.113883.3.26.1.1"
 codeSystemName="NCI Thesaurus"/>
  <!-- Indicate this is a lab category observation.  -->
  <value xsi:type="CD" code="xxx" displayName="BLOOD CHEMISTRY"
 codeSystem="1.22.116"/>
  <!-- We need an OID to designate a local code system for lab result
 categories.  -->
 </observation>
</entryRelationship>
```

- **Baseline, Derived, Excluded Values**: A data item may be characterized as a baseline value, as a value that has been derived from other data points, or (in SEND) as a value to be excluded from calculations. Since these characterizations are used to aid in interpreting the associated data item, they are treated as interpretation codes within CDA.

  For example:

```
 <interpretationCode code="CXXXXX" codeSystem="2.16.840.1.113883.3.26.1.1"
 codeSystemName="NCI Thesaurus"/>
 <!-- The IG captures the Baseline designation as an interpretation code
 value. This requires the needed concept within NCI.  -->
```

  Note that, since interpretation code repeats, an item may be characterized in multiple ways. In the case of laboratory results, intpretation code values such as "normal," "high" may be passed as well.

- **Study Day of Start, Study Day of End**:In many cases, the timing of an event, intervention or finding is oriented both with reference to a calendar date and time but also to "study day". This captures the number of days since a reference date that has been set as the point of origin for the subject's participation in the study. Since events and interventions can take place over a number of days, it is possible to record both the beginning and ending study days.

  For example:

```
<entryRelationship typeCode="REFR">
 <observation classCode="OBS" moodCode="EVN">
```

```
  <code code="SDPtbd" codeSystem="2.16.840.1.113883.3.26.1.1"
 codeSystemName="NCI Thesaurus"/>
  <!-- Study Day Period -->
  <value xsi:type="IVL_INT">
   <low value="1"/>
   <high value="2"/>
  </value>
 </observation>
</entryRelationship>
```

- **Association to Reference Time Points**: One of the more complex notions within the study data tabulation model is the notion of relating an activity to a defined reference time point. It is possible to indicate when some act needs to be performed (or when it has been performed) as a timing offset from a reference point. This reference point may be assigned a date/time in its own right, or it may be a particular event, e.g., first dose of the study drug, in the course of the study or the life of the study subject. The Implementation Guides support this notion through creation of the "Timing Reference" template. This template contains two linked observations. The first specified the timing offset, and the second identifies the reference point - the "anchoring time point" - that the offset is measured against.

  For example:

```
<entryRelationship typeCode="REFR">
 <observation classCode="OBS" moodCode="EVN">
  <code code="TRtbd" codeSystem="2.16.840.1.113883.3.26.1.1"
 codeSystemName="NCI Thesaurus"/>
  <!-- Indicate "timing reference" -->
  <effectiveTime>
   <width value="15" unit="min"/>
   </effectiveTime>
  <entryRelationship typeCode="COMP">
   <observation classCode="OBS" moodCode="EVN">
    <code code="ATPtbd" codeSystem="2.16.840.1.113883.3.26.1.1"
 codeSystemName="NCI Thesaurus"/>
    <!-- Indicate "anchor time point" -->
    <text mediaType="text/plain>First Dose</text>
   </observation>
  </entryRelationship>
 </observation>
</entryRelationship>
```

- **Results: Character and Numeric**: The explanatory text for the CDISC implementation guides makes it clear that finding results typically are recorded as physical quantities using standard and local units of measure. It is also possible for a result to be provided as text, or as a coded value. In the case of coded values, the codes may be drawn from a locally defined code system or from a standard code system. Note, for our purposes, a standard code system is one that is defined within, or accessible through, EVS.

  A typical example, capturing body weight shows physical quantities, with the numeric value also provided as a text field:

```
<value xsi:type="PQR" value="143" code="g"
 codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus"/>
<!-- CDISC Units of measure  -->
<value xsi:type="PQR" value="143" code="g" codeSystem="1.22.155"/>
<!-- We need an OID to designate a local code system for  original units of
 measure.  -->
<value xsi:type="ED" mediaType="text/plain">143</value>
```

- **Specimen Information**: Within CDA, a specimen is captured in relationship to the act of specimen collection. Therefore, the effectiveTime of the collection act records the date/time of specimen collection, while specimen type is recorded as the .code value for the specimen entity itself. An identifier for the specimen may be recorded as well. When it is relevant to capture information about the specimen usability or condition, these are recorded as observations associated with specimen collection.

  For example:

```
<entryRelationship typeCode="COMP">
 <procedure classCode="PROC" moodCode="EVN">
  <code code="CXXXXX" codeSystem="2.16.840.1.113883.3.26.1.1"
 codeSystemName="NCI Thesaurus"/>
  <!-- The act of specimen collection.  -->
  <effectiveTime>
   <low value="20071104"/>
  </effectiveTime>
  <specimen typeCode="SPC">
   <specimenRole classCode="SPEC">
    <specimenPlayingEntity classCode="MAT" determinerCode="INSTANCE">
     <code code="CXXXXX" displayName="WHOLE_BLOOD"
 codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus"/>
     <!-- Assuming that specimen type values are captured within EVS.  -->
    </specimenPlayingEntity>
   </specimenRole>
  </specimen>
  <entryRelationship typeCode="REFR">
   <observation classCode="OBS" moodCode="EVN">
    <code code="C83450" codeSystem="2.16.840.1.113883.3.26.1.1"
 codeSystemName="NCI Thesaurus"/>
     <!-- Planned Study Day -->
     <value xsi:type="INT" value="1"/>
   </observation>
  </entryRelationship>
 </procedure>
</entryRelationship>
```

  Note, within this example, the planned study day for specimen collection has been included.

- **Specimen Anatomic Region**: It may be relevant (SEND only) to collect information on the anatomic region for the specimen. It is possible to record an anatomic region for the specimen, as well as to indicate the laterality and directionality of the specimen collection within that body site. Each of these items are captured as target site codes within HL7 - they would be used to characterize the specimen collection act. In addition, if the report records whether the specimen represents a portion of the totality of the anatomic region, this will be recorded as an observation associated with the specimen collection.

  For example:

```
<entryRelationship typeCode="COMP">
 <procedure classCode="PROC" moodCode="EVN">
  <code code="CXXXXX" codeSystem="2.16.840.1.113883.3.26.1.1"
 codeSystemName="NCI Thesaurus"/>
  <!-- The act of specimen collection.  -->
  <targetSiteCode code="CXXXXX" displayName="MEDULLA"
 codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus"/>
  <!-- The anatomic site.  -->
  <targetSiteCode code="CXXXXX" displayName="LEFT"
 codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus"/>
  <!-- Laterality  -->
```

```
 <targetSiteCode code="CXXXXX" displayName="PROXIMAL"
codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus"/>
 <!-- Directionality  -->
 <!- .... omitting the specimen type information ->
 <entryRelationship typeCode="COMP">
  <observation classCode="OBS" moodCode="EVN">
   <code code="POTtbd" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
    <!-- Portion or Totality -->
    <value xsi:type="CD" code="CXXXXX" displayName="SEGMENT"
codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus"/>
  </observation>
 </entryRelationship>
</procedure>
</entryRelationship>
```

- **Visit Name and Number**: In many cases (SDTM only) information is recorded within the context of a visit. In the SDTM Implementation Guide, visit name and number may be recorded for an item. This feature is supported within the CDA implementation Guide by providing a Visit template, and including information for these domains, i.e., ECG Test, Human Clinical Laboratory, Physical Examination, Questionnaire Finding, Vital Sign, Pharmacokinetic Concentration, Pharmacokinetic Parameter, Drug Accountability, as entries within the Visit section.

  Here is an example showing the visit section, and two vital sign findings:

```
<section classCode="DOCSECT">
    <code code="CXXXXXX" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
    <!-- Indicate subject visit section,  Note, the Lab and Vital Signs
content will be found nested within. -->
    <title>Subject Visits Section</title>
    <text>Autogenerated Text Goes here</text>
    <!-- Begin Visit #1 -->
    <entry typeCode="COMP">
     <encounter classCode="ENC" moodCode="EVN">
      <id root="1.11.1125" extension="1"/>
      <code code="SCREENING" codeSystem="1.22.113"/>
      <!-- We need an OID to designate a local code system for different
visit names or types.  -->
      <effectiveTime>
       <low value="19980508"/>
       <high value="19990523"/>
      </effectiveTime>
      <entryRelationship typeCode="REFR">
       <observation classCode="OBS" moodCode="EVN">
        <code code="C66734" displayName="Domain Abbreviation"
codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus"/>
        <value xsi:type="CD" code="C49617" displayName="subject visits"
codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus"/>
       </observation>
      </entryRelationship>
      <entryRelationship typeCode="REFR">
       <observation classCode="OBS" moodCode="EVN">
        <code code="C83450" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
        <!-- Planned Study Day -->
        <value xsi:type="INT" value="-7"/>
       </observation>
      </entryRelationship>
      <entryRelationship typeCode="REFR">
```

```
       <observation classCode="OBS" moodCode="EVN">
        <code code="SDPtdb" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
        <!-- Study Day Period -->
        <value xsi:type="IVL_INT">
         <low value="-381"/>
         <high value="-1"/>
        </value>
       </observation>
      </entryRelationship>
      <entryRelationship typeCode="COMP">
       <observation classCode="OBS" moodCode="EVN">
        <id root="1.11.1126" extension="1"/>
        <code code="DIAPB" displayName="Diastolic Blood Pressure"
codeSystem="1.22.117">
         <!-- We need an OID to designate a local code system for vital
sign observations.  -->
        </code>
        <effectiveTime value="199905081510"/>
        <value xsi:type="PQR" value="64.4625" code="MMHG"
codeSystem="1.22.115"/>
        <!-- We need an OID to designate a local code system for  original
units of measure.  -->
        <value xsi:type="PQR" value="64.4625" code="C49670"
displayName="MMHG"  codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
        <!-- CDISC Units of measure  -->
        <value xsi:type="ED" mediaType="text/plain">64.4625</value>
        <entryRelationship typeCode="REFR">
         <observation classCode="OBS" moodCode="EVN">
          <code code="C66734" displayName="Domain Abbreviation"
codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus"/>
          <value xsi:type="CD" code="C49622" displayName="vital signs"
codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus"/>
         </observation>
        </entryRelationship>
        <entryRelationship typeCode="COMP">
         <observation classCode="OBS" moodCode="EVN">
          <code code="CXXXXX" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
          <!-- Indicate this is a vital sign category observation.  -->
          <value xsi:type="CD" code="xxx" displayName="BLOOD CHEMISTRY"
codeSystem="1.22.117"/>
          <!-- We need an OID to designate a local code system for Vital
Sign categories.  -->
         </observation>
        </entryRelationship>
        <entryRelationship typeCode="COMP">
         <observation classCode="OBS" moodCode="EVN">
          <code code="C71148" displayName="Position"
codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus"/>
          <value xsi:type="CD" code="62122" displayName="SITTING"
codeSystem="1.22.118"/>
         </observation>
        </entryRelationship>
        <entryRelationship typeCode="REFR">
         <observation classCode="OBS" moodCode="EVN">
          <code code="C83450" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
          <!-- Planned Study Day -->
          <value xsi:type="INT" value="-16"/>
         </observation>
        </entryRelationship>
       </observation>
```

```
        </entryRelationship>
```

Extending CDA

HL7's Clinical Document Architecture has been chosen as the mechanism for conveying study subject information because of its wide use within the healthcare domain, and because its power and generality allow it to express a wide range of relevant information and concepts. However, not all of the requirements of Subject Data Reporting – as modeled for SDTM and SEND, are supported within the CDA. Fortunately, CDA does provide a mechanism for creating extensions that allows the inclusion of needed features while still assuring interoperability for those who do not support those features.

CDA R2 contains the following regarding extending the standard:

"Locally-defined markup may be used when local semantics have no corresponding representation in the CDA specification. CDA seeks to standardize the highest level of shared meaning while providing a clean and standard mechanism for tagging meaning that is not shared. In order to support local extensibility requirements, it is permitted to include additional XML elements and attributes that are not included in the CDA schema. These extensions should not change the meaning of any of the standard data items, and receivers must be able to safely ignore these elements. Document recipients must be able to faithfully render the CDA document while ignoring extensions."

"Extensions may be included in the instance in a namespace other than the HL7v3 namespace, but must not be included within an element of type ED (e.g., -text- within -procedure--) since the contents of an ED datatype within the conformant document may be in a different namespace. Since all conformant content (outside of elements of type ED) is in the HL7 namespace, the sender can put any extension content into a foreign namespace (any namespace other than the HL7 namespace). Receiving systems must not report an error if such extensions are present."

"When these extension mechanisms mark up content of general relevance, HL7 encourages users to get their requirements formalized in a subsequent version of the standard so as to maximize the use of shared semantics."

This implementation guide follows these principles by defining a custom XML Namespace – (xmlns:ctm=*clinical trial material* to designate the required extensions to the standard.

The following features, which are required for subject data implementation, are not supported within CDA:

- **Material Form Code**: The implementation guides need to capture dose form for study drugs and other substances.
- **Ingredient Role, Ingredient Substance**: The implementation guides need to record the drug strength – the amount of active ingredient within an administered amount as well as to capture information about treatment vehicles.
- **Generalized Material Kind**: The implementation guides need to record the drug class that a medicinal substance belongs in.

Each of these required features is supported by extending the CDA schema.

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 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.

The implementation guide organization is intended to highlight the several templates defined to convey the functional content of a compliant document.

Templates

Templates are organized by document (see Document Templates), by section (see Section Templates), and by clinical statements (see Clinical Statement Templates). Each template defines the particular data structure that is intended for use. In CDA terms, these templates are closed. They define the content that is expected to be provided, and express the position that a conformant document instance will not add additional content.

Vocabulary and Value Sets

The Implementation Guide provides definition for the vocabulary items that are needed as content for those elements using coded data types. The use of coded types, and the precise expression of the valid content of code sets is essential to enable efficient processing of subject data report content, and to allow the proper use of the contained data. Within this guide, the vocabulary section documents the various act code values used to define structural elements - to identify particular acts or observations. It also defines the several value sets needed to constrain the semantic content of coded items. In principle, all the vocabulary needed to support subject data reporting would draw on a common set of concepts. This has been done wherever possible, and the NCI Enterprise Vocabulary Services are used as the repository and source for the commonly agreed upon vocabulary items. In order to streamline the processing of vocabulary items, EVS itself has been treated as the code system for all its contained concepts - therefore the NCI concept id is used as the value in coded fields, and the HL7 assigned OID for the EVS is used as the code system OID. We have provided a reference to the EVS website within this guide, as opposed to including the lists of codes for each value set. This has been done to a) address the problem of updating the vocabulary section when new codes are added, and b) to reduce the size of the document.

However, not all of the coded items used are supported within EVS. These include such items as the set of categories used to organize records within the various SEND and SDTM domains. Items which cannot currently be centrally managed have been defined as code systems in their own right, and are listed as sponsor defined. It is expected that study sponsors will provide reference material to allow these items to be evaluated.

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

Chapter 2

DOCUMENT TEMPLATES

Topics:

This section those templates used to define documents conformant to the implementation guide. Currently, only a single document type - either a human clinical report or a non-human subject report - has been defined for each 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`) (CONF:1)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:2)
3. **SHALL** contain exactly one [1..1] **`code`** (CONF:3)**`/@code`**`="TBD"` (CodeSystem: `2.16.840.1.113883.6.1 LOINC`) (CONF:4)
   - The code value identifies the document as a human clinical subject data report.
4. **SHOULD** contain exactly one [1..1] **`confidentialityCode`** (CONF:5), where the @code **SHALL** be selected from (CodeSystem: `2.16.840.1.113883.5.25 Confidentiality`) (CONF:6)
   - Documents the confidentiality level of the document.
5. **SHALL** contain exactly one [1..1] **`effectiveTime`** (CONF:7)
   - The effective date for the contents of the document.
6. **SHALL** contain exactly one [1..1] **`id`** (CONF:8)
   - 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`** (CONF:9)
   - 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`** (CONF:10)
   - 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`** (CONF:11)
   - 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`** (CONF:12)
    - A unique identifier for a version of a report.
11. **SHALL** contain exactly one [1..1] **`documentationOf`** (CONF:13)

    Identifies the study the subject data report is associated with.

    a. This documentationOf **SHALL** contain exactly one [1..1] **`@typeCode`**`="DOC"` (CONF:18)
    b. This documentationOf **SHALL** contain exactly one [1..1] **`serviceEvent`** (CONF:19)
       a. This serviceEvent **SHALL** contain zero or one [0..1] **`@classCode`**`="CLNTRL"` (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF:20)
       b. This serviceEvent **SHALL** contain zero or one [0..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:23)
       c. This serviceEvent **SHALL** contain exactly one [1..1] **`code`** (CONF:21)

          The code value indicates the related act refers to the study.
       d. This serviceEvent **SHALL** contain exactly one [1..1] **`id`** (CONF:22)

          The identifier of the study. [SDTM: STUDYID]
12. **SHALL** contain exactly one [1..1] **`author`** (CONF:14)

    A required CDA association - it identifies the person responsible for the content of the subject data report. It is true that the investigator is not the absolute source of all the content included within the subject data document,

given that some of the information is derived by the sponsor. However, the subject data document is based on information collected, and therefore "authored" by the investigator. In the last analysis, the investigator is the primary source of the information.

- **a.** This author **SHALL** contain exactly one [1..1] **@typeCode**="AUT" (CONF:40)
- **b.** This author **SHALL** contain exactly one [1..1] **assignedAuthor** (CONF:41)
  - **a.** This assignedAuthor **SHALL** contain exactly one [1..1] **@classCode**="ASSIGNED" (CONF:42)
  - **b.** This assignedAuthor **SHALL** contain exactly one [1..1] **id** (CONF:43)

    An identifier for the investigator who is responsible for the document. [SDTM: INVID]
  - **c.** This assignedAuthor **SHALL** contain exactly one [1..1] **assignedPerson** (CONF:44)
    - **a.** This assignedPerson **SHALL** contain exactly one [1..1] **@classCode**="PSN" (CONF:46)
    - **b.** This assignedPerson **SHALL** contain exactly one [1..1] **@determinerCode**="INSTANCE" (CONF:47)
    - **c.** This assignedPerson **SHALL** contain exactly one [1..1] **name** (CONF:48)

      The name of the investigator. [SDTM: INVNAM]
  - **d.** This assignedAuthor **SHALL** contain exactly one [1..1] **representedOrganization** (CONF:45)
    - **a.** This representedOrganization **SHALL** contain exactly one [1..1] **@classCode**="ORG" (CONF:50)
    - **b.** This representedOrganization **SHALL** contain exactly one [1..1] **@determinerCode**="INSTANCE" (CONF:51)
    - **c.** This representedOrganization **SHALL** contain exactly one [1..1] **addr** (CONF:49)

      The only part of the address that is required is the country. This records the countery of the investigational site associated with the subject's participation in the study. [SDTM: COUNTRY]
    - **d.** This representedOrganization **SHALL** contain exactly one [1..1] **id** (CONF:52)

      An identifier for the study site associated with this subject, and this investigator. [SDTM:SITID]

13. **SHALL** contain exactly one [1..1] **custodian** (CONF:15)

A required CDA association - it identifies the organization that manages custody of the subject data report.

- **a.** This custodian **SHALL** contain exactly one [1..1] **@typeCode**="CST" (CONF:54)
- **b.** This custodian **SHALL** contain exactly one [1..1] **assignedCustodian** (CONF:53)
  - **a.** This assignedCustodian **SHALL** contain exactly one [1..1] **@classCode**="ASSIGNED" (CONF:55)
  - **b.** This assignedCustodian **SHALL** contain exactly one [1..1] **representedCustodianOrganization** (CONF:56)
    - **a.** This representedCustodianOrganization **SHALL** contain exactly one [1..1] **@classCode**="ORG" (CONF:57)
    - **b.** This representedCustodianOrganization **SHALL** contain exactly one [1..1] **@determinerCode**="INSTANCE" (CONF:58)
    - **c.** This representedCustodianOrganization **SHALL** contain exactly one [1..1] **id** (CONF:59)

      An identifier for the custodial organization - the study sponsor.
    - **d.** This representedCustodianOrganization **SHALL** contain exactly one [1..1] **name** (CONF:60)

      The name of the custodial organization - the study sponsor.

14. **SHALL** contain exactly one [1..1] **recordTarget** (CONF:16)

A required CDA association - it identifies the person which is the subject of the study data report.

- **a.** This recordTarget **SHALL** contain exactly one [1..1] **@typeCode**="RCT" (CONF:24)
- **b.** This recordTarget **SHALL** contain exactly one [1..1] **patientRole** (CONF:25)
  - **a.** This patientRole **SHALL** contain exactly one [1..1] **@classCode**="PAT" (CONF:28)
  - **b.** This patientRole **SHALL** contain [2..2] **id** (CONF:29)

A set of identifiers for the study subject. These include the unique study ID) which identifies the subject across all studies for a product, and a study specific ID which identifies the subject within the context of a single study. [SEND: USUBJID, SUBJID]

c. This patientRole **SHALL** contain exactly one [1..1] **`patient`** (CONF:30)

a. This patient **SHALL** contain exactly one [1..1] **`@classCode`**`="PSN"` (CONF:31)

b. This patient **SHALL** contain exactly one [1..1] **`@determinerCode`**`="INSTANCE"` (CONF:32)

c. This patient **SHALL** contain exactly one [1..1] **`administrativeGenderCode`** (CONF:33), where the @code **SHALL** be selected from ValueSet *`Sex`* `C66731` **STATIC** (CONF:34)

[SEND: SEX]

d. This patient **MAY** contain zero or one [0..1] **`birthTime`** (CONF:35)

The date of the study subject's birth. [SEND: BRTHDTC]

d. This patientRole **SHALL** satisfy: The unique subject ID shall be present. [SDTM, USUBJID]. (CONF:26)

e. This patientRole **SHALL** satisfy: Shall include an identifer for the subject within the study. [SDTM, SUBJID]. (CONF:27)

15. SHALL contain zero or one [0..1] **`component`** (CONF:17)

- Provides an association to the subject of the report.

a. Contains exactly one [1..1] *Human Clinical Subject Data Document Section* (templateId: `2.16.840.1.113883.10.20.23.13`)

Chapter 3

SECTION TEMPLATES

Topics:

This section contains templates used to describe the different document sections used within compliant documents.

For Subject data, only a single section type has been defined. The section template allows a choice of several "clinical statement" templates - each based on the CDISC SDTM or SEND Implementation Guides, and all of the content within the section is to be based on that single domain template. Note, however that when a new or custom domain needs to be communicated, its section should draw upon one of the three general domains: Study Subject Event, Study Subject Finding, Study Subject Intervention.

Human Clinical Subject Data Document Section

[Section: templateId `2.16.840.1.113883.10.20.23.13`]

The document is divided into sections as defined by the user. It is reccomended that, with the exeception of the generic "add-on" templates: related records, supplemental values, comments, findings about, each section contain a single type of the possible listed templates, that is, the content of a single SDTM domain. In the case of the visit template, this allows for inclusion of data from other SDTM defined data structures (domain) to be included within the section. The user is also free to create custom sections based on the included generic templates: Study Subject Finding, Study Subject Event, Study Subject Intervention.

1. **SHALL** contain exactly one [1..1] **`@classCode="DOCSECT"`** (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF:175)
2. **SHALL** contain zero or one [0..1] **`@moodCode="EVN"`** *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:176)
3. **SHALL** contain exactly one [1..1] **`code`** (CONF:177)**`/@code="HUStbd"`** (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`) (CONF:178)
   - A code to indicate the nature of the section. This code should indicate the primary domain association for the section.
4. **MAY** contain zero or one [0..1] **`entry`** (CONF:179)
   - The section may include a record based on the defined template. It should also include a record based on the study arm template.

   a. Contains exactly one [1..1] *Human Clinical Subject Demographics* (templateId: `2.16.840.1.113883.10.20.23.46`)
5. **SHOULD** contain zero or more [0..*] **`entry`** (CONF:180)
   - The section may include one or many records based on the defined template.

   a. Contains exactly one [1..1] *Subject Element* (templateId: `2.16.840.1.113883.10.20.23.93`)
6. **SHOULD** contain zero or more [0..*] **`entry`** (CONF:181)
   - If a visit entry is included, the section will only contain visit entries. Note, however, that several other SDTM domains will have their data nested within this entry as shown by the Visit template.

   a. Contains exactly one [1..1] *Visit* (templateId: `2.16.840.1.113883.10.20.23.100`)
7. **MAY** contain zero or more [0..*] **`concommitantMedicationAssociation`** (CONF:182)

   If included, the section will only contain Concommitant Medication entries.

   a. Such concommitantMedicationAssociations **SHALL** contain exactly one [1..1] **`@typeCode="COMP"`** (CONF:201)

   b. Such concommitantMedicationAssociations **SHALL** contain exactly one [1..1] **`substanceAdministration`**, where its type is *Concomitant Medication* (CONF:200)

      a. Contains exactly one [1..1] *Concomitant Medication* (templateId: `2.16.840.1.113883.10.20.25.24`)
8. **MAY** contain zero or more [0..*] **`entry`** (CONF:183)

   If included, the section will only contain Exposure entries.

   a. Such entrys **SHALL** contain exactly one [1..1] **`@typeCode="COMP"`** (CONF:198)

   b. Such entrys **SHALL** contain exactly one [1..1] **`substanceAdministration`**, where its type is *Human Clinical Exposure* (CONF:199)

      a. Contains exactly one [1..1] *Human Clinical Exposure* (templateId: `2.16.840.1.113883.10.20.23.44`)
9. **MAY** contain zero or more [0..*] **`substanceUseAssociation`** (CONF:184)

If included, the section will only contain Substance Use entries.

a. Such substanceUseAssociations **SHALL** contain exactly one [1..1] **`@typeCode="COMP"`** (CONF:202)

b. Such substanceUseAssociations Contains zero or one [0..1] **`substanceAdministration`**, where its type is *Substance Use*

a. Contains exactly one [1..1] *Substance Use* (templateId: `2.16.840.1.113883.10.20.23.95`)

10. MAY contain zero or more [0..*] **`entry`** (CONF:185)

- If included, the section will only contain Adverse Event entries.

a. Contains exactly one [1..1] *Adverse Event* (templateId: `2.16.840.1.113883.10.20.23.15`)

11. SHOULD contain zero or more [0..*] **`entry`** (CONF:186)

- If included, the section will only contain Disposition entries.

a. Contains exactly one [1..1] *Human Clinical Disposition* (templateId: `2.16.840.1.113883.10.20.23.43`)

12. SHOULD contain zero or more [0..*] **`entry`** (CONF:187)

- If included, the section will only contain Medical History entries.

a. Contains exactly one [1..1] *Medical History Item* (templateId: `2.16.840.1.113883.10.20.23.52`)

13. MAY contain zero or more [0..*] **`entry`** (CONF:188)

- If included, the section will only contain Protocol Deviation entries.

a. Contains exactly one [1..1] *Protocol Deviation* (templateId: `2.16.840.1.113883.10.20.23.71`)

14. MAY contain zero or more [0..*] **`entry`** (CONF:189)

- If included, the section will only contain Clinical Event entries.

a. Contains exactly one [1..1] *Clinical Event* (templateId: `2.16.840.1.113883.10.20.23.21`)

15. MAY contain zero or more [0..*] **`entry`** (CONF:190)

- If included, the section will only contain Inclusion or Exclusion Criteria not met entries.

a. Contains exactly one [1..1] *Inclusion or Exclusion Criteria Not Met* (templateId: `2.16.840.1.113883.10.20.23.47`)

16. MAY contain zero or more [0..*] **`entry`** (CONF:191)

- If included, the section will only contain Subject Characteristic entries.

a. Contains exactly one [1..1] *Subject Characteristic* (templateId: `2.16.840.1.113883.10.20.23.92`)

17. MAY contain zero or more [0..*] **`entry`** (CONF:192)

- The template is used in order to allow the creation of new or non-standard domains based on a kind of event, that are not explicitly defined as such. Once an entry from such a domain is entered, all other entries in the section must be drawn from that domain.

a. Contains exactly one [1..1] *Study Subject Event* (templateId: `2.16.840.1.113883.10.20.23.85`)

18. MAY contain zero or more [0..*] **`entry`** (CONF:193)

- The template is used in order to allow the creation of new or non-standard domains based on a kind of finding, that are not explicitly defined as such. Once an entry from such a domain is entered, all other entries in the section must be drawn from that domain.

a. Contains exactly one [1..1] *Study Subject Finding* (templateId: `2.16.840.1.113883.10.20.23.86`)

19. MAY contain zero or more [0..*] **`entry`** (CONF:194)

- The template is used in order to allow the creation of new or non-standard domains based on a kind of intervention, that are not explicitly defined as such. Once an entry from such a domain is entered, all other entries in the section must be drawn from that domain.

a. Contains exactly one [1..1] *Study Subject Intervention* (templateId: `2.16.840.1.113883.10.20.23.87`)

20. **MAY** contain zero or more [0..*] **`entry`** (CONF:195)
    - If included, the section will only contain Comment entries. These are comments that are entered against the subject report as a whole, rather than against a particular data item.

    a. Contains exactly one [1..1] *Comment* (templateId: `2.16.840.1.113883.10.20.23.23`)
21. **SHALL** contain exactly one [1..1] **`text`** (CONF:196)
    - A text representation of the structured content within the section. This material should be presented in a format that can be readily grasped by a reviewer or other reader. It is expected that the text will be autogenerated.
22. **MAY** contain zero or more [0..*] **`entry`** (CONF:197)
    - If included, the section will only contain Finding About entries. These are findings that are entered against the subject report as a whole, rather than against a particular data item.

    a. Contains exactly one [1..1] *Finding About* (templateId: `2.16.840.1.113883.10.20.23.40`)
23. Contains zero or one [0..1] **`title`**
    - The title provides a name for the section. It must be consistent with the value passed within the code element.

Chapter 4

CLINICAL STATEMENT TEMPLATES

Topics:

This section of the Implementation Guide details the bulk of the templates used to model document entries. It includes those templates that are act based and that draw upon the "clinical statement" area of the CDA structure. All the templates referred to within the document section templates are included here. The clinical statement entry templates are arranged alphabetically.

- *Non-Study Treatment Relationship*
- *Other Treatment Action Taken*
- *Pharmacokinetic Concentration Finding*
- *Pharmacokinetic Parameter Finding*
- *Physical Examination Finding*
- *Planned Study Day*
- *Position of Subject*
- *Pre-Specified Event*
- *Protocol Deviation*
- *Questionnaire Finding*
- *Reference Period*
- *Related Record*
- *Result Category*
- *Serious Event*
- *Specimen Information*
- *Start Relative to Reference Period*
- *Stop Relative to Reference Period*
- *Study Arm*
- *Study Day Period*
- *Study Epoch*
- *Study Subject Event*
- *Study Subject Finding*
- *Study Subject Intervention*
- *Study Treatment Action Taken*
- *Study Treatment Causality*
- *Sub- Category*
- *Subject Characteristic*
- *Subject Element*
- *Substance Use*
- *Supplemental Value*
- *Timing Reference*
- *Toxicity*
- *Visit*
- *Vital Sign*

Adverse Event

[Observation: templateId `2.16.840.1.113883.10.20.23.15`]

The template captures data that the SDTM IG organizes into the adverse event domain. It includes information on each adverse event (not necessarily linked to the study treatment) 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).

1. **SHALL** contain exactly one [1..1] **`@classCode="OBS"`** *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF:1517)
2. **SHALL** contain exactly one [1..1] **`@moodCode="EVN"`** *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:108)
3. **SHALL** contain [1..3] **`id`** (CONF:109)
   - One or more identifiers for the adverse event. "An internal or external identifier such as a serial number on an SAE reporting form". [SDTM: AESEQ, AEREFID, AESPID] To be consistent with SDTM, the sequence number is required.
4. **SHALL** contain exactly one [1..1] **`code`** (CONF:110)**`/@code="C49562"`** *Adverse Event - Reported* (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`) (CONF:111)
   - The code value indicates that this observation is an adverse event.
5. **SHOULD** contain zero or one [0..1] **`effectiveTime`** (CONF:112)
   - Used to capture the start date/time of the adverse event, its end date/time, and/or its duration. Implementers should note that only two of the three properties of an interval are supported, since the value of the third would be redundant. It is reccomended that start and stop date/time be valued if known, and that duration be included only if the start or stop information is unavailable or incomplete. [SDTM: AESTDTC, AEENDTC, AEDUR]
6. **SHALL** contain exactly one [1..1] **`value`** with data type CD (CONF:113), where the @code **SHALL** be selected from ValueSet *`Adverse Event`* **STATIC** (CONF:1518)
   - The adverse event information. The adverse event coded value is captured using the code property of the CD type, while the verbatem term - which is required - is captured using the original text property. The modified term, if provided, should be captured as a translation element within the CD type. [SDTM: AETERM, AEMODIFY, AEDECOD]
7. **MAY** contain zero or one [0..1] **`targetSiteCode`** (CONF:114), where the @code **SHALL** be selected from ValueSet *`Anatomical Location`* `C74456` **STATIC** (CONF:115)
   - The anatomic location that is relevant for the adverse event. [SDTM: AELOC]
8. **SHALL** contain exactly one [1..1] **`entryRelationship`** (CONF:116)
   - Indicates the domain assignment for the event.
   a. Contains **`@typeCode="REFR"`** *REFR*
   b. Contains exactly one [1..1] *Domain Assignment* (templateId: `2.16.840.1.113883.10.20.23.30`)
9. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:117)
   - Indicates whether the type of adverse event that is being reported was prespecified on the CRF.
   a. Contains **`@typeCode="COMP"`** *COMP*
   b. Contains exactly one [1..1] *Pre-Specified Event* (templateId: `2.16.840.1.113883.10.20.23.70`)
10. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:118)
    - Allows capture of a group identifier for the adverse event.
    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Group Identifier* (templateId: `2.16.840.1.113883.10.20.23.42`)
11. **SHOULD** contain zero or one [0..1] **`entryRelationship`** (CONF:119)

- A statement both of whether or not the adverse event is considered serious, and a record of various types of seriousness, e.g, results in hospitalization, that may be recorded for the adverse event.

a. Contains **`@typeCode="COMP"`** *COMP*
b. Contains exactly one [1..1] *Serious Event* (templateId: `2.16.840.1.113883.10.20.23.77`)

12. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:120)

- Carries information about the severity or intensity of the adverse event.

a. Contains **`@typeCode="COMP"`** *COMP*
b. Contains exactly one [1..1] *Event or Finding Severity* (templateId: `2.16.840.1.113883.10.20.23.34`)

13. **SHOULD** contain zero or one [0..1] **`entryRelationship`** (CONF:121)

- Allows identification of the relevant body system or organ class for the adverse event.

a. Contains **`@typeCode="COMP"`** *COMP*
b. Contains exactly one [1..1] *Body System or Organ Class* (templateId: `2.16.840.1.113883.10.20.23.17`)

14. **SHOULD** contain zero or one [0..1] **`entryRelationship`** (CONF:122)

- Information on whether adjustments were made to the study treatment as a result of the adverse event.

a. Contains **`@typeCode="COMP"`** *COMP*
b. Contains exactly one [1..1] *Study Treatment Action Taken* (templateId: `2.16.840.1.113883.10.20.23.89`)

15. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:123)

- Information on whether action other than adjustment to the study treatment was taken as a result of the adverse event.

a. Contains **`@typeCode="COMP"`** *COMP*
b. Contains exactly one [1..1] *Other Treatment Action Taken* (templateId: `2.16.840.1.113883.10.20.23.63`)

16. **SHOULD** contain zero or one [0..1] **`entryRelationship`** (CONF:124)

- Captures the investigator's opinion of the causal relationship between the adverse event and study treatment.

a. Contains **`@typeCode="COMP"`** *COMP*
b. Contains exactly one [1..1] *Study Treatment Causality* (templateId: `2.16.840.1.113883.10.20.23.90`)

17. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:125)

- Captures the investigator's opinion of the causal relationship between the adverse event and some event other than the study treatment.

a. Contains **`@typeCode="COMP"`** *COMP*
b. Contains exactly one [1..1] *Non-Study Treatment Relationship* (templateId: `2.16.840.1.113883.10.20.23.61`)

18. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:126)

- Records the pattern of an adverse event.

a. Contains **`@typeCode="COMP"`** *COMP*
b. Contains exactly one [1..1] *Event Pattern* (templateId: `2.16.840.1.113883.10.20.23.36`)

19. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:127)

- Information on the outcome of an adverse event.

a. Contains **`@typeCode="COMP"`** *COMP*
b. Contains exactly one [1..1] *Event Outcome* (templateId: `2.16.840.1.113883.10.20.23.35`)

20. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:128)

- A record of whether a treatment (aside from the study treatment) was provided as a result of the adverse event.

a. Contains **@typeCode="COMP"** *COMP*
b. Contains exactly one [1..1] *Concomitant Treatment* (templateId: 2.16.840.1.113883.10.20.25.25)

21. MAY contain zero or one [0..1] **entryRelationship** (CONF:129)

- A record of the toxicity of the adverse event.

a. Contains **@typeCode="COMP"** *COMP*
b. Contains exactly one [1..1] *Toxicity* (templateId: 2.16.840.1.113883.10.20.23.98)

22. MAY contain zero or one [0..1] **entryRelationship** (CONF:130)

- Records the duration of an event in cases in which this cannot be derived from existing start and stop information.

a. Contains **@typeCode="COMP"** *COMP*
b. Contains exactly one [1..1] *Event Duration* (templateId: 2.16.840.1.113883.10.20.23.102)

23. MAY contain zero or one [0..1] **entryRelationship** (CONF:131)

- 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: 2.16.840.1.113883.10.20.23.82)

24. MAY contain zero or one [0..1] **entryRelationship** (CONF:132)

- Allows positioning of the start of the adverse event with relationship to a defined reference time period.

a. Contains **@typeCode="REFR"** *REFR*
b. Contains exactly one [1..1] *Start Relative to Reference Period* (templateId: 2.16.840.1.113883.10.20.23.79)

25. MAY contain zero or one [0..1] **entryRelationship** (CONF:133)

- Allows positioning of the end of the adverse event with relationship to a defined reference time period.

a. Contains **@typeCode="REFR"** *REFR*
b. Contains exactly one [1..1] *Stop Relative to Reference Period* (templateId: 2.16.840.1.113883.10.20.23.80)

26. MAY contain zero or one [0..1] **entryRelationship** (CONF:134)

- The record of a category to be used in organizing adverse events.

a. Contains **@typeCode="COMP"** *COMP*
b. Contains exactly one [1..1] *Category* (templateId: 2.16.840.1.113883.10.20.23.20)

27. MAY contain zero or one [0..1] **entryRelationship** (CONF:135)

- The record of a sub-category to be used in organizing adverse events.

a. Contains **@typeCode="COMP"** *COMP*
b. Contains exactly one [1..1] *Sub- Category* (templateId: 2.16.840.1.113883.10.20.23.91)

28. MAY contain zero or more [0..*] **entryRelationship** (CONF:136)

- A way to provide a link between the adverse event record and another record situated within this or another domain.

a. Contains **@typeCode="REFR"** *REFR*
b. Contains exactly one [1..1] *Related Record* (templateId: 2.16.840.1.113883.10.20.23.75)

29. MAY contain zero or more [0..*] **entryRelationship** (CONF:137)

- Allows the association of a supplemental value - outside of the content specfied for the domain - to the record.

a. Contains **@typeCode="COMP"** *COMP*
b. Contains exactly one [1..1] *Supplemental Value* (templateId: 2.16.840.1.113883.10.20.23.96)

30. **MAY** contain zero or more [0..*] **`entryRelationship`** (CONF:138)
    - A place to insert comments related to a particular adverse event.
    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Comment* (templateId: `2.16.840.1.113883.10.20.23.23`)
31. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:139)
    - Allows recording of additional findings related to the adverse event.
    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Finding About* (templateId: `2.16.840.1.113883.10.20.23.40`)

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">
  <templateId root="2.16.840.1.113883.10.20.23.15"/>
  <id root="2006996462" extension="MDHT"/>
  <code codeSystem="2.16.840.1.113883.3.26.1.1" displayName="Adverse Event -
 Reported"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <value xsi:type="CD" code="1327597418"/>
  <targetSiteCode code="1515179908"/>
  <entryRelationship>
    <act classCode="ACT">
      <templateId root="2.16.840.1.113883.10.20.23.42"/>
      <id root="43530188" extension="MDHT"/>
      <code code="C83204" 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/>
  </entryRelationship>
  <entryRelationship>
    <observation/>
  </entryRelationship>
  <entryRelationship>
    <observation>
      <id root="224453611" extension="MDHT"/>
      <code code="699106186"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <value xsi:type="IVL_INT" value="1"/>
      <targetSiteCode code="2140632704"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation>
      <templateId root="2.16.840.1.113883.10.20.23.30"/>
```

```
     <id root="1993658485" extension="MDHT"/>
     <code code="C66734" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
     <value xsi:type="CD" code="927997751"/>
     <targetSiteCode code="1032281258"/>
   </observation>
 </entryRelationship>
 <entryRelationship>
   <observation classCode="OBS" moodCode="EVN">
     <templateId root="2.16.840.1.113883.10.20.23.23"/>
     <id root="1338774657" extension="MDHT"/>
     <code code="C49569" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
     <value xsi:type="ED">Text Value</value>
     <targetSiteCode code="308850021"/>
     <participant/>
     <entryRelationship/>
   </observation>
 </entryRelationship>
 <entryRelationship>
   <act classCode="ACT">
     <templateId root="2.16.840.1.113883.10.20.23.75"/>
     <id root="1864655868" 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>
 <entryRelationship>
   <observation classCode="OBS" moodCode="EVN">
     <templateId root="2.16.840.1.113883.10.20.23.96"/>
     <id root="656410889" extension="MDHT"/>
     <code codeSystem="locally defined" codeSystemName="Supplemental Value
Type"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
     <targetSiteCode code="1138241460"/>
     <participant/>
     <entryRelationship typeCode="COMP"/>
   </observation>
 </entryRelationship>
 <entryRelationship>
   <observation/>
 </entryRelationship>
 <entryRelationship>
   <observation/>
 </entryRelationship>
 <entryRelationship>
   <observation>
     <id root="1013252801" extension="MDHT"/>
     <code code="1222618307"/>
```

```
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <value xsi:type="BL"/>
      <targetSiteCode code="988464735"/>
      <entryRelationship typeCode="COMP"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.89"/>
      <id root="1721877042" extension="MDHT"/>
      <code code="C66767" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <value xsi:type="CD" code="1028730583"/>
      <targetSiteCode code="44196998"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation classCode="OBS">
      <templateId root="2.16.840.1.113883.10.20.23.63"/>
      <id root="1830682128" extension="MDHT"/>
      <code code="OATtbd" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <value xsi:type="ED">Text Value</value>
      <targetSiteCode code="1952577605"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation>
      <id root="355248646" extension="MDHT"/>
      <code codeSystem="2.16.840.1.113883.3.26.1.1"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <value xsi:type="CD" code="1616565889"/>
      <targetSiteCode code="396416058"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation/>
  </entryRelationship>
  <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.36"/>
      <id root="1320440011" extension="MDHT"/>
      <code code="C83208" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus" displayName="Adverse Event Pattern"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <value xsi:type="CD" code="421600599"/>
      <targetSiteCode code="1327266158"/>
```

```
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation>
      <templateId root="2.16.840.1.113883.10.20.23.35"/>
      <id root="1949622044" extension="MDHT"/>
      <code codeSystem="2.16.840.1.113883.3.26.1.1" displayName="Adverse Event
Outcome"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <value xsi:type="CD" code="751421345"/>
      <targetSiteCode code="1940760289"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation>
      <templateId root="2.16.840.1.113883.10.20.25.25"/>
      <id root="762206932" extension="MDHT"/>
      <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus" displayName="Adverse Event Concommitant Treatment"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <value xsi:type="BL"/>
      <targetSiteCode code="1175195541"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.98"/>
      <id root="1854063565" extension="MDHT"/>
      <code code="TOtbd" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <value xsi:type="CD" code="73539599"/>
      <targetSiteCode code="21880596"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.20"/>
      <id root="124763319" 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="CD" code="210760348"/>
      <targetSiteCode code="235076780"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation/>
  </entryRelationship>
  <entryRelationship>
    <observation>
      <id root="14903342" extension="MDHT"/>
```

```
      <code code="417530702"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <targetSiteCode code="1102555479"/>
      <participant/>
      <entryRelationship typeCode="REFR"/>
      <entryRelationship>
        <act classCode="ACT">
          <templateId root="2.16.840.1.113883.10.20.23.42"/>
          <code code="C83204" codeSystem="2.16.840.1.113883.3.26.1.1"
 codeSystemName="NCI Thesaurus"/>
        </act>
      </entryRelationship>
      <entryRelationship>
        <observation classCode="OBS">
          <templateId root="2.16.840.1.113883.10.20.23.56"/>
          <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
 Thesaurus" displayName="Reason for non completion"/>
        </observation>
      </entryRelationship>
      <entryRelationship>
        <act/>
      </entryRelationship>
      <entryRelationship>
        <observation classCode="OBS" moodCode="EVN">
          <templateId root="2.16.840.1.113883.10.20.23.20"/>
          <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
 Thesaurus"/>
        </observation>
      </entryRelationship>
      <entryRelationship>
        <observation/>
      </entryRelationship>
      <entryRelationship>
        <observation>
          <templateId root="2.16.840.1.113883.10.20.23.30"/>
          <code code="C66734" codeSystem="2.16.840.1.113883.3.26.1.1"
 codeSystemName="NCI Thesaurus"/>
        </observation>
      </entryRelationship>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.102"/>
      <id root="1878206963" extension="MDHT"/>
      <code code="EDtbd" codeSystem="2.16.840.1.113883.3.26.1.1"
 codeSystemName="NCI Thesaurus"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <value xsi:type="PQR" code="1893092810"/>
      <targetSiteCode code="1485291505"/>
    </observation>
  </entryRelationship>
</observation>
```

Assay Quantitation

[Observation: templateId `2.16.840.1.113883.10.20.23.16`]

An indication of the lower limit of quantitation for an assay. This structure is captured as a template to facilitate its reuse as a characteristic of different types of finding within clinical and non-clinical trial reporting.

1. **SHALL** contain exactly one [1..1] **`@classCode="OBS"`** *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF:1502)
2. **SHALL** contain exactly one [1..1] **`@moodCode="DEF"`** (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:1503)
3. **SHALL** contain exactly one [1..1] **`code`** (CONF:1504)**`/@code="AQtbd"`** (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`) (CONF:1505)
   - The code value identifies this as an asssay quantitation observation.
4. **SHALL** contain exactly one [1..1] **`value`** with data type IVL_PQ (CONF:1506)
   - 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], [SEND: PCLLOQ], [Study Data Tabulation Model: -LLOQ]

Assay Quantitation 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">
  <id root="953842054" extension="MDHT"/>
  <code code="334252393"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <value xsi:type="IVL_PQ"/>
</observation>
```

Body System or Organ Class

[Observation: templateId `2.16.840.1.113883.10.20.23.17`]

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 or non-clinical trial reporting.

1. **SHALL** contain exactly one [1..1] **`@classCode="OBS"`** *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF:245)
2. **SHALL** contain exactly one [1..1] **`@moodCode="EVN"`** *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:246)
3. **SHALL** contain exactly one [1..1] **`code`** (CONF:247)**`/@code="C88026"`** *Body System or Organ Class* (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`) (CONF:248)
   - The code value identifies this as a body system or organ class observation.
4. **SHALL** contain exactly one [1..1] **`value`** with data type CD (CONF:249), where the @code **SHALL** be selected from ValueSet *`Body System/Organ Class`* `C88026` **STATIC** (CONF:250)
   - Provide the Body System or Organ class code. [SDTM: AEBODSYS, MHBODSYS, CEBODSYS. PEBODSYS], [SEND: CLBODSYS, MABODSYS, MIBODSYS], [Study Data Tabulation Model: -BODYSYS].

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"
 classCode="OBS">
  <templateId root="2.16.840.1.113883.10.20.23.17"/>
  <id root="2111610611" extension="MDHT"/>
  <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus"
 displayName="Body System or Organ Class"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <value xsi:type="CD" code="621465039"/>
</observation>
```

Category

[Observation: templateId `2.16.840.1.113883.10.20.23.20`]

The structure is used to provide a classification for a reported item, whether it be an event, finding, or intervention. This structure is captured as a template to facilitate its reuse as a characteristic of different types of data item within clinical and non-clinical trial reporting.

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF:1464)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:1465)
3. **SHALL** contain exactly one [1..1] **`code`** (CONF:1466), where the @code **SHALL** be selected from ValueSet *`Subject Data Domain Category Type`* `CXXXXX` **STATIC** (CONF:1467)
   - The code is used to capture the type of category. The set of categories is defined based on the list of individual domains that have been defined. In general, there will be a category set defined for each domain.
4. **SHALL** contain exactly one [1..1] **`value`** with data type CD (CONF:1468), where the @code **SHALL** be selected from (CONF:1469)
   - Provide the category value - based on the category type - that corresponds to the reported data item. Category values are locally defined - by the study sponsor. In addition, there will be different code sets used for each category type - as defined in observation.code. [SDTM: AECAT, CECAT, CMCAT, DACAT, EGCAT, FACAT, DSCAT, EXCAT, LBCAT, IECAT, MHCAT, MBCAT, MSCAT, PCCAT, PPCAT, PECAT, DVCAT, QSCAT, SCCAT, SUCAT, VSCAT], [SEND: CLCAT, EGCAT, FACAT, EXCAT, LBCAT, PCCAT, PPCAT, VSCAT][Study Data Tabulation Model: -CAT]

Category 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="2.16.840.1.113883.10.20.23.20"/>
  <id root="318883938" 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="CD" code="1562079758"/>
</observation>
```

Clinical Event

[Observation: templateId `2.16.840.1.113883.10.20.23.21`]

The template is based on the Clincial Event domain. It captures clinical events of interest that are not classified as adverse events. The data for a clinical event may include information 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`) (CONF:458)
2. **SHALL** contain exactly one [1..1] **`@moodCode="EVN"`** *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:459)
3. **SHALL** contain exactly one [1..1] **`code`** (CONF:460)**`/@code="CEtbd"`** (CONF:1529)
   - The code value indicates that this observation records a clinical event.
4. **MAY** contain zero or one [0..1] **`effectiveTime`** (CONF:462)
   - The start and stop date/times of the clinical event. The high and low properties of the IVL_TS type are used to capture the start and stop date/times of the event. [SDTM: CESTDTC, CEENDTC]
5. **SHALL** contain [1..3] **`id`** (CONF:463)
   - 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`** (CONF:464), where the @code **SHALL** be selected from (CodeSystem: `2.16.840.1.113883.5.14 ActStatus`) (CONF:1530)
   - Used to indicate whether the activity - occurrence of the clinical event - did occur. Use statusCode "Completed" if the event occurred. [SDTM: CEOCCUR]
7. **SHALL** contain exactly one [1..1] **`value`** with data type CD (CONF:465), where the @code **SHALL** be selected from ValueSet *`Clinical Event`* `locally defined` **STATIC** (CONF:1531)
   - A code value and descriptive text to provide information on the nature of the clinical event. Use the original text property of the CD type to capture the verbatim tem for the event. [SDTM: CETERM, CEDECOD]
8. **SHALL** contain exactly one [1..1] **`entryRelationship`** (CONF:466)
   - Identifies the SDTM or SEND domain the record is assigned to.
   a. Contains **`@typeCode="REFR"`** *REFR*
   b. Contains exactly one [1..1] *Domain Assignment* (templateId: `2.16.840.1.113883.10.20.23.30`)
9. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:467)
   - 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: `2.16.840.1.113883.10.20.23.27`)
10. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:468)
    - 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: `2.16.840.1.113883.10.20.23.70`)
11. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:469)
    - Information on the reason the clinical event was not carried out.

   a. Contains **@typeCode="COMP"** *COMP*
   b. Contains exactly one [1..1] *Non Performance Reason* (templateId: 2.16.840.1.113883.10.20.23.56)
12. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:470)
    - 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: 2.16.840.1.113883.10.20.23.17)
13. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:471)
    - Captures information about the severity of the clinical event.
    a. Contains **@typeCode="COMP"** *COMP*
    b. Contains exactly one [1..1] *Event or Finding Severity* (templateId: 2.16.840.1.113883.10.20.23.34)
14. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:472)
    - Allows positioning of the start of the event with relationship to a defined reference time period.
    a. Contains **@typeCode="REFR"** *REFR*
    b. Contains exactly one [1..1] *Start Relative to Reference Period* (templateId: 2.16.840.1.113883.10.20.23.79)
15. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:473)
    - Allows positioning of the termination of the event with relationship to a defined reference time period.
    a. Contains **@typeCode="REFR"** *REFR*
    b. Contains exactly one [1..1] *Stop Relative to Reference Period* (templateId: 2.16.840.1.113883.10.20.23.80)
16. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:474)
    - The record of a category to be used in organizing information items.
    a. Contains **@typeCode="COMP"** *COMP*
    b. Contains exactly one [1..1] *Category* (templateId: 2.16.840.1.113883.10.20.23.20)
17. Contains zero or one [0..1] **entryRelationship**
    - The record of a sub-category to be used in organizing information items.
    a. Contains exactly one [1..1] *Sub- Category* (templateId: 2.16.840.1.113883.10.20.23.91)
18. **MAY** contain zero or more [0..*] **entryRelationship** (CONF:475)
    - Establishes a relationship between this record and another record.
    a. Contains **@typeCode="REFR"** *REFR*
    b. Contains exactly one [1..1] *Related Record* (templateId: 2.16.840.1.113883.10.20.23.75)
19. **MAY** contain zero or more [0..*] **entryRelationship** (CONF:476)
    - Allows the association of a supplemental value - outside of the content specfied for the domain - to the record.
    a. Contains **@typeCode="COMP"** *COMP*
    b. Contains exactly one [1..1] *Supplemental Value* (templateId: 2.16.840.1.113883.10.20.23.96)
20. **MAY** contain zero or more [0..*] **entryRelationship** (CONF:477)
    - A place to insert comments related to a particular finding.
    a. Contains **@typeCode="COMP"** *COMP*
    b. Contains exactly one [1..1] *Comment* (templateId: 2.16.840.1.113883.10.20.23.23)
21. **MAY** contain zero or more [0..*] **entryRelationship** (CONF:478)
    - Allows recording of additional findings related to the event.
    a. Contains **@typeCode="COMP"** *COMP*

b. Contains exactly one [1..1] *Finding About* (templateId: `2.16.840.1.113883.10.20.23.40`)

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">
  <id root="1211983290" extension="MDHT"/>
  <code code="1341448987"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <value xsi:type="CD" code="598575725"/>
  <entryRelationship>
    <observation/>
  </entryRelationship>
  <entryRelationship>
    <observation classCode="OBS">
      <templateId root="2.16.840.1.113883.10.20.23.56"/>
      <id root="1903477641" extension="MDHT"/>
      <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
 Thesaurus" displayName="Reason for non completion"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <value xsi:type="CD" code="2131305185"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation/>
  </entryRelationship>
  <entryRelationship>
    <act>
      <id root="1789421331" extension="MDHT"/>
      <code code="1660256043"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <entryRelationship>
        <observation/>
      </entryRelationship>
    </act>
  </entryRelationship>
  <entryRelationship>
    <observation/>
  </entryRelationship>
  <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.23"/>
      <id root="914360177" extension="MDHT"/>
      <code code="C49569" 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="ED">Text Value</value>
```

```
      <participant/>
      <entryRelationship/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation>
      <templateId root="2.16.840.1.113883.10.20.23.30"/>
      <id root="1040717527" extension="MDHT"/>
      <code code="C66734" 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="CD" code="904942871"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <act classCode="ACT">
      <templateId root="2.16.840.1.113883.10.20.23.75"/>
      <id root="619943525" 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>
    </act>
  </entryRelationship>
  <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.96"/>
      <id root="709753401" extension="MDHT"/>
      <code codeSystem="locally defined" codeSystemName="Supplemental Value
Type"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <participant/>
      <entryRelationship typeCode="COMP"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation/>
  </entryRelationship>
  <entryRelationship>
    <observation/>
  </entryRelationship>
  <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.20"/>
      <id root="744817545" 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="CD" code="379559903"/>
```

```
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation/>
  </entryRelationship>
  <entryRelationship>
    <observation>
      <id root="425472743" extension="MDHT"/>
      <code code="651431401"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <participant/>
      <entryRelationship typeCode="REFR"/>
      <entryRelationship>
        <act classCode="ACT">
          <templateId root="2.16.840.1.113883.10.20.23.42"/>
          <code code="C83204" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
        </act>
      </entryRelationship>
      <entryRelationship>
        <observation classCode="OBS">
          <templateId root="2.16.840.1.113883.10.20.23.56"/>
          <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus" displayName="Reason for non completion"/>
        </observation>
      </entryRelationship>
      <entryRelationship>
        <act/>
      </entryRelationship>
      <entryRelationship>
        <observation classCode="OBS" moodCode="EVN">
          <templateId root="2.16.840.1.113883.10.20.23.20"/>
          <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus"/>
        </observation>
      </entryRelationship>
      <entryRelationship>
        <observation/>
      </entryRelationship>
      <entryRelationship>
        <observation>
          <templateId root="2.16.840.1.113883.10.20.23.30"/>
          <code code="C66734" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
        </observation>
      </entryRelationship>
    </observation>
  </entryRelationship>
</observation>
```

Comment

[Observation: templateId `2.16.840.1.113883.10.20.23.23`]

The template is used for submitting free-text comments. A comment may be related to a particular data item or collected seperately on a form dedicated to comments. Comments are generally not responses to specific questions; instead, comments usually consist of voluntary, free-text or unsolicited observations. This structure is captured as a template to facilitate its reuse as a general mechanism for attaching comments.

1. **SHALL** contain exactly one [1..1] **`@classCode="OBS"`** *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF:1339)
2. **SHALL** contain exactly one [1..1] **`@moodCode="EVN"`** *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:1340)
3. **SHALL** contain exactly one [1..1] **`id`** (CONF:1341)
   - A sequence number for the comment. [SDTM: COSEQ], [SEND: COSEQ]
4. **SHOULD** contain exactly one [1..1] **`code`** (CONF:1342)**`/@code="C49569"`** (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`) (CONF:1343)
   - The code value indicates that this observation is a comment.
5. **MAY** contain zero or one [0..1] **`effectiveTime`** (CONF:1344)
   - The date time of the comment. [SDTM: CODTC], [SEND: CODTC]
6. **SHOULD** contain zero or one [0..1] **`participant`** (CONF:1345)
   - The author of the comment.
   a. Contains exactly one [1..1] *Study Finding Evaluator* (templateId: `2.16.840.1.113883.10.20.23.84`)
7. **SHALL** contain exactly one [1..1] **`value`** with data type ED (CONF:1346)
   - The comment text. [SDTM: COVAL], [SEND: COVAL]
8. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:1347)

   A reference to identify the subject of the the comment.
   a. This entryRelationship Contains exactly one [1..1] **`@typeCode`**
   b. This entryRelationship **SHALL** contain exactly one [1..1] **`act`** (CONF:1348)
      a. This act **SHALL** contain exactly one [1..1] **`@classCode="ACT"`** *Act* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF:1349)
      b. This act **SHALL** contain exactly one [1..1] **`@moodCode="EVN"`** *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:1351)
      c. This act **SHALL** contain exactly one [1..1] **`code`** (CONF:1350)

         Indicates the nature of the item that the comment refers to. SDTM notes: "May be the CRF page number (e.g. 650), or a module name (e.g. DEMOG), or a combination of information that identifies the reference (e.g. 650-VITALS-VISIT 2)". [SDTM: COREF], [SEND: COREF]

Comment 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="2.16.840.1.113883.10.20.23.23"/>
  <id root="2117390670" extension="MDHT"/>
  <code code="C49569" codeSystem="2.16.840.1.113883.3.26.1.1"
 codeSystemName="NCI Thesaurus"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <value xsi:type="ED">Text Value</value>
  <participant>
    <participantRole classCode="ASSIGNED">
      <templateId root="null"/>
      <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
 Thesaurus"/>
    </participantRole>
  </participant>
  <entryRelationship>
    <act classCode="ACT" moodCode="EVN"/>
  </entryRelationship>
```

```
</observation>
```

Concomitant Medication

[SubstanceAdministration: templateId `2.16.840.1.113883.10.20.25.24`]

The template 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.

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="SBADM"` (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF:257)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:258)
3. **SHALL** contain [1..2] **`id`** (CONF:259)
   - A sponsor supplied reference number for the concommitant medication. [SDTM: CMSEQ, CMSPID] A sequence number is required.
4. **SHOULD** contain zero or one [0..1] **`statusCode`** (CONF:260)
   - Used to indicate whether the activity - use of a particular medication - did occur. Use statusCode "Completed" if the use occurred. [SDTM: CMOCCUR]
5. **MAY** contain zero or one [0..1] **`text`** (CONF:261)
   - A text description of dosing amounts or a range of dosing information. The element is to be used when the features of the effectiveTime element - as described here - are insuffient to capture the dosing frequency. [SDTM: CMDOSTXT]
6. **MAY** contain zero or one [0..1] **`effectiveTime`** (CONF:262)
   - Information on when and how oftern the concommitant medication was taken. The effectiveTime element is used to support both the duration of the administration, and to record the frequency of administration. Possible values for time interval include start date, stop date, and duration. Note, only two of these need to be valued, and only two values are supported. It is expected that start date and stop date will be provided if both are known with sufficient precision. However, if necessary and duration is included, then either stop date (the more usual case), start date, or both will be omitted. More specifically: The periodic time interval (PIVL_TS) type is used to record requency. This captures the number of hours, days, weeks, between two administrations of the substance. (For example, BID is recorded as 12 hours) [SDTM: CMSTDTC, CMENDTC, CMDUR, CMDOSFRQ] 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.
7. **MAY** contain zero or one [0..1] **`doseQuantity`** (CONF:263)
   - The amount of medication taken at a single administration. The amount of the dose is stored using the value property of the PQ type, while the unit of measure is included in the unit property. The guide shows the use of IVL_PQ (interval of physical quanitities) to allow the entry of dose ranges instead of an single value. In the case where only a single value is needed, the instance can use PQ instead of IVL_PQ. [SDTM: CMDOSE, CMDOSU]
8. **MAY** contain zero or one [0..1] **`maxDoseQuantity`** (CONF:264)
   - Information on the total daily dose of the medication. The structure also accommodates periods other than a day. Thefore the time period = 1 day needs to be indicated as the denominator of the ratio. [SDTM: CMDOSTOT] Note, this attribute could also be used if multiple total dosage amounts need to be reported.
9. **MAY** contain zero or one [0..1] **`routeCode`** (CONF:265), where the @code **SHALL** be selected from ValueSet *`Route of Administration`* `C66729` **STATIC** (CONF:1521)
   - The route by which the medication is administered. [SDTM: CMROUTE]
10. **SHALL** contain exactly one [1..1] **`entryRelationship`** (CONF:266)

- Identifies the SDTM or SEND domain the record is assigned to.

a. Contains **@typeCode="REFR"** *REFR*
b. Contains exactly one [1..1] *Domain Assignment* (templateId: 2.16.840.1.113883.10.20.23.30)

11. MAY contain zero or one [0..1] **entryRelationship** (CONF:267)

- 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: 2.16.840.1.113883.10.20.23.42)

12. MAY contain zero or one [0..1] **entryRelationship** (CONF:268)

- Used to capture information, most particularly the timing, regarding the collection of data for an event. This is relevant especially in cases where the timing and duration of an event are distinct from that of data collection.

a. Contains **@typeCode="COMP"** *COMP*
b. Contains exactly one [1..1] *Data Collection* (templateId: 2.16.840.1.113883.10.20.23.27)

13. MAY contain zero or one [0..1] **entryRelationship** (CONF:269)

- Provides a reason for not capturing information for the concomitant medication.

a. Contains **@typeCode="COMP"** *COMP*
b. Contains exactly one [1..1] *Non Performance Reason* (templateId: 2.16.840.1.113883.10.20.23.56)

14. SHALL contain exactly one [1..1] **consumable** (CONF:270)

- Identifies and carries information for the consumable item that is being referred to.

a. Contains exactly one [1..1] *Consumable Material* (templateId: 2.16.840.1.113883.10.20.23.26)

15. MAY contain zero or one [0..1] **entryRelationship** (CONF:271)

- Information on the indication/reason for the substance administration.

a. Contains **@typeCode="COMP"** *COMP*
b. Contains exactly one [1..1] *Indication* (templateId: 2.16.840.1.113883.10.20.23.48)

16. MAY contain zero or one [0..1] **entryRelationship** (CONF:272)

- Information on the intended dose regimen of the medication. It supplements the frequency information provided within the effectiveTime element.

a. Contains **@typeCode="COMP"** *COMP*
b. Contains exactly one [1..1] *Intended Regimen* (templateId: 2.16.840.1.113883.10.20.23.49)

17. MAY contain zero or one [0..1] **entryRelationship** (CONF:273)

- Used to indicate whether collection of data regarding an event of this type has been pre-specified, usually on a reporting form.

a. Contains **@typeCode="COMP"** *COMP*
b. Contains exactly one [1..1] *Pre-Specified Event* (templateId: 2.16.840.1.113883.10.20.23.70)

18. MAY contain zero or one [0..1] **entryRelationship** (CONF:274)

- Records the duration of an event in cases in which this cannot be derived from existing start and stop information.

a. Contains **@typeCode="COMP"** *COMP*
b. Contains exactly one [1..1] *Event Duration* (templateId: 2.16.840.1.113883.10.20.23.102)

19. MAY contain zero or one [0..1] **entryRelationship** (CONF:275)

- Used to record the study days associated with the beginning and end points of an activity that may extend over a period of time.

a. Contains **@typeCode="REFR"** *REFR*
b. Contains exactly one [1..1] *Study Day Period* (templateId: 2.16.840.1.113883.10.20.23.82)

20. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:276)
    - Creates an assoication between the timing of an activity and a defined reference time point.
    a. Contains **`@typeCode="REFR"`** *REFR*
    b. Contains exactly one [1..1] *Timing Reference* (templateId: `2.16.840.1.113883.10.20.23.97`)
21. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:277)
    - Allows positioning of the start of the event with relationship to a defined reference time period.
    a. Contains **`@typeCode="REFR"`** *REFR*
    b. Contains exactly one [1..1] *Start Relative to Reference Period* (templateId: `2.16.840.1.113883.10.20.23.79`)
22. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:278)
    - Allows positioning of the termination of the event with relationship to a defined reference time period.
    a. Contains **`@typeCode="REFR"`** *REFR*
    b. Contains exactly one [1..1] *Stop Relative to Reference Period* (templateId: `2.16.840.1.113883.10.20.23.80`)
23. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:279)
    - The record of a category to be used in organizing information items.
    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Category* (templateId: `2.16.840.1.113883.10.20.23.20`)
24. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:280)
    - The record of a sub-category to be used in organizing information items.
    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Sub- Category* (templateId: `2.16.840.1.113883.10.20.23.91`)
25. **MAY** contain zero or more [0..*] **`entryRelationship`** (CONF:281)
    - Establishes a relationship between this record and another record.
    a. Contains **`@typeCode="REFR"`** *REFR*
    b. Contains exactly one [1..1] *Related Record* (templateId: `2.16.840.1.113883.10.20.23.75`)
26. **MAY** contain zero or more [0..*] **`entryRelationship`** (CONF:282)
    - Allows the association of a supplemental value - outside of the content specfied for the domain - to the record.
    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Supplemental Value* (templateId: `2.16.840.1.113883.10.20.23.96`)
27. **MAY** contain zero or more [0..*] **`entryRelationship`** (CONF:283)
    - A place to insert comments related to a particular intervention.
    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Comment* (templateId: `2.16.840.1.113883.10.20.23.23`)
28. **MAY** contain zero or more [0..*] **`entryRelationship`** (CONF:284)
    - Allows recording of additional findings related to the concommitant medication.
    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Finding About* (templateId: `2.16.840.1.113883.10.20.23.40`)
29. Contains zero or one [0..1] **`ageAssociation`**
    a. This ageAssociation **SHALL** contain exactly one [1..1] **`@typeCode`**`="COMP"` (CONF:74)
    b. This ageAssociation **SHALL** contain exactly one [1..1] **`observation`** (CONF:75)
        a. This observation **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF:76)

b. This observation **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:77)

c. This observation **SHALL** contain exactly one [1..1] **`code`** (CONF:78)**`/@code`**`="C25150"` *Reported Age* (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`) (CONF:79)

The code value indicates this is an age observation.

d. This observation **SHALL** contain exactly one [1..1] **`value`** with data type PQ (CONF:80)

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], [SEND: AGE, AGEU]

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">
  <id root="1402864761" extension="MDHT"/>
  <text>Text Value</text>
  <statusCode code="completed"/>
  <effectiveTime value="20121004"/>
  <routeCode code="571810477"/>
  <doseQuantity/>
  <maxDoseQuantity/>
  <consumable>
    <manufacturedProduct classCode="MANU"/>
  </consumable>
  <entryRelationship>
    <act classCode="ACT">
      <templateId root="2.16.840.1.113883.10.20.23.42"/>
      <id root="1337300070" extension="MDHT"/>
      <code code="C83204" 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">
      <templateId root="2.16.840.1.113883.10.20.23.56"/>
      <id root="1475903346" extension="MDHT"/>
      <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
 Thesaurus" displayName="Reason for non completion"/>
      <text>Text Value</text>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation/>
  </entryRelationship>
  <entryRelationship>
    <act>
      <id root="1370403054" extension="MDHT"/>
      <code code="1668241473"/>
      <text>Text Value</text>
      <statusCode code="completed"/>
      <effectiveTime>
```

```
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <entryRelationship>
        <observation/>
      </entryRelationship>
    </act>
 </entryRelationship>
 <entryRelationship>
   <observation>
     <id root="799029320" extension="MDHT"/>
     <code code="66980621"/>
     <text>Text Value</text>
     <statusCode code="completed"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
   </observation>
 </entryRelationship>
 <entryRelationship>
   <act>
     <templateId root="2.16.840.1.113883.10.20.23.97"/>
     <id root="2033279273" extension="MDHT"/>
     <code codeSystem="2.16.840.1.113883.3.26.1.1"/>
     <text>Text Value</text>
     <statusCode code="completed"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
     <entryRelationship typeCode="COMP"/>
   </act>
 </entryRelationship>
 <entryRelationship>
   <observation classCode="OBS" moodCode="EVN">
     <templateId root="2.16.840.1.113883.10.20.23.23"/>
     <id root="1241916998" extension="MDHT"/>
     <code code="C49569" 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>
     <participant/>
     <entryRelationship/>
   </observation>
 </entryRelationship>
 <entryRelationship>
   <observation>
     <templateId root="2.16.840.1.113883.10.20.23.30"/>
     <id root="231774487" extension="MDHT"/>
     <code code="C66734" 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">
     <templateId root="2.16.840.1.113883.10.20.23.75"/>
     <id root="28349323" 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>
   </act>
 </entryRelationship>
 <entryRelationship>
   <observation classCode="OBS" moodCode="EVN">
     <templateId root="2.16.840.1.113883.10.20.23.96"/>
     <id root="1982425307" extension="MDHT"/>
     <code codeSystem="locally defined" codeSystemName="Supplemental Value
Type"/>
     <text>Text Value</text>
     <statusCode code="completed"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
     <participant/>
     <entryRelationship typeCode="COMP"/>
   </observation>
 </entryRelationship>
 <entryRelationship>
   <observation/>
 </entryRelationship>
 <entryRelationship>
   <observation/>
 </entryRelationship>
 <entryRelationship>
   <observation classCode="OBS" moodCode="EVN">
     <templateId root="2.16.840.1.113883.10.20.23.48"/>
     <id root="1339369353" extension="MDHT"/>
     <code code="C83085" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus" displayName="Concomitant Medication
Indication"/>
     <text>Text Value</text>
     <statusCode code="completed"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
   </observation>
 </entryRelationship>
 <entryRelationship>
   <observation>
     <templateId root="2.16.840.1.113883.10.20.23.49"/>
     <id root="337741950" 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>
   </observation>
```

```
 </entryRelationship>
 <entryRelationship>
   <observation classCode="OBS" moodCode="EVN">
     <templateId root="2.16.840.1.113883.10.20.23.20"/>
     <id root="1412758175" 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>
   </observation>
 </entryRelationship>
 <entryRelationship>
   <observation/>
 </entryRelationship>
 <entryRelationship>
   <observation>
     <id root="1834735433" extension="MDHT"/>
     <code code="1644651974"/>
     <text>Text Value</text>
     <statusCode code="completed"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
     <participant/>
     <entryRelationship typeCode="REFR"/>
     <entryRelationship>
       <act classCode="ACT">
         <templateId root="2.16.840.1.113883.10.20.23.42"/>
         <code code="C83204" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
       </act>
     </entryRelationship>
     <entryRelationship>
       <observation classCode="OBS">
         <templateId root="2.16.840.1.113883.10.20.23.56"/>
         <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus" displayName="Reason for non completion"/>
       </observation>
     </entryRelationship>
     <entryRelationship>
       <act/>
     </entryRelationship>
     <entryRelationship>
       <observation classCode="OBS" moodCode="EVN">
         <templateId root="2.16.840.1.113883.10.20.23.20"/>
         <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus"/>
       </observation>
     </entryRelationship>
     <entryRelationship>
       <observation/>
     </entryRelationship>
     <entryRelationship>
       <observation>
         <templateId root="2.16.840.1.113883.10.20.23.30"/>
         <code code="C66734" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
       </observation>
     </entryRelationship>
```

```
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.102"/>
      <id root="668740501" extension="MDHT"/>
      <code code="EDtbd" 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>
</substanceadministration>
```

Concomitant Treatment

[Observation: templateId `2.16.840.1.113883.10.20.25.25`]

The template is used to record information on whether another treatment was provided to the study subject as a result of an event occurrence. This structure is captured as a template to facilitate its reuse as a characteristic of different types of event within clinical and non-clinical trial reporting.

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF:1452)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:1453)
3. **SHALL** contain exactly one [1..1] **`code`** (CONF:1454)**`/@code`**`="C83199"` *Adverse Event Concommitant Treatment* (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`) (CONF:1455)
   - The code value indicates the observation contains concomitant or additional treatment information.
4. **SHALL** contain exactly one [1..1] **`value`** with data type BL (CONF:1456)
   - Indicate whether or not concomitant or additional treatment was given because of the occurrence of the event. [SDTM: AECONTRT], Study Data Tabulation Model: -CONTRT]

Concomitant Treatment 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="2.16.840.1.113883.10.20.25.25"/>
  <id root="683963329" extension="MDHT"/>
  <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus"
 displayName="Adverse Event Concommitant Treatment"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <value xsi:type="BL"/>
</observation>
```

Data Collection

[Act: templateId `2.16.840.1.113883.10.20.23.27`]

The template is used for the collection of data, or the completion of a question with regard to an activity or other event. It captures indication about the peformance and timing of data collection. This structure is captured as a template to facilitate its reuse as a characteristic of different types of data within clinical trial reporting. Use of this

template is particularly relevant when there is a potential distinction between the timing of when an activity occurred and when it was reported.

1. **SHALL** contain exactly one [1..1] **@classCode**="ACT" *Act* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) (CONF:411)
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) (CONF:412)
3. **MAY** contain zero or one [0..1] **@negationInd** (CONF:417)
   - 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], [Study Data Tablulation Model: -STAT]
4. **SHALL** contain exactly one [1..1] **code** (CONF:413)**/@code**="DCtbd" (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus) (CONF:415)
   - 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 (CONF:416)
   - The date/time of data collection. [SDTM: DMDTC, SUDTC, DSDTC, MHDTC, PEDTC, CEDTC, IEDTC, QSDTC, SCDTC, MSDTC] [SEND: BWDTC, CLDTC, DDDTC, MADTC, MIDTC, OMDTC, PMDTC, SCDTC]
6. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:418)
   - Used to record the study day associated with the data collection.
   a. Contains **@typeCode="**REFR" *REFR*
   b. Contains exactly one [1..1] *Event Study Day* (templateId: 2.16.840.1.113883.10.20.23.37)

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">
  <id root="1151022441" extension="MDHT"/>
  <code code="502939648"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <entryRelationship>
    <observation>
      <id root="1671938223" extension="MDHT"/>
      <code code="1589018432"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
    </observation>
  </entryRelationship>
</act>
```

Domain Assignment

[Observation: templateId 2.16.840.1.113883.10.20.23.30]

The template provides information on the domain - general information category - that an information item is assigned to. The current list of domains is drawn from the SEND and SDTM implementation guides. Each discrete information item will be assigned to at least one domain. The is defined as a template to allow its reuse. In addition, there is a possiblity that - going forward - more than one domain could be assigned to a data item; use of this structure makes it easier to introduce such a change.

1. **SHALL** contain exactly one [1..1] **@classCode**="ACT" *Act* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) (CONF:1335)

2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:1334)
3. **SHALL** contain exactly one [1..1] **`code`** (CONF:1336)**`/@code`**`="C66734"` (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`) (CONF:1337)
   - Designation of the SDTM or SEND domain that a data instance is assigned to.
4. **SHALL** contain exactly one [1..1] **`value`** with data type CD, where the @code **SHALL** be selected from ValueSet *`Domain Abbreviation`* `C66734` **STATIC** (CONF:1338)

Domain Assignment 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="2.16.840.1.113883.10.20.23.30"/>
  <id root="1359877460" extension="MDHT"/>
  <code code="C66734" codeSystem="2.16.840.1.113883.3.26.1.1"
 codeSystemName="NCI Thesaurus"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
</observation>
```

Dose Adjustment Reason

[Observation: templateId `2.16.840.1.113883.10.20.23.31`]

The template is used to provide a description of the reason for, or explanation of, an adjustment to the administered dosage.

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF:1400)
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`** (CONF:1401)**`/@code`**`="DARtbd"` (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`) (CONF:1402)
   - The code value indicates this is a dose adjustment observation.
4. **SHALL** contain exactly one [1..1] **`value`** with data type ED (CONF:1403)
   - A text entry describing the reason for a dose adjustment. [SDTM: EXADJ]. [SEND: EXADJ]

Dose Adjustment 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">
  <id root="12853527" extension="MDHT"/>
  <code code="1767544995"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <value xsi:type="ED">Text Value</value>
</observation>
```

Drug Accountability

[Observation: templateId `2.16.840.1.113883.10.20.23.32`]

The template supports the content sof the Drug Accountability domain. It 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`) (CONF:804)
2. **SHALL** contain exactly one [1..1] **`@moodCode="EVN"`** *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:805)
3. **SHALL** contain [1..3] **`id`** (CONF:806)
   - 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.
4. **SHALL** contain exactly one [1..1] **`code`** (CONF:807), where the @code **SHALL** be selected from ValueSet *`Drug Accountability Finding Set`* `C78732` **STATIC** (CONF:808)
   - 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]
5. **MAY** contain zero or one [0..1] **`statusCode`** (CONF:809)
   - Used to indicate whether the activity - recording the drug accountability value - did occur. Use statusCode "Completed" if the use occurred. [SDTM: DASTAT]
6. **SHOULD** contain zero or one [0..1] **`effectiveTime`** with data type TS (CONF:810)
   - The date/time of the accountability assessment. [SDTM: DADTC]
7. **SHOULD** contain [0..3] **`value`** (CONF:811)
   - 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. Each form for the result is collected as a separate observation - up to three may be valued. [SDTM: DAORRES, DAORRESU, DASTRESC, DASTRESN, DASTRESU]
8. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:812)
   - Identifies the SDTM or SEND domain the record is assigned to.
   a. Contains **`@typeCode="COMP"`** *COMP*
   b. Contains exactly one [1..1] *Domain Assignment* (templateId: `2.16.840.1.113883.10.20.23.30`)
9. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:813)
   - 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: `2.16.840.1.113883.10.20.23.42`)
10. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:814)
    - Provides a reason for not capturing information for the drug accountability item.
    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Non Performance Reason* (templateId: `2.16.840.1.113883.10.20.23.56`)
11. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:815)
    - Used to record the study day associated with an activity taking place during a single day.
    a. Contains **`@typeCode="REFR"`** *REFR*
    b. Contains exactly one [1..1] *Event Study Day* (templateId: `2.16.840.1.113883.10.20.23.37`)
12. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:816)

- The record of a category to be used in organizing information items.

a. Contains **@typeCode="COMP"** *COMP*
b. Contains exactly one [1..1] *Category* (templateId: 2.16.840.1.113883.10.20.23.20)

13. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:817)

- The record of a sub-category to be used in organizing information items.

a. Contains **@typeCode="COMP"** *COMP*
b. Contains exactly one [1..1] *Sub- Category* (templateId: 2.16.840.1.113883.10.20.23.91)

14. **MAY** contain zero or more [0..*] **entryRelationship** (CONF:818)

- Establishes a relationship between this record and another record.

a. Contains **@typeCode="REFR"** *REFR*
b. Contains exactly one [1..1] *Related Record* (templateId: 2.16.840.1.113883.10.20.23.75)

15. **MAY** contain zero or more [0..*] **entryRelationship** (CONF:819)

- Allows the association of a supplemental value - outside of the content specfied for the domain - to the record.

a. Contains **@typeCode="COMP"** *COMP*
b. Contains exactly one [1..1] *Supplemental Value* (templateId: 2.16.840.1.113883.10.20.23.96)

16. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:820)

- A place to insert comments related to a particular finding.

a. Contains **@typeCode="COMP"** *COMP*
b. Contains exactly one [1..1] *Comment* (templateId: 2.16.840.1.113883.10.20.23.23)

17. **MAY** contain zero or more [0..*] **entryRelationship** (CONF:821)

- Allows recording of additional findings related to the event.

a. Contains **@typeCode="COMP"** *COMP*
b. Contains exactly one [1..1] *Finding About* (templateId: 2.16.840.1.113883.10.20.23.40)

Drug Accountability 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">
  <id root="1555795084" extension="MDHT"/>
  <code code="574914940"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <entryRelationship>
    <act classCode="ACT">
      <templateId root="2.16.840.1.113883.10.20.23.42"/>
      <id root="1336252946" extension="MDHT"/>
      <code code="C83204" 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">
      <templateId root="2.16.840.1.113883.10.20.23.56"/>
```

```
      <id root="1104783425" extension="MDHT"/>
      <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus" displayName="Reason for non completion"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <value xsi:type="CD" code="798381272"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation>
      <id root="485162661" extension="MDHT"/>
      <code code="402788716"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <value xsi:type="INT" value="1"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.20"/>
      <id root="47077106" 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="CD" code="25489553"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation/>
  </entryRelationship>
  <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.23"/>
      <id root="1779376510" extension="MDHT"/>
      <code code="C49569" 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="ED">Text Value</value>
      <participant/>
      <entryRelationship/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation>
      <templateId root="2.16.840.1.113883.10.20.23.30"/>
      <id root="2081048757" extension="MDHT"/>
      <code code="C66734" 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="CD" code="884057132"/>
    </observation>
 </entryRelationship>
 <entryRelationship>
    <act classCode="ACT">
      <templateId root="2.16.840.1.113883.10.20.23.75"/>
      <id root="513060539" 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>
    </act>
 </entryRelationship>
 <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.96"/>
      <id root="1278014871" extension="MDHT"/>
      <code codeSystem="locally defined" codeSystemName="Supplemental Value
Type"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <participant/>
      <entryRelationship typeCode="COMP"/>
    </observation>
 </entryRelationship>
 <entryRelationship>
    <observation>
      <id root="810425779" extension="MDHT"/>
      <code code="2118259330"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <participant/>
      <entryRelationship typeCode="REFR"/>
      <entryRelationship>
        <act classCode="ACT">
          <templateId root="2.16.840.1.113883.10.20.23.42"/>
          <code code="C83204" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
        </act>
      </entryRelationship>
      <entryRelationship>
        <observation classCode="OBS">
          <templateId root="2.16.840.1.113883.10.20.23.56"/>
          <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus" displayName="Reason for non completion"/>
        </observation>
      </entryRelationship>
      <entryRelationship>
        <act/>
      </entryRelationship>
      <entryRelationship>
        <observation classCode="OBS" moodCode="EVN">
```

```
          <templateId root="2.16.840.1.113883.10.20.23.20"/>
          <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus"/>
        </observation>
      </entryRelationship>
      <entryRelationship>
        <observation/>
      </entryRelationship>
      <entryRelationship>
        <observation>
          <templateId root="2.16.840.1.113883.10.20.23.30"/>
          <code code="C66734" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
        </observation>
      </entryRelationship>
    </observation>
  </entryRelationship>
</observation>
```

ECG Test Result

[Observation: templateId `2.16.840.1.113883.10.20.23.33`]

The template is used for capturing ECG results.

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF:481)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:482)
3. **SHALL** contain [1..3] **`id`** (CONF:483)
   - A value that is provided to ensure the uniqueness of ECG test result items. [SDTM: EGSEQ, EGREFID, EGSPID], [SEND: EGSEQ, EGREFID, EGSPID] A single identifier, the sequence number, is required.
4. **SHALL** contain exactly one [1..1] **`code`** (CONF:484), where the @code **SHALL** be selected from ValueSet *`ECG Test Type`* `C71153` **STATIC** (CONF:485)
   - 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], [SEND: EGTESTCD, EGTEST]
5. **MAY** contain zero or one [0..1] **`text`** (CONF:486)
   - 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], [SEND: EGXFN]
6. **MAY** contain zero or one [0..1] **`statusCode`** (CONF:487), where the @code **SHALL** be selected from (CodeSystem: `2.16.840.1.113883.5.14 ActStatus`) (CONF:1532)
   - Used to indicate whether the activity - performance of the ECG - did occur. Use statusCode "Completed" if the use occurred. [SDTM: EGSTAT], [SEND: EGSTAT]
7. **SHOULD** contain zero or one [0..1] **`effectiveTime`** (CONF:488)
   - The performance date of the ECG test. [SDTM: EGDTC], [SEND: EGDTC, EGENDTC]
8. **SHOULD** contain [0..3] **`value`** (CONF:489)
   - Captures the ECG measurement or finding as up to three observation values. 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. The value set ECG Test Result Type should be used for coded findings. [SDTM: EGORRES, EGORRESU, EGSTRESC, EGSTRESN, EGSTRESU], [SEND: EGORRES, EGORRESU, EGSTRESC, EGSTRESN, EGSTRESU]
9. **SHALL** contain exactly one [1..1] **`entryRelationship`** (CONF:490)
   - Identifies the SDTM or SEND domain the record is assigned to.

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

b. Contains exactly one [1..1] *Domain Assignment* (templateId: `2.16.840.1.113883.10.20.23.30`)

10. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:491)
    - Allows capture of a group identifier for the ECG result.
    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Group Identifier* (templateId: `2.16.840.1.113883.10.20.23.42`)
11. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:492)
    - Provides a reason for not capturing information for the ECG test result.
    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Non Performance Reason* (templateId: `2.16.840.1.113883.10.20.23.56`)
12. **MAY** contain zero or one [0..1] **`methodCode`** (CONF:493), where the @code **SHALL** be selected from ValueSet *`ECG Test Method`* `C71151` **STATIC** (CONF:494)
    - Capture the method of the ECG test. [SDTM: EGMETHOD], [SEND: EGMETHOD]
13. **SHOULD** contain zero or one [0..1] **`entryRelationship`** (CONF:495)

    Captures the location - on the subject's body - of a lead used for collecting ECG information.
    a. This entryRelationship **SHALL** contain zero or one [0..1] **`@typeCode="COMP"`** (CONF:511)
    b. This entryRelationship **SHALL** contain exactly one [1..1] **`observation`** (CONF:512)

       An observation of the actual lead location.
       a. This observation **SHALL** contain exactly one [1..1] **`@classCode="OBS"`** *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF:513)
       b. This observation **SHALL** contain exactly one [1..1] **`@moodCode="EVN"`** *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:516)
       c. This observation **SHALL** contain exactly one [1..1] **`code`** (CONF:514)**`/@code="C87881"`** (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`) (CONF:515)

          A code that indicates the observation contains information regarding the ECG lead that the result relates to.
       d. This observation **SHALL** contain zero or more [0..*] **`value`** with data type CD (CONF:517), where the @code **SHALL** be selected from ValueSet *`ECG Lead Location`* `C90013` **STATIC** (CONF:518)

          Provides information on the lead location associated with the reported ECG result. [SDTM: EGLOC], [SEND: EGLOC]

       An observation of the actual lead location.
14. **MAY** contain zero or one [0..1] **`participant`** (CONF:496)
    - Used to record the organization performing the test.
    a. Contains exactly one [1..1] *Study Test Organization* (templateId: `2.16.840.1.113883.10.20.23.88`)
15. **MAY** contain zero or one [0..1] **`participant`** (CONF:497)
    - Used to record the role played by the person providing the value of a subjective finding.
    a. Contains exactly one [1..1] *Study Finding Evaluator* (templateId: `2.16.840.1.113883.10.20.23.84`)
16. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:498)
    - Records the position of the subject at the time of measurement.
    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Position of Subject* (templateId: `2.16.840.1.113883.10.20.23.69`)
17. **SHOULD** contain zero or one [0..1] **`entryRelationship`** (CONF:499)

    A record of the consciousness state of the subject at the time of measurement.
    a. This entryRelationship **SHALL** contain exactly one [1..1] **`@typeCode="COMP"`** (CONF:519)
    b. This entryRelationship **SHALL** contain exactly one [1..1] **`observation`** (CONF:520)

An observation of the state of consciousness.

a. This observation **SHALL** contain exactly one [1..1] **`@classCode`** (CONF:521)

b. This observation **SHALL** contain exactly one [1..1] **`@moodCode`** (CONF:524)

c. This observation **SHALL** contain exactly one [1..1] **`code`** (CONF:522)**`/@code="CStbd"`** (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`) (CONF:523)

A code value that indicates that the observation is that of consciousness state.

d. This observation **SHALL** contain exactly one [1..1] **`value`** with data type CD (CONF:525), where the @code **SHALL** be selected from ValueSet *`Consciousness State`* `CXXXXX` **STATIC** (CONF:526)

A coded value that indicates the state of consciousness of the subject when the ECG measurement was recorded. [SEND: EGCSTATE]

An observation of the state of consciousness.

18. **SHOULD** contain zero or one [0..1] **`entryRelationship`** (CONF:500)

- Captures the planned study day for making an observation or recording a finding.

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

b. Contains exactly one [1..1] *Planned Study Day* (templateId: `2.16.840.1.113883.10.20.23.68`)

19. **SHALL** contain zero or one [0..1] **`entryRelationship`** (CONF:501)

- A reference to the study days corresponding to the time period of the observation.

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

b. Contains exactly one [1..1] *Study Day Period* (templateId: `2.16.840.1.113883.10.20.23.82`)

20. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:502)

- Orients the performance of the ECG test with respect to a study defined timepoint.

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

b. Contains exactly one [1..1] *Timing Reference* (templateId: `2.16.840.1.113883.10.20.23.97`)

21. **SHOULD** contain [0..3] **`interpretationCode`** (CONF:503), where the @code **SHALL** be selected from ValueSet *`Subject Data Interpretation Type`* `CXXXXX` **STATIC** (CONF:504)

- Includes information used to better interpret the observation value (result). In particular, it is used to note if an observation is a baseline value, if it is derived, and/or if it should be excluded from tabulation of results. [SDTM: EGBLFL, EGDRVFL, EGEXCLFL], [SEND: EGBLFL, EGDRVFL, EGEXCLFL]

22. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:505)

- The record of a category to be used in organizing information items.

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

b. Contains exactly one [1..1] *Category* (templateId: `2.16.840.1.113883.10.20.23.20`)

23. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:506)

- The record of a sub-category to be used in organizing information items.

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

b. Contains exactly one [1..1] *Sub- Category* (templateId: `2.16.840.1.113883.10.20.23.91`)

24. **MAY** contain zero or more [0..*] **`entryRelationship`** (CONF:507)

- Establishes a relationship between this record and another record.

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

b. Contains exactly one [1..1] *Related Record* (templateId: `2.16.840.1.113883.10.20.23.75`)

25. **MAY** contain zero or more [0..*] **`entryRelationship`** (CONF:508)

- Allows the association of a supplemental value - outside of the content specfied for the domain - to the record.

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

b. Contains exactly one [1..1] *Supplemental Value* (templateId: `2.16.840.1.113883.10.20.23.96`)

26. MAY contain zero or more [0..*] **`entryRelationship`** (CONF:509)

- A place to insert comments related to a particular finding.

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

b. Contains exactly one [1..1] *Comment* (templateId: `2.16.840.1.113883.10.20.23.23`)

27. MAY contain zero or more [0..*] **`entryRelationship`** (CONF:510)

- Allows recording of additional findings related to the finding.

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

b. Contains exactly one [1..1] *Finding About* (templateId: `2.16.840.1.113883.10.20.23.40`)

28. 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. (CONF:479)

29. 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. (CONF:480)

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">
  <templateId root="2.16.840.1.113883.10.20.23.33"/>
  <id root="2023195774" extension="MDHT"/>
  <code codeSystem="2.16.840.1.113883.3.26.1.1"/>
  <text>Text Value</text>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <interpretationCode codeSystemName="NCI Thesaurus"/>
  <methodCode code="455969859"/>
  <participant>
    <participantRole classCode="ASSIGNED">
      <templateId root="null"/>
    </participantRole>
  </participant>
  <participant>
    <participantRole classCode="ASSIGNED">
      <templateId root="null"/>
      <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
 Thesaurus"/>
    </participantRole>
  </participant>
  <entryRelationship typeCode="COMP">
    <observation classCode="OBS" moodCode="EVN">
      <code code="C87881" codeSystem="2.16.840.1.113883.3.26.1.1"
 codeSystemName="NCI Thesaurus"/>
    </observation>
  </entryRelationship>
  <entryRelationship typeCode="COMP">
    <observation>
      <code code="CStbd" codeSystem="2.16.840.1.113883.3.26.1.1"
 codeSystemName="NCI Thesaurus"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <act classCode="ACT">
      <templateId root="2.16.840.1.113883.10.20.23.42"/>
```

```
      <id root="189855992" extension="MDHT"/>
      <code code="C83204" 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">
      <templateId root="2.16.840.1.113883.10.20.23.56"/>
      <id root="1094637505" extension="MDHT"/>
      <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus" displayName="Reason for non completion"/>
      <text>Text Value</text>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <value xsi:type="CD" code="681384161"/>
      <interpretationCode code="1331535386"/>
      <methodCode code="261360428"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <act>
      <templateId root="2.16.840.1.113883.10.20.23.97"/>
      <id root="448039542" extension="MDHT"/>
      <code codeSystem="2.16.840.1.113883.3.26.1.1"/>
      <text>Text Value</text>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <entryRelationship typeCode="COMP"/>
    </act>
  </entryRelationship>
  <entryRelationship>
    <observation>
      <id root="606892169" extension="MDHT"/>
      <code code="317434329"/>
      <text>Text Value</text>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <value xsi:type="INT" value="1"/>
      <interpretationCode code="1924663523"/>
      <methodCode code="203924187"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation>
      <id root="226314028" extension="MDHT"/>
      <code code="688167473"/>
      <text>Text Value</text>
      <statusCode code="completed"/>
      <effectiveTime>
```

```
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <value xsi:type="IVL_INT" value="1"/>
      <interpretationCode code="1791959530"/>
      <methodCode code="964306778"/>
    </observation>
 </entryRelationship>
 <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.23"/>
      <id root="1145498431" extension="MDHT"/>
      <code code="C49569" 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="ED">Text Value</value>
      <interpretationCode code="1776572380"/>
      <methodCode code="598823406"/>
      <participant/>
      <entryRelationship/>
    </observation>
 </entryRelationship>
 <entryRelationship>
    <observation>
      <templateId root="2.16.840.1.113883.10.20.23.30"/>
      <id root="527127042" extension="MDHT"/>
      <code code="C66734" 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="CD" code="887262238"/>
      <interpretationCode code="1060557921"/>
      <methodCode code="403697653"/>
    </observation>
 </entryRelationship>
 <entryRelationship>
    <act classCode="ACT">
      <templateId root="2.16.840.1.113883.10.20.23.75"/>
      <id root="1611193951" 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>
    </act>
 </entryRelationship>
 <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.96"/>
      <id root="2073452733" extension="MDHT"/>
      <code codeSystem="locally defined" codeSystemName="Supplemental Value
Type"/>
```

```
     <text>Text Value</text>
     <statusCode code="completed"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
     <interpretationCode code="1518781846"/>
     <methodCode code="1430658171"/>
     <participant/>
     <entryRelationship typeCode="COMP"/>
   </observation>
 </entryRelationship>
 <entryRelationship>
   <observation classCode="OBS" moodCode="EVN">
     <templateId root="2.16.840.1.113883.10.20.23.20"/>
     <id root="1531060216" 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="CD" code="504212629"/>
     <interpretationCode code="1933900703"/>
     <methodCode code="865416528"/>
   </observation>
 </entryRelationship>
 <entryRelationship>
   <observation/>
 </entryRelationship>
 <entryRelationship>
   <observation/>
 </entryRelationship>
 <entryRelationship>
   <observation>
     <id root="588442969" extension="MDHT"/>
     <code code="1276562081"/>
     <text>Text Value</text>
     <statusCode code="completed"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
     <interpretationCode code="11069482"/>
     <methodCode code="425659019"/>
     <participant/>
     <entryRelationship typeCode="REFR"/>
     <entryRelationship>
       <act classCode="ACT">
         <templateId root="2.16.840.1.113883.10.20.23.42"/>
         <code code="C83204" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
       </act>
     </entryRelationship>
     <entryRelationship>
       <observation classCode="OBS">
         <templateId root="2.16.840.1.113883.10.20.23.56"/>
         <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus" displayName="Reason for non completion"/>
       </observation>
     </entryRelationship>
     <entryRelationship>
```

```
        <act/>
      </entryRelationship>
      <entryRelationship>
        <observation classCode="OBS" moodCode="EVN">
          <templateId root="2.16.840.1.113883.10.20.23.20"/>
          <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
 Thesaurus"/>
        </observation>
      </entryRelationship>
      <entryRelationship>
        <observation/>
      </entryRelationship>
      <entryRelationship>
        <observation>
          <templateId root="2.16.840.1.113883.10.20.23.30"/>
          <code code="C66734" codeSystem="2.16.840.1.113883.3.26.1.1"
 codeSystemName="NCI Thesaurus"/>
        </observation>
      </entryRelationship>
    </observation>
  </entryRelationship>
</observation>
```

Event Duration

[Observation: templateId `2.16.840.1.113883.10.20.23.102`]

An observation that captures the duration of an event. The rationale for this observation is the presence within SDTM and SEND domains of elements to record start time , stop time AND duration of an event. It is to be used only when duration is provided directly, and cannot be derived from existing start and stop values.

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF:1512)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:1515)
3. **SHALL** contain exactly one [1..1] **`code`** (CONF:1513)**`/@code`**`="EDtbd"` (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`) (CONF:1514)
   - A code that indicates the observation records the duration of an event.
4. **SHALL** contain exactly one [1..1] **`value`** with data type PQR (CONF:1516)
   - Captures the duration of an event.

sdtm::Event Duration							
cda::observation[cda:templateId/@root = 2.16.840.1.113883.10.20.23.102]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
classCode	@classCode	1..1	SHALL	NO	ActClassObservation	CONF:1512	ALRT
moodCode	@moodCode	1..1	SHALL	NO	x_ActMoodDocumentObservation	CONF:1515	DEF
negationInd	@negationInd	0..1		NO	Boolean		
nullFlavor	@nullFlavor	0..1		NO	NullFlavor		ASKU
code	code	1..1	SHALL	YES	CD	CONF:1513	NCI Thesaurus 2.16.840.1.113883.3.26.1.1 EDtbd
derivationExpr	derivationExpr	0..1		YES	ST		
effectiveTime	effectiveTime	0..1		YES	IVL_TS		

sdtm::Event Duration							
cda::observation[cda:templateId/@root = 2.16.840.1.113883.10.20.23.102]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
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		2.16.840.1.113883.10.20.23.102
text	text	0..1		YES	ED		
value	value	1..1	SHALL	YES	PQR	CONF:1516	
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 Duration 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="2.16.840.1.113883.10.20.23.102"/>
  <id root="189377599" extension="MDHT"/>
  <code code="EDtbd" codeSystem="2.16.840.1.113883.3.26.1.1"
 codeSystemName="NCI Thesaurus"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <value xsi:type="PQR" code="635035214"/>
</observation>
```

Event or Finding Severity

[Observation: templateId `2.16.840.1.113883.10.20.23.34`]

The template provides a reusable stucture to record information regarding the severity or intensity of an observed event or a recorded finding. 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`) (CONF:251)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:254)
3. **SHALL** contain exactly one [1..1] **`code`** (CONF:252)**`/@code`**`="C66769"` (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`) (CONF:253)
   - The code value indicates this is a severity observation.
4. **SHALL** contain exactly one [1..1] **`value`** with data type CD (CONF:255), where the @code **SHALL** be selected from ValueSet *`Event Severity`* `C66769` **STATIC** (CONF:256)
   - Provide the severity or intensity of the event. [SDTM: AESEV, CESEV], [SEND: CLSEV, MASEV, MISEV], [Study Data Tabulation Model: -SEV]

Event or Finding 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="2.16.840.1.113883.10.20.23.34"/>
  <id root="1708323944" extension="MDHT"/>
  <code code="C66769" codeSystem="2.16.840.1.113883.3.26.1.1"
 codeSystemName="NCI Thesaurus"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <value xsi:type="CD" code="1382198770"/>
</observation>
```

Event Outcome

[Observation: templateId `2.16.840.1.113883.10.20.23.35`]

The template is used to provide a description of the outcome of an event. This structure is captured as a template to facilitate its reuse as a characteristic of different types of event within clinical and non-clinical trial reporting.

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF:1446)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:1449)
3. **SHALL** contain exactly one [1..1] **`code`** (CONF:1447)**`/@code`**`="C49489"` *Adverse Event Outcome* (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`) (CONF:1448)
   - A code that indicates this observation contains adverse event outcome information.
4. **SHALL** contain exactly one [1..1] **`value`** with data type CD (CONF:1450), where the @code **SHALL** be selected from ValueSet *`Outcome of Event`* `C66768` **STATIC** (CONF:1451)
   - A description of the outcome of the event. [SDTM: AEOUT], [Study Data Tabulation Model: -OUT]

Event Outcome 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="2.16.840.1.113883.10.20.23.35"/>
  <id root="776472669" extension="MDHT"/>
  <code codeSystem="2.16.840.1.113883.3.26.1.1" displayName="Adverse Event
 Outcome"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <value xsi:type="CD" code="468790550"/>
</observation>
```

Event Pattern

[Observation: templateId `2.16.840.1.113883.10.20.23.36`]

The templated is used to provide information that indicates the pattern of an event over time. This structure is captured as a template to facilitate its reuse as a characteristic of different types of event within clinical and non-clinical trial reporting.

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF:1440)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:1443)
3. **SHALL** contain exactly one [1..1] **`code`** (CONF:1441)**`/@code`**`="C83208"` *Adverse Event Pattern* (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`) (CONF:1442)
   - A code that indicates the observation contains information regarding the pattern of the adverse event over time.
4. **SHALL** contain exactly one [1..1] **`value`** with data type CD (CONF:1444), where the @code **SHALL** be selected from ValueSet *`Event Pattern`* `CXXXXX` **STATIC** (CONF:1445)
   - Provides information on the pattern of the event over time. [SDTM: AEPATT], [Study Data Tabulation Model: -PATT]

Event Pattern 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="2.16.840.1.113883.10.20.23.36"/>
  <id root="61648930" extension="MDHT"/>
  <code code="C83208" codeSystem="2.16.840.1.113883.3.26.1.1"
 codeSystemName="NCI Thesaurus" displayName="Adverse Event Pattern"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <value xsi:type="CD" code="1599498844"/>
</observation>
```

Event Study Day

[Observation: templateId `2.16.840.1.113883.10.20.23.37`]

The template 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) (CONF:220)
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) (CONF:221)
3. **SHALL** contain exactly one [1..1] **code** (CONF:222)**/@code**="ESDtbd" (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus) (CONF:223)
   - 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 (CONF:224)
   - The applicable study day value. [SDTM: DMDY, MHDY, CEDY, IEDY, LBDY, PEDY, QSDY, SCDY, VSDY, DADY, MBDY, MSDY, PCDY, FADY] [SEND: BWDY, CLDY, DDDY, MADY, MIDY, OMDY, PMDY, PCDY, SCDY]

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">
  <id root="1253988469" extension="MDHT"/>
  <code code="461613936"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <value xsi:type="INT" value="1"/>
</observation>
```

Fasting Status

[Observation: templateId 2.16.840.1.113883.10.20.23.39]

The template is used to store information regarding whether or not the subject was fasting at the effective time - when the specimen was drawn - of the test producing the finding.

1. **SHALL** contain exactly one [1..1] **@classCode**="OBS" *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) (CONF:1492)
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) (CONF:1495)
3. **SHALL** contain exactly one [1..1] **code** (CONF:1493)**/@code**="FStbd" (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus) (CONF:1494)
   - The code value indicates the observation concerns the subject's fasting status.
4. **SHALL** contain exactly one [1..1] **value** with data type BL (CONF:1496)
   - A Boolean indicator to provide nformation on whether the person was fasting at the effective time for the test. [SDTM: LBFAST, PCFAST], [SEND: LBFAST, PCFAST, BWFAST], [Study Data Tabulation Model: FAST]

Fasting Status 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">
  <templateId root="2.16.840.1.113883.10.20.23.39"/>
  <id root="1511881921" extension="MDHT"/>
  <code code="FStbd" 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>
```

Finding About

[Observation: templateId `2.16.840.1.113883.10.20.23.40`]

The Findings About template 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. This structure is captured as a template to facilitate its reuse across the various domains of clinical and non-clincial trial reporting.

1. **SHALL** contain exactly one [1..1] **`@classCode="OBS"`** *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF:771)
2. **SHALL** contain exactly one [1..1] **`@moodCode="EVN"`** *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:772)
3. **MAY** contain zero or one [0..1] **`effectiveTime`** (CONF:773)
4. **SHALL** contain [1..2] **`id`** (CONF:774)
   - 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.
5. **MAY** contain zero or one [0..1] **`statusCode`** (CONF:775)
   - Used to indicate whether or not a measurement has been performed. [SDTM: FASTAT]
6. **SHALL** contain exactly one [1..1] **`code`** (CONF:776), where the @code **SHALL** be selected from ValueSet *`Finding About Finding Set`* `C101852` **STATIC** (CONF:777)
   - 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]
7. **SHALL** contain exactly one [1..1] **`value`** (CONF:778)
   - The findings about result, as up to three observation values, using both original units and a standard format or set of units. 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: FAORRES, FAORRESU, FASTRESC, FASTRESN, FASTRESU]
8. **MAY** contain zero or one [0..1] **`targetSiteCode`** (CONF:779), where the @code **SHALL** be selected from ValueSet *`Anatomical Location`* `C74456` **STATIC** (CONF:780)
   - Used to specify the location of a clinical evaluation. [SDTM: FALOC]
9. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:781)
   - Identifies the SDTM or SEND domain the record is assigned to.

   a. Contains **`@typeCode="COMP"`** *COMP*
   b. Contains exactly one [1..1] *Domain Assignment* (templateId: `2.16.840.1.113883.10.20.23.30`)
10. **SHALL** contain zero or one [0..1] **`entryRelationship`** (CONF:782)

    Indicates the type of observation that the finding about observation expands upon or relates to.

    a. This entryRelationship **SHALL** contain exactly one [1..1] **`@typeCode="REFR"`** (CONF:792)
    b. This entryRelationship **SHALL** contain zero or one [0..1] **`observation`** (CONF:791)
       a. This observation **SHALL** contain exactly one [1..1] **`@classCode="OBS"`** *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF:793)
       b. This observation **SHALL** contain exactly one [1..1] **`@moodCode="DEF"`** (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:796)
       c. This observation **SHALL** contain exactly one [1..1] **`code`** (CONF:794), where the @code **SHALL** be selected from (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`) (CONF:795)
       d. This observation **SHALL** contain exactly one [1..1] **`value`** with data type CD (CONF:797), where the @code **SHALL** be selected from (CodeSystem: `locally defined Finding About Object Type`) (CONF:798)

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

11. **SHALL** contain zero or one [0..1] **`entryRelationship`** (CONF:783)
    - Allows capture of a group identifier for the finding.
    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Group Identifier* (templateId: `2.16.840.1.113883.10.20.23.42`)
12. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:784)
    - Used to capture information, most particularly the timing, regarding the collection of data for an event. This is relevant especially in cases where the timing and duration of an event are distinct from that of data collection.
    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Data Collection* (templateId: `2.16.840.1.113883.10.20.23.27`)
13. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:785)
    - Provides a reason for not capturing information for the finding.
    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Non Performance Reason* (templateId: `2.16.840.1.113883.10.20.23.56`)
14. **MAY** contain zero or one [0..1] **`participant`** (CONF:786)
    - Used to record the role played by the person providing the value of a subjective finding.
    a. Contains exactly one [1..1] *Study Finding Evaluator* (templateId: `2.16.840.1.113883.10.20.23.84`)
15. **MAY** contain zero or one [0..1] **`interpretationCode`** (CONF:787), where the @code **SHALL** be selected from ValueSet *`Subject Data Interpretation Type`* `CXXXXX` **STATIC** (CONF:788)
    - Includes information used to better interpret the observation value (result). [SDTM: FABLFL]
16. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:789)
    - The record of a category to be used in organizing information items.
    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Category* (templateId: `2.16.840.1.113883.10.20.23.20`)
17. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:790)
    - The record of a sub-category to be used in organizing information items.
    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Sub- Category* (templateId: `2.16.840.1.113883.10.20.23.91`)

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">
  <id root="2028719626" extension="MDHT"/>
  <code code="1580353346"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <interpretationCode code="464558798"/>
  <targetSiteCode code="1967048723"/>
  <participant>
    <participantRole classCode="ASSIGNED">
      <templateId root="null"/>
      <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
 Thesaurus"/>
    </participantRole>
  </participant>
```

```
 <entryRelationship typeCode="REFR">
   <observation classCode="OBS" moodCode="DEF">
     <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus"/>
   </observation>
 </entryRelationship>
 <entryRelationship>
   <act classCode="ACT">
     <templateId root="2.16.840.1.113883.10.20.23.42"/>
     <id root="1753766046" extension="MDHT"/>
     <code code="C83204" 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">
     <templateId root="2.16.840.1.113883.10.20.23.56"/>
     <id root="974209968" extension="MDHT"/>
     <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus" displayName="Reason for non completion"/>
     <statusCode code="completed"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
     <value xsi:type="CD" code="1347799389"/>
     <interpretationCode code="1078969723"/>
     <targetSiteCode code="1876350798"/>
   </observation>
 </entryRelationship>
 <entryRelationship>
   <act>
     <id root="1435904028" extension="MDHT"/>
     <code code="2121618264"/>
     <statusCode code="completed"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
     <entryRelationship>
       <observation/>
     </entryRelationship>
   </act>
 </entryRelationship>
 <entryRelationship>
   <observation classCode="OBS" moodCode="EVN">
     <templateId root="2.16.840.1.113883.10.20.23.20"/>
     <id root="428180215" 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="CD" code="870660910"/>
     <interpretationCode code="473973689"/>
     <targetSiteCode code="1212519498"/>
   </observation>
```

```
  </entryRelationship>
  <entryRelationship>
    <observation/>
  </entryRelationship>
  <entryRelationship>
    <observation>
      <templateId root="2.16.840.1.113883.10.20.23.30"/>
      <id root="1052692516" extension="MDHT"/>
      <code code="C66734" 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="CD" code="219358948"/>
      <interpretationCode code="1025099023"/>
      <targetSiteCode code="1336394840"/>
    </observation>
  </entryRelationship>
</observation>
```

Group Identifier

[Act: templateId `2.16.840.1.113883.10.20.23.42`]

The template provides a reusable structure to contain information on an identifier that can be assigned to a concommitant medication, adverse event or other event. It is used as a mechanism to group related records within a domain. This structure is captured as a template to facilitate its reuse as a characteristic of different types of data within clinical and non-clinical trial reporting.

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="ACT"` *Act* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF:240)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:241)
3. **SHALL** contain exactly one [1..1] **`id`** (CONF:242)
   - The group identifier value. [SDTM: CMGRPID, EXGRPID, SUGRPID, AEGRPID, DSGRPID, MHGRPID, CEGRPID, EGGRPID, LBGRPID, PEGRPID, QSGRPID, SCGRPID, VSGRPID, DAGRPID, MBGRPID, MSGRPID, PCGRPID, PPGRPID, FAGRPID] [SEND: CLGRPID, FWGRPID, LBGRPID, MAGRPID, PPGRPID, TFGRPID, EGGPID]
4. **SHALL** contain exactly one [1..1] **`code`** (CONF:243)**`/@code`**`="C83204"` (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`) (CONF:244)
   - The code value indicates that the act contains group identifier information.

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">
  <templateId root="2.16.840.1.113883.10.20.23.42"/>
  <id root="1696746782" extension="MDHT"/>
  <code code="C83204" 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 `2.16.840.1.113883.10.20.23.43`]

Th template supports the contnets of the SDTM Disposition domain. This 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`) (CONF:395)
2. **SHALL** contain exactly one [1..1] **`@moodCode="EVN"`** *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:400)
3. **SHALL** contain exactly one [1..1] **`code`** (CONF:396), where the @code **SHALL** be selected from ValueSet *`Disposition Item Set`* `CXXXXX` **STATIC** (CONF:397)
   - A code drawn from a controlled terminology for the disposition 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`** (CONF:398)
   - The start date/time of the disposition event. Use of the IVL_TS type, clearly indicates that the start of the event is captured. [SDTM: DSSTDTC]
5. **SHALL** contain [1..2] **`id`** (CONF:399)
   - 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. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:401)
   - Records the study epoch during which the information was collected.
   a. Contains **`@typeCode="REFR"`** *REFR*
   b. Contains exactly one [1..1] *Study Epoch* (templateId: `2.16.840.1.113883.10.20.23.83`)
7. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:402)
   - Allows capture of a group identifier for the disposition item.
   a. Contains **`@typeCode="COMP"`** *COMP*
   b. Contains exactly one [1..1] *Group Identifier* (templateId: `2.16.840.1.113883.10.20.23.42`)
8. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:403)
   - Used to record the study days associated with the beginning and end points of an activity that may extend over a period of time.
   a. Contains **`@typeCode="REFR"`** *REFR*
   b. Contains exactly one [1..1] *Study Day Period* (templateId: `2.16.840.1.113883.10.20.23.82`)
9. **MAY** contain zero or more [0..*] **`entryRelationship`** (CONF:404)
   - A place to insert comments related to a particular finding.
   a. Contains **`@typeCode="COMP"`** *COMP*
   b. Contains exactly one [1..1] *Comment* (templateId: `2.16.840.1.113883.10.20.23.23`)
10. **SHALL** contain exactly one [1..1] **`entryRelationship`** (CONF:405)
    - Identifies the SDTM or SEND domain the record is assigned to.
    a. Contains **`@typeCode="REFR"`** *REFR*
    b. Contains exactly one [1..1] *Domain Assignment* (templateId: `2.16.840.1.113883.10.20.23.30`)
11. **MAY** contain zero or more [0..*] **`entryRelationship`** (CONF:406)
    - Establishes a relationship between this record and another record.

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

b. Contains exactly one [1..1] *Related Record* (templateId: 2.16.840.1.113883.10.20.23.75)

12. **MAY** contain zero or more [0..*] **entryRelationship** (CONF:407)

- Allows the association of a supplemental value - outside of the content specfied for the domain - to the record.

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

b. Contains exactly one [1..1] *Supplemental Value* (templateId: 2.16.840.1.113883.10.20.23.96)

13. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:408)

- The record of a category to be used in organizing information items.

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

b. Contains exactly one [1..1] *Category* (templateId: 2.16.840.1.113883.10.20.23.20)

14. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:409)

- The record of a sub-category to be used in organizing information items.

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

b. Contains exactly one [1..1] *Sub- Category* (templateId: 2.16.840.1.113883.10.20.23.91)

15. **MAY** contain zero or more [0..*] **entryRelationship** (CONF:410)

- Allows recording of additional findings related to the event.

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

b. Contains exactly one [1..1] *Finding About* (templateId: 2.16.840.1.113883.10.20.23.40)

Human Clinical Disposition 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="2.16.840.1.113883.10.20.23.43"/>
  <id root="476067424" extension="MDHT"/>
  <code code="1713579724"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <entryRelationship>
    <act>
      <templateId root="2.16.840.1.113883.10.20.23.83"/>
      <id root="1670568171" extension="MDHT"/>
      <code codeSystem="locally defined" codeSystemName="Study Epoch Type"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
    </act>
  </entryRelationship>
  <entryRelationship>
    <act classCode="ACT">
      <templateId root="2.16.840.1.113883.10.20.23.42"/>
      <id root="83455296" extension="MDHT"/>
      <code code="C83204" 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>
     <id root="440511535" extension="MDHT"/>
     <code code="1558886104"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
   </observation>
 </entryRelationship>
 <entryRelationship>
   <observation classCode="OBS" moodCode="EVN">
     <templateId root="2.16.840.1.113883.10.20.23.23"/>
     <id root="1938539721" extension="MDHT"/>
     <code code="C49569" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
     <participant/>
     <entryRelationship/>
   </observation>
 </entryRelationship>
 <entryRelationship>
   <observation>
     <templateId root="2.16.840.1.113883.10.20.23.30"/>
     <id root="1370829993" extension="MDHT"/>
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codeSystemName="NCI Thesaurus"/>
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     </effectiveTime>
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     <id root="21673915" extension="MDHT"/>
     <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus"/>
     <effectiveTime>
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     </effectiveTime>
   </act>
 </entryRelationship>
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     <id root="957306767" extension="MDHT"/>
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Type"/>
     <effectiveTime>
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     </effectiveTime>
     <participant/>
     <entryRelationship typeCode="COMP"/>
   </observation>
 </entryRelationship>
 <entryRelationship>
   <observation classCode="OBS" moodCode="EVN">
```

```
      <templateId root="2.16.840.1.113883.10.20.23.20"/>
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 Thesaurus"/>
      <effectiveTime>
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      </effectiveTime>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation/>
  </entryRelationship>
  <entryRelationship>
    <observation>
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      <code code="584310230"/>
      <effectiveTime>
        <low value="2012"/>
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      </effectiveTime>
      <participant/>
      <entryRelationship typeCode="REFR"/>
      <entryRelationship>
        <act classCode="ACT">
          <templateId root="2.16.840.1.113883.10.20.23.42"/>
          <code code="C83204" codeSystem="2.16.840.1.113883.3.26.1.1"
 codeSystemName="NCI Thesaurus"/>
        </act>
      </entryRelationship>
      <entryRelationship>
        <observation classCode="OBS">
          <templateId root="2.16.840.1.113883.10.20.23.56"/>
          <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
 Thesaurus" displayName="Reason for non completion"/>
        </observation>
      </entryRelationship>
      <entryRelationship>
        <act/>
      </entryRelationship>
      <entryRelationship>
        <observation classCode="OBS" moodCode="EVN">
          <templateId root="2.16.840.1.113883.10.20.23.20"/>
          <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
 Thesaurus"/>
        </observation>
      </entryRelationship>
      <entryRelationship>
        <observation/>
      </entryRelationship>
      <entryRelationship>
        <observation>
          <templateId root="2.16.840.1.113883.10.20.23.30"/>
          <code code="C66734" codeSystem="2.16.840.1.113883.3.26.1.1"
 codeSystemName="NCI Thesaurus"/>
        </observation>
      </entryRelationship>
    </observation>
  </entryRelationship>
</act>
```

Human Clinical Exposure

[SubstanceAdministration: templateId `2.16.840.1.113883.10.20.23.44`]

The template captures details of a human 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.

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="SBADM"` (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF:312)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:316)
3. **SHOULD** contain zero or one [0..1] **`doseQuantity`** (CONF:313)
   - The amount of the study medication or treatment taken at a single administration. The physical quantity type captures both dose amount and unit of measure. [SDTM: EXDOSE, EXDOSU]
4. **SHOULD** contain zero or one [0..1] **`effectiveTime`** (CONF:314)
   - Information on when and how often the study treatment was taken. Possible values for time interval include start date, stop date, and duration. Note, only two of these need to be valued, and only two values are supported. It is expected that start date and stop date will be provided if both are known with sufficient precision. However, if necessary and duration is included, then either stop date (the more usual case), start date, or both will be omitted. More specifically: The periodic time interval (PIVL_TS) type is used to record requency. This captures the number of hours, days, weeks, between two administrations of the substance. (For example, BID is recorded as 12 hours) [SDTM: CMSTDTC, CMENDTC, CMDUR, CMDOSFRQ] 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: EXSTDTC, EXENDTC, EXDUR, EXDOSFRQ]
5. **SHALL** contain [1..2] **`id`** (CONF:315)
   - 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`** (CONF:317), where the @code **SHALL** be selected from ValueSet *`Route of Administration`* `C66729` **STATIC** (CONF:1523)
   - The route by which the treatment is administered. [SDTM: EXROUTE]
7. **MAY** contain zero or one [0..1] **`maxDoseQuantity`** (CONF:318)
   - Information on the total daily dose of the study treatment. The structure also accommodates periods other than a day. Thefore the time period = 1 day needs to be indicated as the denominator of the ratio. [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`** (CONF:319)
   - Allows capture of a group identifier for the exposure information.
   a. Contains **`@typeCode="COMP"`** *COMP*
   b. Contains exactly one [1..1] *Group Identifier* (templateId: `2.16.840.1.113883.10.20.23.42`)
9. **SHALL** contain exactly one [1..1] **`consumable`** (CONF:320)
   - Identifies and carries information for the consumable item that is being referred to.
   a. Contains exactly one [1..1] *Consumable Material* (templateId: `2.16.840.1.113883.10.20.23.26`)
10. **MAY** contain zero or one [0..1] **`text`** (CONF:321)
    - A text description of the dosing. [SDTM: EXDOSTXT]
11. **MAY** contain zero or one [0..1] **`approachSiteCode`** with data type CE (CONF:322), where the @code **SHALL** be selected from ValueSet *`Anatomical Location`* `C74456` **STATIC** (CONF:323)

- An indication of the location, e.g. left arm, where the substance was administered. [SDTM: EXLOC]

12. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:324)

    - Records the study epoch during which the information was collected.

    a. Contains **`@typeCode="REFR"`** *REFR*
    b. Contains exactly one [1..1] *Study Epoch* (templateId: `2.16.840.1.113883.10.20.23.83`)
13. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:325)

    Used to record the order, within the appropriate study arm, of the element associated with the exposure within the study arm to which the subject is assigned.

    a. This entryRelationship **SHALL** contain exactly one [1..1] **`@typeCode`**`="REFR"` (CONF:338)
    b. This entryRelationship **SHALL** contain exactly one [1..1] **`observation`** (CONF:339)

        a. This observation **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF:340)
        b. This observation **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:343)
        c. This observation **SHALL** contain exactly one [1..1] **`code`** (CONF:341), where the @code **SHALL** be selected from (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`) (CONF:342)

            The code value indicates the observation captures an element's order within a trial arm.
        d. This observation **SHALL** contain exactly one [1..1] **`value`** with data type ED (CONF:344)

            A value that gives the order of an element within the trial arm. Since this order could be hierachically represented as a collection of integers separated by ".", e.g., "2.1", the text (ED) data type is assigned. [SDTM: TAETORD]
14. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:326)

    - Records the duration of an event in cases in which this cannot be derived from existing start and stop information.

    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Event Duration* (templateId: `2.16.840.1.113883.10.20.23.102`)
15. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:327)

    - Orients the consumption of the study drug with respect to a study defined timepoint.

    a. Contains **`@typeCode="REFR"`** *REFR*
    b. Contains exactly one [1..1] *Timing Reference* (templateId: `2.16.840.1.113883.10.20.23.97`)
16. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:328)

    - Used to record the study days associated with the beginning and end points of an activity that may extend over a period of time.

    a. Contains **`@typeCode="REFR"`** *REFR*
    b. Contains exactly one [1..1] *Study Day Period* (templateId: `2.16.840.1.113883.10.20.23.82`)
17. **MAY** contain zero or more [0..*] **`entryRelationship`** (CONF:329)

    - A place to insert comments related to a particular finding.

    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Comment* (templateId: `2.16.840.1.113883.10.20.23.23`)
18. **SHALL** contain exactly one [1..1] **`entryRelationship`** (CONF:330)

    - Identifies the SDTM or SEND domain the record is assigned to.

    a. Contains **`@typeCode="REFR"`** *REFR*
    b. Contains exactly one [1..1] *Domain Assignment* (templateId: `2.16.840.1.113883.10.20.23.30`)
19. **MAY** contain zero or more [0..*] **`entryRelationship`** (CONF:331)

- Establishes a relationship between this record and another record.

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

b. Contains exactly one [1..1] *Related Record* (templateId: 2.16.840.1.113883.10.20.23.75)

20. MAY contain zero or more [0..*] **entryRelationship** (CONF:332)

- Allows the association of a supplemental value - outside of the content specfied for the domain - to the record.

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

b. Contains exactly one [1..1] *Supplemental Value* (templateId: 2.16.840.1.113883.10.20.23.96)

21. MAY contain zero or one [0..1] **entryRelationship** (CONF:333)

- Information on the intended dose regimen of the medication. It supplements the frequency information provided within the effectiveTime element.

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

b. Contains exactly one [1..1] *Intended Regimen* (templateId: 2.16.840.1.113883.10.20.23.49)

22. MAY contain zero or one [0..1] **entryRelationship** (CONF:334)

- A description of the reason for adjusting the dosage of the study medication. It should only be valued if the dose adjustment has been recorded as a data item.

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

b. Contains exactly one [1..1] *Dose Adjustment Reason* (templateId: 2.16.840.1.113883.10.20.23.31)

23. MAY contain zero or one [0..1] **entryRelationship** (CONF:335)

- The record of a category to be used in organizing information items.

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

b. Contains exactly one [1..1] *Category* (templateId: 2.16.840.1.113883.10.20.23.20)

24. MAY contain zero or one [0..1] **entryRelationship** (CONF:336)

- The record of a sub-category to be used in organizing information items.

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

b. Contains exactly one [1..1] *Sub- Category* (templateId: 2.16.840.1.113883.10.20.23.91)

25. MAY contain zero or more [0..*] **entryRelationship** (CONF:337)

- Allows recording of additional findings related to the event.

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

b. Contains exactly one [1..1] *Finding About* (templateId: 2.16.840.1.113883.10.20.23.40)

Human Clinical Exposure 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">
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  <effectiveTime value="20121004"/>
  <routeCode code="871726307"/>
  <approachSiteCode xsi:type="CE" code="1466350990"/>
  <doseQuantity/>
  <maxDoseQuantity/>
  <consumable>
    <manufacturedProduct classCode="MANU"/>
  </consumable>
  <entryRelationship typeCode="REFR">
    <observation classCode="OBS" moodCode="EVN">
      <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
 Thesaurus"/>
```

```
    </observation>
  </entryRelationship>
  <entryRelationship>
    <act classCode="ACT">
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codeSystemName="NCI Thesaurus"/>
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        <high value="2012"/>
      </effectiveTime>
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  <entryRelationship>
    <act>
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codeSystemName="NCI Thesaurus"/>
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        <high value="2012"/>
      </effectiveTime>
      <participant/>
      <entryRelationship/>
```

```
    </observation>
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  <entryRelationship>
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codeSystemName="NCI Thesaurus"/>
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    </observation>
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Thesaurus"/>
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        <high value="2012"/>
      </effectiveTime>
    </act>
  </entryRelationship>
  <entryRelationship>
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      <templateId root="2.16.840.1.113883.10.20.23.96"/>
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Type"/>
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      <participant/>
      <entryRelationship typeCode="COMP"/>
    </observation>
  </entryRelationship>
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      <templateId root="2.16.840.1.113883.10.20.23.49"/>
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Thesaurus"/>
      <text>Text Value</text>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
    </observation>
  </entryRelationship>
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    <observation>
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      <text>Text Value</text>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
```

```
      </effectiveTime>
    </observation>
 </entryRelationship>
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     <id root="1460483583" extension="MDHT"/>
     <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus"/>
     <text>Text Value</text>
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       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
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 </entryRelationship>
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   <observation>
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     <code code="278954101"/>
     <text>Text Value</text>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
     <participant/>
     <entryRelationship typeCode="REFR"/>
     <entryRelationship>
       <act classCode="ACT">
         <templateId root="2.16.840.1.113883.10.20.23.42"/>
         <code code="C83204" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
       </act>
     </entryRelationship>
     <entryRelationship>
       <observation classCode="OBS">
         <templateId root="2.16.840.1.113883.10.20.23.56"/>
         <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus" displayName="Reason for non completion"/>
       </observation>
     </entryRelationship>
     <entryRelationship>
       <act/>
     </entryRelationship>
     <entryRelationship>
       <observation classCode="OBS" moodCode="EVN">
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Thesaurus"/>
       </observation>
     </entryRelationship>
     <entryRelationship>
       <observation/>
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       <observation>
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         <code code="C66734" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
       </observation>
     </entryRelationship>
```

```
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.102"/>
      <id root="1930586303" extension="MDHT"/>
      <code code="EDtbd" 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>
</substanceadministration>
```

Human Clinical Laboratory Test Result

[Observation: templateId `2.16.840.1.113883.10.20.23.45`]

The template includes 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`) (CONF:915)
2. **SHALL** contain exactly one [1..1] **`@moodCode="EVN"`** *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:916)
3. **SHALL** contain [1..2] **`id`** (CONF:917)
   - A value that is provided to ensure the uniqueness of the laboratory result. [SDTM: LBSEQ, LBSPID] A single identifier, the sequence number, is required.
4. **SHALL** contain exactly one [1..1] **`code`** (CONF:918), where the @code **SHALL** be selected from ValueSet *`Laboratory Test Code`* `C65047` **STATIC** (CONF:919)
   - 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 situated using the translation property within the CD type.
5. **MAY** contain zero or one [0..1] **`statusCode`** (CONF:920), where the @code **SHALL** be selected from (CodeSystem: `2.16.840.1.113883.5.14 ActStatus`) (CONF:1546)
   - Used to indicate whether or not an exam has been performed. [SDTM: LBSTAT]
6. **SHOULD** contain zero or one [0..1] **`value`** (CONF:921)
   - The laboratory result, using both original units and a standard format or set of units. The information is captured as up to three observation values. [SDTM: LBORRES, LBORRESU, LBSTRESC, LBSTRESN, LBSTRESU] The data type for .value is listed as "ANY" since it may be coded - type = CD - it may be a physical quantity - type = PQR - or it may be text - type = ED. (Note, the PQR form is used to allow the use units of measure expressed as coded values.) The value presented by the investigator or party entering the data is captured as the base value. If this value is transformed to use standard units, or a standard code set, the transformed or normalized values are included as translations.
7. **MAY** contain zero or one [0..1] **`methodCode`** (CONF:922), where the @code **SHALL** be selected from ValueSet *`Method`* `C85492` **STATIC** (CONF:923)
   - Indicates the method of the test or examination. [SDTM: LBMETHOD]
8. **MAY** contain zero or more [0..*] **`entryRelationship`** (CONF:924)
   - A place to insert comments related to a particular finding.

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

   b. Contains exactly one [1..1] *Comment* (templateId: `2.16.840.1.113883.10.20.23.23`)

9. **SHALL** contain exactly one [1..1] **`entryRelationship`** (CONF:925)
   - Identifies the SDTM or SEND domain the record is assigned to.
   a. Contains **`@typeCode="REFR"`** *REFR*
   b. Contains exactly one [1..1] *Domain Assignment* (templateId: `2.16.840.1.113883.10.20.23.30`)
10. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:926)
    - Allows capture of a group identifier for the test result.
    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Group Identifier* (templateId: `2.16.840.1.113883.10.20.23.42`)
11. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:927)
    - Information on the reason a scheduled activity was not carried out.
    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Non Performance Reason* (templateId: `2.16.840.1.113883.10.20.23.56`)
12. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:928)
    - Information on the specimen that was tested to derive the observation value. It may include information on the collection of the specimen as well as on the specimen itself.
    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Specimen Information* (templateId: `2.16.840.1.113883.10.20.23.78`)
13. **SHOULD** contain zero or one [0..1] **`reference Range`** (CONF:929)
    - Information on the reference range defined for a test. It is used to support interpretation of the test result.
    a. Contains exactly one [1..1] *Reference Range* (templateId: `2.16.840.1.113883.10.20.23.74`)
14. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:930)
    - Used to indicate the fasting status - time since consuption of food - for the study subject.
    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Fasting Status* (templateId: `2.16.840.1.113883.10.20.23.39`)
15. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:931)
    - A record of the toxicity measured by the test.
    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Toxicity* (templateId: `2.16.840.1.113883.10.20.23.98`)
16. **MAY** contain zero or one [0..1] **`participant`** (CONF:932)
    - Used to identify the organization that performed the test.
    a. Contains exactly one [1..1] *Study Test Organization* (templateId: `2.16.840.1.113883.10.20.23.88`)
17. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:933)
    - Creates an assoication between the timing of an activity and a defined reference time point.
    a. Contains **`@typeCode="REFR"`** *REFR*
    b. Contains exactly one [1..1] *Timing Reference* (templateId: `2.16.840.1.113883.10.20.23.97`)
18. **SHOULD** contain [0..3] **`interpretationCode`** (CONF:934), where the @code **SHALL** be selected from ValueSet *`Subject Data Interpretation Consolidated Type`* `CXXXXX` **STATIC** (CONF:935)
    - Includes information used to better interpret the observation value (result). The information recorded may note whether the value is a base line value, whether it is derived, and/or its relationship to the reference range defined for the test. [SDTM: LBBLFL, LBDRVFL, LBNRIND]
19. **SHOULD** contain zero or one [0..1] **`entryRelationship`** (CONF:936)
    - The record of a category to be used in organizing information items.
    a. Contains **`@typeCode="COMP"`** *COMP*

b. Contains exactly one [1..1] *Category* (templateId: `2.16.840.1.113883.10.20.23.20`)

20. MAY contain zero or one [0..1] **`entryRelationship`** (CONF:937)

- The record of a sub-category to be used in organizing information items.

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

b. Contains exactly one [1..1] *Sub- Category* (templateId: `2.16.840.1.113883.10.20.23.91`)

21. MAY contain zero or more [0..*] **`entryRelationship`** (CONF:938)

- Establishes a relationship between this record and another record.

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

b. Contains exactly one [1..1] *Related Record* (templateId: `2.16.840.1.113883.10.20.23.75`)

22. MAY contain zero or more [0..*] **`entryRelationship`** (CONF:939)

- Allows the association of a supplemental value - outside of the content specfied for the domain - to the record.

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

b. Contains exactly one [1..1] *Supplemental Value* (templateId: `2.16.840.1.113883.10.20.23.96`)

23. MAY contain zero or more [0..*] **`entryRelationship`** (CONF:940)

- Allows recording of additional findings related to the event.

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

b. Contains exactly one [1..1] *Finding About* (templateId: `2.16.840.1.113883.10.20.23.40`)

Human Clinical Laboratory 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">
  <id root="1939833455" extension="MDHT"/>
  <code code="651118847"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <interpretationCode codeSystemName="NCI Thesaurus"/>
  <methodCode code="1719797717"/>
  <participant>
    <participantRole classCode="ASSIGNED">
      <templateId root="null"/>
    </participantRole>
  </participant>
  <entryRelationship>
    <act classCode="ACT">
      <templateId root="2.16.840.1.113883.10.20.23.42"/>
      <id root="1934893348" extension="MDHT"/>
      <code code="C83204" 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>
      <id root="1365714732" extension="MDHT"/>
      <code code="985638099"/>
      <statusCode code="completed"/>
      <effectiveTime>
```

```
      <low value="2012"/>
      <high value="2012"/>
    </effectiveTime>
    <methodCode code="1739777940"/>
    <specimen typeCode="SPC">
      <templateId root="null"/>
    </specimen>
    <entryRelationship typeCode="COMP"/>
    <entryRelationship typeCode="COMP"/>
    <entryRelationship typeCode="COMP"/>
    <entryRelationship>
      <observation/>
    </entryRelationship>
    <entryRelationship>
      <act>
        <templateId root="2.16.840.1.113883.10.20.23.97"/>
        <code codeSystem="2.16.840.1.113883.3.26.1.1"/>
      </act>
    </entryRelationship>
  </procedure>
 </entryRelationship>
 <entryRelationship>
   <observation classCode="OBS">
     <templateId root="2.16.840.1.113883.10.20.23.56"/>
     <id root="732917542" extension="MDHT"/>
     <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus" displayName="Reason for non completion"/>
     <statusCode code="completed"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
     <value xsi:type="CD" code="1716433994"/>
     <interpretationCode code="745411879"/>
     <methodCode code="918947728"/>
   </observation>
 </entryRelationship>
 <entryRelationship>
   <act>
     <templateId root="2.16.840.1.113883.10.20.23.97"/>
     <id root="1430021" extension="MDHT"/>
     <code codeSystem="2.16.840.1.113883.3.26.1.1"/>
     <statusCode code="completed"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
     <entryRelationship typeCode="COMP"/>
   </act>
 </entryRelationship>
 <entryRelationship>
   <observation classCode="OBS" moodCode="EVN">
     <templateId root="2.16.840.1.113883.10.20.23.23"/>
     <id root="731138255" extension="MDHT"/>
     <code code="C49569" 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="ED">Text Value</value>
     <interpretationCode code="34836436"/>
     <methodCode code="536291010"/>
```

```
      <participant/>
      <entryRelationship/>
    </observation>
 </entryRelationship>
 <entryRelationship>
    <observation>
      <templateId root="2.16.840.1.113883.10.20.23.30"/>
      <id root="543151470" extension="MDHT"/>
      <code code="C66734" 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="CD" code="1663507733"/>
      <interpretationCode code="1415768607"/>
      <methodCode code="1791314609"/>
    </observation>
 </entryRelationship>
 <entryRelationship>
    <act classCode="ACT">
      <templateId root="2.16.840.1.113883.10.20.23.75"/>
      <id root="987646725" 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>
    </act>
 </entryRelationship>
 <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.96"/>
      <id root="492424329" extension="MDHT"/>
      <code codeSystem="locally defined" codeSystemName="Supplemental Value
Type"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <interpretationCode code="1385470887"/>
      <methodCode code="2069771419"/>
      <participant/>
      <entryRelationship typeCode="COMP"/>
    </observation>
 </entryRelationship>
 <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.98"/>
      <id root="560520618" extension="MDHT"/>
      <code code="TOtbd" 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="CD" code="817195610"/>
      <interpretationCode code="69710778"/>
      <methodCode code="1033690303"/>
```

```
   </observation>
 </entryRelationship>
 <entryRelationship>
   <observation classCode="OBS" moodCode="EVN">
     <templateId root="2.16.840.1.113883.10.20.23.20"/>
     <id root="282345727" 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="CD" code="832213790"/>
     <interpretationCode code="452156071"/>
     <methodCode code="469168291"/>
   </observation>
 </entryRelationship>
 <entryRelationship>
   <observation/>
 </entryRelationship>
 <entryRelationship>
   <observation classCode="OBS">
     <templateId root="2.16.840.1.113883.10.20.23.39"/>
     <id root="1912493672" extension="MDHT"/>
     <code code="FStbd" 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"/>
     <interpretationCode code="71047005"/>
     <methodCode code="748347280"/>
   </observation>
 </entryRelationship>
 <entryRelationship>
   <observation>
     <id root="461810639" extension="MDHT"/>
     <code code="1377150976"/>
     <statusCode code="completed"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
     <interpretationCode code="1161367949"/>
     <methodCode code="220781619"/>
     <participant/>
     <entryRelationship typeCode="REFR"/>
     <entryRelationship>
       <act classCode="ACT">
         <templateId root="2.16.840.1.113883.10.20.23.42"/>
         <code code="C83204" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
       </act>
     </entryRelationship>
     <entryRelationship>
       <observation classCode="OBS">
         <templateId root="2.16.840.1.113883.10.20.23.56"/>
         <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus" displayName="Reason for non completion"/>
       </observation>
     </entryRelationship>
```

```
      <entryRelationship>
        <act/>
      </entryRelationship>
      <entryRelationship>
        <observation classCode="OBS" moodCode="EVN">
          <templateId root="2.16.840.1.113883.10.20.23.20"/>
          <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
 Thesaurus"/>
        </observation>
      </entryRelationship>
      <entryRelationship>
        <observation/>
      </entryRelationship>
      <entryRelationship>
        <observation>
          <templateId root="2.16.840.1.113883.10.20.23.30"/>
          <code code="C66734" codeSystem="2.16.840.1.113883.3.26.1.1"
 codeSystemName="NCI Thesaurus"/>
        </observation>
      </entryRelationship>
    </observation>
  </entryRelationship>
</observation>
```

Human Clinical Subject Demographics

[Act: templateId `2.16.840.1.113883.10.20.23.46`]

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

1. Contains 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`) (CONF:61)
3. **SHOULD** contain zero or one [0..1] **`ageAssociation`** (CONF:62)

   Used to record the age of the subject.

   a. This ageAssociation **SHALL** contain exactly one [1..1] **`@typeCode`**`="COMP"` (CONF:74)
   b. This ageAssociation **SHALL** contain exactly one [1..1] **`observation`** (CONF:75)
      a. This observation **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF:76)
      b. This observation **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:77)
      c. This observation **SHALL** contain exactly one [1..1] **`code`** (CONF:78)**`/@code`**`="C25150"` *Reported Age* (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`) (CONF:79)

         The code value indicates this is an age observation.
      d. This observation **SHALL** contain exactly one [1..1] **`value`** with data type PQ (CONF:80)

         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], [SEND: AGE, AGEU]
4. **SHOULD** contain zero or one [0..1] **`entryRelationship`** (CONF:63)
   - Used to capture information, most particularly the timing, regarding the collection of data for an event. This is relevant especially in cases where the timing and duration of an event are distinct from that of data collection.

   a. Contains **`@typeCode="`**`COMP"` *COMP*
   b. Contains exactly one [1..1] *Data Collection* (templateId: `2.16.840.1.113883.10.20.23.27`)

5. **SHALL** contain [2..2] **`entryRelationship`** (CONF:64)
   - Information may be collected on both the Planned Study Arm, and the Actual Study Arm. The Planned Study Arm must be provided.

   a. Contains **`@typeCode="REFR"`** *REFR*
   b. Contains exactly one [1..1] *Study Arm* (templateId: `2.16.840.1.113883.10.20.23.81`)
6. **SHALL** contain exactly one [1..1] **`participant`** (CONF:65)

   The association makes it possible to capture the study site location - in particular the country - for the site at which the subject will participate in the study.

   a. This participant **SHALL** contain exactly one [1..1] **`@typeCode`**`="LOC"` (CONF:81)
   b. This participant Contains exactly one [1..1] **`participantRole`**

      a. This participantRole **SHALL** contain zero or one [0..1] **`@classCode`**`="SDLOC"` (CONF:82)
      b. This participantRole **SHALL** contain exactly one [1..1] **`addr`** (CONF:83)

         Use the country property of the address data type to capture the country of the study site. [SDTM: COUNTRY]
7. **MAY** contain zero or more [0..*] **`entryRelationship`** (CONF:66)
   - A place to insert comments related to a particular finding.

   a. Contains **`@typeCode="COMP"`** *COMP*
   b. Contains exactly one [1..1] *Comment* (templateId: `2.16.840.1.113883.10.20.23.23`)
8. **SHALL** contain exactly one [1..1] **`entryRelationship`** (CONF:67)
   - Identifies the SDTM domain the record is assigned to.

   a. Contains **`@typeCode="REFR"`** *REFR*
   b. Contains exactly one [1..1] *Domain Assignment* (templateId: `2.16.840.1.113883.10.20.23.30`)
9. **MAY** contain zero or more [0..*] **`entryRelationship`** (CONF:68)
   - Establishes a relationship between this record and another record.

   a. Contains **`@typeCode="REFR"`** *REFR*
   b. Contains exactly one [1..1] *Related Record* (templateId: `2.16.840.1.113883.10.20.23.75`)
10. **MAY** contain zero or more [0..*] **`entryRelationship`** (CONF:69)
    - Allows the association of a supplemental value - outside of the content specfied for the domain - to the record.

    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Supplemental Value* (templateId: `2.16.840.1.113883.10.20.23.96`)
11. **SHALL** contain exactly one [1..1] **`code`** (CONF:70)**`/@code="DMGtbd"`** (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`) (CONF:71)
    - Indicates that the contained information includes subject demographic data that is not acommodated by the record target participation.
12. **SHALL** contain exactly one [1..1] **`entryRelationship`** (CONF:72)
    - Provides information on the reference period that has been defined for the subject's participation in the study.

    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Reference Period* (templateId: `2.16.840.1.113883.10.20.23.73`)
13. **MAY** contain zero or more [0..*] **`entryRelationship`** (CONF:73)
    - Allows recording of additional findings related to the event.

    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Finding About* (templateId: `2.16.840.1.113883.10.20.23.40`)

Human Clinical Subject Demographics 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">
  <id root="547169088" extension="MDHT"/>
  <code code="663226230"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <participant typeCode="LOC">
    <participantRole classCode="SDLOC"/>
  </participant>
  <entryRelationship>
    <act>
      <id root="1314806750" extension="MDHT"/>
      <code code="1064920260"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <entryRelationship>
        <observation/>
      </entryRelationship>
    </act>
  </entryRelationship>
  <entryRelationship>
    <act>
      <templateId root="2.16.840.1.113883.10.20.23.81"/>
      <id root="759830457" extension="MDHT"/>
      <code codeSystem="locally defined" codeSystemName="Study Arm Type"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
    </act>
  </entryRelationship>
  <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.23"/>
      <id root="1292936898" extension="MDHT"/>
      <code code="C49569" codeSystem="2.16.840.1.113883.3.26.1.1"
 codeSystemName="NCI Thesaurus"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <participant/>
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    <observation>
      <templateId root="2.16.840.1.113883.10.20.23.30"/>
      <id root="2073604893" extension="MDHT"/>
      <code code="C66734" codeSystem="2.16.840.1.113883.3.26.1.1"
 codeSystemName="NCI Thesaurus"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
    </observation>
  </entryRelationship>
```

```
 <entryRelationship>
   <act classCode="ACT">
     <templateId root="2.16.840.1.113883.10.20.23.75"/>
     <id root="1143278626" 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>
 <entryRelationship>
   <observation classCode="OBS" moodCode="EVN">
     <templateId root="2.16.840.1.113883.10.20.23.96"/>
     <id root="31582938" extension="MDHT"/>
     <code codeSystem="locally defined" codeSystemName="Supplemental Value
Type"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
     <participant/>
     <entryRelationship typeCode="COMP"/>
   </observation>
 </entryRelationship>
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   <act>
     <id root="1773695359" extension="MDHT"/>
     <code code="1864593207"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
   </act>
 </entryRelationship>
 <entryRelationship>
   <observation>
     <id root="1420719247" extension="MDHT"/>
     <code code="1956921681"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
     <participant/>
     <entryRelationship typeCode="REFR"/>
     <entryRelationship>
       <act classCode="ACT">
         <templateId root="2.16.840.1.113883.10.20.23.42"/>
         <code code="C83204" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
       </act>
     </entryRelationship>
     <entryRelationship>
       <observation classCode="OBS">
         <templateId root="2.16.840.1.113883.10.20.23.56"/>
         <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus" displayName="Reason for non completion"/>
       </observation>
     </entryRelationship>
     <entryRelationship>
       <act/>
     </entryRelationship>
     <entryRelationship>
```

```
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          <templateId root="2.16.840.1.113883.10.20.23.20"/>
          <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
 Thesaurus"/>
        </observation>
      </entryRelationship>
      <entryRelationship>
        <observation/>
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        <observation>
          <templateId root="2.16.840.1.113883.10.20.23.30"/>
          <code code="C66734" codeSystem="2.16.840.1.113883.3.26.1.1"
 codeSystemName="NCI Thesaurus"/>
        </observation>
      </entryRelationship>
    </observation>
  </entryRelationship>
</act>
```

Inclusion or Exclusion Criteria Not Met

[Observation: templateId `2.16.840.1.113883.10.20.23.47`]

The template provides a structure to include 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`) (CONF:527)
2. **SHALL** contain exactly one [1..1] **`@moodCode="EVN"`** *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:528)
3. **SHALL** contain [1..2] **`id`** (CONF:529)
   - 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.
4. **SHALL** contain exactly one [1..1] **`code`** (CONF:530), where the @code **SHALL** be selected from ValueSet *`Inclusion/Exclusion Criterion Set`* `locally defined` **STATIC** (CONF:1533)
   - 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]
5. **SHALL** contain exactly one [1..1] **`value`** with data type BL (CONF:532)
   - The response to the question - was the inclusion or exclusion criteria met? [SDTM: IEORRES, IESTRESC]
6. **SHALL** contain exactly one [1..1] **`entryRelationship`** (CONF:533)
   - Identifies the SDTM domain the record is assigned to.
   a. Contains **`@typeCode="REFR"`** *REFR*
   b. Contains exactly one [1..1] *Domain Assignment* (templateId: `2.16.840.1.113883.10.20.23.30`)
7. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:534)
   - Used to capture information, most particularly the timing, regarding the collection of data for an event. This is relevant especially in cases where the timing and duration of an event are distinct from that of data collection.
   a. Contains **`@typeCode="COMP"`** *COMP*
   b. Contains exactly one [1..1] *Data Collection* (templateId: `2.16.840.1.113883.10.20.23.27`)
8. **SHALL** contain exactly one [1..1] **`entryRelationship`** (CONF:535)
   - The record of a category to be used in organizing information items.

   a. Contains **@typeCode="COMP"** *COMP*
   b. Contains exactly one [1..1] *Category* (templateId: 2.16.840.1.113883.10.20.23.20)
9. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:536)
   - The record of a sub-category to be used in organizing information items.
   a. Contains **@typeCode="COMP"** *COMP*
   b. Contains exactly one [1..1] *Sub- Category* (templateId: 2.16.840.1.113883.10.20.23.91)
10. **MAY** contain zero or more [0..*] **entryRelationship** (CONF:537)
   - Establishes a relationship between this record and another record.
   a. Contains **@typeCode="REFR"** *REFR*
   b. Contains exactly one [1..1] *Related Record* (templateId: 2.16.840.1.113883.10.20.23.75)
11. **MAY** contain zero or more [0..*] **entryRelationship** (CONF:538)
   - Allows the association of a supplemental value - outside of the content specfied for the domain - to the record.
   a. Contains **@typeCode="COMP"** *COMP*
   b. Contains exactly one [1..1] *Supplemental Value* (templateId: 2.16.840.1.113883.10.20.23.96)
12. **MAY** contain zero or more [0..*] **entryRelationship** (CONF:539)
   - A place to insert comments related to a particular finding.
   a. Contains **@typeCode="COMP"** *COMP*
   b. Contains exactly one [1..1] *Comment* (templateId: 2.16.840.1.113883.10.20.23.23)
13. **MAY** contain zero or more [0..*] **entryRelationship** (CONF:540)
   - Allows recording of additional findings related to the event.
   a. Contains **@typeCode="COMP"** *COMP*
   b. Contains exactly one [1..1] *Finding About* (templateId: 2.16.840.1.113883.10.20.23.40)

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">
  <id root="1881983666" extension="MDHT"/>
  <code code="1782371356"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <value xsi:type="BL"/>
  <entryRelationship>
    <act>
      <id root="2007621487" extension="MDHT"/>
      <code code="197464077"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <entryRelationship>
        <observation/>
      </entryRelationship>
    </act>
  </entryRelationship>
  <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.23"/>
      <id root="534278264" extension="MDHT"/>
```

```
     <code code="C49569" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
     <value xsi:type="ED">Text Value</value>
     <participant/>
     <entryRelationship/>
   </observation>
 </entryRelationship>
 <entryRelationship>
   <observation>
     <templateId root="2.16.840.1.113883.10.20.23.30"/>
     <id root="1468418884" extension="MDHT"/>
     <code code="C66734" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
     <value xsi:type="CD" code="1366962344"/>
   </observation>
 </entryRelationship>
 <entryRelationship>
   <act classCode="ACT">
     <templateId root="2.16.840.1.113883.10.20.23.75"/>
     <id root="103108566" 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>
 <entryRelationship>
   <observation classCode="OBS" moodCode="EVN">
     <templateId root="2.16.840.1.113883.10.20.23.96"/>
     <id root="1085566253" extension="MDHT"/>
     <code codeSystem="locally defined" codeSystemName="Supplemental Value
Type"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
     <participant/>
     <entryRelationship typeCode="COMP"/>
   </observation>
 </entryRelationship>
 <entryRelationship>
   <observation classCode="OBS" moodCode="EVN">
     <templateId root="2.16.840.1.113883.10.20.23.20"/>
     <id root="207474483" 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="CD" code="639759243"/>
   </observation>
 </entryRelationship>
 <entryRelationship>
```

```
    <observation/>
  </entryRelationship>
  <entryRelationship>
    <observation>
      <id root="1345726233" extension="MDHT"/>
      <code code="781106670"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <participant/>
      <entryRelationship typeCode="REFR"/>
      <entryRelationship>
        <act classCode="ACT">
          <templateId root="2.16.840.1.113883.10.20.23.42"/>
          <code code="C83204" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
        </act>
      </entryRelationship>
      <entryRelationship>
        <observation classCode="OBS">
          <templateId root="2.16.840.1.113883.10.20.23.56"/>
          <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus" displayName="Reason for non completion"/>
        </observation>
      </entryRelationship>
      <entryRelationship>
        <act/>
      </entryRelationship>
      <entryRelationship>
        <observation classCode="OBS" moodCode="EVN">
          <templateId root="2.16.840.1.113883.10.20.23.20"/>
          <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus"/>
        </observation>
      </entryRelationship>
      <entryRelationship>
        <observation/>
      </entryRelationship>
      <entryRelationship>
        <observation>
          <templateId root="2.16.840.1.113883.10.20.23.30"/>
          <code code="C66734" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
        </observation>
      </entryRelationship>
    </observation>
  </entryRelationship>
</observation>
```

Indication

[Observation: templateId `2.16.840.1.113883.10.20.23.48`]

The template provides a reusable structure to include information on the indication for an intevention.

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF:1389)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:1390)
3. **SHALL** contain exactly one [1..1] **`code`** (CONF:1391)**`/@code`**`="C83085"` *Concomitant Medication Indication* (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`) (CONF:1392)

- A code value to indicate the observation contains indication information.

4. **SHALL** contain exactly one [1..1] **`value`** with data type CD (CONF:1393), where the @code **SHALL** be selected from (CodeSystem: `unknown Intervention Indication Type`) (CONF:1394)
   - Information about the reason for the medication being taken. [SDTM: CMINDC] [SDM: -INDC]

Indication 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="2.16.840.1.113883.10.20.23.48"/>
  <id root="1603101860" extension="MDHT"/>
  <code code="C83085" codeSystem="2.16.840.1.113883.3.26.1.1"
 codeSystemName="NCI Thesaurus" displayName="Concomitant Medication
 Indication"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <value xsi:type="CD" code="1158619177"/>
</observation>
```

Intended Regimen

[Observation: templateId `2.16.840.1.113883.10.20.23.49`]

The template provides a reusable structure for including a text description of the intended schedule or regimen for an intervention or treatment. It is used to supplement frequency information provided using the effectiveTime element.

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF:1395)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:1396)
3. **SHALL** contain exactly one [1..1] **`code`** (CONF:1397)**`/@code`**`="IRtbd"` (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`) (CONF:1398)
   - A code to indicate the information refers to an intended regimen for an intervention.
4. **SHALL** contain exactly one [1..1] **`value`** with data type ED (CONF:1399)
   - Text description of the intended schedule or regimen for the intervention. [SDTM: CMDOSRGM, EXDOSRGM], [Study Data Tabulation Model: DOSRGM]

Intended Regimen 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="2.16.840.1.113883.10.20.23.49"/>
  <id root="2091016667" 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="ED">Text Value</value>
</observation>
```

Medical History Item

[Observation: templateId `2.16.840.1.113883.10.20.23.52`]

The template records the content of the SDTM medical history domain. It generally includes the subject's prior and concomitant conditions at the start of the trial.

1. **SHALL** contain exactly one [1..1] **`@classCode="OBS"`** *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF:419)
2. **SHALL** contain exactly one [1..1] **`@moodCode="EVN"`** *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:420)
3. **SHALL** contain [1..3] **`id`** (CONF:421)
   - 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.
4. **SHALL** contain exactly one [1..1] **`code`** (CONF:422)**`/@code="MHItbd"`** (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`) (CONF:424)
   - The code value indicates that this observation is a medical history item.
5. **MAY** contain zero or one [0..1] **`statusCode`** (CONF:425)
   - Used to indicate whether the activity - occurrence of the medical history event - did occur. Use statusCode "Completed" if the use occurred. [SDTM: MHOCCUR]
6. **MAY** contain zero or one [0..1] **`effectiveTime`** (CONF:426)
   - The start and stop date/times of the medical history event. [SDTM: MHSTDTC, MHENDTC]
7. **SHALL** contain exactly one [1..1] **`value`** with data type CD (CONF:427), where the @code **SHALL** be selected from ValueSet ***`Medical History Item Set`*** `locally defined` **STATIC** (CONF:1527)
   - A code value and descriptive text and the verbatim entry in order to provide information on the nature of the medical condition or event. [SDTM: MHTERM, MHMODIFY, MHDECOD]
8. **SHALL** contain exactly one [1..1] **`entryRelationship`** (CONF:429)
   - Identifies the SDTM or SEND domain the record is assigned to.
   a. Contains **`@typeCode="REFR"`** *REFR*
   b. Contains exactly one [1..1] *Domain Assignment* (templateId: `2.16.840.1.113883.10.20.23.30`)
9. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:430)
   - Allows capture of a group identifier for the medical history item.
   a. Contains **`@typeCode="COMP"`** *COMP*
   b. Contains exactly one [1..1] *Group Identifier* (templateId: `2.16.840.1.113883.10.20.23.42`)
10. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:431)
    - Used to capture information, most particularly the timing, regarding the collection of data for an event. This is relevant especially in cases where the timing and duration of an event are distinct from that of data collection.
    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Data Collection* (templateId: `2.16.840.1.113883.10.20.23.27`)
11. **SHALL** contain zero or one [0..1] **`entryRelationship`** (CONF:432)
    - Used to indicate whether collection of data regarding an event of this type has been pre-specified, usually on a reporting form.
    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Pre-Specified Event* (templateId: `2.16.840.1.113883.10.20.23.70`)
12. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:433)
    - Provides a reason for not capturing information for the medical history item.

   a. Contains **@typeCode="COMP"** *COMP*
   b. Contains exactly one [1..1] *Non Performance Reason* (templateId: 2.16.840.1.113883.10.20.23.56)
13. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:434)
   - 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: 2.16.840.1.113883.10.20.23.17)
14. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:435)
   - Allows positioning of the start of the event with relationship to a defined reference time period.
   a. Contains **@typeCode="REFR"** *REFR*
   b. Contains exactly one [1..1] *Start Relative to Reference Period* (templateId: 2.16.840.1.113883.10.20.23.79)
15. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:436)
   - Allows positioning of the termination of the event with relationship to a defined reference time period.
   a. Contains **@typeCode="REFR"** *REFR*
   b. Contains exactly one [1..1] *Stop Relative to Reference Period* (templateId: 2.16.840.1.113883.10.20.23.80)
16. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:437)
   - The record of a category to be used in organizing information items.
   a. Contains **@typeCode="COMP"** *COMP*
   b. Contains exactly one [1..1] *Category* (templateId: 2.16.840.1.113883.10.20.23.20)
17. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:438)
   - The record of a sub-category to be used in organizing information items.
   a. Contains **@typeCode="COMP"** *COMP*
   b. Contains exactly one [1..1] *Sub- Category* (templateId: 2.16.840.1.113883.10.20.23.91)
18. **MAY** contain zero or more [0..*] **entryRelationship** (CONF:439)
   - Establishes a relationship between this record and another record.
   a. Contains **@typeCode="REFR"** *REFR*
   b. Contains exactly one [1..1] *Related Record* (templateId: 2.16.840.1.113883.10.20.23.75)
19. **MAY** contain zero or more [0..*] **entryRelationship** (CONF:440)
   - Allows the association of a supplemental value - outside of the content specfied for the domain - to the record.
   a. Contains **@typeCode="COMP"** *COMP*
   b. Contains exactly one [1..1] *Supplemental Value* (templateId: 2.16.840.1.113883.10.20.23.96)
20. **MAY** contain zero or more [0..*] **entryRelationship** (CONF:441)
   - A place to insert comments related to a particular finding.
   a. Contains **@typeCode="COMP"** *COMP*
   b. Contains exactly one [1..1] *Comment* (templateId: 2.16.840.1.113883.10.20.23.23)
21. **MAY** contain zero or more [0..*] **entryRelationship** (CONF:442)
   - Allows recording of additional findings related to the event.
   a. Contains **@typeCode="COMP"** *COMP*
   b. Contains exactly one [1..1] *Finding About* (templateId: 2.16.840.1.113883.10.20.23.40)

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="2.16.840.1.113883.10.20.23.52"/>
  <id root="270092974" extension="MDHT"/>
  <code code="MHItbd" 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="CD" code="795716404"/>
  <entryRelationship>
    <act classCode="ACT">
      <templateId root="2.16.840.1.113883.10.20.23.42"/>
      <id root="1215463261" extension="MDHT"/>
      <code code="C83204" 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">
      <templateId root="2.16.840.1.113883.10.20.23.56"/>
      <id root="1699503871" extension="MDHT"/>
      <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
 Thesaurus" displayName="Reason for non completion"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <value xsi:type="CD" code="803759591"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation/>
  </entryRelationship>
  <entryRelationship>
    <act>
      <id root="479631815" extension="MDHT"/>
      <code code="1172804308"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <entryRelationship>
        <observation/>
      </entryRelationship>
    </act>
  </entryRelationship>
  <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.23"/>
      <id root="634127740" extension="MDHT"/>
```

```
     <code code="C49569" 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="ED">Text Value</value>
     <participant/>
     <entryRelationship/>
   </observation>
 </entryRelationship>
 <entryRelationship>
   <observation>
     <templateId root="2.16.840.1.113883.10.20.23.30"/>
     <id root="1165878484" extension="MDHT"/>
     <code code="C66734" 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="CD" code="392016895"/>
   </observation>
 </entryRelationship>
 <entryRelationship>
   <act classCode="ACT">
     <templateId root="2.16.840.1.113883.10.20.23.75"/>
     <id root="34259652" 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>
   </act>
 </entryRelationship>
 <entryRelationship>
   <observation classCode="OBS" moodCode="EVN">
     <templateId root="2.16.840.1.113883.10.20.23.96"/>
     <id root="1623741154" extension="MDHT"/>
     <code codeSystem="locally defined" codeSystemName="Supplemental Value
Type"/>
     <statusCode code="completed"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
     <participant/>
     <entryRelationship typeCode="COMP"/>
   </observation>
 </entryRelationship>
 <entryRelationship>
   <observation/>
 </entryRelationship>
 <entryRelationship>
   <observation/>
 </entryRelationship>
 <entryRelationship>
   <observation classCode="OBS" moodCode="EVN">
     <templateId root="2.16.840.1.113883.10.20.23.20"/>
     <id root="937100125" 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="CD" code="859970738"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation/>
  </entryRelationship>
  <entryRelationship>
    <observation>
      <id root="1655062572" extension="MDHT"/>
      <code code="669436404"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <participant/>
      <entryRelationship typeCode="REFR"/>
      <entryRelationship>
        <act classCode="ACT">
          <templateId root="2.16.840.1.113883.10.20.23.42"/>
          <code code="C83204" codeSystem="2.16.840.1.113883.3.26.1.1"
 codeSystemName="NCI Thesaurus"/>
        </act>
      </entryRelationship>
      <entryRelationship>
        <observation classCode="OBS">
          <templateId root="2.16.840.1.113883.10.20.23.56"/>
          <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
 Thesaurus" displayName="Reason for non completion"/>
        </observation>
      </entryRelationship>
      <entryRelationship>
        <act/>
      </entryRelationship>
      <entryRelationship>
        <observation classCode="OBS" moodCode="EVN">
          <templateId root="2.16.840.1.113883.10.20.23.20"/>
          <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
 Thesaurus"/>
        </observation>
      </entryRelationship>
      <entryRelationship>
        <observation/>
      </entryRelationship>
      <entryRelationship>
        <observation>
          <templateId root="2.16.840.1.113883.10.20.23.30"/>
          <code code="C66734" codeSystem="2.16.840.1.113883.3.26.1.1"
 codeSystemName="NCI Thesaurus"/>
        </observation>
      </entryRelationship>
    </observation>
  </entryRelationship>
</observation>
```

Microbiology Specimen Finding

[Observation: templateId `2.16.840.1.113883.10.20.23.53`]

The template 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`) (CONF:679)
2. **SHALL** contain exactly one [1..1] **`@moodCode="EVN"`** *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:680)
3. **SHALL** contain [1..2] **`id`** (CONF:681)
   - A value that is provided to ensure the uniqueness of the microbiology finding. [SDTM: MBSEQ, MBSPID] A single identifier, the sequence number, is required.
4. **SHALL** contain exactly one [1..1] **`code`** (CONF:682), where the @code **SHALL** be selected from ValueSet *`Microbiology Finding Set`* `locally defined` **STATIC** (CONF:1539)
   - 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.
5. **MAY** contain zero or one [0..1] **`statusCode`** (CONF:684), where the @code **SHALL** be selected from (CodeSystem: `2.16.840.1.113883.5.14 ActStatus`) (CONF:1540)
   - Used to indicate whether or not an exam has been performed. [SDTM: MBSTAT]
6. **SHOULD** contain zero or more [0..*] **`value`** (CONF:685)
   - The microbiology specimen result, as up to three observation values, using both original units and a standard format or set of units. 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: MBORRES, MBORRESU, MBSTRESC, MBSTRESN, MBSTRESU]
7. **SHOULD** contain zero or one [0..1] **`methodCode`** (CONF:686), where the @code **SHALL** be selected from ValueSet *`Method`* `C85492` **STATIC** (CONF:687)
   - Indicates the method of the test or examination. [SDTM: MBMETHOD]
8. **SHALL** contain exactly one [1..1] **`entryRelationship`** (CONF:688)
   - Identifies the SDTM or SEND domain the record is assigned to.
   a. Contains **`@typeCode="REFR"`** *REFR*
   b. Contains exactly one [1..1] *Domain Assignment* (templateId: `2.16.840.1.113883.10.20.23.30`)
9. **SHOULD** contain zero or one [0..1] **`entryRelationship`** (CONF:689)
   - Allows capture of a group identifier for the finding.
   a. Contains **`@typeCode="COMP"`** *COMP*
   b. Contains exactly one [1..1] *Group Identifier* (templateId: `2.16.840.1.113883.10.20.23.42`)
10. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:690)
    - Provides a reason for not capturing information for the finding.
    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Non Performance Reason* (templateId: `2.16.840.1.113883.10.20.23.56`)
11. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:691)
    - Information on the specimen that was tested to derive the observation value. It may include information on the collection of the specimen as well as on the specimen itself.
    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Specimen Information* (templateId: `2.16.840.1.113883.10.20.23.78`)
12. **MAY** contain zero or one [0..1] **`participant`** (CONF:692)

- Used to identify the organization that performed the test.

a. Contains exactly one [1..1] *Study Test Organization* (templateId: `2.16.840.1.113883.10.20.23.88`)

13. **MAY** contain [0..2] **`interpretationCode`** (CONF:693), where the @code **SHALL** be selected from ValueSet *`Subject Data Interpretation Type`* `CXXXXX` **STATIC** (CONF:694)
    - Includes information used to better interpret the observation value (result). In particular, whether a value is a baseline value, and whether it has been derived. [SDTM: MBBLFL, MBDRVFL]
14. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:695)
    - The record of a category to be used in organizing information items.

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

    b. Contains exactly one [1..1] *Category* (templateId: `2.16.840.1.113883.10.20.23.20`)
15. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:696)
    - The record of a sub-category to be used in organizing information items.

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

    b. Contains exactly one [1..1] *Sub- Category* (templateId: `2.16.840.1.113883.10.20.23.91`)
16. **SHOULD** contain zero or one [0..1] **`entryRelationship`** (CONF:697)
    - The record of a category to be used in organizing finding or observation results.

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

    b. Contains exactly one [1..1] *Result Category* (templateId: `2.16.840.1.113883.10.20.23.76`)
17. **MAY** contain zero or more [0..*] **`entryRelationship`** (CONF:698)
    - Establishes a relationship between this record and another record.

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

    b. Contains exactly one [1..1] *Related Record* (templateId: `2.16.840.1.113883.10.20.23.75`)
18. **MAY** contain zero or more [0..*] **`entryRelationship`** (CONF:699)
    - Allows the association of a supplemental value - outside of the content specfied for the domain - to the record.

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

    b. Contains exactly one [1..1] *Supplemental Value* (templateId: `2.16.840.1.113883.10.20.23.96`)
19. **MAY** contain zero or more [0..*] **`entryRelationship`** (CONF:700)
    - A place to insert comments related to a particular finding.

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

    b. Contains exactly one [1..1] *Comment* (templateId: `2.16.840.1.113883.10.20.23.23`)
20. **MAY** contain zero or more [0..*] **`entryRelationship`** (CONF:701)
    - Allows recording of additional findings related to the event.

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

    b. Contains exactly one [1..1] *Finding About* (templateId: `2.16.840.1.113883.10.20.23.40`)

Microbiology Specimen 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">
  <templateId root="2.16.840.1.113883.10.20.23.53"/>
  <id root="1711932635" extension="MDHT"/>
  <code codeSystem="unknown"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
```

```
 <interpretationCode codeSystemName="NCI Thesaurus"/>
 <methodCode codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus"/>
 <participant>
   <participantRole classCode="ASSIGNED">
     <templateId root="null"/>
   </participantRole>
 </participant>
 <entryRelationship>
   <act classCode="ACT">
     <templateId root="2.16.840.1.113883.10.20.23.42"/>
     <id root="53289719" extension="MDHT"/>
     <code code="C83204" 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">
     <templateId root="2.16.840.1.113883.10.20.23.56"/>
     <id root="941469954" extension="MDHT"/>
     <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus" displayName="Reason for non completion"/>
     <statusCode code="completed"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
     <value xsi:type="CD" code="1390927113"/>
     <interpretationCode code="1315463991"/>
     <methodCode code="1776178520"/>
   </observation>
 </entryRelationship>
 <entryRelationship>
   <procedure>
     <id root="256341141" extension="MDHT"/>
     <code code="1962270271"/>
     <statusCode code="completed"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
     <methodCode code="880851312"/>
     <specimen typeCode="SPC">
       <templateId root="null"/>
     </specimen>
     <entryRelationship typeCode="COMP"/>
     <entryRelationship typeCode="COMP"/>
     <entryRelationship typeCode="COMP"/>
     <entryRelationship>
       <observation/>
     </entryRelationship>
     <entryRelationship>
       <act>
         <templateId root="2.16.840.1.113883.10.20.23.97"/>
         <code codeSystem="2.16.840.1.113883.3.26.1.1"/>
       </act>
     </entryRelationship>
   </procedure>
 </entryRelationship>
```

```
 <entryRelationship>
   <observation classCode="OBS" moodCode="EVN">
     <templateId root="2.16.840.1.113883.10.20.23.23"/>
     <id root="334690864" extension="MDHT"/>
     <code code="C49569" 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="ED">Text Value</value>
     <interpretationCode code="1615058317"/>
     <methodCode code="272568773"/>
     <participant/>
     <entryRelationship/>
   </observation>
 </entryRelationship>
 <entryRelationship>
   <observation>
     <templateId root="2.16.840.1.113883.10.20.23.30"/>
     <id root="1861913945" extension="MDHT"/>
     <code code="C66734" 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="CD" code="1761955919"/>
     <interpretationCode code="410232982"/>
     <methodCode code="1258129585"/>
   </observation>
 </entryRelationship>
 <entryRelationship>
   <act classCode="ACT">
     <templateId root="2.16.840.1.113883.10.20.23.75"/>
     <id root="555642566" 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>
   </act>
 </entryRelationship>
 <entryRelationship>
   <observation classCode="OBS" moodCode="EVN">
     <templateId root="2.16.840.1.113883.10.20.23.96"/>
     <id root="20480189" extension="MDHT"/>
     <code codeSystem="locally defined" codeSystemName="Supplemental Value
Type"/>
     <statusCode code="completed"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
     <interpretationCode code="690156774"/>
     <methodCode code="1125377595"/>
     <participant/>
     <entryRelationship typeCode="COMP"/>
   </observation>
 </entryRelationship>
```

```
 <entryRelationship>
   <observation classCode="OBS" moodCode="EVN">
     <templateId root="2.16.840.1.113883.10.20.23.20"/>
     <id root="1874607168" 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="CD" code="114615766"/>
     <interpretationCode code="230964744"/>
     <methodCode code="213655075"/>
   </observation>
 </entryRelationship>
 <entryRelationship>
   <observation/>
 </entryRelationship>
 <entryRelationship>
   <observation>
     <templateId root="2.16.840.1.113883.10.20.23.76"/>
     <id root="2136330045" extension="MDHT"/>
     <code codeSystem="2.16.840.1.113883.3.26.1.1"/>
     <statusCode code="completed"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
     <value xsi:type="CD" code="1274763650"/>
     <interpretationCode code="1767388682"/>
     <methodCode code="794199648"/>
   </observation>
 </entryRelationship>
 <entryRelationship>
   <observation>
     <id root="551860009" extension="MDHT"/>
     <code code="756427737"/>
     <statusCode code="completed"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
     <interpretationCode code="1546760694"/>
     <methodCode code="1897871848"/>
     <participant/>
     <entryRelationship typeCode="REFR"/>
     <entryRelationship>
       <act classCode="ACT">
         <templateId root="2.16.840.1.113883.10.20.23.42"/>
         <code code="C83204" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
       </act>
     </entryRelationship>
     <entryRelationship>
       <observation classCode="OBS">
         <templateId root="2.16.840.1.113883.10.20.23.56"/>
         <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus" displayName="Reason for non completion"/>
       </observation>
     </entryRelationship>
     <entryRelationship>
       <act/>
     </entryRelationship>
```

```
      <entryRelationship>
        <observation classCode="OBS" moodCode="EVN">
          <templateId root="2.16.840.1.113883.10.20.23.20"/>
          <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
 Thesaurus"/>
        </observation>
      </entryRelationship>
      <entryRelationship>
        <observation/>
      </entryRelationship>
      <entryRelationship>
        <observation>
          <templateId root="2.16.840.1.113883.10.20.23.30"/>
          <code code="C66734" codeSystem="2.16.840.1.113883.3.26.1.1"
 codeSystemName="NCI Thesaurus"/>
        </observation>
      </entryRelationship>
    </observation>
  </entryRelationship>
</observation>
```

Microbiology Susceptibility

[Observation: templateId `2.16.840.1.113883.10.20.23.54`]

The template defines the structure 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`) (CONF:702)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:703)
3. **SHALL** contain [1..3] **`id`** (CONF:704)
   - 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.
4. **SHALL** contain exactly one [1..1] **`code`** (CONF:705), where the @code **SHALL** be selected from ValueSet *`Microbiology Susceptibility Finding Set`* `locally defined` **STATIC** (CONF:1541)
   - 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.
5. **MAY** contain zero or one [0..1] **`statusCode`** (CONF:707), where the @code **SHALL** be selected from (CodeSystem: `2.16.840.1.113883.5.14 ActStatus`) (CONF:1542)
   - Used to indicate whether or not an exam has been performed. [SDTM: MSSTAT]
6. **MAY** contain zero or one [0..1] **`effectiveTime`** with data type TS (CONF:708)
   - The date/time that the test was performed. [SDTM: MSDTC]
7. **SHOULD** contain zero or more [0..*] **`value`** (CONF:709)
   - The microbiology specimen result, as up to three observation values, using both original units and a standard format or set of units. 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: MSORRES, MSORRESU, MSSTRESC, MSSTRESN, MSSTRESU]
8. **SHOULD** contain zero or one [0..1] **`methodCode`** (CONF:710), where the @code **SHALL** be selected from ValueSet *`Method`* `C85492` **STATIC** (CONF:711)
   - Indicates the method of the test or examination. [SDTM: MSMETHOD]
9. **SHALL** contain exactly one [1..1] **`entryRelationship`** (CONF:712)

- Identifies the SDTM or SEND domain the record is assigned to.

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

b. Contains exactly one [1..1] *Domain Assignment* (templateId: 2.16.840.1.113883.10.20.23.30)

10. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:713)
    - Allows capture of a group identifier for the finding.

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

    b. Contains exactly one [1..1] *Group Identifier* (templateId: 2.16.840.1.113883.10.20.23.42)
11. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:714)
    - Provides a reason for not capturing information for the finding.

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

    b. Contains exactly one [1..1] *Non Performance Reason* (templateId: 2.16.840.1.113883.10.20.23.56)
12. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:715)
    - Used to record the study day associated with an activity taking place during a single day.

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

    b. Contains exactly one [1..1] *Event Study Day* (templateId: 2.16.840.1.113883.10.20.23.37)
13. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:716)
    - Orients the performance of the susceptibility test with respect to a study defined timepoint.

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

    b. Contains exactly one [1..1] *Timing Reference* (templateId: 2.16.840.1.113883.10.20.23.97)
14. **MAY** contain zero or one [0..1] **participant** (CONF:717)
    - Used to record the organization performing the test.

    a. Contains exactly one [1..1] *Study Test Organization* (templateId: 2.16.840.1.113883.10.20.23.88)
15. **MAY** contain [0..2] **interpretationCode** (CONF:718), where the @code **SHALL** be selected from ValueSet *Subject Data Interpretation Type* CXXXXX **STATIC** (CONF:719)
    - Includes information used to better interpret the observation value (result). In particular, whether a value is a baseline value, and whether it has been derived. [SDTM: MSBLFL, MSDRVFL]
16. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:720)
    - The record of a category to be used in organizing information items.

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

    b. Contains exactly one [1..1] *Category* (templateId: 2.16.840.1.113883.10.20.23.20)
17. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:721)
    - The record of a sub-category to be used in organizing information items.

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

    b. Contains exactly one [1..1] *Sub- Category* (templateId: 2.16.840.1.113883.10.20.23.91)
18. **SHOULD** contain zero or one [0..1] **entryRelationship** (CONF:722)
    - The record of a category to be used in organizing finding or observation results.

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

    b. Contains exactly one [1..1] *Result Category* (templateId: 2.16.840.1.113883.10.20.23.76)
19. **MAY** contain zero or more [0..*] **entryRelationship** (CONF:723)
    - Establishes a relationship between this record and another record.

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

    b. Contains exactly one [1..1] *Related Record* (templateId: 2.16.840.1.113883.10.20.23.75)
20. **MAY** contain zero or more [0..*] **entryRelationship** (CONF:724)

- Allows the association of a supplemental value - outside of the content specfied for the domain - to the record.

a. Contains **`@typeCode="COMP"`** *COMP*
b. Contains exactly one [1..1] *Supplemental Value* (templateId: `2.16.840.1.113883.10.20.23.96`)

21. MAY contain zero or more [0..*] **`entryRelationship`** (CONF:725)

- A place to insert comments related to a particular finding.

a. Contains **`@typeCode="COMP"`** *COMP*
b. Contains exactly one [1..1] *Comment* (templateId: `2.16.840.1.113883.10.20.23.23`)

22. MAY contain zero or more [0..*] **`entryRelationship`** (CONF:726)

- Allows recording of additional findings related to the event.

a. Contains **`@typeCode="COMP"`** *COMP*
b. Contains exactly one [1..1] *Finding About* (templateId: `2.16.840.1.113883.10.20.23.40`)

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">
  <id root="1543483881" extension="MDHT"/>
  <code code="630256070"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <interpretationCode codeSystemName="NCI Thesaurus"/>
  <methodCode code="2020347126"/>
  <participant>
    <participantRole classCode="ASSIGNED">
      <templateId root="null"/>
    </participantRole>
  </participant>
  <entryRelationship>
    <observation>
      <id root="1278249029" extension="MDHT"/>
      <code code="217297638"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <value xsi:type="INT" value="1"/>
      <interpretationCode code="945788706"/>
      <methodCode code="638202647"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <act>
      <templateId root="2.16.840.1.113883.10.20.23.97"/>
      <id root="182644504" extension="MDHT"/>
      <code codeSystem="2.16.840.1.113883.3.26.1.1"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <entryRelationship typeCode="COMP"/>
    </act>
  </entryRelationship>
```

```
 <entryRelationship>
   <act classCode="ACT">
     <templateId root="2.16.840.1.113883.10.20.23.42"/>
     <id root="1488684335" extension="MDHT"/>
     <code code="C83204" 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">
     <templateId root="2.16.840.1.113883.10.20.23.56"/>
     <id root="1323826069" extension="MDHT"/>
     <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus" displayName="Reason for non completion"/>
     <statusCode code="completed"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
     <value xsi:type="CD" code="1928167628"/>
     <interpretationCode code="465984834"/>
     <methodCode code="1495410558"/>
   </observation>
 </entryRelationship>
 <entryRelationship>
   <observation classCode="OBS" moodCode="EVN">
     <templateId root="2.16.840.1.113883.10.20.23.23"/>
     <id root="1050957335" extension="MDHT"/>
     <code code="C49569" 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="ED">Text Value</value>
     <interpretationCode code="513782071"/>
     <methodCode code="547752986"/>
     <participant/>
     <entryRelationship/>
   </observation>
 </entryRelationship>
 <entryRelationship>
   <observation>
     <templateId root="2.16.840.1.113883.10.20.23.30"/>
     <id root="958708823" extension="MDHT"/>
     <code code="C66734" 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="CD" code="1873862010"/>
     <interpretationCode code="1408595306"/>
     <methodCode code="1935575538"/>
   </observation>
 </entryRelationship>
 <entryRelationship>
```

```
   <act classCode="ACT">
     <templateId root="2.16.840.1.113883.10.20.23.75"/>
     <id root="2115045048" 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>
   </act>
 </entryRelationship>
 <entryRelationship>
   <observation classCode="OBS" moodCode="EVN">
     <templateId root="2.16.840.1.113883.10.20.23.96"/>
     <id root="554436640" extension="MDHT"/>
     <code codeSystem="locally defined" codeSystemName="Supplemental Value
Type"/>
     <statusCode code="completed"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
     <interpretationCode code="1103781353"/>
     <methodCode code="681707866"/>
     <participant/>
     <entryRelationship typeCode="COMP"/>
   </observation>
 </entryRelationship>
 <entryRelationship>
   <observation classCode="OBS" moodCode="EVN">
     <templateId root="2.16.840.1.113883.10.20.23.20"/>
     <id root="1364783296" 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="CD" code="832187875"/>
     <interpretationCode code="281154006"/>
     <methodCode code="1589780162"/>
   </observation>
 </entryRelationship>
 <entryRelationship>
   <observation/>
 </entryRelationship>
 <entryRelationship>
   <observation>
     <templateId root="2.16.840.1.113883.10.20.23.76"/>
     <id root="1409661104" extension="MDHT"/>
     <code codeSystem="2.16.840.1.113883.3.26.1.1"/>
     <statusCode code="completed"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
     <value xsi:type="CD" code="715855685"/>
     <interpretationCode code="1824119564"/>
     <methodCode code="1219623210"/>
   </observation>
 </entryRelationship>
 <entryRelationship>
```

```
   <observation>
     <id root="767053803" extension="MDHT"/>
     <code code="1292215806"/>
     <statusCode code="completed"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
     <interpretationCode code="1366921640"/>
     <methodCode code="1923538779"/>
     <participant/>
     <entryRelationship typeCode="REFR"/>
     <entryRelationship>
       <act classCode="ACT">
         <templateId root="2.16.840.1.113883.10.20.23.42"/>
         <code code="C83204" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
       </act>
     </entryRelationship>
     <entryRelationship>
       <observation classCode="OBS">
         <templateId root="2.16.840.1.113883.10.20.23.56"/>
         <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus" displayName="Reason for non completion"/>
       </observation>
     </entryRelationship>
     <entryRelationship>
       <act/>
     </entryRelationship>
     <entryRelationship>
       <observation classCode="OBS" moodCode="EVN">
         <templateId root="2.16.840.1.113883.10.20.23.20"/>
         <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus"/>
       </observation>
     </entryRelationship>
     <entryRelationship>
       <observation/>
     </entryRelationship>
     <entryRelationship>
       <observation>
         <templateId root="2.16.840.1.113883.10.20.23.30"/>
         <code code="C66734" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
       </observation>
     </entryRelationship>
   </observation>
  </entryRelationship>
</observation>
```

Non Performance Reason

[Observation: templateId `2.16.840.1.113883.10.20.23.56`]

The template provides a reusable structure that 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`) (CONF:209)
2. **SHALL** contain exactly one [1..1] **`@moodCode="EVN"`** *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:212)

3. **SHALL** contain exactly one [1..1] **code** (CONF:210)**/@code**="C66727" *Reason for non completion* (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus) (CONF:211)
   - The code value identifies this observation as a non-performance reason.
4. **SHALL** contain exactly one [1..1] **value** with data type CD (CONF:213), where the @code **SHALL** be selected from ValueSet *Non Performance Reason* C66727 **STATIC** (CONF:214)
   - 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], [SEND: BWREASND, BGREASND, FWREASND, LBREASND, MAREASND,MIREASND, OMREASND, PMREASND, PCREASND, PPREASND, TFREASND, VSREASND, EGREASND], [Study Data Tablulation Model: -REASND]

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">
  <templateId root="2.16.840.1.113883.10.20.23.56"/>
  <id root="1760434616" extension="MDHT"/>
  <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus"
 displayName="Reason for non completion"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <value xsi:type="CD" code="1080537311"/>
</observation>
```

Non-Study Treatment Relationship

[Observation: templateId 2.16.840.1.113883.10.20.23.61]

The template is used to record an opinion as to whether the event may be associated with a treatment or other occurrence that is different from the study drug. This structure is captured as a template to facilitate its reuse as a characteristic of different types of data within clinical and non-clinical trial reporting.

1. **SHALL** contain exactly one [1..1] **@classCode**="OBS" *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) (CONF:1435)
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) (CONF:1438)
3. **SHALL** contain exactly one [1..1] **code** (CONF:1436)**/@code**="NSTtbd" (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus) (CONF:1437)
   - A value to indicate that the observation provides the investigator's opinon regarding the causality of the event to a non-study treatment.
4. **SHALL** contain exactly one [1..1] **value** with data type ED (CONF:1439)
   - Information on the causal relationship between the event and a treatment other than the study treatment. [SDTM: AERELNST]. [Study Data Tabulation Model: -RELNST]

Non-Study Treatment Relationship 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">
  <templateId root="2.16.840.1.113883.10.20.23.61"/>
  <id root="254315034" extension="MDHT"/>
  <code code="NSTtbd" codeSystem="2.16.840.1.113883.3.26.1.1"
 codeSystemName="NCI Thesaurus"/>
```

```
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <value xsi:type="ED">Text Value</value>
</observation>
```

Other Treatment Action Taken

[Observation: templateId `2.16.840.1.113883.10.20.23.63`]

The template provides a description of other actions - aside from changes to the study treatment - that were taken as a response to the event. This structure is captured as a template to facilitate its reuse as a characteristic of different types of data within clinical and non-clinical trial reporting.

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF:1424)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:1425)
3. **SHALL** contain exactly one [1..1] **`code`** (CONF:1426)**`/@code`**`="OATtbd"` (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`) (CONF:1427)
   - A code value to indicate information regarding other actions - unrelated to the study treatment - that were taken as a result of the adverse event.
4. **SHALL** contain exactly one [1..1] **`value`** with data type ED (CONF:1428)
   - Information on an action taken other than changes to the study treatment as a result of the event. [SDTM: AEACNOTH]. [Study Data Tabulation Model: -ACNOTH]

Other Treatment Action Taken 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">
  <templateId root="2.16.840.1.113883.10.20.23.63"/>
  <id root="1530973256" extension="MDHT"/>
  <code code="OATtbd" codeSystem="2.16.840.1.113883.3.26.1.1"
 codeSystemName="NCI Thesaurus"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <value xsi:type="ED">Text Value</value>
</observation>
```

Pharmacokinetic Concentration Finding

[Observation: templateId `2.16.840.1.113883.10.20.23.65`]

The template is used to record 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`) (CONF:727)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:728)
3. **SHALL** contain [1..3] **`id`** (CONF:729)
   - A value that is provided to ensure the uniqueness of the pharacokinetics result. [SDTM: PCSEQ, PCREFID, PCSPID], [SEND: PCSEQ, PCREFID, PCSPID] A single identifier, the sequence number, is required.

4. **SHALL** contain exactly one [1..1] **code** (CONF:730), where the @code **SHALL** be selected from ValueSet *Pharmacokinetics Concentration Finding Set* `locally defined` **STATIC** (CONF:1543)
   - 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], [SEND: PCTESTCD, PCTEST].
5. **MAY** contain zero or one [0..1] **statusCode** (CONF:732), where the @code **SHALL** be selected from (CodeSystem: `2.16.840.1.113883.5.14 ActStatus`) (CONF:1544)
   - Used to indicate whether or not an exam has been performed. [SDTM: PCSTAT], [SEND: PCSTAT]
6. **SHOULD** contain zero or one [0..1] **value** with data type CD (CONF:733)
   - The pharmacokinetics result, as up to three observation values, using both original units and a standard format or set of units. 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: PCORRES, PCORRESU, PCSTRESC, PCSTRESN, PCSTRESU], [SEND: PCORRES, PCORRESU, PCSTRESC, PCSTRESN, PCSTRESU]
7. **MAY** contain zero or one [0..1] **methodCode** (CONF:734), where the @code **SHALL** be selected from ValueSet *Method* `C85492` **STATIC** (CONF:735)
   - Indicates the method of the test or examination. [SDTM: PCMETHOD], [SEND: PCMETHOD]
8. **SHALL** contain exactly one [1..1] **entryRelationship** (CONF:736)
   - Identifies the SDTM or SEND domain the record is assigned to.
   a. Contains **@typeCode="REFR"** *REFR*
   b. Contains exactly one [1..1] *Domain Assignment* (templateId: `2.16.840.1.113883.10.20.23.30`)
9. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:737)
   - Allows capture of a group identifier for the finding.
   a. Contains **@typeCode="COMP"** *COMP*
   b. Contains exactly one [1..1] *Group Identifier* (templateId: `2.16.840.1.113883.10.20.23.42`)
10. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:738)
    - Provides a reason for not capturing information for the finding.
    a. Contains **@typeCode="COMP"** *COMP*
    b. Contains exactly one [1..1] *Non Performance Reason* (templateId: `2.16.840.1.113883.10.20.23.56`)
11. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:739)
    - Information on the reason that a data item is to be excluded from tabulation.
    a. Contains **@typeCode="COMP"** *COMP*
    b. Contains exactly one [1..1] *Exclusion Reason* (templateId: `2.16.840.1.113883.10.20.23.38`)
12. **SHALL** contain zero or one [0..1] **entryRelationship** (CONF:740)
    - Information on the specimen that was tested to derive the observation value. It may include information on the collection of the specimen as well as on the specimen itself.
    a. Contains **@typeCode="COMP"** *COMP*
    b. Contains exactly one [1..1] *Specimen Information* (templateId: `2.16.840.1.113883.10.20.23.78`)
13. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:741)
    - Used to indicate the fasting status - time since consuption of food - for the study subject.
    a. Contains **@typeCode="COMP"** *COMP*
    b. Contains exactly one [1..1] *Fasting Status* (templateId: `2.16.840.1.113883.10.20.23.39`)
14. **SHOULD** contain zero or one [0..1] **entryRelationship** (CONF:742)
    - Records the lower limit of quantitation for an assay.
    a. Contains **@typeCode="COMP"** *COMP*
    b. Contains exactly one [1..1] *Assay Quantitation* (templateId: `2.16.840.1.113883.10.20.23.16`)
15. **MAY** contain zero or one [0..1] **participant** (CONF:743)

- Used to record the organization performing the test.

a. Contains exactly one [1..1] *Study Test Organization* (templateId: `2.16.840.1.113883.10.20.23.88`)

16. **SHOULD** contain zero or one [0..1] **`entryRelationship`** (CONF:744)
    - Captures the planned study day for making an observation or recording a finding.

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

    b. Contains exactly one [1..1] *Planned Study Day* (templateId: `2.16.840.1.113883.10.20.23.68`)
17. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:745)
    - The record of a category to be used in organizing information items.

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

    b. Contains exactly one [1..1] *Category* (templateId: `2.16.840.1.113883.10.20.23.20`)
18. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:746)
    - The record of a sub-category to be used in organizing information items.

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

    b. Contains exactly one [1..1] *Sub- Category* (templateId: `2.16.840.1.113883.10.20.23.91`)
19. **SHOULD** contain [0..3] **`interpretationCode`** (CONF:747), where the @code **SHALL** be selected from ValueSet *`Subject Data Interpretation Type`* `CXXXXX` **STATIC** (CONF:748)
    - Includes information used to better interpret the observation value (result). [SDTM: PCDRVFL]. [SEND: PCBLFL, PCDRVFL, PCEXCLFL]
20. **MAY** contain zero or more [0..*] **`entryRelationship`** (CONF:749)
    - Establishes a relationship between this record and another record.

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

    b. Contains exactly one [1..1] *Related Record* (templateId: `2.16.840.1.113883.10.20.23.75`)
21. **MAY** contain zero or more [0..*] **`entryRelationship`** (CONF:750)
    - Allows the association of a supplemental value - outside of the content specfied for the domain - to the record.

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

    b. Contains exactly one [1..1] *Supplemental Value* (templateId: `2.16.840.1.113883.10.20.23.96`)
22. **MAY** contain zero or more [0..*] **`entryRelationship`** (CONF:751)
    - A place to insert comments related to a particular finding.

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

    b. Contains exactly one [1..1] *Comment* (templateId: `2.16.840.1.113883.10.20.23.23`)
23. **MAY** contain zero or more [0..*] **`entryRelationship`** (CONF:752)
    - Allows recording of additional findings related to the finding.

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

    b. Contains exactly one [1..1] *Finding About* (templateId: `2.16.840.1.113883.10.20.23.40`)

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">
  <id root="1191667279" extension="MDHT"/>
  <code code="573045574"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <value xsi:type="CD" code="1332031706"/>
```

```
 <interpretationCode code="331441562"/>
 <methodCode code="1159196001"/>
 <participant>
   <participantRole classCode="ASSIGNED">
     <templateId root="null"/>
   </participantRole>
 </participant>
 <entryRelationship>
   <act classCode="ACT">
     <templateId root="2.16.840.1.113883.10.20.23.42"/>
     <id root="8764247" extension="MDHT"/>
     <code code="C83204" 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>
     <id root="1907978591" extension="MDHT"/>
     <code code="587637573"/>
     <statusCode code="completed"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
     <methodCode code="139119943"/>
     <specimen typeCode="SPC">
       <templateId root="null"/>
     </specimen>
     <entryRelationship typeCode="COMP"/>
     <entryRelationship typeCode="COMP"/>
     <entryRelationship typeCode="COMP"/>
     <entryRelationship>
       <observation/>
     </entryRelationship>
     <entryRelationship>
       <act>
         <templateId root="2.16.840.1.113883.10.20.23.97"/>
         <code codeSystem="2.16.840.1.113883.3.26.1.1"/>
       </act>
     </entryRelationship>
   </procedure>
 </entryRelationship>
 <entryRelationship>
   <observation classCode="OBS">
     <templateId root="2.16.840.1.113883.10.20.23.56"/>
     <id root="1966530304" extension="MDHT"/>
     <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus" displayName="Reason for non completion"/>
     <statusCode code="completed"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
     <value xsi:type="CD" code="345276323"/>
     <interpretationCode code="1238610879"/>
     <methodCode code="849152922"/>
   </observation>
 </entryRelationship>
 <entryRelationship>
```

```
   <observation>
     <id root="354951395" extension="MDHT"/>
     <code code="1554529421"/>
     <statusCode code="completed"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
     <value xsi:type="INT" value="1"/>
     <interpretationCode code="1787281570"/>
     <methodCode code="831204605"/>
   </observation>
 </entryRelationship>
 <entryRelationship>
   <observation classCode="OBS">
     <templateId root="2.16.840.1.113883.10.20.23.38"/>
     <id root="1249534837" extension="MDHT"/>
     <code code="EXCtbd" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus" displayName="Baseline Indicator"/>
     <statusCode code="completed"/>
     <effectiveTime>
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     </effectiveTime>
     <value xsi:type="CD" code="475336748"/>
     <interpretationCode code="1578609463"/>
     <methodCode code="379628933"/>
   </observation>
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   <observation classCode="OBS" moodCode="EVN">
     <templateId root="2.16.840.1.113883.10.20.23.23"/>
     <id root="1433447634" extension="MDHT"/>
     <code code="C49569" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
     <statusCode code="completed"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
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     <value xsi:type="ED">Text Value</value>
     <interpretationCode code="1357106876"/>
     <methodCode code="722666924"/>
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   <observation>
     <templateId root="2.16.840.1.113883.10.20.23.30"/>
     <id root="1820592463" extension="MDHT"/>
     <code code="C66734" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
     <statusCode code="completed"/>
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       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
     <value xsi:type="CD" code="3479038"/>
     <interpretationCode code="2139712362"/>
     <methodCode code="1295370661"/>
   </observation>
 </entryRelationship>
 <entryRelationship>
```

```
   <act classCode="ACT">
     <templateId root="2.16.840.1.113883.10.20.23.75"/>
     <id root="1729495264" 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>
   </act>
 </entryRelationship>
 <entryRelationship>
   <observation classCode="OBS" moodCode="EVN">
     <templateId root="2.16.840.1.113883.10.20.23.96"/>
     <id root="863538698" extension="MDHT"/>
     <code codeSystem="locally defined" codeSystemName="Supplemental Value
Type"/>
     <statusCode code="completed"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
     <interpretationCode code="587231331"/>
     <methodCode code="1579233619"/>
     <participant/>
     <entryRelationship typeCode="COMP"/>
   </observation>
 </entryRelationship>
 <entryRelationship>
   <observation classCode="OBS" moodCode="EVN">
     <templateId root="2.16.840.1.113883.10.20.23.20"/>
     <id root="100235295" 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="CD" code="389613414"/>
     <interpretationCode code="1002653657"/>
     <methodCode code="255295135"/>
   </observation>
 </entryRelationship>
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   <observation classCode="OBS">
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     <id root="1388117149" extension="MDHT"/>
     <code code="FStbd" 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"/>
     <interpretationCode code="849823728"/>
     <methodCode code="2046954814"/>
   </observation>
 </entryRelationship>
```

```
 <entryRelationship>
   <observation>
     <id root="270153810" extension="MDHT"/>
     <code code="2028424074"/>
     <statusCode code="completed"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
     <value xsi:type="IVL_PQ"/>
     <interpretationCode code="213678782"/>
     <methodCode code="1134003015"/>
   </observation>
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   <observation>
     <id root="1567893048" extension="MDHT"/>
     <code code="1526565961"/>
     <statusCode code="completed"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
     <interpretationCode code="1404772151"/>
     <methodCode code="664057387"/>
     <participant/>
     <entryRelationship typeCode="REFR"/>
     <entryRelationship>
       <act classCode="ACT">
         <templateId root="2.16.840.1.113883.10.20.23.42"/>
         <code code="C83204" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
       </act>
     </entryRelationship>
     <entryRelationship>
       <observation classCode="OBS">
         <templateId root="2.16.840.1.113883.10.20.23.56"/>
         <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus" displayName="Reason for non completion"/>
       </observation>
     </entryRelationship>
     <entryRelationship>
       <act/>
     </entryRelationship>
     <entryRelationship>
       <observation classCode="OBS" moodCode="EVN">
         <templateId root="2.16.840.1.113883.10.20.23.20"/>
         <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus"/>
       </observation>
     </entryRelationship>
     <entryRelationship>
       <observation/>
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     <entryRelationship>
       <observation>
         <templateId root="2.16.840.1.113883.10.20.23.30"/>
         <code code="C66734" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
       </observation>
     </entryRelationship>
   </observation>
 </entryRelationship>
</observation>
```

Pharmacokinetic Parameter Finding

[Observation: templateId `2.16.840.1.113883.10.20.23.66`]

The template records 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`) (CONF:753)
2. **SHALL** contain exactly one [1..1] **`@moodCode="EVN"`** *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:754)
3. **SHALL** contain exactly one [1..1] **`id`** (CONF:755)
   - A value that is provided to ensure the uniqueness of the pharacokinetics parameter result. [SDTM: PPSEQ], [SEND: PPSEQ]
4. **SHALL** contain exactly one [1..1] **`code`** (CONF:756), where the @code **SHALL** be selected from ValueSet *`Pharmacokinetics Parameter Finding Set`* `C85839` **STATIC** (CONF:757)
   - 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], [SEND: PPTESTCD, PPTEST]
5. **MAY** contain zero or one [0..1] **`statusCode`** (CONF:758), where the @code **SHALL** be selected from (CodeSystem: `2.16.840.1.113883.5.14 ActStatus`) (CONF:1545)
   - Used to indicate whether or not an exam has been performed. [SDTM: PPSTAT], [SEND: PPSTAT]
6. **SHOULD** contain [0..3] **`value`** (CONF:759)
   - The pharmacokinetics parameter result, as up to three observation values, using both original units and a standard format or set of units. 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: PPORRES, PPORRESU, PPSTRESC, PPSTRESN, PPSTRESU], [SEND: PPORRES, PPORRESU, PPSTRESC, PPSTRESN, PPSTRESU]
7. **SHALL** contain exactly one [1..1] **`entryRelationship`** (CONF:760)
   - Identifies the SDTM or SEND domain the record is assigned to.
   a. Contains **`@typeCode="REFR"`** *REFR*
   b. Contains exactly one [1..1] *Domain Assignment* (templateId: `2.16.840.1.113883.10.20.23.30`)
8. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:761)
   - Allows capture of a group identifier for the finding.
   a. Contains **`@typeCode="COMP"`** *COMP*
   b. Contains exactly one [1..1] *Group Identifier* (templateId: `2.16.840.1.113883.10.20.23.42`)
9. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:762)
   - Provides a reason for not capturing information for the finding.
   a. Contains **`@typeCode="COMP"`** *COMP*
   b. Contains exactly one [1..1] *Non Performance Reason* (templateId: `2.16.840.1.113883.10.20.23.56`)
10. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:763)
    - Information on the specimen that was tested to derive the observation value. It may include information on the collection of the specimen as well as on the specimen itself.
    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Specimen Information* (templateId: `2.16.840.1.113883.10.20.23.78`)
11. **SHOULD** contain zero or one [0..1] **`entryRelationship`** (CONF:764)
    - Orients the performance of the test leading to the pharmacokinetic parameter with respect to a study defined timepoint.
    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Timing Reference* (templateId: `2.16.840.1.113883.10.20.23.97`)

12. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:765)
    - The record of a category to be used in organizing information items.
    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Category* (templateId: `2.16.840.1.113883.10.20.23.20`)
13. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:766)
    - The record of a sub-category to be used in organizing information items.
    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Sub- Category* (templateId: `2.16.840.1.113883.10.20.23.91`)
14. **MAY** contain zero or more [0..*] **`entryRelationship`** (CONF:767)
    - Establishes a relationship between this record and another record.
    a. Contains **`@typeCode="REFR"`** *REFR*
    b. Contains exactly one [1..1] *Related Record* (templateId: `2.16.840.1.113883.10.20.23.75`)
15. **MAY** contain zero or more [0..*] **`entryRelationship`** (CONF:768)
    - Allows the association of a supplemental value - outside of the content specfied for the domain - to the record.
    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Supplemental Value* (templateId: `2.16.840.1.113883.10.20.23.96`)
16. **MAY** contain zero or more [0..*] **`entryRelationship`** (CONF:769)
    - A place to insert comments related to a particular finding.
    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Comment* (templateId: `2.16.840.1.113883.10.20.23.23`)
17. **MAY** contain zero or more [0..*] **`entryRelationship`** (CONF:770)
    - Allows recording of additional findings related to the finding.
    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Finding About* (templateId: `2.16.840.1.113883.10.20.23.40`)

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">
  <id root="816210072" extension="MDHT"/>
  <code code="1965422593"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <entryRelationship>
    <act classCode="ACT">
      <templateId root="2.16.840.1.113883.10.20.23.42"/>
      <id root="780324468" extension="MDHT"/>
      <code code="C83204" 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>
```

```
      <id root="1918978471" extension="MDHT"/>
      <code code="64984337"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <specimen typeCode="SPC">
        <templateId root="null"/>
      </specimen>
      <entryRelationship typeCode="COMP"/>
      <entryRelationship typeCode="COMP"/>
      <entryRelationship typeCode="COMP"/>
      <entryRelationship>
        <observation/>
      </entryRelationship>
      <entryRelationship>
        <act>
          <templateId root="2.16.840.1.113883.10.20.23.97"/>
          <code codeSystem="2.16.840.1.113883.3.26.1.1"/>
        </act>
      </entryRelationship>
    </procedure>
  </entryRelationship>
  <entryRelationship>
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      <templateId root="2.16.840.1.113883.10.20.23.56"/>
      <id root="2097094770" extension="MDHT"/>
      <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus" displayName="Reason for non completion"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <value xsi:type="CD" code="675479336"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <act>
      <templateId root="2.16.840.1.113883.10.20.23.97"/>
      <id root="1350981414" extension="MDHT"/>
      <code codeSystem="2.16.840.1.113883.3.26.1.1"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <entryRelationship typeCode="COMP"/>
    </act>
  </entryRelationship>
  <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.23"/>
      <id root="1485318265" extension="MDHT"/>
      <code code="C49569" 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="ED">Text Value</value>
      <participant/>
```

```
      <entryRelationship/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation>
      <templateId root="2.16.840.1.113883.10.20.23.30"/>
      <id root="700825220" extension="MDHT"/>
      <code code="C66734" 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="CD" code="1053014659"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <act classCode="ACT">
      <templateId root="2.16.840.1.113883.10.20.23.75"/>
      <id root="137810171" 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>
    </act>
  </entryRelationship>
  <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.96"/>
      <id root="269294207" extension="MDHT"/>
      <code codeSystem="locally defined" codeSystemName="Supplemental Value
Type"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <participant/>
      <entryRelationship typeCode="COMP"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.20"/>
      <id root="693310275" 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="CD" code="266386363"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation/>
  </entryRelationship>
  <entryRelationship>
    <observation>
```

```
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      <code code="2009003443"/>
      <statusCode code="completed"/>
      <effectiveTime>
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        <high value="2012"/>
      </effectiveTime>
      <participant/>
      <entryRelationship typeCode="REFR"/>
      <entryRelationship>
        <act classCode="ACT">
          <templateId root="2.16.840.1.113883.10.20.23.42"/>
          <code code="C83204" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
        </act>
      </entryRelationship>
      <entryRelationship>
        <observation classCode="OBS">
          <templateId root="2.16.840.1.113883.10.20.23.56"/>
          <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus" displayName="Reason for non completion"/>
        </observation>
      </entryRelationship>
      <entryRelationship>
        <act/>
      </entryRelationship>
      <entryRelationship>
        <observation classCode="OBS" moodCode="EVN">
          <templateId root="2.16.840.1.113883.10.20.23.20"/>
          <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus"/>
        </observation>
      </entryRelationship>
      <entryRelationship>
        <observation/>
      </entryRelationship>
      <entryRelationship>
        <observation>
          <templateId root="2.16.840.1.113883.10.20.23.30"/>
          <code code="C66734" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
        </observation>
      </entryRelationship>
    </observation>
  </entryRelationship>
</observation>
```

Physical Examination Finding

[Observation: templateId `2.16.840.1.113883.10.20.23.67`]

The template supports the collection of findings derived from physical exams, other than vital signs.

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF:618)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:619)
3. **SHALL** contain [1..2] **`id`** (CONF:620)

    - 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.

4. **SHALL** contain exactly one [1..1] **code** (CONF:621), where the @code **SHALL** be selected from ValueSet *Physical Exam Finding Set* locally defined **STATIC** (CONF:1535)
   - 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]
5. **MAY** contain zero or one [0..1] **statusCode** (CONF:623), where the @code **SHALL** be selected from (CodeSystem: 2.16.840.1.113883.5.14 ActStatus) (CONF:1536)
   - Used to indicate whether or not the specified physical exam has been performed. [SDTM: PESTAT]
6. **SHOULD** contain [0..2] **value** (CONF:624)
   - The result of the component of the physical exam indicated by the code value, captured as one or two observations. 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. **SHALL** contain exactly one [1..1] **entryRelationship** (CONF:625)
   - Identifies the SDTM or SEND domain the record is assigned to.
   a. Contains **@typeCode="REFR"** *REFR*
   b. Contains exactly one [1..1] *Domain Assignment* (templateId: 2.16.840.1.113883.10.20.23.30)
8. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:626)
   - Allows capture of a group identifier for the finding.
   a. Contains **@typeCode="COMP"** *COMP*
   b. Contains exactly one [1..1] *Group Identifier* (templateId: 2.16.840.1.113883.10.20.23.42)
9. **MAY** contain zero or one [0..1] **methodCode** (CONF:627), where the @code **SHALL** be selected from ValueSet *Method* C85492 **STATIC** (CONF:628)
   - The method used for conducting the test or examination. [SDTM: PEMETHOD]
10. **MAY** contain zero or one [0..1] **targetSiteCode** (CONF:629), where the @code **SHALL** be selected from ValueSet *Anatomical Location* C74456 **STATIC** (CONF:630)
    - Can be used to specify where a physical exam finding occurred. [SDTM: PELOC]
11. **SHOULD** contain zero or one [0..1] **entryRelationship** (CONF:631)
    - Information on whether a predefined data item was collected, and the timing of collection.
    a. Contains **@typeCode="COMP"** *COMP*
    b. Contains exactly one [1..1] *Data Collection* (templateId: 2.16.840.1.113883.10.20.23.27)
12. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:632)
    - Provides a reason for not capturing information for the finding.
    a. Contains **@typeCode="COMP"** *COMP*
    b. Contains exactly one [1..1] *Non Performance Reason* (templateId: 2.16.840.1.113883.10.20.23.56)
13. **MAY** contain zero or one [0..1] **participant** (CONF:633)
    - Used to record the role played by the person providing the value of a subjective finding.
    a. Contains exactly one [1..1] *Study Finding Evaluator* (templateId: 2.16.840.1.113883.10.20.23.84)
14. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:634)
    - 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: 2.16.840.1.113883.10.20.23.17)
15. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:635)
    - The record of a category to be used in organizing information items.

   a. Contains **@typeCode="COMP"** *COMP*
   b. Contains exactly one [1..1] *Category* (templateId: 2.16.840.1.113883.10.20.23.20)
16. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:636)
   - The record of a sub-category to be used in organizing information items.
   a. Contains **@typeCode="COMP"** *COMP*
   b. Contains exactly one [1..1] *Sub- Category* (templateId: 2.16.840.1.113883.10.20.23.91)
17. **MAY** contain zero or more [0..*] **entryRelationship** (CONF:637)
   - Establishes a relationship between this record and another record.
   a. Contains **@typeCode="REFR"** *REFR*
   b. Contains exactly one [1..1] *Related Record* (templateId: 2.16.840.1.113883.10.20.23.75)
18. **MAY** contain zero or more [0..*] **entryRelationship** (CONF:638)
   - Allows the association of a supplemental value - outside of the content specfied for the domain - to the record.
   a. Contains **@typeCode="COMP"** *COMP*
   b. Contains exactly one [1..1] *Supplemental Value* (templateId: 2.16.840.1.113883.10.20.23.96)
19. **MAY** contain zero or more [0..*] **entryRelationship** (CONF:639)
   - A place to insert comments related to a particular finding.
   a. Contains **@typeCode="COMP"** *COMP*
   b. Contains exactly one [1..1] *Comment* (templateId: 2.16.840.1.113883.10.20.23.23)
20. **MAY** contain zero or more [0..*] **entryRelationship** (CONF:640)
   - Allows recording of additional findings related to the finding.
   a. Contains **@typeCode="COMP"** *COMP*
   b. Contains exactly one [1..1] *Finding About* (templateId: 2.16.840.1.113883.10.20.23.40)

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">
  <id root="327631129" extension="MDHT"/>
  <code code="1471162414"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <methodCode code="1989421955"/>
  <targetSiteCode code="1117695391"/>
  <participant>
    <participantRole classCode="ASSIGNED">
      <templateId root="null"/>
      <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
 Thesaurus"/>
    </participantRole>
  </participant>
  <entryRelationship>
    <act classCode="ACT">
      <templateId root="2.16.840.1.113883.10.20.23.42"/>
      <id root="979544458" extension="MDHT"/>
      <code code="C83204" 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">
      <templateId root="2.16.840.1.113883.10.20.23.56"/>
      <id root="272571265" extension="MDHT"/>
      <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus" displayName="Reason for non completion"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <value xsi:type="CD" code="389261546"/>
      <methodCode code="1829167349"/>
      <targetSiteCode code="1113249566"/>
    </observation>
 </entryRelationship>
 <entryRelationship>
    <act>
      <id root="1834627423" extension="MDHT"/>
      <code code="1278360803"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <entryRelationship>
        <observation/>
      </entryRelationship>
    </act>
 </entryRelationship>
 <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.23"/>
      <id root="528213541" extension="MDHT"/>
      <code code="C49569" 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="ED">Text Value</value>
      <methodCode code="1401097671"/>
      <targetSiteCode code="575246951"/>
      <participant/>
      <entryRelationship/>
    </observation>
 </entryRelationship>
 <entryRelationship>
    <observation>
      <templateId root="2.16.840.1.113883.10.20.23.30"/>
      <id root="57008080" extension="MDHT"/>
      <code code="C66734" 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="CD" code="1258909508"/>
      <methodCode code="1340032663"/>
      <targetSiteCode code="1702852127"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <act classCode="ACT">
      <templateId root="2.16.840.1.113883.10.20.23.75"/>
      <id root="250519858" 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>
    </act>
  </entryRelationship>
  <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.96"/>
      <id root="1331921582" extension="MDHT"/>
      <code codeSystem="locally defined" codeSystemName="Supplemental Value
Type"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <methodCode code="1297798192"/>
      <targetSiteCode code="436025126"/>
      <participant/>
      <entryRelationship typeCode="COMP"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.20"/>
      <id root="1619383858" 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="CD" code="960173799"/>
      <methodCode code="1813131141"/>
      <targetSiteCode code="270905789"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation/>
  </entryRelationship>
  <entryRelationship>
    <observation>
      <id root="1462763503" extension="MDHT"/>
      <code code="255125152"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
```

```
      </effectiveTime>
      <methodCode code="2010532968"/>
      <targetSiteCode code="872903245"/>
      <participant/>
      <entryRelationship typeCode="REFR"/>
      <entryRelationship>
        <act classCode="ACT">
          <templateId root="2.16.840.1.113883.10.20.23.42"/>
          <code code="C83204" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
        </act>
      </entryRelationship>
      <entryRelationship>
        <observation classCode="OBS">
          <templateId root="2.16.840.1.113883.10.20.23.56"/>
          <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus" displayName="Reason for non completion"/>
        </observation>
      </entryRelationship>
      <entryRelationship>
        <act/>
      </entryRelationship>
      <entryRelationship>
        <observation classCode="OBS" moodCode="EVN">
          <templateId root="2.16.840.1.113883.10.20.23.20"/>
          <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus"/>
        </observation>
      </entryRelationship>
      <entryRelationship>
        <observation/>
      </entryRelationship>
      <entryRelationship>
        <observation>
          <templateId root="2.16.840.1.113883.10.20.23.30"/>
          <code code="C66734" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
        </observation>
      </entryRelationship>
    </observation>
  </entryRelationship>
</observation>
```

Planned Study Day

[Observation: templateId `2.16.840.1.113883.10.20.23.68`]

The template contains information that is used to identify the study day on which the event it is related to was planned to occur. "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`) (CONF:215)
2. **SHALL** contain exactly one [1..1] **`@moodCode="INT"`** (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:216)
3. **SHALL** contain exactly one [1..1] **`code`** (CONF:217)**`/@code="C83450"`** *Planned Study Day of Visit* (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`) (CONF:218)
   - A fixed value that indicates the observation captures the planned study day for an event.
4. **SHALL** contain exactly one [1..1] **`value`** with data type INT (CONF:219)

- The applicable study day value. [SDTM: VISITDY]. [SEND: VISITDY]

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">
  <id root="1558114262" extension="MDHT"/>
  <code code="86244881"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <value xsi:type="INT" value="1"/>
</observation>
```

Position of Subject

[Observation: templateId `2.16.840.1.113883.10.20.23.69`]

The template records the position of the subject during a measurement or examination.

1. **SHALL** contain exactly one [1..1] **`@classCode`** (CONF:1475)
2. **SHALL** contain exactly one [1..1] **`@moodCode`** (CONF:1476)
3. **SHALL** contain exactly one [1..1] **`code`** (CONF:1477)**`/@code="C71148"`** (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`) (CONF:1478)
   - A code value that indicates that the observation is that of body position.
4. **SHALL** contain exactly one [1..1] **`value`** with data type CD (CONF:1479), where the @code **SHALL** be selected from ValueSet *`Body Position`* `C71148` **STATIC** (CONF:1480)
   - A coded value that indicates the body position for the subject when the ECG test result was recorded. [SDTM: EGPOS], [SEND: EGPOS], [Study Data Tabulation Model: -POS]

Position of Subject 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="2.16.840.1.113883.10.20.23.69"/>
  <id root="1950779351" extension="MDHT"/>
  <code code="C71148" codeSystem="2.16.840.1.113883.3.26.1.1"
 codeSystemName="NCI Thesaurus"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <value xsi:type="CD" code="243793270"/>
</observation>
```

Pre-Specified Event

[Observation: templateId `2.16.840.1.113883.10.20.23.70`]

The template supports an observation that indicates whether a pre-specified event (usually this refers to an item listed on a CRF) 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`) (CONF:1507)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:1508)

3. **SHALL** contain exactly one [1..1] **`code`** (CONF:1509)**`/@code="PSEtbd"`** (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`) (CONF:1510)
   - The code value indicates that the observation refers to the occurrence of a pre-specified event.
4. **SHALL** contain exactly one [1..1] **`value`** with data type BL (CONF:1511)
   - Indicate whether or not the the indicated activity or event was prespecified on the CRF. [SDTM: CMPRESP, SUPRESP, AEPRESP, MHPRESP, CEPHRESP], [Study Data Tablulation Model: -PRESP]

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">
  <templateId root="2.16.840.1.113883.10.20.23.70"/>
  <id root="352336928" 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 `2.16.840.1.113883.10.20.23.71`]

The template supports the need 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`** (CONF:443)
2. **SHALL** contain exactly one [1..1] **`@moodCode`** (CONF:444)
3. **SHALL** contain [1..3] **`id`** (CONF:445)
   - 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.
4. **SHALL** contain exactly one [1..1] **`code`** (CONF:446)**`/@code="PDtbd"`** (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`) (CONF:447)
   - A fixed value that indicates the observation carries protocol deviation information.
5. **MAY** contain zero or one [0..1] **`effectiveTime`** (CONF:448)
   - Used to record the start and stop date/times of the protocol deviation. [SDTM: DVSTDTC, DVENDTC]
6. **SHALL** contain exactly one [1..1] **`value`** with data type CD (CONF:449)
   - 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`** (CONF:450)
   - Records the study epoch during which the information was collected.
   a. Contains **`@typeCode="`**`REFR`**`"`** *REFR*
   b. Contains exactly one [1..1] *Study Epoch* (templateId: `2.16.840.1.113883.10.20.23.83`)
8. **SHALL** contain exactly one [1..1] **`entryRelationship`** (CONF:451)
   - Identifies the SDTM or SEND domain the record is assigned to.
   a. Contains **`@typeCode="`**`REFR`**`"`** *REFR*
   b. Contains exactly one [1..1] *Domain Assignment* (templateId: `2.16.840.1.113883.10.20.23.30`)
9. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:452)

- The record of a category to be used in organizing information items.

a. Contains **@typeCode="COMP"** *COMP*
b. Contains exactly one [1..1] *Category* (templateId: 2.16.840.1.113883.10.20.23.20)

10. MAY contain zero or one [0..1] **entryRelationship** (CONF:453)

- The record of a sub-category to be used in organizing information items.

a. Contains **@typeCode="COMP"** *COMP*
b. Contains exactly one [1..1] *Sub- Category* (templateId: 2.16.840.1.113883.10.20.23.91)

11. MAY contain zero or more [0..*] **entryRelationship** (CONF:454)

- Establishes a relationship between this record and another record.

a. Contains **@typeCode="REFR"** *REFR*
b. Contains exactly one [1..1] *Related Record* (templateId: 2.16.840.1.113883.10.20.23.75)

12. MAY contain zero or more [0..*] **entryRelationship** (CONF:455)

- Allows the association of a supplemental value - outside of the content specfied for the domain - to the record.

a. Contains **@typeCode="COMP"** *COMP*
b. Contains exactly one [1..1] *Supplemental Value* (templateId: 2.16.840.1.113883.10.20.23.96)

13. MAY contain zero or more [0..*] **entryRelationship** (CONF:456)

- A place to insert comments related to a particular finding.

a. Contains **@typeCode="COMP"** *COMP*
b. Contains exactly one [1..1] *Comment* (templateId: 2.16.840.1.113883.10.20.23.23)

14. MAY contain zero or more [0..*] **entryRelationship** (CONF:457)

- Allows recording of additional findings related to the finding.

a. Contains **@typeCode="COMP"** *COMP*
b. Contains exactly one [1..1] *Finding About* (templateId: 2.16.840.1.113883.10.20.23.40)

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="2.16.840.1.113883.10.20.23.71"/>
  <id root="121757817" 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="CD" code="1090580304"/>
  <entryRelationship>
    <act>
      <templateId root="2.16.840.1.113883.10.20.23.83"/>
      <id root="1532979493" extension="MDHT"/>
      <code codeSystem="locally defined" codeSystemName="Study Epoch Type"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
    </act>
  </entryRelationship>
  <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.23"/>
```

```
     <id root="1140329986" extension="MDHT"/>
     <code code="C49569" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
     <value xsi:type="ED">Text Value</value>
     <participant/>
     <entryRelationship/>
   </observation>
 </entryRelationship>
 <entryRelationship>
   <observation>
     <templateId root="2.16.840.1.113883.10.20.23.30"/>
     <id root="1534472349" extension="MDHT"/>
     <code code="C66734" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
     <value xsi:type="CD" code="1819481442"/>
   </observation>
 </entryRelationship>
 <entryRelationship>
   <act classCode="ACT">
     <templateId root="2.16.840.1.113883.10.20.23.75"/>
     <id root="26819321" 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>
 <entryRelationship>
   <observation classCode="OBS" moodCode="EVN">
     <templateId root="2.16.840.1.113883.10.20.23.96"/>
     <id root="574369067" extension="MDHT"/>
     <code codeSystem="locally defined" codeSystemName="Supplemental Value
Type"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
     <participant/>
     <entryRelationship typeCode="COMP"/>
   </observation>
 </entryRelationship>
 <entryRelationship>
   <observation classCode="OBS" moodCode="EVN">
     <templateId root="2.16.840.1.113883.10.20.23.20"/>
     <id root="125323937" 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="CD" code="1746995802"/>
   </observation>
 </entryRelationship>
```

```
 <entryRelationship>
   <observation/>
 </entryRelationship>
 <entryRelationship>
   <observation>
     <id root="1211532332" extension="MDHT"/>
     <code code="1541118577"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
     <participant/>
     <entryRelationship typeCode="REFR"/>
     <entryRelationship>
       <act classCode="ACT">
         <templateId root="2.16.840.1.113883.10.20.23.42"/>
         <code code="C83204" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
       </act>
     </entryRelationship>
     <entryRelationship>
       <observation classCode="OBS">
         <templateId root="2.16.840.1.113883.10.20.23.56"/>
         <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus" displayName="Reason for non completion"/>
       </observation>
     </entryRelationship>
     <entryRelationship>
       <act/>
     </entryRelationship>
     <entryRelationship>
       <observation classCode="OBS" moodCode="EVN">
         <templateId root="2.16.840.1.113883.10.20.23.20"/>
         <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus"/>
       </observation>
     </entryRelationship>
     <entryRelationship>
       <observation/>
     </entryRelationship>
     <entryRelationship>
       <observation>
         <templateId root="2.16.840.1.113883.10.20.23.30"/>
         <code code="C66734" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
       </observation>
     </entryRelationship>
   </observation>
 </entryRelationship>
</observation>
```

Questionnaire Finding

[Observation: templateId `2.16.840.1.113883.10.20.23.72`]

The template is used to record questionnaire information. 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`) (CONF:641)

2. **SHALL** contain exactly one [1..1] **@moodCode="EVN"** *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) (CONF:642)
3. **SHALL** contain [1..2] **id** (CONF:643)
   - A value that is provided to ensure the uniqueness of the questionnaire finding. [SDTM: QSSEQ, QSSPID] A single identifier, the sequence number, is required.
4. **SHALL** contain exactly one [1..1] **code** (CONF:644), where the @code **SHALL** be selected from ValueSet *Question Set* locally defined **STATIC** (CONF:1537)
   - 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]
5. **MAY** contain zero or one [0..1] **statusCode** (CONF:646), where the @code **SHALL** be selected from (CodeSystem: 2.16.840.1.113883.5.14 ActStatus) (CONF:1538)
   - Used to indicate whether or not the specified questionnaire response was elicited. [SDTM: QSSTAT]
6. **MAY** contain zero or one [0..1] **effectiveTime** (CONF:647)
   - 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]
7. **SHOULD** contain [0..3] **value** (CONF:648)
   - The response to the questionnaire item indicated by the code value, as up to three observations. 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]
8. **SHALL** contain exactly one [1..1] **entryRelationship** (CONF:649)
   - Identifies the SDTM or SEND domain the record is assigned to.
   a. Contains **@typeCode="REFR"** *REFR*
   b. Contains exactly one [1..1] *Domain Assignment* (templateId: 2.16.840.1.113883.10.20.23.30)
9. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:650)
   - Allows capture of a group identifier for the response to the question.
   a. Contains exactly one [1..1] *Group Identifier* (templateId: 2.16.840.1.113883.10.20.23.42)
10. **SHOULD** contain zero or one [0..1] **entryRelationship** (CONF:651)
    - Used to capture information, most particularly the timing, regarding the collection of data for an event. This is relevant especially in cases where the timing and duration of an event are distinct from that of data collection.
    a. Contains **@typeCode="COMP"** *COMP*
    b. Contains exactly one [1..1] *Data Collection* (templateId: 2.16.840.1.113883.10.20.23.27)
11. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:652)
    - Provides a reason for not capturing information for the question.
    a. Contains **@typeCode="COMP"** *COMP*
    b. Contains exactly one [1..1] *Non Performance Reason* (templateId: 2.16.840.1.113883.10.20.23.56)
12. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:653)
    - Orients the timing of the question and response with respect to a study defined timepoint.
    a. Contains **@typeCode="REFR"** *REFR*
    b. Contains exactly one [1..1] *Timing Reference* (templateId: 2.16.840.1.113883.10.20.23.97)
13. **SHOULD** contain [0..2] **interpretationCode** (CONF:654), where the @code **SHALL** be selected from ValueSet *Subject Data Interpretation Type* CXXXXX **STATIC** (CONF:655)
    - Includes information used to better interpret the observation value (result). In particular, it is used to indicate baseline values, and derived results. [SDTM: QSBLFL, QSDRVFL]
14. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:656)
    - The record of a category to be used in organizing information items.

   a. Contains **@typeCode="COMP"** *COMP*
   b. Contains exactly one [1..1] *Category* (templateId: 2.16.840.1.113883.10.20.23.20)
15. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:657)
   - The record of a sub-category to be used in organizing information items.
   a. Contains **@typeCode="COMP"** *COMP*
   b. Contains exactly one [1..1] *Sub- Category* (templateId: 2.16.840.1.113883.10.20.23.91)
16. **MAY** contain zero or more [0..*] **entryRelationship** (CONF:658)
   - Establishes a relationship between this record and another record.
   a. Contains **@typeCode="REFR"** *REFR*
   b. Contains exactly one [1..1] *Related Record* (templateId: 2.16.840.1.113883.10.20.23.75)
17. **MAY** contain zero or more [0..*] **entryRelationship** (CONF:659)
   - Allows the association of a supplemental value - outside of the content specfied for the domain - to the record.
   a. Contains **@typeCode="COMP"** *COMP*
   b. Contains exactly one [1..1] *Supplemental Value* (templateId: 2.16.840.1.113883.10.20.23.96)
18. **MAY** contain zero or more [0..*] **entryRelationship** (CONF:660)
   - A place to insert comments related to a particular finding.
   a. Contains **@typeCode="COMP"** *COMP*
   b. Contains exactly one [1..1] *Comment* (templateId: 2.16.840.1.113883.10.20.23.23)
19. **MAY** contain zero or more [0..*] **entryRelationship** (CONF:661)
   - Allows recording of additional findings related to the finding.
   a. Contains **@typeCode="COMP"** *COMP*
   b. Contains exactly one [1..1] *Finding About* (templateId: 2.16.840.1.113883.10.20.23.40)

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">
  <id root="1914525636" extension="MDHT"/>
  <code code="519105517"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <interpretationCode code="574132056"/>
  <entryRelationship>
    <act classCode="ACT">
      <templateId root="2.16.840.1.113883.10.20.23.42"/>
      <id root="886519962" extension="MDHT"/>
      <code code="C83204" 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">
      <templateId root="2.16.840.1.113883.10.20.23.56"/>
      <id root="1315696754" extension="MDHT"/>
```

```
      <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus" displayName="Reason for non completion"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <value xsi:type="CD" code="1236194950"/>
      <interpretationCode code="481596728"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <act>
      <templateId root="2.16.840.1.113883.10.20.23.97"/>
      <id root="69397679" extension="MDHT"/>
      <code codeSystem="2.16.840.1.113883.3.26.1.1"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <entryRelationship typeCode="COMP"/>
    </act>
  </entryRelationship>
  <entryRelationship>
    <act>
      <id root="128050779" extension="MDHT"/>
      <code code="1638513094"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <entryRelationship>
        <observation/>
      </entryRelationship>
    </act>
  </entryRelationship>
  <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.23"/>
      <id root="2049511556" extension="MDHT"/>
      <code code="C49569" 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="ED">Text Value</value>
      <interpretationCode code="1776049891"/>
      <participant/>
      <entryRelationship/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation>
      <templateId root="2.16.840.1.113883.10.20.23.30"/>
      <id root="1549273884" extension="MDHT"/>
      <code code="C66734" 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="CD" code="1258082526"/>
      <interpretationCode code="89528156"/>
    </observation>
 </entryRelationship>
 <entryRelationship>
    <act classCode="ACT">
      <templateId root="2.16.840.1.113883.10.20.23.75"/>
      <id root="1274816588" 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>
    </act>
 </entryRelationship>
 <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.96"/>
      <id root="2105583694" extension="MDHT"/>
      <code codeSystem="locally defined" codeSystemName="Supplemental Value
Type"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <interpretationCode code="1311421530"/>
      <participant/>
      <entryRelationship typeCode="COMP"/>
    </observation>
 </entryRelationship>
 <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.20"/>
      <id root="322964006" 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="CD" code="1104617484"/>
      <interpretationCode code="1809984986"/>
    </observation>
 </entryRelationship>
 <entryRelationship>
    <observation/>
 </entryRelationship>
 <entryRelationship>
    <observation>
      <id root="109439888" extension="MDHT"/>
      <code code="325553408"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <interpretationCode code="1200662015"/>
      <participant/>
```

```
      <entryRelationship typeCode="REFR"/>
      <entryRelationship>
        <act classCode="ACT">
          <templateId root="2.16.840.1.113883.10.20.23.42"/>
          <code code="C83204" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
        </act>
      </entryRelationship>
      <entryRelationship>
        <observation classCode="OBS">
          <templateId root="2.16.840.1.113883.10.20.23.56"/>
          <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus" displayName="Reason for non completion"/>
        </observation>
      </entryRelationship>
      <entryRelationship>
        <act/>
      </entryRelationship>
      <entryRelationship>
        <observation classCode="OBS" moodCode="EVN">
          <templateId root="2.16.840.1.113883.10.20.23.20"/>
          <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus"/>
        </observation>
      </entryRelationship>
      <entryRelationship>
        <observation/>
      </entryRelationship>
      <entryRelationship>
        <observation>
          <templateId root="2.16.840.1.113883.10.20.23.30"/>
          <code code="C66734" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
        </observation>
      </entryRelationship>
    </observation>
  </entryRelationship>
</observation>
```

Reference Period

[Act: templateId `2.16.840.1.113883.10.20.23.73`]

The template records the reference start and stop time for the subject's particiaption in the trial. This is normally recorded as the period starting with the subjects first exposure to study treatment, and ending at the point that the subject was determined to have ended the trial. The information is captured as a template to allow resuse across several SDTM and SEND domains.

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="ACT"` *Act* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF:1372)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:1373)
3. **SHALL** contain exactly one [1..1] **`code`** (CONF:1374)**`/@code`**`="RPtbd"` (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`) (CONF:1375)
   - A code value that indicates that the act captures reference period information.
4. **SHALL** contain exactly one [1..1] **`effectiveTime`** (CONF:1376)
   - The reference start and stop time for the subject's particiaption the trial. This is normally recorded as the period starting with the subjects first exposure to study treatment, and ending at the point that the subject was determined to have ended the trial. [SDTM: RFSTDTC, FTENDTC], [SEND: RFSTDTC, FTENDTC]

Reference Period 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">
  <id root="1290077002" extension="MDHT"/>
  <code code="1898862905"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
</act>
```

Related Record

[Act: templateId `2.16.840.1.113883.10.20.23.75`]

The template is used to define the relationship between an information item and another item or group of items. This structure is captured as a template to facilitate its reuse as a generic mechanism for documenting relationships.

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="ACT"` *Act* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF:1352)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:1353)
3. **SHALL** contain exactly one [1..1] **`id`** (CONF:1354)
   - An identifier of the record that is being related. The root property of the II type is used to indicate the namespace for the identifier, in particular whether it is a group id or a sequence number. [SDTM: RELID], [SEND: RELID]
4. **SHALL** contain exactly one [1..1] **`code`** (CONF:1355)**`/@code`**`="RRtbd"` (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`) (CONF:1356)
   - An indication of the nature of the relationship, specifically of its cardinality. [SDTM: RELTYPE], [SEND: RELTYPE]

Related Record 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">
  <templateId root="2.16.840.1.113883.10.20.23.75"/>
  <id root="982376309" 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>
```

Result Category

[Observation: templateId `2.16.840.1.113883.10.20.23.76`]

The template supports a structure that is used to assign a category to the result of a finding.

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF:1487)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:1488)
3. **SHALL** contain exactly one [1..1] **`code`** (CONF:1489), where the @code **SHALL** be selected from ValueSet *`Subject Data Domain Result Category Type`* `CXXXXX` **STATIC** (CONF:1490)

- The code is used to capture the type of category. The set of categories is defined based on the individual domains for which result categories have been or will be defined.

4. **SHALL** contain exactly one [1..1] **`value`** with data type CD (CONF:1491)
   - Provide the result category value. [SDTM: MBRESCAT, MSRESCAT], [SEND: CLRESCAT, DDRESCAT, MIRESCAT], [Study Data Tabulation Model: -RESCAT]

Result Category 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="2.16.840.1.113883.10.20.23.76"/>
  <id root="529664549" extension="MDHT"/>
  <code codeSystem="2.16.840.1.113883.3.26.1.1"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <value xsi:type="CD" code="596731629"/>
</observation>
```

Serious Event

[Observation: templateId `2.16.840.1.113883.10.20.23.77`]

The template is used to record nformation whether or not this is a serious event. It is also possible to record different aspects of the event, e.g., whether it was life threatening, that bear on its seriousness. It is is captured as a template to facilitate its reuse as a characteristic of different types of event within clinical and non-clinical trial reporting. [SDTM:]. [Study Data Tabulation Model; -SER]

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF:1404)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:1405)
3. **SHALL** contain exactly one [1..1] **`code`** (CONF:1406)**`/@code`**`="SEtbd"` *Serious Event* (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`) (CONF:1407)
   - A code value that indicates that the observation captures event seriousness information.
4. **SHALL** contain exactly one [1..1] **`value`** with data type BL (CONF:1408)
   - A Boolean indicator that shows whether or not the event is considered to be serious. [SDTM: AESER]. [Study Data Tabulation Model: -SER]
5. **MAY** contain zero or more [0..*] **`entryRelationship`** (CONF:1409)
   a. Such entryRelationships **SHALL** contain exactly one [1..1] **`@typeCode`**`="COMP"` (CONF:1410)
   b. Such entryRelationships **SHALL** contain exactly one [1..1] **`observation`** (CONF:1411)
      a. This observation **SHALL** contain exactly one [1..1] **`@classCode`** (CONF:1412)
      b. This observation **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:1413)
      c. This observation **SHALL** contain exactly one [1..1] **`code`** (CONF:1414)**`/@code`**`="SETtbd"` (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`) (CONF:1415)

         The code value indicates the observation conveys information on the nature of the seriousness of the adverse event.
      d. This observation **SHALL** contain exactly one [1..1] **`value`** with data type CD (CONF:1416), where the @code **SHALL** be selected from ValueSet *`Serious Event Type`* `CXXXXX` **STATIC** (CONF:1417)

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]

Serious 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">
  <id root="2043247036" extension="MDHT"/>
  <code code="1019473227"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <value xsi:type="BL"/>
  <entryRelationship typeCode="COMP">
    <observation moodCode="EVN">
      <code code="SETtbd" codeSystem="2.16.840.1.113883.3.26.1.1"
 codeSystemName="NCI Thesaurus"/>
    </observation>
  </entryRelationship>
</observation>
```

Specimen Information

[Procedure: templateId `2.16.840.1.113883.10.20.23.78`]

The template is used to record specimen related information that is captured in several SDTM and SEND domains. The structure carrying specimen information 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`**`="PROC"` (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF:569)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:570)
3. **SHALL** contain exactly one [1..1] **`code`** (CONF:571)**`/@code`**`="SCLtbd"` (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`) (CONF:572)
   - A fixed code value to indicate the act is one of specimen collection.
4. **SHOULD** contain zero or one [0..1] **`effectiveTime`** (CONF:573)
   - The point in time at which the specimen on which the test is based was collected from the study subject. In some cases the data collected is a time interval with a start point and a stopping point. [SDTM: LBDTC, LBENDTC, MBDTC, PCDTC, PCENDTC], [SEND: 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.
5. **SHOULD** contain zero or one [0..1] **`specimen`** (CONF:574)

   Captures information regarding the entity - material item - playing the role of specimen.

   a. This specimen **SHALL** contain zero or one [0..1] **`@typeCode`**`="SPC"` (CONF:582)
   b. This specimen **SHOULD** contain zero or one [0..1] **`specimenRole`** (CONF:583)
      a. This specimenRole **SHALL** contain zero or one [0..1] **`@classCode`**`="SPEC"` (CONF:584)
      b. This specimenRole **MAY** contain zero or one [0..1] **`id`** (CONF:585)

         An identifier for the specimen on which the test result is based. [SDTM: LBREFID, MBREFID, MSREFID, PCREFID], [SEND: LBREFID, MAREFID, PCREFID, TFREFID]

      c. This specimenRole **SHOULD** contain zero or one [0..1] **`specimenEntity`** (CONF:586)

   a. This specimenEntity **SHALL** contain exactly one [1..1] **@classCode**="ENT" (CONF:587)
   b. This specimenEntity **SHALL** contain exactly one [1..1] **@determinerCode**="INSTANCE" (CONF:588)
   c. This specimenEntity **SHALL** contain exactly one [1..1] **code** (CONF:589), where the @code **SHALL** be selected from ValueSet *Specimen Type* C78734 **STATIC** (CONF:590)

      Used to indicate the specimen material type. [SDTM: LBSPEC, MBSPEC, PCSPEC, PPSPEC], [SEND: MASPEC, MISPEC, OMSPEC, PCSPEC, PPSPEC, TFSPEC], [Study Data Tabulation Model: SPEC]

6. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:575)

   Characterizes the relationship of the specimen to the antomic feature it was collected from, namely whether it represents a portion, the totality of the structure. The association is only used for non-clinical studies.

   a. This entryRelationship **SHALL** contain exactly one [1..1] **@typeCode**="COMP" (CONF:592)
   b. This entryRelationship **SHALL** contain exactly one [1..1] **observation** (CONF:591)

      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) (CONF:593)
      c. This observation **SHALL** contain exactly one [1..1] **code** (CONF:594)**/@code**="POTtbd" (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus) (CONF:595)

         A fixed value that indicates the nature of the observation. It provides information on the relationship of the specmen to the anatomic structure it was drawn from..
      d. This observation **SHALL** contain exactly one [1..1] **value** with data type CD (CONF:596), where the @code **SHALL** be selected from ValueSet *Portion or Totality Type* CXXXXX **STATIC** (CONF:597)

         Information on the portion or totality of a specimen used for testing. [SEND: LBPORTOT, MAPORTOT, OMPORTOT]

7. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:576)

   Records information regarding the usability of the specimen.

   a. This entryRelationship **SHALL** contain exactly one [1..1] **@typeCode**="COMP" (CONF:605)
   b. This entryRelationship **SHALL** contain exactly one [1..1] **observation** (CONF:606)

      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) (CONF:607)
      c. This observation **SHALL** contain exactly one [1..1] **code** (CONF:608)**/@code**="SUtbd" (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus) (CONF:609)

         The value indicates the nature of the observation. It provides information on the usability of the specimen.
      d. This observation **SHALL** contain exactly one [1..1] **value** with data type CD (CONF:610)

         Information on the usability of a specimen used for testing. [SEND: LBSPCUFL, MACUFL, MISPCUFL, OMSPCUFL]

8. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:577)

   Captures information on the condition of the specimen at the point of testing.

   a. This entryRelationship **SHALL** contain exactly one [1..1] **@typeCode**="COMP" (CONF:598)
   b. This entryRelationship **SHALL** contain exactly one [1..1] **observation** (CONF:599)

      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`) (CONF:600)

c. This observation **SHALL** contain exactly one [1..1] **`code`** (CONF:601)**`/@code`**`="C78733"` (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`) (CONF:602)

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 CD (CONF:603), where the @code **SHALL** be selected from ValueSet *`Specimen Condition Type`* `C78733` **STATIC** (CONF:604)

Information on the condition of a specimen used for testing. [SDTM: LBSPCCND, MBSPCCND, PCSPCCND], [SEND: LBSPCCND, MASPCCND, MISPCCND, PCSPCCND, TFSPCCND], [Study Data Tabulation Model: -SPCCND]

9. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:578)
   - Used to record the study day associated with an activity taking place during a single day.

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

   b. Contains exactly one [1..1] *Event Study Day* (templateId: `2.16.840.1.113883.10.20.23.37`)
10. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:579)
    - Orients the performance of the test on the specimen with respect to a study defined timepoint.

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

    b. Contains exactly one [1..1] *Timing Reference* (templateId: `2.16.840.1.113883.10.20.23.97`)
11. **SHOULD** contain zero or one [0..1] **`targetSiteCode`** (CONF:580), where the @code **SHALL** be selected from ValueSet *`Anatomical Location`* `C74456` **STATIC** (CONF:581)
    - Information about the anatomic region from which the specimen was extracted. The location may be described by providing a body site, it may also be described by indicating specimen directionality and/or laterality within the subject [SEND: LBANTREG, LBLAT, LBDIR, MAANTREG, MALAT, MADIR, MIANTREG, MILAT, MIDIR, MANTREG, OMLAT, OMDIR, TFANTREG, TFLAT, TFDIR]

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">
  <id root="1178499038" extension="MDHT"/>
  <code code="973548759"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <targetSiteCode code="1555422455"/>
  <specimen typeCode="SPC">
    <templateId root="null"/>
    <specimenRole classCode="SPEC"/>
  </specimen>
  <entryRelationship typeCode="COMP">
    <observation classCode="OBS" moodCode="EVN">
      <code code="POTtbd" codeSystem="2.16.840.1.113883.3.26.1.1"
 codeSystemName="NCI Thesaurus"/>
    </observation>
  </entryRelationship>
  <entryRelationship typeCode="COMP">
    <observation classCode="OBS" moodCode="EVN">
      <code code="SUtbd" codeSystem="2.16.840.1.113883.3.26.1.1"
 codeSystemName="NCI Thesaurus"/>
    </observation>
  </entryRelationship>
  <entryRelationship typeCode="COMP">
    <observation classCode="OBS" moodCode="EVN">
```

```
      <code code="C78733" codeSystem="2.16.840.1.113883.3.26.1.1"
 codeSystemName="NCI Thesaurus"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation>
      <id root="564827165" extension="MDHT"/>
      <code code="2112719933"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <targetSiteCode code="1817270709"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <act>
      <templateId root="2.16.840.1.113883.10.20.23.97"/>
      <id root="1314298858" extension="MDHT"/>
      <code codeSystem="2.16.840.1.113883.3.26.1.1"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <entryRelationship typeCode="COMP"/>
    </act>
  </entryRelationship>
</procedure>
```

Start Relative to Reference Period

[Observation: templateId `2.16.840.1.113883.10.20.23.79`]

The template captures the qualitative relationship between the start of an activity and the reference period defined within the demographics domain. This structure is captured as a template to facilitate its reuse as a significant relationship between an event and the conduct of the study.

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF:1377)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:1378)
3. **SHALL** contain exactly one [1..1] **`code`** (CONF:1379)**`/@code`**`="STRPtbd"` (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`) (CONF:1380)
   - The fixed code value indicates the observation captures information regarding the start of an activity relative to the previously defined reference period.
4. **SHALL** contain exactly one [1..1] **`value`** with data type CD (CONF:1381), where the @code **SHALL** be selected from ValueSet *`Reference Period Relationship`* `C66728` **STATIC** (CONF:1382)
   - Information on the timing of an activity's start with respect to the previously defined reference period.

Start Relative to Reference Period 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="2.16.840.1.113883.10.20.23.79"/>
  <id root="131001624" extension="MDHT"/>
  <code code="STRPtbd" codeSystem="2.16.840.1.113883.3.26.1.1"
 codeSystemName="NCI Thesaurus"/>
  <effectiveTime>
    <low value="2012"/>
```

```
    <high value="2012"/>
  </effectiveTime>
  <value xsi:type="CD" code="1333962032"/>
</observation>
```

Stop Relative to Reference Period

[Observation: templateId `2.16.840.1.113883.10.20.23.80`]

The template captures the qualitative relationship between the ending of an activity and the reference period defined within the demographics domain. This structure is captured as a template to facilitate its reuse as a significant relationship between an event and the conduct of the study.

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF:1383)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:1384)
3. **SHALL** contain exactly one [1..1] **`code`** (CONF:1385)**`/@code`**`="ENRPtbd"` (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`) (CONF:1386)
   - The fixed code value indicates the observation captures information regarding the ending of an activity relative to the previously defined reference period.
4. **SHALL** contain exactly one [1..1] **`value`** with data type CD (CONF:1387), where the @code **SHALL** be selected from ValueSet *`Reference Period Relationship`* `C66728` **STATIC** (CONF:1388)
   - Information on the timing of an activity's ending with respect to the previously defined reference period.

Stop Relative to Reference Period 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="2.16.840.1.113883.10.20.23.80"/>
  <id root="1134378485" extension="MDHT"/>
  <code codeSystem="2.16.840.1.113883.3.26.1.1"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <value xsi:type="CD" code="964730447"/>
</observation>
```

Study Arm

[Act: templateId `2.16.840.1.113883.10.20.23.81`]

The template contains information on the study arm to which the subject was assigned. 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. Study arm information may refer either to the planned arm for a subject or to the actual arm. Which is being referred to is determined by the mood code value.

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="ACT"` *Act* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF:203)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="INT"` (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:204)
   - The mood code value - EVN or INT - indicates whether the study arm information refers to the planned study arm, or to the actual one.
3. **SHALL** contain exactly one [1..1] **`code`** (CONF:205), where the @code **SHALL** be selected from ValueSet *`Study Arm Set`* `locally defined` **STATIC** (CONF:1520)

- The fixed value includes the code for the study arm. [SDTM: ARMCD]

4. **SHALL** contain zero or one [0..1] **`text`** (CONF:207)
   - Provide the description of the planned arm for the subject. [SDTM, ARM].
5. **SHOULD** contain zero or one [0..1] **`effectiveTime`** (CONF:208)
   - 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].

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">
  <templateId root="2.16.840.1.113883.10.20.23.81"/>
  <id root="1807094588" extension="MDHT"/>
  <code codeSystem="locally defined" codeSystemName="Study Arm Type"/>
  <text>Text Value</text>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
</act>
```

Study Day Period

[Observation: templateId `2.16.840.1.113883.10.20.23.82`]

The template 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 to 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 study reporting.

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF:822)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:823)
3. **SHALL** contain exactly one [1..1] **`code`** (CONF:824)**`/@code`**`="STPtbd"` (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`) (CONF:825)
   - 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 (CONF:826)
   - The applicable study day or study day interval value. In some domains, it is assumed that the relevant activity takes place at a single point in time, while in others a time interval is possible. Note, for those cases allowing a time interval, the start time point of activity may be expected, while the ending time point is left optional. [SDTM: SVSTDY, SVENDY, CMSTDY, CMENDY, EGDY, EXSTDY, EXENDY, SUSTDY, SUENDY, AESTDY, AEENDY, DSSTDY], [SEND: EXSTDY, EXENDY, BGSTDY, BGENDY, FWDY, FWENDY, LBDY, LBENDY, VSDY, VSENDY, EGDY, EGENDY]

Study Day Period 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">
  <id root="1220315757" extension="MDHT"/>
  <code code="308396561"/>
  <effectiveTime>
```

```
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <value xsi:type="IVL_INT" value="1"/>
</observation>
```

Study Epoch

[Act: templateId `2.16.840.1.113883.10.20.23.83`]

The template records the epoch for an element or other activity. 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.

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="ACT"` *Act* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF:345)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:346)
3. **SHALL** contain exactly one [1..1] **`code`** (CONF:347), where the @code **SHALL** be selected from ValueSet *`Study Epoch Set`* `locally defined` **STATIC** (CONF:1524)
   - A code value for the epoch.
4. **SHALL** contain zero or one [0..1] **`text`** (CONF:349)
   - The text name or title of the epoch.

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">
  <templateId root="2.16.840.1.113883.10.20.23.83"/>
  <id root="1502406" extension="MDHT"/>
  <code codeSystem="locally defined" codeSystemName="Study Epoch Type"/>
  <text>Text Value</text>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
</act>
```

Study Subject Event

[Observation: templateId `2.16.840.1.113883.10.20.23.85`]

The template captures planned protocol milestones such as randomization and study completion, and occurrences, conditions, or incidents independent of planned study evaluations occurring during the trial (e.g., adverse events) or prior to the trial (e.g., medical history). It is included to make allowances for the creation of event based domains that are not currently modeled within the SEND or SDTM implementation guides. If a custom domain is added, an appropriate domain designation must be assigned.

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`) (CONF:1270)
3. **SHALL** contain [1..3] **`id`** (CONF:1271)
   - An identifier for the event. "An internal or external identifier such as a serial number on an SAE reporting form". A sequence number is required.
4. **SHALL** contain exactly one [1..1] **`code`** (CONF:1272), where the @code **SHALL** be selected from ValueSet *`Subject Event Set`* `CXXXXX` **STATIC** (CONF:1565)

- The code value indicates the nature of the observation. The verbatim term is captured as original text. A modified term is representated as a translation. [Study Data Tabulation Model: -TERM, -MODIFY, -DCOD]. The code system to be used will be determined by the nature of the data transmitted with the domain.

5. **SHOULD** contain zero or one [0..1] **`effectiveTime`** (CONF:1273)
   - Used to capture the start date/time of an event, its end date/time, and/or its duration. Implementers should note that only two of the three properties of an interval are supported, since the value of the third would be redundant. It is reccomended that start and stop date/time be valued if known, and that duration be included only if the start or stop information is unavailable or incomplete. [SDTM: AESTDTC, AEENDTC, AEDUR]
6. **MAY** contain zero or one [0..1] **`statusCode`** (CONF:1274), where the @code **SHALL** be selected from (CodeSystem: `2.16.840.1.113883.5.14 ActStatus`) (CONF:1566)
   - Used to indicate whether the event did occur. Use statusCode "Completed" if the event in question occurred. [Study Data Tablulation Model: -OCCUR]
7. **SHALL** contain exactly one [1..1] **`value`** with data type CD (CONF:1275)
   - The event information. The event coded value is captured using the code property of the CD type, while the verbatim term - which is required - is captured using the original text property. The modified term, if provided, should be captured as a translation element within the CD type. [Study Data Tabulation Model: -TERM, -MODIFY, -DECOD]
8. **MAY** contain zero or one [0..1] **`targetSiteCode`** (CONF:1276), where the @code **SHALL** be selected from ValueSet *`Anatomical Location`* `C74456` **STATIC** (CONF:1277)
   - The anatomic location that is relevant for the event. [Study Data Tabulation Model: -LOC]
9. **SHALL** contain exactly one [1..1] **`entryRelationship`** (CONF:1278)
   - Identifies the SDTM or SEND domain the record is assigned to.
   a. Contains **`@typeCode="REFR"`** *REFR*
   b. Contains exactly one [1..1] *Domain Assignment* (templateId: `2.16.840.1.113883.10.20.23.30`)
10. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:1279)
    - Information on whether a predefined data item was collected, and the timing of collection.
    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Data Collection* (templateId: `2.16.840.1.113883.10.20.23.27`)
11. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:1280)
    - Information on the reason a scheduled activity was not carried out.
    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Non Performance Reason* (templateId: `2.16.840.1.113883.10.20.23.56`)
12. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:1281)
    - Indicates an identifer that is used to group associated events.
    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Group Identifier* (templateId: `2.16.840.1.113883.10.20.23.42`)
13. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:1282)
    - A record of the severity or intensity of the finding.
    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Event or Finding Severity* (templateId: `2.16.840.1.113883.10.20.23.34`)
14. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:1283)
    - 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: `2.16.840.1.113883.10.20.23.70`)
15. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:1284)

- Allows identification of the relevant body system or organ class for the event.

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

b. Contains exactly one [1..1] *Body System or Organ Class* (templateId: 2.16.840.1.113883.10.20.23.17)

16. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:1285)
    - A statement both of whether or not the event is considered serious, and a record of various types of seriousness, e.g, results in hospitalization, that may be recorded for the adverse event.

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

    b. Contains exactly one [1..1] *Serious Event* (templateId: 2.16.840.1.113883.10.20.23.77)
17. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:1286)
    - Information on whether adjustments were made to the study treatment as a result of the event.

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

    b. Contains exactly one [1..1] *Study Treatment Action Taken* (templateId: 2.16.840.1.113883.10.20.23.89)
18. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:1287)
    - Information on whether action other than adjustment to the study treatment was taken as a result of the event.

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

    b. Contains exactly one [1..1] *Other Treatment Action Taken* (templateId: 2.16.840.1.113883.10.20.23.63)
19. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:1288)
    - Captures the investigator's opinion of the causal relationship between the event and study treatment.

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

    b. Contains exactly one [1..1] *Study Treatment Causality* (templateId: 2.16.840.1.113883.10.20.23.90)
20. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:1289)
    - Captures the investigator's opinion of the causal relationship between the event and some event other than the study treatment.

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

    b. Contains exactly one [1..1] *Non-Study Treatment Relationship* (templateId: 2.16.840.1.113883.10.20.23.61)
21. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:1290)
    - Records the pattern of an event.

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

    b. Contains exactly one [1..1] *Event Pattern* (templateId: 2.16.840.1.113883.10.20.23.36)
22. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:1291)
    - Records the outcome of an event.

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

    b. Contains exactly one [1..1] *Event Outcome* (templateId: 2.16.840.1.113883.10.20.23.35)
23. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:1292)
    - A record of whether a treatment (aside from the study treatment) was provided as a result of the event.

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

    b. Contains exactly one [1..1] *Concomitant Treatment* (templateId: 2.16.840.1.113883.10.20.25.25)
24. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:1293)
    - A record of the toxicity of the event.

   a. Contains **@typeCode="COMP"** *COMP*
   b. Contains exactly one [1..1] *Toxicity* (templateId: 2.16.840.1.113883.10.20.23.98)
25. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:1294)
   - A reference to the study days corresponding to the time period of the observation.
   a. Contains **@typeCode="REFR"** *REFR*
   b. Contains exactly one [1..1] *Study Day Period* (templateId: 2.16.840.1.113883.10.20.23.82)
26. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:1295)
   - The record of a category to be used in organizing information items.
   a. Contains **@typeCode="COMP"** *COMP*
   b. Contains exactly one [1..1] *Category* (templateId: 2.16.840.1.113883.10.20.23.20)
27. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:1296)
   - The record of a sub-category to be used in organizing information items.
   a. Contains **@typeCode="COMP"** *COMP*
   b. Contains exactly one [1..1] *Sub- Category* (templateId: 2.16.840.1.113883.10.20.23.91)
28. **MAY** contain zero or more [0..*] **entryRelationship** (CONF:1297)
   - Establishes a relationship between this record and another record.
   a. Contains **@typeCode="REFR"** *REFR*
   b. Contains exactly one [1..1] *Related Record* (templateId: 2.16.840.1.113883.10.20.23.75)
29. **MAY** contain zero or more [0..*] **entryRelationship** (CONF:1298)
   - Allows the association of a supplemental value - outside of the content specfied for the domain - to the record.
   a. Contains **@typeCode="COMP"** *COMP*
   b. Contains exactly one [1..1] *Supplemental Value* (templateId: 2.16.840.1.113883.10.20.23.96)
30. **MAY** contain zero or more [0..*] **entryRelationship** (CONF:1299)
   - A place to insert comments related to a particular finding.
   a. Contains **@typeCode="COMP"** *COMP*
   b. Contains exactly one [1..1] *Comment* (templateId: 2.16.840.1.113883.10.20.23.23)
31. **MAY** contain zero or more [0..*] **entryRelationship** (CONF:1300)
   - Allows recording of additional findings related to the finding.
   a. Contains **@typeCode="COMP"** *COMP*
   b. Contains exactly one [1..1] *Finding About* (templateId: 2.16.840.1.113883.10.20.23.40)
32. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:1301)
   - Records the duration of an event in cases in which this cannot be derived from existing start and stop information.
   a. Contains **@typeCode="COMP"** *COMP*
   b. Contains exactly one [1..1] *Event Duration* (templateId: 2.16.840.1.113883.10.20.23.102)

Study Subject 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">
  <templateId root="2.16.840.1.113883.10.20.23.85"/>
  <id root="814738140" 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="CD" code="1728235506"/>
  <targetSiteCode code="910558438"/>
  <entryRelationship>
    <act classCode="ACT">
      <templateId root="2.16.840.1.113883.10.20.23.42"/>
      <id root="975123681" extension="MDHT"/>
      <code code="C83204" 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/>
  </entryRelationship>
  <entryRelationship>
    <observation>
      <id root="1077046225" extension="MDHT"/>
      <code code="1108509662"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <value xsi:type="IVL_INT" value="1"/>
      <targetSiteCode code="1083024565"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation/>
  </entryRelationship>
  <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.23"/>
      <id root="872660102" extension="MDHT"/>
      <code code="C49569" 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="ED">Text Value</value>
      <targetSiteCode code="66859723"/>
      <participant/>
      <entryRelationship/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation>
      <templateId root="2.16.840.1.113883.10.20.23.30"/>
      <id root="2023332558" extension="MDHT"/>
      <code code="C66734" 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="CD" code="1539686755"/>
     <targetSiteCode code="259818070"/>
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 <entryRelationship>
   <act classCode="ACT">
     <templateId root="2.16.840.1.113883.10.20.23.75"/>
     <id root="483723379" 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>
   </act>
 </entryRelationship>
 <entryRelationship>
   <observation classCode="OBS" moodCode="EVN">
     <templateId root="2.16.840.1.113883.10.20.23.96"/>
     <id root="1890266160" extension="MDHT"/>
     <code codeSystem="locally defined" codeSystemName="Supplemental Value
Type"/>
     <statusCode code="completed"/>
     <effectiveTime>
       <low value="2012"/>
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     </effectiveTime>
     <targetSiteCode code="1156770800"/>
     <participant/>
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     <id root="1861697680" extension="MDHT"/>
     <code code="958169512"/>
     <statusCode code="completed"/>
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     </effectiveTime>
     <entryRelationship>
       <observation/>
     </entryRelationship>
   </act>
 </entryRelationship>
 <entryRelationship>
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     <id root="1446890521" extension="MDHT"/>
     <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus" displayName="Reason for non completion"/>
     <statusCode code="completed"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
     <value xsi:type="CD" code="602683977"/>
     <targetSiteCode code="1749685703"/>
```

```
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation>
      <id root="1188283734" extension="MDHT"/>
      <code code="2101925698"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <value xsi:type="BL"/>
      <targetSiteCode code="387224121"/>
      <entryRelationship typeCode="COMP"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.89"/>
      <id root="1532231672" extension="MDHT"/>
      <code code="C66767" 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="CD" code="71102959"/>
      <targetSiteCode code="1093606524"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation classCode="OBS">
      <templateId root="2.16.840.1.113883.10.20.23.63"/>
      <id root="1340773552" extension="MDHT"/>
      <code code="OATtbd" 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="ED">Text Value</value>
      <targetSiteCode code="608723236"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation>
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      <code codeSystem="2.16.840.1.113883.3.26.1.1"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <value xsi:type="CD" code="483582851"/>
      <targetSiteCode code="1114721605"/>
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  </entryRelationship>
  <entryRelationship>
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  </entryRelationship>
  <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
```

```
     <templateId root="2.16.840.1.113883.10.20.23.36"/>
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     <code code="C83208" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus" displayName="Adverse Event Pattern"/>
     <statusCode code="completed"/>
     <effectiveTime>
       <low value="2012"/>
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     </effectiveTime>
     <value xsi:type="CD" code="292664215"/>
     <targetSiteCode code="2004946469"/>
   </observation>
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   <observation>
     <templateId root="2.16.840.1.113883.10.20.23.35"/>
     <id root="1452376827" extension="MDHT"/>
     <code codeSystem="2.16.840.1.113883.3.26.1.1" displayName="Adverse Event
Outcome"/>
     <statusCode code="completed"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
     <value xsi:type="CD" code="1710145033"/>
     <targetSiteCode code="530397727"/>
   </observation>
 </entryRelationship>
 <entryRelationship>
   <observation>
     <templateId root="2.16.840.1.113883.10.20.25.25"/>
     <id root="1691484083" extension="MDHT"/>
     <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus" displayName="Adverse Event Concommitant Treatment"/>
     <statusCode code="completed"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
     <value xsi:type="BL"/>
     <targetSiteCode code="381748490"/>
   </observation>
 </entryRelationship>
 <entryRelationship>
   <observation classCode="OBS" moodCode="EVN">
     <templateId root="2.16.840.1.113883.10.20.23.98"/>
     <id root="1612142157" extension="MDHT"/>
     <code code="TOtbd" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
     <statusCode code="completed"/>
     <effectiveTime>
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     </effectiveTime>
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   </observation>
 </entryRelationship>
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   <observation classCode="OBS" moodCode="EVN">
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     <id root="1683505683" extension="MDHT"/>
     <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus"/>
```

```
      <statusCode code="completed"/>
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        <high value="2012"/>
      </effectiveTime>
      <value xsi:type="CD" code="940630035"/>
      <targetSiteCode code="1828774918"/>
    </observation>
 </entryRelationship>
 <entryRelationship>
   <observation/>
 </entryRelationship>
 <entryRelationship>
   <observation>
     <id root="1675268774" extension="MDHT"/>
     <code code="334695569"/>
     <statusCode code="completed"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
     <targetSiteCode code="21611561"/>
     <participant/>
     <entryRelationship typeCode="REFR"/>
     <entryRelationship>
       <act classCode="ACT">
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         <code code="C83204" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
       </act>
     </entryRelationship>
     <entryRelationship>
       <observation classCode="OBS">
         <templateId root="2.16.840.1.113883.10.20.23.56"/>
         <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus" displayName="Reason for non completion"/>
       </observation>
     </entryRelationship>
     <entryRelationship>
       <act/>
     </entryRelationship>
     <entryRelationship>
       <observation classCode="OBS" moodCode="EVN">
         <templateId root="2.16.840.1.113883.10.20.23.20"/>
         <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus"/>
       </observation>
     </entryRelationship>
     <entryRelationship>
       <observation/>
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     <entryRelationship>
       <observation>
         <templateId root="2.16.840.1.113883.10.20.23.30"/>
         <code code="C66734" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
       </observation>
     </entryRelationship>
   </observation>
 </entryRelationship>
 <entryRelationship>
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     <templateId root="2.16.840.1.113883.10.20.23.102"/>
     <id root="1298772551" extension="MDHT"/>
```

```
      <code code="EDtbd" 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="PQR" code="1858190141"/>
      <targetSiteCode code="2105832839"/>
    </observation>
  </entryRelationship>
</observation>
```

Study Subject Finding

[Observation: templateId `2.16.840.1.113883.10.20.23.86`]

The template captures the observations resulting from planned evaluations to address specific tests or questions such as laboratory tests, ECG testing, and questions listed on questionnaires. It is included to make allowances for the creation of finding based domains that are not currently modeled within the SEND or SDTM implementation guides. If a custom domain is added, an appropriate domain designation must be assigned. There is no set of valid codes defined, since the applicable value set is the sum of the value sets for all possible finding domains.

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF:1302)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:1303)
3. **SHALL** contain [1..2] **`id`** (CONF:1304)
   - A value that is provided to ensure the uniqueness of the finding/result. A single identifier, the sequence number, is required.
4. **SHALL** contain exactly one [1..1] **`code`** (CONF:1305)
   - A coded value that identifies the finding. The verbatim text is placed within the original text property of the CD data type. The modified term is captured as a translation. [Study Data Tabulation Model: -TESTCD, TEST-, -MODIFY] The code system to be used will be determined by the nature of the data transmitted with the domain. There is no set of valid codes defined, since the applicable value set is the sum of the value sets for all possible event domains.
5. **MAY** contain zero or one [0..1] **`text`** (CONF:1306)
   - The reference property of the ED data type is used to capture the file name and path for an external file. [Study Data Tabulation Model: -XFN]
6. **MAY** contain zero or one [0..1] **`statusCode`** (CONF:1307), where the @code **SHALL** be selected from (CodeSystem: `2.16.840.1.113883.5.14 ActStatus`) (CONF:1567)
   - Used to indicate whether or not an exam has been performed. [Study Data Tabulation Model: -STAT]
7. **SHOULD** contain [0..3] **`value`** (CONF:1308)
   - The finding result, using both original units and a standard format or set of units. The information is captured as up to three observation values. [Study Data Tabulation Model: -ORRES, ORRESU, STRESC, STRESN, STRESU] The data type for .value is listed as "ANY" since it may be coded - type = CD - it may be a physical quantity - type = PQR - or it may be text - type = ED. (Note, the PQR form is used to allow the use units of measure expressed as coded values.) The value presented by the investigator or party entering the data is captured as the base value. If this value is transformed to use standard units, or a standard code set, the transformed or normalized values are included as translations.
8. **MAY** contain zero or one [0..1] **`methodCode`** (CONF:1309), where the @code **SHALL** be selected from ValueSet *`Method`* `C85492` **STATIC** (CONF:1310)
   - Indicates the method of the test or examination. [Study Data Tabulation Model: = METHOD]
9. **MAY** contain [0..3] **`interpretationCode`** (CONF:1311), where the @code **SHALL** be selected from ValueSet *`Subject Data Interpretation Consolidated Type`* `CXXXXX` **STATIC** (CONF:1568)

- Includes information used to better interpret the observation value (result). [Study Data Tabulation Model: -BLFL, -DRVFL, -NRIND] The interpretation type value set to be used will depend on the nature of the data being reported.

10. **SHALL** contain exactly one [1..1] **`entryRelationship`** (CONF:1312)
    - Identifies the SDTM or SEND domain the record is assigned to.
    a. Contains **`@typeCode="REFR"`** *REFR*
    b. Contains exactly one [1..1] *Domain Assignment* (templateId: `2.16.840.1.113883.10.20.23.30`)
11. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:1313)
    - Indicates an identifer that is used to group associated findings.
    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Group Identifier* (templateId: `2.16.840.1.113883.10.20.23.42`)
12. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:1314)
    - Information on the reason a scheduled activity was not carried out.
    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Non Performance Reason* (templateId: `2.16.840.1.113883.10.20.23.56`)
13. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:1315)
    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Specimen Information* (templateId: `2.16.840.1.113883.10.20.23.78`)
14. **MAY** contain zero or one [0..1] **`participant`** (CONF:1316)
    - Used to identify the organization that performed the test.
    a. Contains exactly one [1..1] *Study Test Organization* (templateId: `2.16.840.1.113883.10.20.23.88`)
15. **MAY** contain zero or more [0..*] **`targetSiteCode`** (CONF:1317), where the @code **SHALL** be selected from ValueSet *`Anatomical Location`* `C74456` **STATIC** (CONF:1318)
    - The body site that is relevant for a finding, e.g., that from which a specimen was collected. Note, in some cases the target site is further qualified by indication of the site's laterality and/or directionality within the subject. When this qualifying information is collected, multiple instances of target site code will be provided, and the fully defined site information is based on the values of all the codes taken together. [Study Data Tabulation Model: -LOC] Note, when laterality, and directionality are collected as part of fully describing the larget location, target site code - which can repeat - is used.
16. **MAY** contain zero or one [0..1] **`participant`** (CONF:1319)
    - Records the role of the person evaluating the finding.
    a. Contains exactly one [1..1] *Study Finding Evaluator* (templateId: `2.16.840.1.113883.10.20.23.84`)
17. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:1320)
    - A record of the toxicity associated with the finding.
    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Toxicity* (templateId: `2.16.840.1.113883.10.20.23.98`)
18. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:1321)
    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Position of Subject* (templateId: `2.16.840.1.113883.10.20.23.69`)
19. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:1322)
    - Allows identification of the relevant body system or organ class for the observation.
    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Body System or Organ Class* (templateId: `2.16.840.1.113883.10.20.23.17`)

20. **MAY** contain zero or one [0..1] **`reference Range`** (CONF:1323)
    - Information on the reference range defined for a test. It is used to support interpretation of the test result.
    a. Contains exactly one [1..1] *Reference Range* (templateId: `2.16.840.1.113883.10.20.23.74`)
21. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:1324)
    - Used to indicate the fasting status - time since consuption of food - for the study subject.
    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Fasting Status* (templateId: `2.16.840.1.113883.10.20.23.39`)
22. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:1325)
    - Carries information about the severity or intensity associated with the finding.
    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Event or Finding Severity* (templateId: `2.16.840.1.113883.10.20.23.34`)
23. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:1326)
    - Records the relationship of the finding to the death of the subject.
    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Death Relationship* (templateId: `2.16.840.1.113883.10.20.23.29`)
24. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:1327)
    - Records the lower limit of quantitation for an assay.
    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Assay Quantitation* (templateId: `2.16.840.1.113883.10.20.23.16`)
25. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:1328)
    - The record of a category to be used in organizing information items.
    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Category* (templateId: `2.16.840.1.113883.10.20.23.20`)
26. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:1329)
    - The record of a sub-category to be used in organizing information items.
    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Sub- Category* (templateId: `2.16.840.1.113883.10.20.23.91`)
27. **MAY** contain zero or more [0..*] **`entryRelationship`** (CONF:1330)
    - Establishes a relationship between this record and another record.
    a. Contains **`@typeCode="REFR"`** *REFR*
    b. Contains exactly one [1..1] *Related Record* (templateId: `2.16.840.1.113883.10.20.23.75`)
28. **MAY** contain zero or more [0..*] **`entryRelationship`** (CONF:1331)
    - Allows the association of a supplemental value - outside of the content specfied for the domain - to the record.
    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Supplemental Value* (templateId: `2.16.840.1.113883.10.20.23.96`)
29. **MAY** contain zero or more [0..*] **`entryRelationship`** (CONF:1332)
    - A place to insert comments related to a particular finding.
    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Comment* (templateId: `2.16.840.1.113883.10.20.23.23`)
30. **MAY** contain zero or more [0..*] **`entryRelationship`** (CONF:1333)
    - Allows recording of additional findings related to the finding.
    a. Contains **`@typeCode="COMP"`** *COMP*

b. Contains exactly one [1..1] *Finding About* (templateId: `2.16.840.1.113883.10.20.23.40`)

Study Subject 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">
  <templateId root="2.16.840.1.113883.10.20.23.86"/>
  <id root="1238269519" extension="MDHT"/>
  <code code="1650320239"/>
  <text>Text Value</text>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <interpretationCode codeSystemName="NCI Thesaurus"/>
  <methodCode codeSystemName="NCI Thesaurus"/>
  <targetSiteCode code="724079867"/>
  <participant>
    <participantRole classCode="ASSIGNED">
      <templateId root="null"/>
    </participantRole>
  </participant>
  <participant>
    <participantRole classCode="ASSIGNED">
      <templateId root="null"/>
      <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
 Thesaurus"/>
    </participantRole>
  </participant>
  <entryRelationship>
    <observation classCode="OBS">
      <templateId root="2.16.840.1.113883.10.20.23.56"/>
      <id root="497735442" extension="MDHT"/>
      <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
 Thesaurus" displayName="Reason for non completion"/>
      <text>Text Value</text>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <value xsi:type="CD" code="337902036"/>
      <interpretationCode code="1593292802"/>
      <methodCode code="1174382228"/>
      <targetSiteCode code="689986452"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <act classCode="ACT">
      <templateId root="2.16.840.1.113883.10.20.23.42"/>
      <id root="520064144" extension="MDHT"/>
      <code code="C83204" 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>
```

```
   <procedure>
     <id root="164530615" extension="MDHT"/>
     <code code="1892975242"/>
     <text>Text Value</text>
     <statusCode code="completed"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
     <methodCode code="582887898"/>
     <targetSiteCode code="842077200"/>
     <specimen typeCode="SPC">
       <templateId root="null"/>
     </specimen>
     <entryRelationship typeCode="COMP"/>
     <entryRelationship typeCode="COMP"/>
     <entryRelationship typeCode="COMP"/>
     <entryRelationship>
       <observation/>
     </entryRelationship>
     <entryRelationship>
       <act>
         <templateId root="2.16.840.1.113883.10.20.23.97"/>
         <code codeSystem="2.16.840.1.113883.3.26.1.1"/>
       </act>
     </entryRelationship>
   </procedure>
 </entryRelationship>
 <entryRelationship>
   <observation classCode="OBS" moodCode="EVN">
     <templateId root="2.16.840.1.113883.10.20.23.23"/>
     <id root="1861772972" extension="MDHT"/>
     <code code="C49569" 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="ED">Text Value</value>
     <interpretationCode code="1385143056"/>
     <methodCode code="1960491927"/>
     <targetSiteCode code="1898362549"/>
     <participant/>
     <entryRelationship/>
   </observation>
 </entryRelationship>
 <entryRelationship>
   <observation>
     <templateId root="2.16.840.1.113883.10.20.23.30"/>
     <id root="1358972740" extension="MDHT"/>
     <code code="C66734" 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="CD" code="2146750946"/>
     <interpretationCode code="559397230"/>
     <methodCode code="1198353745"/>
     <targetSiteCode code="390203105"/>
```

```
    </observation>
  </entryRelationship>
  <entryRelationship>
    <act classCode="ACT">
      <templateId root="2.16.840.1.113883.10.20.23.75"/>
      <id root="466026044" 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>
    </act>
  </entryRelationship>
  <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.96"/>
      <id root="2067525799" extension="MDHT"/>
      <code codeSystem="locally defined" codeSystemName="Supplemental Value
Type"/>
      <text>Text Value</text>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <interpretationCode code="52542733"/>
      <methodCode code="1108244698"/>
      <targetSiteCode code="29333960"/>
      <participant/>
      <entryRelationship typeCode="COMP"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.98"/>
      <id root="1511182142" extension="MDHT"/>
      <code code="TOtbd" 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="CD" code="1510876935"/>
      <interpretationCode code="211622462"/>
      <methodCode code="358844661"/>
      <targetSiteCode code="2102888489"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.20"/>
      <id root="27894922" 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="CD" code="424681191"/>
      <interpretationCode code="2052991513"/>
      <methodCode code="529367765"/>
      <targetSiteCode code="1705809593"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation/>
  </entryRelationship>
  <entryRelationship>
    <observation/>
  </entryRelationship>
  <entryRelationship>
    <observation/>
  </entryRelationship>
  <entryRelationship>
    <observation classCode="OBS">
      <templateId root="2.16.840.1.113883.10.20.23.39"/>
      <id root="1642970417" extension="MDHT"/>
      <code code="FStbd" 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"/>
      <interpretationCode code="1754395388"/>
      <methodCode code="437433091"/>
      <targetSiteCode code="232025385"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation/>
  </entryRelationship>
  <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.29"/>
      <id root="2124468174" extension="MDHT"/>
      <code code="C95087" 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="CD" code="1868723894"/>
      <interpretationCode code="675811279"/>
      <methodCode code="1235398653"/>
      <targetSiteCode code="1890198849"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation>
      <id root="2049965631" extension="MDHT"/>
      <code code="1384296222"/>
      <text>Text Value</text>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
```

```
      </effectiveTime>
      <value xsi:type="IVL_PQ"/>
      <interpretationCode code="209788358"/>
      <methodCode code="1118490022"/>
      <targetSiteCode code="964633478"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation>
      <id root="1247389524" extension="MDHT"/>
      <code code="785393394"/>
      <text>Text Value</text>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <interpretationCode code="1184723850"/>
      <methodCode code="1081121676"/>
      <targetSiteCode code="1238442228"/>
      <participant/>
      <entryRelationship typeCode="REFR"/>
      <entryRelationship>
        <act classCode="ACT">
          <templateId root="2.16.840.1.113883.10.20.23.42"/>
          <code code="C83204" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
        </act>
      </entryRelationship>
      <entryRelationship>
        <observation classCode="OBS">
          <templateId root="2.16.840.1.113883.10.20.23.56"/>
          <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus" displayName="Reason for non completion"/>
        </observation>
      </entryRelationship>
      <entryRelationship>
        <act/>
      </entryRelationship>
      <entryRelationship>
        <observation classCode="OBS" moodCode="EVN">
          <templateId root="2.16.840.1.113883.10.20.23.20"/>
          <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus"/>
        </observation>
      </entryRelationship>
      <entryRelationship>
        <observation/>
      </entryRelationship>
      <entryRelationship>
        <observation>
          <templateId root="2.16.840.1.113883.10.20.23.30"/>
          <code code="C66734" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
        </observation>
      </entryRelationship>
    </observation>
  </entryRelationship>
</observation>
```

Study Subject Intervention

[SubstanceAdministration: templateId `2.16.840.1.113883.10.20.23.87`]

The template captures investigational, therapeutic and other treatments that are administered to the subject (with some actual or expected physiological effect) either as specified by the study protocol (e.g., "exposure"), coincident with the study assessment period (e.g., "concomitant medications"), or other substances self-administered by the subject (such as alcohol, tobacco, or caffeine). It is included to make allowances for the creation of intervention based domains that are not currently modeled within SEND or SDTM. If a custom domain is added, an appropriate domain designation must be assigned.

1. **SHALL** contain exactly one [1..1] **`@classCode="SBADM"`** (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF:1231)
2. **SHALL** contain exactly one [1..1] **`@moodCode="EVN"`** *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:1232)
3. **SHALL** contain [1..2] **`id`** (CONF:1233)
   - A sponsor supplied reference number for the treatment. A sequence number is required.
4. **MAY** contain zero or one [0..1] **`statusCode`** (CONF:1234), where the @code **SHALL** be selected from (CodeSystem: `2.16.840.1.113883.5.14 ActStatus`) (CONF:1563)
   - Used to indicate whether the activity - use of a particular medication or treatment - did occur. Use statusCode "Completed" if the use occurred. [Study Data Tablulation Model: -OCCUR]
5. **MAY** contain zero or one [0..1] **`text`** (CONF:1235)
   - A text description of the intervention or dosing. [Study Data Tablulation Model: -DOSTXT]
6. **MAY** contain zero or one [0..1] **`effectiveTime`** (CONF:1236)
   - Information on when and how ofern the treatment was taken. Possible values for time interval include start date, stop date, and duration. Note, only two of these need to be valued, and only two values are supported. It is expected that start date and stop date will be provided if both are known with sufficient precision. However, if necessary and duration is included, then either stop date (the more usual case), start date, or both will be omitted. More specifically: The periodic time interval (PIVL_TS) type is used to record requency. This captures the number of hours, days, weeks, between two administrations of the substance. (For example, BID is recorded as 12 hours) [SDTM: CMSTDTC, CMENDTC, CMDUR, CMDOSFRQ] 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. [Study Data Tablulation Model: -DOSFRQ,]
7. **SHOULD** contain zero or one [0..1] **`doseQuantity`** (CONF:1237)
   - The amount of a treatment taken at a single administration. The physical quanitity data type is used. Dose units go into the units property of the datatype. [Study Data Tablulation Model: -DOSE, DOSU]
8. **MAY** contain zero or one [0..1] **`routeCode`** (CONF:1238), where the @code **SHALL** be selected from ValueSet *`Route of Administration`* `C66729` **STATIC** (CONF:1239)
   - The route by which the treatment is administered. [Study Data Tabulation Model: -ROUTE]
9. **MAY** contain zero or one [0..1] **`maxDoseQuantity`** (CONF:1240)
   - Information on the total daily dose of the medication or treatment. The structure also accommodates periods other than a day. Thefore the time period = 1 day needs to be indicated as the denominator of the ratio. Note, this attribute can also be used if multiple total dosage amounts need to be reported. [Study Data Tablulation Model: -DOSTOT]
10. **MAY** contain zero or one [0..1] **`approachSiteCode`** with data type CE (CONF:1241), where the @code **SHALL** be selected from ValueSet *`Anatomical Location`* `C74456` **STATIC** (CONF:1242)

- An indication of the location, e.g. left arm, where the substance was administered. [Study Data Tabulation Model: -LOC]

11. **SHALL** contain exactly one [1..1] **`entryRelationship`** (CONF:1243)
    - Identifies the SDTM or SEND domain the record is assigned to.
    a. Contains **`@typeCode="REFR"`** *REFR*
    b. Contains exactly one [1..1] *Domain Assignment* (templateId: `2.16.840.1.113883.10.20.23.30`)
12. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:1244)
    a. Contains **`@typeCode="REFR"`** *REFR*
    b. Contains exactly one [1..1] *Study Epoch* (templateId: `2.16.840.1.113883.10.20.23.83`)
13. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:1245)
    a. This entryRelationship **SHALL** contain exactly one [1..1] **`@typeCode`**`="COMP"` (CONF:1263)
    b. This entryRelationship **SHALL** contain exactly one [1..1] **`observation`** (CONF:1264)
        a. This observation **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF:1265)
        b. This observation **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:1268)
        c. This observation **SHALL** contain exactly one [1..1] **`code`** (CONF:1266)**`/@code`**`="ELOtbd"` (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`) (CONF:1267)

           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 (CONF:1269)

           A value that gives the order of an element within the trial arm. [SDTM: TAETORD]
14. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:1246)
    - Indicates an identifer that is used to group associated interventions.
    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Group Identifier* (templateId: `2.16.840.1.113883.10.20.23.42`)
15. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:1247)
    - Information on whether a predefined data item was collected, and the timing of collection.
    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Data Collection* (templateId: `2.16.840.1.113883.10.20.23.27`)
16. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:1248)
    - Information on the reason a scheduled activity was not carried out.
    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Non Performance Reason* (templateId: `2.16.840.1.113883.10.20.23.56`)
17. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:1249)
    - 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: `2.16.840.1.113883.10.20.23.70`)
18. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:1262)
    - Records the duration of an intervention in cases in which this cannot be derived from existing start and stop information.
    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Event Duration* (templateId: `2.16.840.1.113883.10.20.23.102`)
19. **SHOULD** contain zero or one [0..1] **`consumable`** (CONF:1564)
    - Identifies and carries information for the consumable item used in the course of the intervention.

   a. Contains exactly one [1..1] *Consumable Material* (templateId: `2.16.840.1.113883.10.20.23.26`)

20. MAY contain zero or one [0..1] **`entryRelationship`** (CONF:1251)

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

   b. Contains exactly one [1..1] *Dose Adjustment Reason* (templateId: `2.16.840.1.113883.10.20.23.31`)

21. MAY contain zero or one [0..1] **`entryRelationship`** (CONF:1252)

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

   b. Contains exactly one [1..1] *Indication* (templateId: `2.16.840.1.113883.10.20.23.48`)

22. MAY contain zero or one [0..1] **`entryRelationship`** (CONF:1253)

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

   b. Contains exactly one [1..1] *Intended Regimen* (templateId: `2.16.840.1.113883.10.20.23.49`)

23. MAY contain zero or one [0..1] **`entryRelationship`** (CONF:1254)

   - Creates an assoication between the timing of an activity and a defined reference time point.

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

   b. Contains exactly one [1..1] *Timing Reference* (templateId: `2.16.840.1.113883.10.20.23.97`)

24. MAY contain zero or one [0..1] **`entryRelationship`** (CONF:1255)

   - A reference to the study days corresponding to the time period of the observation.

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

   b. Contains exactly one [1..1] *Study Day Period* (templateId: `2.16.840.1.113883.10.20.23.82`)

25. MAY contain zero or one [0..1] **`entryRelationship`** (CONF:1256)

   - The record of a category to be used in organizing information items.

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

   b. Contains exactly one [1..1] *Category* (templateId: `2.16.840.1.113883.10.20.23.20`)

26. MAY contain zero or one [0..1] **`entryRelationship`** (CONF:1257)

   - The record of a sub-category to be used in organizing information items.

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

   b. Contains exactly one [1..1] *Sub- Category* (templateId: `2.16.840.1.113883.10.20.23.91`)

27. MAY contain zero or more [0..*] **`entryRelationship`** (CONF:1258)

   - Establishes a relationship between this record and another record.

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

   b. Contains exactly one [1..1] *Related Record* (templateId: `2.16.840.1.113883.10.20.23.75`)

28. MAY contain zero or more [0..*] **`entryRelationship`** (CONF:1259)

   - Allows the association of a supplemental value - outside of the content specfied for the domain - to the record.

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

   b. Contains exactly one [1..1] *Supplemental Value* (templateId: `2.16.840.1.113883.10.20.23.96`)

29. MAY contain zero or more [0..*] **`entryRelationship`** (CONF:1260)

   - A place to insert comments related to a particular finding.

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

   b. Contains exactly one [1..1] *Comment* (templateId: `2.16.840.1.113883.10.20.23.23`)

30. MAY contain zero or more [0..*] **`entryRelationship`** (CONF:1261)

   - Allows recording of additional findings related to the intervention.

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

   b. Contains exactly one [1..1] *Finding About* (templateId: `2.16.840.1.113883.10.20.23.40`)

Study Subject Intervention 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">
  <templateId root="2.16.840.1.113883.10.20.23.87"/>
  <id root="1841355551" extension="MDHT"/>
  <text>Text Value</text>
  <statusCode code="completed"/>
  <effectiveTime value="20121004"/>
  <routeCode code="1955007021"/>
  <approachSiteCode xsi:type="CE" code="1427366278"/>
  <doseQuantity/>
  <maxDoseQuantity/>
  <consumable>
    <manufacturedProduct classCode="MANU"/>
  </consumable>
  <entryRelationship typeCode="COMP">
    <observation classCode="OBS" moodCode="EVN">
      <code code="ELOtbd" codeSystem="2.16.840.1.113883.3.26.1.1"
 codeSystemName="NCI Thesaurus"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <act classCode="ACT">
      <templateId root="2.16.840.1.113883.10.20.23.42"/>
      <id root="1506670070" extension="MDHT"/>
      <code code="C83204" 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>
    <act>
      <templateId root="2.16.840.1.113883.10.20.23.83"/>
      <id root="1252262814" extension="MDHT"/>
      <code codeSystem="locally defined" codeSystemName="Study Epoch Type"/>
      <text>Text Value</text>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
    </act>
  </entryRelationship>
  <entryRelationship>
    <act>
      <templateId root="2.16.840.1.113883.10.20.23.97"/>
      <id root="143555291" extension="MDHT"/>
      <code codeSystem="2.16.840.1.113883.3.26.1.1"/>
      <text>Text Value</text>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <entryRelationship typeCode="COMP"/>
    </act>
  </entryRelationship>
```

```
 <entryRelationship>
   <observation>
     <id root="763608427" extension="MDHT"/>
     <code code="417940921"/>
     <text>Text Value</text>
     <statusCode code="completed"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
   </observation>
 </entryRelationship>
 <entryRelationship>
   <observation/>
 </entryRelationship>
 <entryRelationship>
   <act>
     <id root="1972716288" extension="MDHT"/>
     <code code="1638492813"/>
     <text>Text Value</text>
     <statusCode code="completed"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
     <entryRelationship>
       <observation/>
     </entryRelationship>
   </act>
 </entryRelationship>
 <entryRelationship>
   <observation classCode="OBS">
     <templateId root="2.16.840.1.113883.10.20.23.56"/>
     <id root="1446881916" extension="MDHT"/>
     <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus" displayName="Reason for non completion"/>
     <text>Text Value</text>
     <statusCode code="completed"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
   </observation>
 </entryRelationship>
 <entryRelationship>
   <observation classCode="OBS" moodCode="EVN">
     <templateId root="2.16.840.1.113883.10.20.23.23"/>
     <id root="528218552" extension="MDHT"/>
     <code code="C49569" 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>
     <participant/>
     <entryRelationship/>
   </observation>
 </entryRelationship>
 <entryRelationship>
   <observation>
     <templateId root="2.16.840.1.113883.10.20.23.30"/>
     <id root="489690122" extension="MDHT"/>
```

```
      <code code="C66734" 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">
      <templateId root="2.16.840.1.113883.10.20.23.75"/>
      <id root="1682612227" 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>
    </act>
  </entryRelationship>
  <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.96"/>
      <id root="348108247" extension="MDHT"/>
      <code codeSystem="locally defined" codeSystemName="Supplemental Value
Type"/>
      <text>Text Value</text>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <participant/>
      <entryRelationship typeCode="COMP"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.48"/>
      <id root="1794808478" extension="MDHT"/>
      <code code="C83085" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus" displayName="Concomitant Medication
Indication"/>
      <text>Text Value</text>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation>
      <templateId root="2.16.840.1.113883.10.20.23.49"/>
      <id root="1437924881" 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>
    </observation>
 </entryRelationship>
 <entryRelationship>
    <observation>
      <id root="61380037" extension="MDHT"/>
      <code code="1767936192"/>
      <text>Text Value</text>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
    </observation>
 </entryRelationship>
 <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.20"/>
      <id root="697509475" 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>
    </observation>
 </entryRelationship>
 <entryRelationship>
    <observation/>
 </entryRelationship>
 <entryRelationship>
    <observation>
      <id root="1473754013" extension="MDHT"/>
      <code code="460220865"/>
      <text>Text Value</text>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <participant/>
      <entryRelationship typeCode="REFR"/>
      <entryRelationship>
        <act classCode="ACT">
          <templateId root="2.16.840.1.113883.10.20.23.42"/>
          <code code="C83204" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
        </act>
      </entryRelationship>
      <entryRelationship>
        <observation classCode="OBS">
          <templateId root="2.16.840.1.113883.10.20.23.56"/>
          <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus" displayName="Reason for non completion"/>
        </observation>
      </entryRelationship>
      <entryRelationship>
        <act/>
      </entryRelationship>
      <entryRelationship>
```

```
        <observation classCode="OBS" moodCode="EVN">
          <templateId root="2.16.840.1.113883.10.20.23.20"/>
          <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
 Thesaurus"/>
        </observation>
      </entryRelationship>
      <entryRelationship>
        <observation/>
      </entryRelationship>
      <entryRelationship>
        <observation>
          <templateId root="2.16.840.1.113883.10.20.23.30"/>
          <code code="C66734" codeSystem="2.16.840.1.113883.3.26.1.1"
 codeSystemName="NCI Thesaurus"/>
        </observation>
      </entryRelationship>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.102"/>
      <id root="286074385" extension="MDHT"/>
      <code code="EDtbd" 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>
</substanceadministration>
```

Study Treatment Action Taken

[Observation: templateId `2.16.840.1.113883.10.20.23.89`]

A description of any changes made to the study treatment as a result of the event. This structure is captured as a template to facilitate its reuse as a characteristic of different types of data within clinical and non-clinical trial reporting.

1. **SHALL** contain exactly one [1..1] **`@classCode="OBS"`** *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF:1418)
2. **SHALL** contain exactly one [1..1] **`@moodCode="EVN"`** *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:1419)
3. **SHALL** contain exactly one [1..1] **`code`** (CONF:1420)**`/@code="C66767"`** (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`) (CONF:1421)
   - A fixed value that indicates the observation carries information about action taken with the study treatment.
4. **SHALL** contain exactly one [1..1] **`value`** with data type CD (CONF:1422), where the @code **SHALL** be selected from ValueSet *`Action Taken with Study Treatment`* `C66767` **STATIC** (CONF:1423)
   - Information on an action taken with the study treatment as a result of the event. [SDTM: AEACN]. [Study Data Tabulation Model: -ACN]

Study Treatment Action Taken 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="2.16.840.1.113883.10.20.23.89"/>
  <id root="251353644" extension="MDHT"/>
  <code code="C66767" codeSystem="2.16.840.1.113883.3.26.1.1"
 codeSystemName="NCI Thesaurus"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <value xsi:type="CD" code="1695224189"/>
</observation>
```

Study Treatment Causality

[Observation: templateId `2.16.840.1.113883.10.20.23.90`]

A record of the investigator's opinion with regard to the causal relationship between the event and the prior study treatment. This structure is captured as a template to facilitate its reuse as a characteristic of different types of event within clinical and non-clinical trial reporting.

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF:1429)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:1430)
3. **SHALL** contain exactly one [1..1] **`code`** (CONF:1431)**`/@code`**`="STCtbd"` (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`) (CONF:1432)
   - A value to indicate that the observation provides the investigator's opinon regarding the causality of the event to the treatment.
4. **SHALL** contain exactly one [1..1] **`value`** with data type CD (CONF:1433), where the @code **SHALL** be selected from ValueSet *`Study Treatment Causality`* `CXXXXX` **STATIC** (CONF:1434)
   - Information on the causal relationship between the event and the study treatment. [SDTM: AEREL]. [Study Data Tabulation Model: -REL]

Study Treatment Causality 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">
  <id root="319289710" extension="MDHT"/>
  <code codeSystem="2.16.840.1.113883.3.26.1.1"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <value xsi:type="CD" code="610905394"/>
</observation>
```

Sub- Category

[Observation: templateId `2.16.840.1.113883.10.20.23.91`]

The category is used to provide a classification for a reported item, whether it be an event, finding, or intervention. The classification provides a set of more detailed classifications based on the corresponding category definitions. This structure is captured as a template to facilitate its reuse as a characteristic of different types of data item within clinical and non-clinical trial reporting.

1. **SHALL** contain exactly one [1..1] **`@classCode`** (CONF:1470)
2. **SHALL** contain exactly one [1..1] **`@moodCode`** (CONF:1471)
3. **SHALL** contain exactly one [1..1] **`code`** (CONF:1472), where the @code **SHALL** be selected from ValueSet *`Subject Data Domain SubCategory Type`* `CXXXXX` **STATIC** (CONF:1473)

- The code is used to capture the type of category. The set of categories is defined based on the list of individual domains that have been defined.

4. **SHALL** contain exactly one [1..1] **`value`** with data type CD (CONF:1474)
   - Provide the category value - based on the category type - that corresponds to the reported data item. In addition, there will be different code sets used for each category type - as defined in observation.code. [SDTM: AESCAT, CESCAT, CMSCAT, DASCAT, EGSCAT, FASCAT, DSSCAT, EXSCAT, LBSCAT, IESCAT, MHSCAT, MBSCAT, MSSCAT, PCSCAT, PPSCAT, PESCAT, DVSCAT, QSSCAT, SCSCAT, SUSCAT, VSSCAT], [SEND: CLSCAT, EGSCAT, FASCAT, EXSCAT, LBSCAT, PCSCAT, PPSCAT, VSSCAT] [Study Data Tabulation Model: -SCAT]

Sub- Category 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="2.16.840.1.113883.10.20.23.91"/>
  <id root="1481870762" 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="CD" code="2135728288"/>
</observation>
```

Subject Characteristic

[Observation: templateId `2.16.840.1.113883.10.20.23.92`]

The template is ussed to capture subject related data that 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`) (CONF:662)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:663)
3. **SHALL** contain [1..2] **`id`** (CONF:664)
   - A value that is provided to ensure the uniqueness of the subject characteristic item. [SDTM: SCSEQ, SCSPID], [SEND: SCSEQ] A single identifier, the sequence number, is required.
4. **SHALL** contain exactly one [1..1] **`code`** (CONF:665), where the @code **SHALL** be selected from ValueSet *`Subject Characteristic Set`* `C74559` **STATIC** (CONF:666)
   - 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], [SEND: SCTESTCD, SCTEST]
5. **MAY** contain zero or one [0..1] **`statusCode`** (CONF:667)
   - Used to indicate whether or not the specified study characteristic response was elicited. [SDTM: SCSTAT]
6. **SHOULD** contain zero or one [0..1] **`value`** (CONF:668)
   - 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 if the original value was coded. If the original value was a physical quantity, then two observation values will be reported - one with the original units, and the other with standard units. [SDTM: SCORRES, SCORRESU, SCSTRESC, SCSTRESN, SCSTRESU], [SEND: SCORRES, SCORRESU, SCSTRESC, SCSTRESN, SCSTRESU]
7. **SHALL** contain exactly one [1..1] **`entryRelationship`** (CONF:669)
   - Identifies the SDTM or SEND domain the record is assigned to.
   a. Contains **`@typeCode="`**`REFR"` *REFR*

   b. Contains exactly one [1..1] *Domain Assignment* (templateId: `2.16.840.1.113883.10.20.23.30`)
8. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:670)
   - Allows capture of a group identifier for the subject characteristics.
   a. Contains **`@typeCode="COMP"`** *COMP*
   b. Contains exactly one [1..1] *Group Identifier* (templateId: `2.16.840.1.113883.10.20.23.42`)
9. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:671)
   - Used to capture information, most particularly the timing, regarding the collection of data for an event. This is relevant especially in cases where the timing and duration of an event are distinct from that of data collection.
   a. Contains **`@typeCode="REFR"`** *REFR*
   b. Contains exactly one [1..1] *Data Collection* (templateId: `2.16.840.1.113883.10.20.23.27`)
10. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:672)
   - Provides a reason for not capturing information for the subject characteristic.
   a. Contains **`@typeCode="COMP"`** *COMP*
   b. Contains exactly one [1..1] *Non Performance Reason* (templateId: `2.16.840.1.113883.10.20.23.56`)
11. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:673)
   - The record of a category to be used in organizing information items.
   a. Contains **`@typeCode="COMP"`** *COMP*
   b. Contains exactly one [1..1] *Category* (templateId: `2.16.840.1.113883.10.20.23.20`)
12. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:674)
   - The record of a sub-category to be used in organizing information items.
   a. Contains **`@typeCode="COMP"`** *COMP*
   b. Contains exactly one [1..1] *Sub- Category* (templateId: `2.16.840.1.113883.10.20.23.91`)
13. **MAY** contain zero or more [0..*] **`entryRelationship`** (CONF:675)
   - Establishes a relationship between this record and another record.
   a. Contains **`@typeCode="REFR"`** *REFR*
   b. Contains exactly one [1..1] *Related Record* (templateId: `2.16.840.1.113883.10.20.23.75`)
14. **MAY** contain zero or more [0..*] **`entryRelationship`** (CONF:676)
   - Allows the association of a supplemental value - outside of the content specfied for the domain - to the record.
   a. Contains **`@typeCode="REFR"`** *REFR*
   b. Contains exactly one [1..1] *Supplemental Value* (templateId: `2.16.840.1.113883.10.20.23.96`)
15. **MAY** contain zero or more [0..*] **`entryRelationship`** (CONF:677)
   - A place to insert comments related to a particular finding.
   a. Contains **`@typeCode="COMP"`** *COMP*
   b. Contains exactly one [1..1] *Comment* (templateId: `2.16.840.1.113883.10.20.23.23`)
16. **MAY** contain zero or more [0..*] **`entryRelationship`** (CONF:678)
   - Allows recording of additional findings related to the subject characteristic.
   a. Contains **`@typeCode="COMP"`** *COMP*
   b. Contains exactly one [1..1] *Finding About* (templateId: `2.16.840.1.113883.10.20.23.40`)

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">
  <templateId root="2.16.840.1.113883.10.20.23.92"/>
```

```
 <id root="2065640232" 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>
   <act>
     <id root="122428440" extension="MDHT"/>
     <code code="1156926954"/>
     <statusCode code="completed"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
     <entryRelationship>
       <observation/>
     </entryRelationship>
   </act>
 </entryRelationship>
 <entryRelationship>
   <observation classCode="OBS">
     <templateId root="2.16.840.1.113883.10.20.23.56"/>
     <id root="192566328" extension="MDHT"/>
     <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus" displayName="Reason for non completion"/>
     <statusCode code="completed"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
     <value xsi:type="CD" code="2075385662"/>
   </observation>
 </entryRelationship>
 <entryRelationship>
   <act classCode="ACT">
     <templateId root="2.16.840.1.113883.10.20.23.42"/>
     <id root="418775744" extension="MDHT"/>
     <code code="C83204" 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="2.16.840.1.113883.10.20.23.23"/>
     <id root="282915023" extension="MDHT"/>
     <code code="C49569" 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="ED">Text Value</value>
     <participant/>
     <entryRelationship/>
   </observation>
```

```
 </entryRelationship>
 <entryRelationship>
   <observation>
     <templateId root="2.16.840.1.113883.10.20.23.30"/>
     <id root="171247061" extension="MDHT"/>
     <code code="C66734" 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="CD" code="1828826902"/>
   </observation>
 </entryRelationship>
 <entryRelationship>
   <act classCode="ACT">
     <templateId root="2.16.840.1.113883.10.20.23.75"/>
     <id root="1428789183" 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>
   </act>
 </entryRelationship>
 <entryRelationship>
   <observation classCode="OBS" moodCode="EVN">
     <templateId root="2.16.840.1.113883.10.20.23.96"/>
     <id root="1454662771" extension="MDHT"/>
     <code codeSystem="locally defined" codeSystemName="Supplemental Value
Type"/>
     <statusCode code="completed"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
     <participant/>
     <entryRelationship typeCode="COMP"/>
   </observation>
 </entryRelationship>
 <entryRelationship>
   <observation classCode="OBS" moodCode="EVN">
     <templateId root="2.16.840.1.113883.10.20.23.20"/>
     <id root="373282677" 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="CD" code="1180287990"/>
   </observation>
 </entryRelationship>
 <entryRelationship>
   <observation/>
 </entryRelationship>
 <entryRelationship>
   <observation>
     <id root="2034130336" extension="MDHT"/>
     <code code="1642793792"/>
```

```
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <participant/>
      <entryRelationship typeCode="REFR"/>
      <entryRelationship>
        <act classCode="ACT">
          <templateId root="2.16.840.1.113883.10.20.23.42"/>
          <code code="C83204" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
        </act>
      </entryRelationship>
      <entryRelationship>
        <observation classCode="OBS">
          <templateId root="2.16.840.1.113883.10.20.23.56"/>
          <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus" displayName="Reason for non completion"/>
        </observation>
      </entryRelationship>
      <entryRelationship>
        <act/>
      </entryRelationship>
      <entryRelationship>
        <observation classCode="OBS" moodCode="EVN">
          <templateId root="2.16.840.1.113883.10.20.23.20"/>
          <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus"/>
        </observation>
      </entryRelationship>
      <entryRelationship>
        <observation/>
      </entryRelationship>
      <entryRelationship>
        <observation>
          <templateId root="2.16.840.1.113883.10.20.23.30"/>
          <code code="C66734" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
        </observation>
      </entryRelationship>
    </observation>
  </entryRelationship>
</observation>
```

Subject Element

[Act: templateId `2.16.840.1.113883.10.20.23.93`]

The Subject Element template consolidates information about the timing of each subject's 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`) (CONF:350)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:351)
3. **SHALL** contain exactly one [1..1] **`id`** (CONF:352)
   - The identifier is assigned to ensure uniqueness of the subject records within the domain. [SDTM: SESEQ]
4. **SHALL** contain exactly one [1..1] **`code`** (CONF:353), where the @code **SHALL** be selected from ValueSet *`Subject Element Set`* `locally defined` **STATIC** (CONF:1525)

- 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], [SEND: ETCD, ELEMENT, SEUPDES]

5. **SHALL** contain exactly one [1..1] **`effectiveTime`** (CONF:355)
   - 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], [SEND: SESDTC, SEENDTC]
6. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:356)
   - Records the study epoch during which the information was collected.

   a. Contains **`@typeCode="REFR"`** *REFR*
   b. Contains exactly one [1..1] *Study Epoch* (templateId: `2.16.840.1.113883.10.20.23.83`)
7. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:357)

   Used to record the order of the element within the study arm to which the subject is assigned. It is used for human clinical trials, but not for non-human trials.

   a. This entryRelationship **SHALL** contain exactly one [1..1] **`@typeCode`**`="REFR"` (CONF:338)
   b. This entryRelationship **SHALL** contain exactly one [1..1] **`observation`** (CONF:339)

      a. This observation **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF:340)
      b. This observation **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:343)
      c. This observation **SHALL** contain exactly one [1..1] **`code`** (CONF:341), where the @code **SHALL** be selected from (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`) (CONF:342)

      The code value indicates the observation captures an element's order within a trial arm.
      d. This observation **SHALL** contain exactly one [1..1] **`value`** with data type ED (CONF:344)

      A value that gives the order of an element within the trial arm. Since this order could be hierachically represented as a collection of integers separated by ".", e.g., "2.1", the text (ED) data type is assigned. [SDTM: TAETORD]
8. **SHALL** contain exactly one [1..1] **`entryRelationship`** (CONF:358)
   - Identifies the SDTM or SEND domain the record is assigned to.

   a. Contains **`@typeCode="REFR"`** *REFR*
   b. Contains exactly one [1..1] *Domain Assignment* (templateId: `2.16.840.1.113883.10.20.23.30`)
9. **MAY** contain zero or more [0..*] **`entryRelationship`** (CONF:359)
   - Establishes a relationship between this record and another record.

   a. Contains **`@typeCode="REFR"`** *REFR*
   b. Contains exactly one [1..1] *Related Record* (templateId: `2.16.840.1.113883.10.20.23.75`)
10. **MAY** contain zero or more [0..*] **`entryRelationship`** (CONF:360)
    - Allows the association of a supplemental value - outside of the content specfied for the domain - to the record.

    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Supplemental Value* (templateId: `2.16.840.1.113883.10.20.23.96`)
11. **MAY** contain zero or more [0..*] **`entryRelationship`** (CONF:361)
    - A place to insert comments related to a particular finding.

    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Comment* (templateId: `2.16.840.1.113883.10.20.23.23`)
12. **MAY** contain zero or more [0..*] **`entryRelationship`** (CONF:362)
    - Allows recording of additional findings related to the element.

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

b. Contains exactly one [1..1] *Finding About* (templateId: 2.16.840.1.113883.10.20.23.40)

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">
  <templateId root="2.16.840.1.113883.10.20.23.93"/>
  <id root="533997596" extension="MDHT"/>
  <code codeSystem="locally defined"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <entryRelationship typeCode="REFR">
    <observation classCode="OBS" moodCode="EVN">
      <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
 Thesaurus"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <act>
      <templateId root="2.16.840.1.113883.10.20.23.83"/>
      <id root="1204401098" extension="MDHT"/>
      <code codeSystem="locally defined" codeSystemName="Study Epoch Type"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
    </act>
  </entryRelationship>
  <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.23"/>
      <id root="2122545685" extension="MDHT"/>
      <code code="C49569" codeSystem="2.16.840.1.113883.3.26.1.1"
 codeSystemName="NCI Thesaurus"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <participant/>
      <entryRelationship/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation>
      <templateId root="2.16.840.1.113883.10.20.23.30"/>
      <id root="676341905" extension="MDHT"/>
      <code code="C66734" codeSystem="2.16.840.1.113883.3.26.1.1"
 codeSystemName="NCI Thesaurus"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <act classCode="ACT">
      <templateId root="2.16.840.1.113883.10.20.23.75"/>
      <id root="1584359924" 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>
 <entryRelationship>
   <observation classCode="OBS" moodCode="EVN">
     <templateId root="2.16.840.1.113883.10.20.23.96"/>
     <id root="903162666" extension="MDHT"/>
     <code codeSystem="locally defined" codeSystemName="Supplemental Value
Type"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
     <participant/>
     <entryRelationship typeCode="COMP"/>
   </observation>
 </entryRelationship>
 <entryRelationship>
   <observation>
     <id root="958245472" extension="MDHT"/>
     <code code="677616661"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
     <participant/>
     <entryRelationship typeCode="REFR"/>
     <entryRelationship>
       <act classCode="ACT">
         <templateId root="2.16.840.1.113883.10.20.23.42"/>
         <code code="C83204" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
       </act>
     </entryRelationship>
     <entryRelationship>
       <observation classCode="OBS">
         <templateId root="2.16.840.1.113883.10.20.23.56"/>
         <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus" displayName="Reason for non completion"/>
       </observation>
     </entryRelationship>
     <entryRelationship>
       <act/>
     </entryRelationship>
     <entryRelationship>
       <observation classCode="OBS" moodCode="EVN">
         <templateId root="2.16.840.1.113883.10.20.23.20"/>
         <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus"/>
       </observation>
     </entryRelationship>
     <entryRelationship>
       <observation/>
     </entryRelationship>
     <entryRelationship>
       <observation>
         <templateId root="2.16.840.1.113883.10.20.23.30"/>
         <code code="C66734" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
```

```
        </observation>
      </entryRelationship>
    </observation>
  </entryRelationship>
</act>
```

Substance Use

[SubstanceAdministration: templateId `2.16.840.1.113883.10.20.23.95`]

The template 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.

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="SBADM"` (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF:370)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:371)
3. **SHALL** contain [1..2] **`id`** (CONF:372)
   - 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.
4. **MAY** contain zero or one [0..1] **`statusCode`** (CONF:373), where the @code **SHALL** be selected from (CodeSystem: `2.16.840.1.113883.5.14 ActStatus`) (CONF:1526)
   - Used to indicate whether the activity - use of a particular substance - did occur. Use statusCode "Completed" if the use occurred. [SDTM: SUOCCUR]
5. **MAY** contain zero or one [0..1] **`text`** (CONF:374)
   - Used to capture textual information about the use of the substance. [SDTM: SUDOSTXT]
6. **MAY** contain zero or one [0..1] **`effectiveTime`** (CONF:375)
   - Information on when and how ofter the substance was taken. Possible values for time interval include start date, stop date, and duration. Note, only two of these need to be valued, and only two values are supported. It is expected that start date and stop date will be provided if both are known with sufficient precision. However, if necessary and duration is included, then either stop date (the more usual case), start date, or both will be omitted. More specifically: The periodic time interval (PIVL_TS) type is used to record requency. This captures the number of hours, days, weeks, between two administrations of the substance. (For example, BID is recorded as 12 hours) [SDTM: CMSTDTC, CMENDTC, CMDUR, CMDOSFRQ] 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: SUSTDTC, SUENDTC, SUDUR, SUDOSFRQ]
7. **MAY** contain zero or one [0..1] **`doseQuantity`** (CONF:376)
   - Information on the dosage of the substance that was consumed. [SDTM: SUDOSE, SUDOSU]
8. **MAY** contain zero or one [0..1] **`maxDoseQuantity`** (CONF:377)
   - Information on the total daily dose of the substance. The structure also accommodates periods other than a day. Thefore the time period = 1 day needs to be indicated as the denominator of the ratio. [SDTM: SUDOSTOT] Note, this attribute can also be used if multiple total dosage amounts need to be reported.
9. **MAY** contain zero or one [0..1] **`routeCode`** (CONF:378), where the @code **SHALL** be selected from ValueSet *`Route of Administration`* `C66729` **STATIC** (CONF:379)
   - The route by which the substance is administered, applied or ingested. [SDTM: SUROUTE]
10. **SHALL** contain exactly one [1..1] **`entryRelationship`** (CONF:380)

- Identifies the SDTM or SEND domain the record is assigned to.

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

b. Contains exactly one [1..1] *Domain Assignment* (templateId: 2.16.840.1.113883.10.20.23.30)

11. MAY contain zero or one [0..1] **entryRelationship** (CONF:381)

- Used to capture information, most particularly the timing, regarding the collection of data for an event. This is relevant especially in cases where the timing and duration of an event are distinct from that of data collection.

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

b. Contains exactly one [1..1] *Data Collection* (templateId: 2.16.840.1.113883.10.20.23.27)

12. MAY contain zero or one [0..1] **entryRelationship** (CONF:382)

- Used to indicate whether collection of data regarding an event of this type has been pre-specified, usually on a reporting form.

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

b. Contains exactly one [1..1] *Pre-Specified Event* (templateId: 2.16.840.1.113883.10.20.23.70)

13. MAY contain zero or one [0..1] **entryRelationship** (CONF:383)

- Provides a reason for not capturing information for the substance use.

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

b. Contains exactly one [1..1] *Non Performance Reason* (templateId: 2.16.840.1.113883.10.20.23.56)

14. SHALL contain exactly one [1..1] **consumable** (CONF:384)

- Identifies and carries information for the consumable item that is being referred to.

a. Contains exactly one [1..1] *Consumable Material* (templateId: 2.16.840.1.113883.10.20.23.26)

15. MAY contain zero or one [0..1] **entryRelationship** (CONF:385)

- Used to record the study days associated with the beginning and end points of an activity that may extend over a period of time.

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

b. Contains exactly one [1..1] *Study Day Period* (templateId: 2.16.840.1.113883.10.20.23.82)

16. MAY contain zero or one [0..1] **entryRelationship** (CONF:386)

- Allows positioning of the start of the event with relationship to a defined reference time period.

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

b. Contains exactly one [1..1] *Start Relative to Reference Period* (templateId: 2.16.840.1.113883.10.20.23.79)

17. MAY contain zero or one [0..1] **entryRelationship** (CONF:387)

- Allows positioning of the termination of the event with relationship to a defined reference time period.

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

b. Contains exactly one [1..1] *Stop Relative to Reference Period* (templateId: 2.16.840.1.113883.10.20.23.80)

18. MAY contain zero or one [0..1] **entryRelationship** (CONF:388)

- The record of a category to be used in organizing information items.

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

b. Contains exactly one [1..1] *Category* (templateId: 2.16.840.1.113883.10.20.23.20)

19. MAY contain zero or one [0..1] **entryRelationship** (CONF:389)

- The record of a sub-category to be used in organizing information items.

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

b. Contains exactly one [1..1] *Sub- Category* (templateId: 2.16.840.1.113883.10.20.23.91)

20. **MAY** contain zero or more [0..*] **entryRelationship** (CONF:390)
    - Establishes a relationship between this record and another record.
    a. Contains **@typeCode="**REFR" *REFR*
    b. Contains exactly one [1..1] *Related Record* (templateId: 2.16.840.1.113883.10.20.23.75)
21. **MAY** contain zero or more [0..*] **entryRelationship** (CONF:391)
    - Allows the association of a supplemental value - outside of the content specfied for the domain - to the record.
    a. Contains **@typeCode="**COMP" *COMP*
    b. Contains exactly one [1..1] *Supplemental Value* (templateId: 2.16.840.1.113883.10.20.23.96)
22. **MAY** contain zero or more [0..*] **entryRelationship** (CONF:392)
    - A place to insert comments related to a particular finding.
    a. Contains **@typeCode="**COMP" *COMP*
    b. Contains exactly one [1..1] *Comment* (templateId: 2.16.840.1.113883.10.20.23.23)
23. **MAY** contain zero or more [0..*] **entryRelationship** (CONF:393)
    - Allows recording of additional findings related to the event.
    a. Contains **@typeCode="**COMP" *COMP*
    b. Contains exactly one [1..1] *Finding About* (templateId: 2.16.840.1.113883.10.20.23.40)
24. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:394)
    - Records the duration of an event in cases in which this cannot be derived from existing start and stop information.
    a. Contains **@typeCode="**COMP" *COMP*
    b. Contains exactly one [1..1] *Event Duration* (templateId: 2.16.840.1.113883.10.20.23.102)
25. **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. (CONF:369)

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">
  <id root="1507385222" extension="MDHT"/>
  <text>Text Value</text>
  <statusCode code="completed"/>
  <effectiveTime value="20121004"/>
  <routeCode code="587231692"/>
  <doseQuantity/>
  <maxDoseQuantity/>
  <consumable>
    <manufacturedProduct classCode="MANU"/>
  </consumable>
  <entryRelationship>
    <observation/>
  </entryRelationship>
  <entryRelationship>
    <observation classCode="OBS">
      <templateId root="2.16.840.1.113883.10.20.23.56"/>
      <id root="2048098416" extension="MDHT"/>
      <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
 Thesaurus" displayName="Reason for non completion"/>
```

```
      <text>Text Value</text>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <act>
      <id root="1084669437" extension="MDHT"/>
      <code code="1758676524"/>
      <text>Text Value</text>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <entryRelationship>
        <observation/>
      </entryRelationship>
    </act>
  </entryRelationship>
  <entryRelationship>
    <observation>
      <id root="326226491" extension="MDHT"/>
      <code code="2038571734"/>
      <text>Text Value</text>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.23"/>
      <id root="871297188" extension="MDHT"/>
      <code code="C49569" 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>
      <participant/>
      <entryRelationship/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation>
      <templateId root="2.16.840.1.113883.10.20.23.30"/>
      <id root="218478865" extension="MDHT"/>
      <code code="C66734" 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">
     <templateId root="2.16.840.1.113883.10.20.23.75"/>
     <id root="1868125752" 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>
   </act>
 </entryRelationship>
 <entryRelationship>
   <observation classCode="OBS" moodCode="EVN">
     <templateId root="2.16.840.1.113883.10.20.23.96"/>
     <id root="419410055" extension="MDHT"/>
     <code codeSystem="locally defined" codeSystemName="Supplemental Value
Type"/>
     <text>Text Value</text>
     <statusCode code="completed"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
     <participant/>
     <entryRelationship typeCode="COMP"/>
   </observation>
 </entryRelationship>
 <entryRelationship>
   <observation/>
 </entryRelationship>
 <entryRelationship>
   <observation/>
 </entryRelationship>
 <entryRelationship>
   <observation classCode="OBS" moodCode="EVN">
     <templateId root="2.16.840.1.113883.10.20.23.20"/>
     <id root="1381771488" 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>
   </observation>
 </entryRelationship>
 <entryRelationship>
   <observation/>
 </entryRelationship>
 <entryRelationship>
   <observation>
     <id root="1094875930" extension="MDHT"/>
     <code code="46131773"/>
     <text>Text Value</text>
     <statusCode code="completed"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
```

```
      <participant/>
      <entryRelationship typeCode="REFR"/>
      <entryRelationship>
        <act classCode="ACT">
          <templateId root="2.16.840.1.113883.10.20.23.42"/>
          <code code="C83204" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
        </act>
      </entryRelationship>
      <entryRelationship>
        <observation classCode="OBS">
          <templateId root="2.16.840.1.113883.10.20.23.56"/>
          <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus" displayName="Reason for non completion"/>
        </observation>
      </entryRelationship>
      <entryRelationship>
        <act/>
      </entryRelationship>
      <entryRelationship>
        <observation classCode="OBS" moodCode="EVN">
          <templateId root="2.16.840.1.113883.10.20.23.20"/>
          <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus"/>
        </observation>
      </entryRelationship>
      <entryRelationship>
        <observation/>
      </entryRelationship>
      <entryRelationship>
        <observation>
          <templateId root="2.16.840.1.113883.10.20.23.30"/>
          <code code="C66734" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
        </observation>
      </entryRelationship>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.102"/>
      <id root="1717464489" extension="MDHT"/>
      <code code="EDtbd" 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>
</substanceadministration>
```

Supplemental Value

[Observation: templateId `2.16.840.1.113883.10.20.23.96`]

The template will allow the addition of supplemental information to a particular data item. This general purpose structure makes it possible to capture unexpected (non-standard) data items, and to relate them to the appropriate record within one of the previously defined domains. It is is captured as a template to facilitate its reuse as a generic capability.

1. **SHALL** contain exactly one [1..1] **`@classCode="OBS"`** *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF:1357)
2. **SHALL** contain exactly one [1..1] **`@moodCode="EVN"`** *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:1358)
3. **SHALL** contain exactly one [1..1] **`code`** (CONF:1359), where the @code **SHALL** be selected from ValueSet *`Supplemental Value Set`* `locally defined` **STATIC** (CONF:1569)
   - A code that indicates the type of information being provided. [SDTM: QNAM, QLABEL], [SEND: QNAM, QLABEL]
4. **SHALL** contain exactly one [1..1] **`value`** (CONF:1361)
   - The data value that is being provided. Note, since data type of the data is not predefined, it must be indicated in the instance. Similarly, if the data is coded, the list of valid codes must be defined. [SDTM: QVAL], [SEND: QVAL]
5. **SHALL** contain exactly one [1..1] **`entryRelationship`** (CONF:1362)

   Information on the source of the supplemental information.

   a. This entryRelationship **SHALL** contain exactly one [1..1] **`@typeCode="COMP"`** (CONF:1364)

   b. This entryRelationship **SHALL** contain zero or one [0..1] **`observation`** (CONF:1365)

   a. This observation **SHALL** contain exactly one [1..1] **`@classCode="OBS"`** *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF:1366)

   b. This observation **SHALL** contain exactly one [1..1] **`@moodCode="EVN"`** *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:1369)

   c. This observation **SHALL** contain exactly one [1..1] **`code`** (CONF:1367)**`/@code="DOtbd"`** (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`) (CONF:1368)

   A fixed code value that indicates the observation conveys information about the origin of the data.

   d. This observation **SHALL** contain exactly one [1..1] **`value`** with data type CD (CONF:1370), where the @code **SHALL** be selected from ValueSet *`Data Origin Type`* `CXXXXX` **STATIC** (CONF:1371)

   An indication of the origin of the data. Example values include CRF, ASSIGNED, Derived. [SDTM: QORIG], [SEND: QORIG]
6. **MAY** contain zero or one [0..1] **`participant`** (CONF:1363)
   - Identification of the party responsible for (author of) the supplemental information.

   a. Contains exactly one [1..1] *Study Finding Evaluator* (templateId: `2.16.840.1.113883.10.20.23.84`)

Supplemental Value 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="2.16.840.1.113883.10.20.23.96"/>
  <id root="169991793" extension="MDHT"/>
  <code codeSystem="locally defined" codeSystemName="Supplemental Value Type"/
>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <participant>
    <participantRole classCode="ASSIGNED">
      <templateId root="null"/>
      <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
 Thesaurus"/>
    </participantRole>
  </participant>
  <entryRelationship typeCode="COMP">
    <observation classCode="OBS" moodCode="EVN">
```

```
      <code code="DOtbd" codeSystem="2.16.840.1.113883.3.26.1.1"
 codeSystemName="NCI Thesaurus"/>
    </observation>
  </entryRelationship>
</observation>
```

Timing Reference

[Act: templateId `2.16.840.1.113883.10.20.23.97`]

The timing reference template 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`) (CONF:225)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:226)
3. **MAY** contain zero or one [0..1] **`id`** (CONF:227)
   - A numeric identifier for the planned time point in order to facilitate sorting of the data content. [SDTM:LNPTNUM, VSTPTNUM], [SEND: CLTPTNUM, LBTPTNUM, EGTPTNUM]
4. **SHALL** contain exactly one [1..1] **`code`** (CONF:228)**`/@code`**`="TRtbd"` (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`) (CONF:229)
   - A fixed code value to indicate the observation contains timing refence information.
5. **MAY** contain zero or one [0..1] **`effectiveTime`** (CONF:230)
   - The planned elapsed time - a duration - at which the event or measurement is to take place with reference to the anchoring time point. The width property of the IVL_TS data type is used. [SDTM: LBELTM, VSELTM], [SEND: EXELTM, BGELM, CLELTM, VSELTM, EGELTM]
6. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:231)

   Indicates the reference point associated with a timing offset.

   a. This entryRelationship **SHALL** contain exactly one [1..1] **`@typeCode`**`="COMP"` (CONF:233)
   b. This entryRelationship **SHALL** contain exactly one [1..1] **`act`** (CONF:234)

      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`) (CONF:235)
      b. This act **SHALL** contain exactly one [1..1] **`@moodCode`** (CONF:236)
      c. This act **SHALL** contain exactly one [1..1] **`code`** (CONF:237)**`/@code`**`="ATPtbd"` (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`) (CONF:238)

         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: LBTPTFEF, VSTPTREF]. [SEND: EXTPTREF, BGTPTREF, CLTPTREF. LBTPTREF, VSTPTREF, EGTPTREF]

      d. This act **MAY** contain zero or one [0..1] **`effectiveTime`** (CONF:239)

         The date time of the anchor time point. [SDTM: LBRFTDTC, VSRFTDTC], [SEND: EXRFDTC, BGRFTDTC, CLRFTDTC. LBRFTDTC, VSRFTDTC, EGRFTDTC]

      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.
7. **MAY** contain zero or one [0..1] **`text`** (CONF:232)

- A text description of the time for a measurement to be taken. It is expressed as an elapsed time relative to the fixed reference point defined within the Anchor Time Point observation. [SDTM: XTPT, EGTPT, LBTPT, QSTPT, VSTPT, MBTPT, MSTPT, PCTPT], [SEND: EXPTP, LBTPT. PCTPT, VSTPT, EGTPT, [Study Data Tabulation Model: -TPT]

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">
  <templateId root="2.16.840.1.113883.10.20.23.97"/>
  <id root="434219774" extension="MDHT"/>
  <code codeSystem="2.16.840.1.113883.3.26.1.1"/>
  <text>Text Value</text>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <entryRelationship typeCode="COMP">
    <act classCode="ACT">
      <code code="ATPtbd" codeSystem="2.16.840.1.113883.3.26.1.1"
 codeSystemName="NCI Thesaurus"/>
    </act>
  </entryRelationship>
</act>
```

Toxicity

[Observation: templateId `2.16.840.1.113883.10.20.23.98`]

The template holds information on the toxicity of an event. The toxicity measure is recorded using a standard toxicity scale. This structure is captured as a template to facilitate its reuse as a characteristic of different types of event or finding within clinical and non-clinical trial reporting.

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF:1457)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:1458)
3. **SHALL** contain exactly one [1..1] **`code`** (CONF:1459)**`/@code`**`="TOtbd"` (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`) (CONF:1461)
   - The code value indicates that toxicity information is being provided.
4. **SHALL** contain exactly one [1..1] **`value`** with data type CD (CONF:1462), where the @code **SHALL** be selected from ValueSet *`Toxicity Measure Type`* `CXXXXX` **STATIC** (CONF:1463)
   - Provides information on the toxicity of the event. A standard toxicity scale is intended to be used. The code system property of the Concept Description data type indicates the toxicity grade (scale) that is used for the toxicity score. The toxicity score is recorded as the code. [SDTM: AETOX, AETOXGR, LBTOX, LBTOXGR], [SEND: LBTOX, LBTOXGR], Study Data Tabulation Model: -TOX, -TOXGR]

Toxicity 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="2.16.840.1.113883.10.20.23.98"/>
  <id root="1591954159" extension="MDHT"/>
  <code code="TOtbd" codeSystem="2.16.840.1.113883.3.26.1.1"
 codeSystemName="NCI Thesaurus"/>
  <effectiveTime>
    <low value="2012"/>
```

```
    <high value="2012"/>
  </effectiveTime>
  <value xsi:type="CD" code="1671258738"/>
</observation>
```

Visit

[Encounter: templateId `2.16.840.1.113883.10.20.23.100`]

The template records 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`) (CONF:84)
2. **SHALL** contain exactly one [1..1] **`@moodCode="EVN"`** *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:85)
3. **SHALL** contain exactly one [1..1] **`code`** (CONF:86), where the @code **SHALL** be selected from ValueSet *`Visit Classification`* `CXXXXX` **STATIC** (CONF:87)
   - 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. **SHALL** contain exactly one [1..1] **`id`** (CONF:88)
   - The clinical encounter number. It is a numeric value that is used for sorting. [SDTM, VISITNUM].
5. **SHALL** contain exactly one [1..1] **`entryRelationship`** (CONF:89)
   - Identifies the SDTM or SEND domain the record is assigned to.
   a. Contains **`@typeCode="REFR"`** *REFR*
   b. Contains exactly one [1..1] *Domain Assignment* (templateId: `2.16.840.1.113883.10.20.23.30`)
6. **MAY** contain zero or more [0..*] **`entryRelationship`** (CONF:90)
   a. Contains **`@typeCode="COMP"`** *COMP*
   b. Contains exactly one [1..1] *ECG Test Result* (templateId: `2.16.840.1.113883.10.20.23.33`)
7. **MAY** contain zero or more [0..*] **`entryRelationship`** (CONF:91)
   a. Contains **`@typeCode="COMP"`** *COMP*
   b. Contains exactly one [1..1] *Human Clinical Laboratory Test Result* (templateId: `2.16.840.1.113883.10.20.23.45`)
8. **MAY** contain zero or more [0..*] **`entryRelationship`** (CONF:92)
   a. Contains **`@typeCode="COMP"`** *COMP*
   b. Contains exactly one [1..1] *Physical Examination Finding* (templateId: `2.16.840.1.113883.10.20.23.67`)
9. **MAY** contain zero or more [0..*] **`entryRelationship`** (CONF:93)
   a. Contains **`@typeCode="COMP"`** *COMP*
   b. Contains exactly one [1..1] *Questionnaire Finding* (templateId: `2.16.840.1.113883.10.20.23.72`)
10. **MAY** contain zero or more [0..*] **`entryRelationship`** (CONF:94)
    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Vital Sign* (templateId: `2.16.840.1.113883.10.20.23.101`)
11. **MAY** contain zero or one [0..1] **`text`** (CONF:95)
    - A text block to be used for description of an unplanned visit. [SDTM: SVUPDES]
12. **SHOULD** contain exactly one [1..1] **`effectiveTime`** (CONF:96)
    - The interval data type allows entry of the start date/time of the visit and of the end/date time. [SDTM: SVSTDTC, SVENDTC]

13. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:97)
    a. Contains **@typeCode="COMP"** *COMP*
    b. Contains exactly one [1..1] *Microbiology Specimen Finding* (templateId: 2.16.840.1.113883.10.20.23.53)
14. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:98)
    a. Contains **@typeCode="COMP"** *COMP*
    b. Contains exactly one [1..1] *Microbiology Susceptibility* (templateId: 2.16.840.1.113883.10.20.23.54)
15. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:99)
    a. Contains **@typeCode="COMP"** *COMP*
    b. Contains exactly one [1..1] *Pharmacokinetic Concentration Finding* (templateId: 2.16.840.1.113883.10.20.23.65)
16. **MAY** contain zero or more [0..*] **entryRelationship** (CONF:100)
    a. Contains **@typeCode="COMP"** *COMP*
    b. Contains exactly one [1..1] *Pharmacokinetic Parameter Finding* (templateId: 2.16.840.1.113883.10.20.23.66)
17. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:101)
    a. Contains **@typeCode="COMP"** *COMP*
    b. Contains exactly one [1..1] *Drug Accountability* (templateId: 2.16.840.1.113883.10.20.23.32)
18. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:102)
    - Records the study day on which collection of the information was originally scheduled.

    a. Contains **@typeCode="REFR"** *REFR*
    b. Contains exactly one [1..1] *Planned Study Day* (templateId: 2.16.840.1.113883.10.20.23.68)
19. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:103)
    - Used to record the study days associated with the beginning and end points of a visit that may extend over a period of time.

    a. Contains **@typeCode="REFR"** *REFR*
    b. Contains exactly one [1..1] *Study Day Period* (templateId: 2.16.840.1.113883.10.20.23.82)
20. **MAY** contain zero or more [0..*] **entryRelationship** (CONF:104)
    - Establishes a relationship between this record and another record.

    a. Contains **@typeCode="REFR"** *REFR*
    b. Contains exactly one [1..1] *Related Record* (templateId: 2.16.840.1.113883.10.20.23.75)
21. **MAY** contain zero or more [0..*] **entryRelationship** (CONF:105)
    - Allows the association of a supplemental value - outside of the content specfied for the domain - to the record.

    a. Contains **@typeCode="COMP"** *COMP*
    b. Contains exactly one [1..1] *Supplemental Value* (templateId: 2.16.840.1.113883.10.20.23.96)
22. **MAY** contain zero or more [0..*] **entryRelationship** (CONF:106)
    a. Contains **@typeCode="COMP"** *COMP*
    b. Contains exactly one [1..1] *Comment* (templateId: 2.16.840.1.113883.10.20.23.23)
23. **MAY** contain zero or more [0..*] **entryRelationship** (CONF:107)
    - Allows recording of additional findings related to the visit.

    a. Contains **@typeCode="COMP"** *COMP*
    b. Contains exactly one [1..1] *Finding About* (templateId: 2.16.840.1.113883.10.20.23.40)

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="2.16.840.1.113883.10.20.23.100"/>
  <id root="491883130" 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>
    <observation>
      <templateId root="2.16.840.1.113883.10.20.23.101"/>
      <id root="1024156452" extension="MDHT"/>
      <code codeSystem="2.16.840.1.113883.3.26.1.1"/>
      <text>Text Value</text>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <interpretationCode codeSystemName="NCI Thesaurus"/>
      <entryRelationship>
        <observation/>
      </entryRelationship>
      <entryRelationship>
        <act>
          <templateId root="2.16.840.1.113883.10.20.23.97"/>
          <code codeSystem="2.16.840.1.113883.3.26.1.1"/>
        </act>
      </entryRelationship>
      <entryRelationship>
        <observation classCode="OBS">
          <templateId root="2.16.840.1.113883.10.20.23.56"/>
          <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
 Thesaurus" displayName="Reason for non completion"/>
        </observation>
      </entryRelationship>
      <entryRelationship>
        <observation/>
      </entryRelationship>
      <entryRelationship>
        <observation/>
      </entryRelationship>
      <entryRelationship>
        <observation/>
      </entryRelationship>
      <entryRelationship>
        <observation classCode="OBS">
          <templateId root="2.16.840.1.113883.10.20.23.38"/>
          <code code="EXCtbd" codeSystem="2.16.840.1.113883.3.26.1.1"
 codeSystemName="NCI Thesaurus" displayName="Baseline Indicator"/>
        </observation>
      </entryRelationship>
      <entryRelationship>
        <act classCode="ACT">
          <templateId root="2.16.840.1.113883.10.20.23.42"/>
          <code code="C83204" codeSystem="2.16.840.1.113883.3.26.1.1"
 codeSystemName="NCI Thesaurus"/>
        </act>
```

```
      </entryRelationship>
      <entryRelationship>
        <observation classCode="OBS" moodCode="EVN">
          <templateId root="2.16.840.1.113883.10.20.23.23"/>
          <code code="C49569" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
        </observation>
      </entryRelationship>
      <entryRelationship>
        <observation>
          <templateId root="2.16.840.1.113883.10.20.23.30"/>
          <code code="C66734" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
        </observation>
      </entryRelationship>
      <entryRelationship>
        <act classCode="ACT">
          <templateId root="2.16.840.1.113883.10.20.23.75"/>
          <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus"/>
        </act>
      </entryRelationship>
      <entryRelationship>
        <observation classCode="OBS" moodCode="EVN">
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     </effectiveTime>
     <interpretationCode codeSystemName="NCI Thesaurus"/>
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       <act classCode="ACT">
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         <code code="C83204" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
       </act>
     </entryRelationship>
     <entryRelationship>
       <procedure/>
     </entryRelationship>
     <entryRelationship>
       <observation classCode="OBS">
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         <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus" displayName="Reason for non completion"/>
       </observation>
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       <act>
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         <code codeSystem="2.16.840.1.113883.3.26.1.1"/>
       </act>
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       <observation classCode="OBS" moodCode="EVN">
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codeSystemName="NCI Thesaurus"/>
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Thesaurus"/>
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      </entryRelationship>
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Thesaurus" displayName="Reason for non completion"/>
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```

```
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codeSystemName="NCI Thesaurus"/>
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        <observation>
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codeSystemName="NCI Thesaurus"/>
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      </entryRelationship>
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Value Type"/>
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Thesaurus"/>
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```

```
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codeSystemName="NCI Thesaurus"/>
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Thesaurus" displayName="Reason for non completion"/>
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Thesaurus"/>
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Thesaurus"/>
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      </entryRelationship>
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  </entryRelationship>
</encounter>
```

Vital Sign

[Observation: templateId `2.16.840.1.113883.10.20.23.101`]

A vital sign measurement that is collected from 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`) (CONF:140)
2. **SHALL** contain exactly one [1..1] **`@moodCode="EVN"`** *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:141)
3. **SHALL** contain exactly one [1..1] **`id`** (CONF:142)
   - A value that is provided to ensure the uniqueness of the vital sign item. [SDTM: VSSEQ, VSSPID], [SEND: VSSEQ, VSSPID] A single identifier, the sequence number, is required.
4. **SHALL** contain exactly one [1..1] **`code`**, where the @code **SHALL** be selected from ValueSet *`Vital Sign`* `C66741` **STATIC** (CONF:143)
   - A coded indication of the nature of the vital sign. [SDTM, VSTESTCD, VSTEST], [SEND, VSTESTCD, VSTEST]- the descriptive text associated with the code.
5. **SHALL** contain exactly one [1..1] **`statusCode`** (CONF:144), where the @code **SHALL** be selected from (CodeSystem: `2.16.840.1.113883.5.14 ActStatus`) (CONF:1519)
   - Use the value "completed" to indicate a desired observation was performed. If no observation was performed, provide the null flavor "NI". [SDTM: VSSTAT], [SEND: VSSTAT],
6. **SHOULD** contain zero or one [0..1] **`effectiveTime`** (CONF:145)
   - The date time on which the measurement was taken. In some cases, particularly for non-human trials, a time interval may be recorded. [SDTM: VSDTC], [SEND: VSDTC, VSENDTC]
7. **MAY** contain [0..3] **`value`** (CONF:146)
   - 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], [SEND: VSORRES, VSORRESU, VSSTRESN, VSSTRESU].
8. **SHOULD** contain [0..3] **`interpretationCode`** (CONF:147), where the @code **SHALL** be selected from ValueSet *`Subject Data Interpretation Type`* `CXXXXX` **STATIC** (CONF:148)
   - Includes information used to better interpret the observation value (result). [SDTM: VSBLFL, VSDRVFL], [SEND: VSBLFL, VSDRVFL, VSEXCLFL].
9. **MAY** contain zero or one [0..1] **`targetSiteCode`** (CONF:149), where the @code **SHALL** be selected from ValueSet *`Anatomical Location`* `C74456` **STATIC** (CONF:150)
   - The body location relevant to the vital sign measurement. [SDTM: VSLOC], [SEND: VSLOC]
10. **SHALL** contain exactly one [1..1] **`entryRelationship`** (CONF:151)
    - Identifies the SDTM or SEND domain the record is assigned to.
    a. Contains **`@typeCode="REFR"`** *REFR*
    b. Contains exactly one [1..1] *Domain Assignment* (templateId: `2.16.840.1.113883.10.20.23.30`)
11. **SHOULD** contain zero or one [0..1] **`entryRelationship`** (CONF:152)
    - Indicates an identifer that is used to group associated findings.
    a. Contains **`@typeCode="COMP"`** *COMP*
    b. Contains exactly one [1..1] *Group Identifier* (templateId: `2.16.840.1.113883.10.20.23.42`)
12. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:153)

- Provides a reason for not capturing information for the vital sign.

a. Contains **@typeCode="COMP"** *COMP*
b. Contains exactly one [1..1] *Non Performance Reason* (templateId: 2.16.840.1.113883.10.20.23.56)

13. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:154)

- Information on the reason that a data item is to be excluded from tabulation.

a. Contains **@typeCode="COMP"** *COMP*
b. Contains exactly one [1..1] *Exclusion Reason* (templateId: 2.16.840.1.113883.10.20.23.38)

14. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:155)

a. Contains **@typeCode="COMP"** *COMP*
b. Contains exactly one [1..1] *Position of Subject* (templateId: 2.16.840.1.113883.10.20.23.69)

15. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:156)

A record of the consciousness state of the subject at the time of measurement. It is not used for SDTM associated reporting.

a. This entryRelationship **SHALL** contain exactly one [1..1] **@classCode** (CONF:169)
b. This entryRelationship **SHALL** contain exactly one [1..1] **@moodCode** (CONF:172)
c. This entryRelationship **SHALL** contain exactly one [1..1] **code** (CONF:170)**/@code**="CStbd" (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus) (CONF:171)

A code value that indicates that the observation records information regarding the subject's level of consciousness.

d. This entryRelationship **SHALL** contain exactly one [1..1] **value** with data type CD (CONF:173), where the @code **SHALL** be selected from ValueSet *Consciousness State* CXXXXX **STATIC** (CONF:174)

A coded value that indicates the state of consciousness of the subject when the vital sign measurement was recorded. [SEND: VSCSTATE]

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

16. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:157)

- Used to record the study day associated with an activity taking place during a single day.

a. Contains **@typeCode="REFR"** *REFR*
b. Contains exactly one [1..1] *Event Study Day* (templateId: 2.16.840.1.113883.10.20.23.37)

17. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:158)

- Orients the collection of the vital sign information with respect to a study defined timepoint.

a. Contains **@typeCode="REFR"** *REFR*
b. Contains exactly one [1..1] *Timing Reference* (templateId: 2.16.840.1.113883.10.20.23.97)

18. **SHOULD** contain zero or one [0..1] **entryRelationship** (CONF:159)

- A record of the study day on which the vital statistics observation was planned for.

a. Contains **@typeCode="REFR"** *REFR*
b. Contains exactly one [1..1] *Planned Study Day* (templateId: 2.16.840.1.113883.10.20.23.68)

19. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:160)

- A record of the study date/time on which an activity took place. If relevant, both starting and stopping time points can be recorded.

a. Contains **@typeCode="REFR"** *REFR*
b. Contains exactly one [1..1] *Study Day Period* (templateId: 2.16.840.1.113883.10.20.23.82)

20. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:161)

- The record of a category to be used in organizing information items.

   a. Contains **@typeCode="COMP"** *COMP*
   b. Contains exactly one [1..1] *Category* (templateId: 2.16.840.1.113883.10.20.23.20)
21. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:162)
   - The record of a sub-category to be used in organizing information items.
   a. Contains **@typeCode="COMP"** *COMP*
   b. Contains exactly one [1..1] *Sub- Category* (templateId: 2.16.840.1.113883.10.20.23.91)
22. **MAY** contain zero or more [0..*] **entryRelationship** (CONF:163)
   - Establishes a relationship between this record and another record.
   a. Contains **@typeCode="REFR"** *REFR*
   b. Contains exactly one [1..1] *Related Record* (templateId: 2.16.840.1.113883.10.20.23.75)
23. **MAY** contain zero or more [0..*] **entryRelationship** (CONF:164)
   - Allows the association of a supplemental value - outside of the content specfied for the domain - to the record.
   a. Contains **@typeCode="REFR"** *REFR*
   b. Contains exactly one [1..1] *Supplemental Value* (templateId: 2.16.840.1.113883.10.20.23.96)
24. **MAY** contain zero or more [0..*] **entryRelationship** (CONF:165)
   - A place to insert comments related to a particular finding.
   a. Contains **@typeCode="COMP"** *COMP*
   b. Contains exactly one [1..1] *Comment* (templateId: 2.16.840.1.113883.10.20.23.23)
25. **MAY** contain zero or more [0..*] **entryRelationship** (CONF:166)
   - Allows recording of additional findings related to the finding.
   a. Contains **@typeCode="COMP"** *COMP*
   b. Contains exactly one [1..1] *Finding About* (templateId: 2.16.840.1.113883.10.20.23.40)

Vital Sign 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="2.16.840.1.113883.10.20.23.101"/>
  <id root="1505498710" extension="MDHT"/>
  <code codeSystem="2.16.840.1.113883.3.26.1.1"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <interpretationCode codeSystemName="NCI Thesaurus"/>
  <targetSiteCode code="1341485750"/>
  <entryRelationship>
    <observation>
      <id root="1379464853" extension="MDHT"/>
      <code code="462286435"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <value xsi:type="INT" value="1"/>
      <interpretationCode code="90240080"/>
      <targetSiteCode code="224840827"/>
    </observation>
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```
    <act>
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      <effectiveTime>
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  </entryRelationship>
  <entryRelationship>
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Thesaurus" displayName="Reason for non completion"/>
      <statusCode code="completed"/>
      <effectiveTime>
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      </effectiveTime>
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      <targetSiteCode code="1862514896"/>
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        <high value="2012"/>
      </effectiveTime>
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      <interpretationCode code="474440735"/>
      <targetSiteCode code="1350594836"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation>
      <id root="942318094" extension="MDHT"/>
      <code code="520097541"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <value xsi:type="IVL_INT" value="1"/>
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      <targetSiteCode code="1913022655"/>
    </observation>
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      <id root="1709082137" extension="MDHT"/>
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```
      <code code="EXCtbd" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus" displayName="Baseline Indicator"/>
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      </effectiveTime>
      <value xsi:type="CD" code="856948278"/>
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      <targetSiteCode code="91423043"/>
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  <entryRelationship>
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      <templateId root="2.16.840.1.113883.10.20.23.42"/>
      <id root="965816714" extension="MDHT"/>
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codeSystemName="NCI Thesaurus"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
    </act>
  </entryRelationship>
  <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
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codeSystemName="NCI Thesaurus"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
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      <value xsi:type="ED">Text Value</value>
      <interpretationCode code="1223635087"/>
      <targetSiteCode code="53777439"/>
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      <id root="1666547639" extension="MDHT"/>
      <code code="C66734" 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="CD" code="2050391115"/>
      <interpretationCode code="582190459"/>
      <targetSiteCode code="1437960956"/>
    </observation>
  </entryRelationship>
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    <act classCode="ACT">
      <templateId root="2.16.840.1.113883.10.20.23.75"/>
      <id root="1216688553" extension="MDHT"/>
```

```
     <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
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     <statusCode code="completed"/>
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 <entryRelationship>
   <observation classCode="OBS" moodCode="EVN">
     <templateId root="2.16.840.1.113883.10.20.23.96"/>
     <id root="2039479642" extension="MDHT"/>
     <code codeSystem="locally defined" codeSystemName="Supplemental Value
Type"/>
     <statusCode code="completed"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
     <interpretationCode code="139993587"/>
     <targetSiteCode code="560776972"/>
     <participant/>
     <entryRelationship typeCode="COMP"/>
   </observation>
 </entryRelationship>
 <entryRelationship>
   <observation classCode="OBS" moodCode="EVN">
     <templateId root="2.16.840.1.113883.10.20.23.20"/>
     <id root="1677125880" 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="CD" code="293506708"/>
     <interpretationCode code="1293958627"/>
     <targetSiteCode code="880413791"/>
   </observation>
 </entryRelationship>
 <entryRelationship>
   <observation/>
 </entryRelationship>
 <entryRelationship>
   <observation/>
 </entryRelationship>
 <entryRelationship>
   <observation>
     <id root="399204783" extension="MDHT"/>
     <code code="1578987902"/>
     <statusCode code="completed"/>
     <effectiveTime>
       <low value="2012"/>
       <high value="2012"/>
     </effectiveTime>
     <interpretationCode code="487499252"/>
     <targetSiteCode code="1046399082"/>
     <participant/>
     <entryRelationship typeCode="REFR"/>
     <entryRelationship>
       <act classCode="ACT">
         <templateId root="2.16.840.1.113883.10.20.23.42"/>
```

```
          <code code="C83204" codeSystem="2.16.840.1.113883.3.26.1.1"
 codeSystemName="NCI Thesaurus"/>
        </act>
      </entryRelationship>
      <entryRelationship>
        <observation classCode="OBS">
          <templateId root="2.16.840.1.113883.10.20.23.56"/>
          <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
 Thesaurus" displayName="Reason for non completion"/>
        </observation>
      </entryRelationship>
      <entryRelationship>
        <act/>
      </entryRelationship>
      <entryRelationship>
        <observation classCode="OBS" moodCode="EVN">
          <templateId root="2.16.840.1.113883.10.20.23.20"/>
          <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
 Thesaurus"/>
        </observation>
      </entryRelationship>
      <entryRelationship>
        <observation/>
      </entryRelationship>
      <entryRelationship>
        <observation>
          <templateId root="2.16.840.1.113883.10.20.23.30"/>
          <code code="C66734" codeSystem="2.16.840.1.113883.3.26.1.1"
 codeSystemName="NCI Thesaurus"/>
        </observation>
      </entryRelationship>
    </observation>
  </entryRelationship>
</observation>
```

Chapter 5

OTHER TEMPLATES

Topics:

This section of the Implementation Guide describes those templates used in entries that are not derived from the act choice structure known as "clinical statement". These represent reusable structures that provide concepts needed within the other templates.

Consumable Material

[Consumable: templateId `2.16.840.1.113883.10.20.23.26`]

The template captures information for medicinal substances tested in trials and/or substances consumed by trial subjects. It is called upon when recording information about exposures, concommitant medication and/or substance use. All treatments are managed as uses of a consumable material.

1. **SHALL** contain zero or one [0..1] **`@typeCode="CSM"`** (CONF:285)
2. **SHALL** contain zero or one [0..1] **`manufacturedProduct`** (CONF:286)

   Information for the substance that is playing the role of medication.

   a. This manufacturedProduct **SHALL** contain exactly one [1..1] **`@classCode="MANU"`** (CONF:287)
   b. This manufacturedProduct Contains exactly one [1..1] **`manufacturedMaterial`**

      An association to the material substance.

      a. This manufacturedMaterial **SHALL** contain exactly one [1..1] **`@classCode="MMAT"`** (CONF:291)
      b. This manufacturedMaterial Contains exactly one [1..1] **`@determinerCode="KIND"`**
      c. This manufacturedMaterial **SHALL** contain exactly one [1..1] **`code`** (CONF:292), where the @code **SHALL** be selected from ValueSet *`Medication Item Set`* `locally defined` **STATIC** (CONF:1522)

         The code attribute captures information about the nature of the drug, medication or therapy. Within SDTM, medication information can appear as a concommitant medication, as the study medication within the exposure domain, or as a substance that is used. The standard code for the substance is captured using the code property of the CD type. A verbatim description of the substance is recored using original text, while sponsor specific coding uses the translation property of the type. [SDTM: CMTRT, CMMODIFY, CMDECOD, EXTRT, SUTRT, SUMODIFY, SUDECOD], [SEND: EXTRT] [Study Data Tablulation Model: -TRT, MODIFY, DECOD]
      d. This manufacturedMaterial **SHOULD** contain zero or one [0..1] **`formCode`** with data type CD (CONF:294), where the @code **SHALL** be selected from ValueSet *`Pharmaceutical Dose Form`* `C66726` **STATIC** (CONF:295)

         Captures the dose form of the medication. Note, while expected for an exposure drug, it is permitted for a concommitant medication. [SDTM: EXDOSFRM, SUDOSFRM, CMDOSFRM], [SEND: EXDOSFRM], [SDM: -DOSFRM]
      e. This manufacturedMaterial **MAY** contain zero or one [0..1] **`lotNumberText`** (CONF:296)

         The lot number is relevant when information regarding the study treatment is provided. [SDTM: EXLOT], [SEND: EXLOT], [Study Data Tabulation Model; -LOT]
      f. This manufacturedMaterial **MAY** contain zero or one [0..1] **`asSpecializedKind`** (CONF:297)

         Used to capture information about the drug class into which the medication falls.

         a. This asSpecializedKind **SHALL** contain exactly one [1..1] **`@classCode="ASSIGNED"`** (CONF:299)

            The assigned class code is included here due to limitations of the MDHT tooling. The actual preferred class code is "GEN" generalization.
         b. This asSpecializedKind **SHALL** contain exactly one [1..1] **`code`** (CONF:300), where the @code **SHALL** be selected from (CodeSystem: `unknown Medication Class Type`) (CONF:301)

            May specify a certain use of the generalization relationship. Since things may be classified in various ways, this code may be used to allow systems with limited understanding of the classes to show the classes in distinguished slots (e.g., product by effect, by mechanism of action, by chemical nature, etc.
         c. This asSpecializedKind **SHALL** contain exactly one [1..1] **`representedOrganization`** (CONF:302)

MDHT tooling requires use of the "represented organization" stereotype of HL7's role scoper relationship. This allows recording of the drug class information.

a. This representedOrganization **SHALL** contain exactly one [1..1] **`@classCode="ORG"`** (CONF:303)

The proper class code is "MAT", material.

b. This representedOrganization **SHALL** contain exactly one [1..1] **`@determinerCode="KIND"`** (CONF:304)

c. This representedOrganization Contains zero or one [0..1] **`code`**

The class defined for a medication or administered treatment. [SDTM: CMCLAS, CMCLASCD, SUCLAS, SUCLASCD]. [SDM: -CLAS. -CLASCD]

MDHT tooling requires use of the "represented organization" stereotype of HL7's role scoper relationship. This allows recording of the drug class information.

Used to capture information about the drug class into which the medication falls.

g. This manufacturedMaterial **MAY** contain zero or more [0..*] **`ingredientRole`** (CONF:298)

Used to provide information about active ingredients and/or treatment vehicles.

a. Such ingredientRoles **SHALL** contain exactly one [1..1] **`@classCode="ASSIGNED"`** (CONF:305)

The role class code value is limited by the constraints of extending CDA within the MDHT environment. The proper class code value is "BASE" to indicate that the infomation provided is related to the base substance or treatment vehicle. For active ingredients, the value "ACTI" shall be used.

b. Such ingredientRoles **SHALL** contain exactly one [1..1] **`assignedPerson`** (CONF:306)

INLINE

a. This assignedPerson **SHALL** contain exactly one [1..1] **`@classCode="MMAT"`** (CONF:308)

b. This assignedPerson **SHALL** contain exactly one [1..1] **`@determinerCode="INSTANCE"`** (CONF:309)

c. This assignedPerson **SHALL** contain exactly one [1..1] **`code`** (CONF:310), where the @code **SHALL** be selected from (CodeSystem: `unknown Substance Ingredient Type`) (CONF:311)

Identifies an ingredient within the formulation provided to the patient as a study treatment. The substance identfied may be the active ingredient. It may also be the treatment vehicle. [SDTM: EXTRTV], [Study Data Tabulation Model: -TRTV. The terminology used may vary depending on whether the active ingredient or the treatment substance is addressed.

INLINE

c. Such ingredientRoles **SHALL** contain exactly one [1..1] **`quantity`** with data type RTO_PQ_PQ (CONF:307)

Identifies the ingredient amount - the amount of treatment vehicle provided within a single administration. The denominator of the ratio is set as '1'. [SDTM: EXVAMT, EXVAMTU], [Study Data Tabulation Model; -VAMT, VAMTU]

Used to provide information about active ingredients and/or treatment vehicles.

h. This manufacturedMaterial **SHALL** satisfy: The vebatim medication name is captured as the original text property within the material.code attribute. (CONF:288)

i. 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. (CONF:289)

j. 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. (CONF:290)

An association to the material substance.

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="2.16.840.1.113883.10.20.23.26"/>
  <manufacturedProduct classCode="MANU">
    <manufacturedMaterial classCode="MMAT" determinerCode="KIND">
      <code codeSystem="locally defined" codeSystemName="Medication Item
 Type"/>
    </manufacturedMaterial>
  </manufacturedProduct>
</consumable>
```

Reference Range

[ObservationRange: templateId `2.16.840.1.113883.10.20.23.74`]

The reference range template is used to convey information about the standard - normal - values for a given finding. The values provided which can indicate the upper and lower bounds of the normal range for a test. It can also indicate which values of a categorical test are normal, and support interpretation of the value recorded for the study subject.

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF:1481)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN.CRT"` (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:1482)
3. **SHALL** contain exactly one [1..1] **`code`** (CONF:1483)**`/@code`**`="C78736"` (CodeSystem: `2.16.840.1.113883.3.26.1.1 NCI Thesaurus`) (CONF:1484)
   - The code value indicates the observation includes reference range information, as well as conveying whether the reference range is provided in original units or standard units.
4. **SHALL** contain exactly one [1..1] **`value`** (CONF:1485)
   - 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. Standard referemce range values go into the base value and unt, while the orginal values use the translation property of the PQR type. [SDTM: LBORNRLO, LBORNRHI, LBSTRRLO, LBSTNRHI, LBSTNRC], [SEND: LBORNRLO, LBORNRHI, LBSTRRLO, LBSTNRHI, LBSTNRC] [Study Data Tabulation Model: -STRNLO, STRNHI, STRNC] The data type for .value is listed as "ANY" since it may either be coded - type = CD - or a physical quantity - type = PQR. (Note, the PQR form is used to allow the use units of measure expressed as coded values.) The value presented by the investigator or party entering the data is captured as the base value. If this value is transformed to use standard units, or a standard code set, the transformed or normalized values are included as translations.
5. **SHALL** contain zero or one [0..1] **`interpretationCode`**, where the @code **SHALL** be selected from ValueSet *`Reference Range`* `C78736` **STATIC** (CONF:1486)
   - The value is used to interpret the meaning of the range information. Is it the upper bound of the range, the lower bound of the range, or a characterization of the normal range for character based results?

Reference Range example

```
<?xml version="1.0" encoding="UTF-8"?>
<observationrange 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.CRT">
  <templateId root="2.16.840.1.113883.10.20.23.74"/>
  <code code="C78736" codeSystem="2.16.840.1.113883.3.26.1.1"
 codeSystemName="NCI Thesaurus"/>
```

```
  <interpretationCode codeSystem="2.16.840.1.113883.3.26.1.1"
 codeSystemName="NCI Thesaurus"/>
</observationrange>
```

Study Finding Evaluator

[Participant2: templateId `2.16.840.1.113883.10.20.23.84`]

The template provides a resusable structure to capture information on the role of a person who evaluates a study finding.

1. **SHALL** contain exactly one [1..1] **`@typeCode`**`="PRF"` (CONF:799)
2. **SHALL** contain exactly one [1..1] **`participantRole`** (CONF:800)
    a. This participantRole **SHALL** contain zero or one [0..1] **`@classCode`**`="ASSIGNED"` (CONF:801)
    b. This participantRole **SHALL** contain zero or one [0..1] **`code`** with data type CD (CONF:802), where the @code **SHALL** be selected from ValueSet *`Evaluator Role Type`* `C76735` **STATIC** (CONF:803)

    The role of the person providing the evaluation. This is used only for results that are subjective. [SDTM: PEEVAL, FAEVAL], [SEND: CLEVAL, DDEVAL, MAEVAL, MIEVAL, PMEVAL, EGEVAL], [Study Data Tabulation Model: -EVAL]

Study Finding Evaluator example

```
<?xml version="1.0" encoding="UTF-8"?>
<participant2 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="2.16.840.1.113883.10.20.23.84"/>
  <time>
    <low value="2012"/>
    <high value="2012"/>
  </time>
  <participantRole classCode="ASSIGNED">
    <templateId root="null"/>
    <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
 Thesaurus"/>
  </participantRole>
</participant2>
```

Study Test Organization

[Participant2: templateId `2.16.840.1.113883.10.20.23.88`]

The template is used to record information on the organization performing a test or other activity within the context of the study. Within SDTM, this is referred to as a "vendor".

1. **SHALL** contain exactly one [1..1] **`@typeCode`**`="AUT"` (CONF:611)
2. **SHALL** contain exactly one [1..1] **`participantRole`** (CONF:612)
    a. This participantRole **SHALL** contain zero or one [0..1] **`@classCode`**`="ASSIGNED"` (CONF:613)
    b. This participantRole **SHALL** contain zero or one [0..1] **`performer`** (CONF:614)
        a. This performer **SHALL** contain zero or one [0..1] **`@classCode`**`="ORG"` (CONF:615)
        b. This performer **SHALL** contain zero or one [0..1] **`@determinerCode`**`="INSTANCE"` (CONF:616)
        c. This performer **SHALL** contain exactly one [1..1] **`name`** (CONF:617)

        The name of the organization ("vendor") that performed the test. [SDTM: LBNAM, EGNAM, MBNAM, MSNAM, PCNAM], [SEND: LBNAM, MANAM, MINAM, PCNAM, EGNAM, TSTFNAM], [Study Data Tabulation Model: -NAM]

Study Test Organization example

```
<?xml version="1.0" encoding="UTF-8"?>
<participant2 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="2.16.840.1.113883.10.20.23.88"/>
  <time>
    <low value="2012"/>
    <high value="2012"/>
  </time>
  <participantRole classCode="ASSIGNED">
    <templateId root="null"/>
  </participantRole>
</participant2>
```

Chapter 6

VALUE SETS

Topics:

The following tables provide information on the vocabulary items provided within the Implementation Guide. The content includes both those items used for human clinical and for non-human studies.

The value set - Act Type - provides a reference to the act code values used to clarify the semantics of included content.

Value sets will be either centrally controlled or locally created by the study sponsor. Currently, all the centrally controlled value sets are managed within the NCI Enterprise Vocabulary Services. We are treating the EVS as the code system for all of the relevant codes. Therefore, for those value sets that have the NCI Thesaurus listed as the code system, and NCI EVS listed as the source, it is expected that NCI concept codes will be provided in document instances. These values sets will be both maintained and distributed by NCI. NCI EVS will provide a file for the Subject Data Report user community to be located at: *http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/fda.*

The locally defined value sets draw are developed by study sponsors, and are drawn from code systems - typically with the same name as the value set - created and maintained by the study sponsor. It is expected that protocol submissions using the Study Design Structured Document specification will provide a listing of the relevant value sets.

- *Drug Accountability Category*
- *Drug Accountability Category Type*
- *Drug Accountability Finding Set*
- *Drug Accountability Sub-Category*
- *Drug Accountability Sub-Category Type*
- *ECG Lead Location*
- *ECG Test Method*
- *ECG Test Result Category*
- *ECG Test Result Category Type*
- *ECG Test Result Sub-Category*
- *ECG Test Result Sub-Category Type*
- *ECG Test Result Type*
- *ECG Test Type*
- *Ethnic Group*
- *Evaluator Role Type*
- *Event Pattern*
- *Event Severity*
- *Exclusion Reason*
- *Exposure Category*
- *Exposure Category Type*
- *Exposure Sub-Category*
- *Exposure Sub-Category Type*
- *Finding About Category*
- *Finding About Category Type*
- *Finding About Finding Set*
- *Finding About Object*
- *Finding About Object Type*
- *Finding About Sub-Category*
- *Finding About Sub-Category Type*
- *Food/Water Consumption Test Type*
- *Inclusion/Exclusion Criteria Category*
- *Inclusion/Exclusion Criteria Sub-Category*
- *Inclusion/Exclusion Criteria Sub-Category Type*
- *Inclusion/Exclusion Criteria Type*
- *Inclusion/Exclusion Criterion Set*
- *Intervention Indication Set*
- *Intervention Indication Type*
- *Laboratory Test Code*

- *Laboratory Test Result Category*
- *Laboratory Test Result Category Type*
- *Laboratory Test Result Sub-Category*
- *Laboratory Test Result Sub-Category Type*
- *Macroscopic Examination Set*
- *Macroscopic Examination Type*
- *Med DRA*
- *Medical History Category*
- *Medical History Category Type*
- *Medical History Item Set*
- *Medical History Item Type*
- *Medical History Sub-Category*
- *Medical History Sub-Category Type*
- *Medication Class*
- *Medication Class Type*
- *Medication Item Set*
- *Medication Item Type*
- *Method*
- *Microbiology Finding Category*
- *Microbiology Finding Category Type*
- *Microbiology Finding Set*
- *Microbiology Finding Sub-Category*
- *Microbiology Finding Sub-Category Type*
- *Microbiology Finding Type*
- *Microbiology Susceptibility Finding Category*
- *Microbiology Susceptibility Finding Category Type*
- *Microbiology Susceptibility Finding Set*
- *Microbiology Susceptibility Finding Sub-Category*
- *Microbiology Susceptibility Finding Sub-Category Type*
- *Microbiology Susceptibility Finding Type*
- *Microbiology Susceptibility Result Category*
- *Microscopic Finding Set*
- *Microscopic Finding Type*
- *NCI Thesaurus*

- *Non Performance Reason*
- *Organ Measurement Examination Set*
- *Organ Measurement Examination Type*
- *Outcome of Event*
- *Palpable Mass Examination Set*
- *Palpable Mass Examination Type*
- *Pharmaceutical Dose Form*
- *Pharmacokinetics Concentration Category*
- *Pharmacokinetics Concentration Category Type*
- *Pharmacokinetics Concentration Finding Set*
- *Pharmacokinetics Concentration Finding Type*
- *Pharmacokinetics Concentration Sub-Category*
- *Pharmacokinetics Concentration Sub-Category Type*
- *Pharmacokinetics Parameter Category*
- *Pharmacokinetics Parameter Category Type*
- *Pharmacokinetics Parameter Finding Set*
- *Pharmacokinetics Parameter Sub-Category*
- *Pharmacokinetics Parameter Sub-Category Type*
- *Physical Exam Finding Category*
- *Physical Exam Finding Category Type*
- *Physical Exam Finding Set*
- *Physical Exam Finding Sub-Category*
- *Physical Exam Finding Sub-Category Type*
- *Physical Exam Finding Type*
- *Portion or Totality Type*
- *Question Set*
- *Question Type*
- *Questionairre Category*
- *Questionairre Sub-Category*
- *Questionnaire Category Type*

- *Questionnaire Sub-Category Type*
- *Race*
- *Reference Period Relationship*
- *Reference Range*
- *Route of Administration*
- *Serious Event Type*
- *Sex*
- *Species Type*
- *Specimen Condition Type*
- *Specimen Type*
- *Strain/Substrain Type*
- *Study Arm Set*
- *Study Arm Type*
- *Study Epoch Set*
- *Study Epoch Type*
- *Study Treatment Causality*
- *Subject Characteristic*
- *Subject Characteristic Category Type*
- *Subject Characteristic Set*
- *Subject Characteristic Sub-Category*
- *Subject Characteristic Sub-Category Type*
- *Subject Data Domain Category Type*
- *Subject Data Domain Result Category Type*
- *Subject Data Domain SubCategory Type*
- *Subject Data Interpretation Consolidated Type*
- *Subject Data Interpretation Type*
- *Subject Element Set*
- *Subject Element Type*
- *Subject Event Set*
- *Substance Ingredient Set*
- *Substance Ingredient Type*
- *Substance Use Category*
- *Substance Use Category Type*
- *Substance Use Sub-Category*
- *Substance Use Sub-Category Type*
- *Supplemental Value Set*
- *Supplemental Value Type*
- *Test Method Type*
- *Toxicity Grade Type*

- *Toxicity Measure Type*
- *Tumor Examination Set*
- *Tumor Examination Type*
- *Unit of Measure*
- *Visit Classification*
- *Vital Sign*

Act Type

Value Set	Act Type - CXXXXX
Code System	NCI Thesaurus - 2.16.840.1.113883.3.26.1.1
Description	A list of the act types, prinicipally observations that are used within the implementation guides for human clinical and non-human non-clinical studies.

Concept Code	Concept Name	Code System	Description
C25150	Age	NCI Thesaurus	An observation to record the age of the subject.
ATPtbd	Anchor Time Point	NCI Thesaurus	An observation that defines a reference time point against which the occurance of an event is measured.
C49562	Adverse Event	NCI Thesaurus	The code value indicates the presence of an adverse event.
AQtbd	Assay Quantitation	NCI Thesaurus	An observation that records the lower quantitation limit of an assay.
CEtbd	Clinical Event	NCI Thesaurus	
C49569	Comment	NCI Thesaurus	Identifies an observation as a comment. Note, the SDTM/SEND concept ID for the domain of the same name is being used.
C83199	Concommitant Treatment	NCI Thesaurus	A observation to record the fact that an event received treatment.
CStbd	Consciousness State	NCI Thesaurus	An observation to provide information the consciousness state of the subject.
C88026	Body System or Organ Class	NCI Thesaurus	Indicates the observation conveys the identity of a body system or organ class.
DCtbd	Data Collection	NCI Thesaurus	An observation to provide information on whether or when an expected item of data was collected.
DOtbd	Data Origin	NCI Thesaurus	An observation that records the source of data which is added to the report as a supplemental value.
C95087	Death Diagnosis	NCI Thesaurus	Indicates that the observation carries information about the death diagnosis.
DRtbd	Death Relationship	NCI Thesaurus	Captures whether or not an intervention was associated with the death of a subject.
DMGtbd	Demographics	NCI Thesaurus	An observation used to collect demographic information for a subject that goes beyond that provided by CDA for a record target.
C66734	Domain Assignment	NCI Thesaurus	An observation to note the SEND/SDTM domain assigned to an information item.

Concept Code	Concept Name	Code System	Description
DARtbd	Dose Adjustment Reason	NCI Thesaurus	A expression of the relationship of a particular finding to the death of a subject.
ELOtbd	Element Order	NCI Thesaurus	An observation to record the order assigned to an element within an arm.
EDtbd	Event Duration	NCI Thesaurus	An observation to capture the duration of an event.
C66769	Event or Finding Severity	NCI Thesaurus	An observation to record the severity of an event or finding.
C49489	Event Outcome	NCI Thesaurus	An observation to record the outcome of an event.
C83208	Event Pattern	NCI Thesaurus	An observation to record the temporal pattern of an event that occurs multiple times.
ESDtbd	Event Study Day	NCI Thesaurus	An observation to record the study day on which an event occurrs.
EXCtbd	Exclusion Reason	NCI Thesaurus	An observation to record the reason for excluding a finding from tabulation of study results.
FStbd	Fasting Status	NCI Thesaurus	An observation to record the fasting status of the subject.
FAOtbd	Finding About Object Type	NCI Thesaurus	An observation to record the object of a finding about observation.
C83204	Group Identifier	NCI Thesaurus	The code value indicates that the act is the group identifier.
HUStbd	Human Clinical Subject Report Document Section	NCI Thesaurus	Identifies the document as a Human Clinical Subject Report
C83085	Indication	NCI Thesaurus	An observation of the reason for performing an intervention.
IRtbd	Intended Regimen	NCI Thesaurus	An observation of the intended pattern of events for a subject. It is used to supplement frequency information provided as the effective time for an act.
C87881	Lead Location	NCI Thesaurus	An observation of the location of a particular ECG lead on the subject's body.
MHItbd	Medical History Item	NCI Thesaurus	An observation that records an item of the subject's medical history
NHStbd	Non-Human Subject Report Document Section	NCI Thesaurus	Identifies the document as a Non-Human Subject Report
NPRtbd	Non-Performance Reason	NCI Thesaurus	An observation recording the reason for not performing a scheduled activity or collecting a scheduled data item.
NSTtbd	Non-Study Treatment Relationship	NCI Thesaurus	A observation recording the association of an event with a treatment other than that mandated by the study.

Concept Code	Concept Name	Code System	Description
OWAtbd	Order Within Arm	NCI Thesaurus	An observation to record the order in which an element is to be performed within the designated arm.
OATtbd	Other Action Taken	NCI Thesaurus	An observation recording action, other than adjustment to the study treatment, which is taken to address the occurance of an event.
C83450	Planned Study Day	NCI Thesaurus	An observation to record the study data on which an event is planned to occur.
POTtbd	Portion or Totality	NCI Thesaurus	An observation to record the relationship of an extracted specimen to the structure from which it is extracted.
C71148	Position of Subject	NCI Thesaurus	An observation to record the body position of the subject during the collection of a finding.
PSEtbd	Pre-Specified Event	NCI Thesaurus	An observation to record the fact that collection of information regarding an event or to record a finding was prespecified on the CRF.
PDtbd	Protocol Deviation	NCI Thesaurus	An observation to record a deviation from the study protocol.
RPtbd	Reference Period	NCI Thesaurus	An observation to record the reference period for a study subject - typically the time period between a subject's first exposure to the study drug and the time the subject left the study.
RRtbd	Related Record	NCI Thesaurus	An observation to establish a relationship between two data items defined within the subject data report.
C78736	Reference Range	NCI Thesaurus	An observation used to convey information about the standard - normal - values for a given finding.
SETtbd	Serious Event Type	NCI Thesaurus	An observation that defines a type of consequence of an adverse event that classifies that event as serious.
C53252	Serious Event	NCI Thesaurus	An observation to indicate whether or not an adverse event is considered to be serious.
SPCtbd	Species	NCI Thesaurus	An observation to record the species of a living subject.
SCLtbd	Specimen Collection	NCI Thesaurus	An observation to record the collection of a specimen.
C78733	Specimen Condition	NCI Thesaurus	An observation to record the condition of a specimen.

Concept Code	Concept Name	Code System	Description
C78734	Specimen Type	NCI Thesaurus	An observation to record the specimen type - the type of tissue or body structure form which the specimen was extracted.
SUtbd	Specimen Usability	NCI Thesaurus	An observation to record whether or not the specimen can be used to perform a desired observation.
STRPtbd	Start Relative to Reference Period	NCI Thesaurus	An observation that records the relationship of the beginning of an event to the established reference period for the subject.
ENRPtbd	Stop Relative to Reference Period	NCI Thesaurus	An observation that records the relationship of the end of an event to the established reference period for the subject.
SStbd	Strain/Substrain	NCI Thesaurus	An observation that records the strain and or substrain designation given to a living subject.
STPtbd	Study Day Period	NCI Thesaurus	An observation that records the study data period during which an event occurred.
ARMtbd	Study Arm	NCI Thesaurus	An observation to record an arm defined for a study.
C99079	Study Epoch	NCI Thesaurus	An observation to record an epoch defined for a study.
STAtbd	Study Treatment Action Taken	NCI Thesaurus	An observation to record the action taken with the study treatment in response to an event.
STCtbd	Study Treatment Causality	NCI Thesaurus	An observation to record the causal relationship beween an event and the study treatment provided to a subject.
SPtbd	Subject Pool	NCI Thesaurus	An act which establishes a pool used to define a group of subjects for which findings, interventions or events may be recorded.
TRtbd	Timing Reference	NCI Thesaurus	An act which is defined to create a relationship between the timing of an event and either a specific point in time, or an anchoring time point.
TOtbd	Toxicity Observation	NCI Thesaurus	An observation of the toxicity of an event or finding.

Action Taken with Study Treatment

Value Set	Action Taken with Study Treatment - C66767
Code System	NCI Thesaurus - 2.16.840.1.113883.3.26.1.1

Source	NCI EVS
Source URL	http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/fda

Adverse Event

Value Set	Adverse Event - (OID not specified)
Code System	MedDRA - (OID not specified)
Description	The collection of adverse event codes defined within the MedDRA code system.

Adverse Event Category

Value Set	Adverse Event Category - locally defined
Code System	Adverse Event Category Type - locally defined
Description	A record of the list of categories used to group adverse events by a study sponsor. The value set is drawn from a locally defined code system. In practice, the code system and value set will be identical.

Adverse Event Category Type

Value Set	Adverse Event Category Type
Description	The locally defined universe of adverse event categories.

Adverse Event Set

Value Set	Adverse Event Set - locally defined
Code System	Adverse Event Type - unknown
Description	A record of the list of adverse events that may be reported on within a subject data report. The value set is drawn from a locally defined code system. In practice, the code system and value set are likely to be identical.

Adverse Event Sub-Category

Value Set	Adverse Event Sub-Category - locally defined
Code System	Adverse Event Sub-Category Type - locally defined
Description	A record of the list of sub-categories used to group adverse events by a study sponsor. The value set is drawn from a locally defined code system. In practice, the code system and value set will be identical.

Adverse Event Sub-Category Type

Value Set	Adverse Event Sub-Category Type

Description	The locally defined universe of adverse event sub-categories.

Adverse Event Type

Value Set	Adverse Event Type
Description	The universe of possible adverse events. The set of concepts is defined as a locally defined, sponsor generated code system. However, there is a strong case, and perhaps compelling case for using a generally available clincial vocabulary such as MedDRA or SNOMED.

Anatomical Location

Value Set	Anatomical Location - C74456
Code System	NCI Thesaurus - 2.16.840.1.113883.3.26.1.1
Source	NCI EVS
Source URL	http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/fda
Description	Captures the list of relevant body sites.

Body Position

Value Set	Body Position - C71148
Code System	NCI Thesaurus - 2.16.840.1.113883.3.26.1.1
Source	NCI EVS
Source URL	http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/fda
Description	A list of body positions that may be referred to as context for a finding.

Body System/Organ Class

Value Set	Body System/Organ Class - C88026
Code System	NCI Thesaurus - 2.16.840.1.113883.3.26.1.1
Source	NCI EVS
Source URL	http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/fda
Description	Captures the list of body systems and organ types. We need an EVS cite.

Body Weight Gain

Value Set	Body Weight Gain - CXXXXX
Code System	NCI Thesaurus - 2.16.840.1.113883.3.26.1.1
Source	NCI EVS
Source URL	http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/fda

Description	A type of measure of the change in body weight of a study subject.

Body Weight Measurement

Value Set	Body Weight Measurement - CXXXXX
Code System	NCI Thesaurus - 2.16.840.1.113883.3.26.1.1
Source	NCI EVS
Source URL	http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/fda
Description	A type of measurement of the body weight of a study subject.

Clinical Event

Value Set	Clinical Event - locally defined
Code System	MedDRA - (OID not specified)
Description	A record of the list of clinical events that may be reported on within a subject data report. The value set is drawn from a locally defined code system. In practice, the code system and value set are likely to be identical.

Clinical Observation

Value Set	Clinical Observation - locally defined
Code System	Clinical Observation Type - unknown
Description	A record of the list of clinical observations that may be reported on within a subject data report. The value set is drawn from a locally defined code system. In practice, the code system and value set are likely to be identical.

Clinical Observation Type

Value Set	Clinical Observation Type
Description	The universe of possible clincial observations.. The set of concepts is defined as a locally defined, sponsor generated code system. However, there would be a strong case for using a generally available clincial vocabulary such as LOINC or SNOMED.

Concomitant Medication Category

Value Set	Concomitant Medication Category - localy defined
Code System	Concomitant Medication Category Type - locally defined
Description	A record of the list of concomitant medication categories that may be reported on within a subject data report. The value set is drawn from a locally defined code system. In practice, the code system and value set are likely to be identical.

Concomitant Medication Category Type

Value Set	Concomitant Medication Category Type
Description	The universe of categories that could be used for organizing concomitant medications. The code system to be used is defined by the study sponsor.

Concomitant Medication Sub-Category

Value Set	Concomitant Medication Sub-Category - locally defined
Code System	Concomitant Medication Sub-Category Type - locally defined
Description	A record of the list of concomitant medication sub-categories that may be reported on within a subject data report. The value set is drawn from a locally defined code system. In practice, the code system and value set are likely to be identical.

Concomitant Medication Sub-Category Type

Value Set	Concomitant Medication Sub-Category Type
Description	A list of sub-categories used for organizing concomitant medications. The code system to be used is defined by the study sponsor.

Consciousness State

Value Set	Consciousness State - CXXXXX
Code System	NCI Thesaurus - 2.16.840.1.113883.3.26.1.1
Source	NCI EVS
Source URL	http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/fda
Description	A set of different consciousness states that may apply to a study subject will be tested or examined.

Data Origin Type

Value Set	Data Origin Type - CXXXXX
Code System	NCI Thesaurus - 2.16.840.1.113883.3.26.1.1
Source	NCI EVS
Source URL	http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/fda
Description	A set of the different origins, e.g., CRF, derived, that may be ascribed to a data item that is added to a subject data report as a supplemental value.

Death Diagnosis

Value Set	Death Diagnosis - locally defined
Code System	Death Diagnosis Type - unknown
Description	A record of the list of death diagnoses that may be reported on within a subject data report. The value set is drawn from a locally defined code system. In practice, the code system and value set are likely to be identical.

Death Diagnosis Type

Value Set	Death Diagnosis Type
Description	A standardized form that expresses cause of death as a diagnosis. The set of concepts is defined as a locally defined, sponsor generated code system. However, there would be a strong case for using a generally available clincial vocabulary such as ICD or SNOMED.

Death Relationship Set

Value Set	Death Relationship Set - CXXXXX
Code System	NCI Thesaurus - 2.16.840.1.113883.3.26.1.1
Source	NCI EVS
Source URL	http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/fda
Description	A set of different types or relationship a finding may have to the death of a study subject.

Disposition Category

Value Set	Disposition Category - C74558
Code System	NCI Thesaurus - 2.16.840.1.113883.3.26.1.1
Source URL	http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/fda
Definition	Classifications that describe and group pertinent events that occur throughout the conduct of a clinical trial.
Description	A list of categories used for organizing dispositions. The code system to be used is defined by the study sponsor.

Disposition Item Set

Value Set	Disposition Item Set - CXXXXX
Description	A list of possible types of study subject disposition. Is there an EVS set, or is it sponsor defined?

Disposition Sub-Category

Value Set	Disposition Sub-Category
Description	A record of the list of disposition sub-categories that may be reported on within a subject data report. The value set is drawn from a locally defined code system. In practice, the code system and value set are likely to be identical.

Disposition Sub-Category Type

Value Set	Disposition Sub-Category Type
Description	A list of sub-categories used for organizing dispositions. The code system to be used is defined by the study sponsor.

Domain Abbreviation

Value Set	Domain Abbreviation - C66734
Code System	NCI Thesaurus - 2.16.840.1.113883.3.26.1.1
Source	NCI EVS
Source URL	http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/fda

Drug Accountability Category

Value Set	Drug Accountability Category - locally defined
Code System	Drug Accountability Category Type - locally defined
Description	A record of the list of drug accountability categories that may be reported on within a subject data report. The value set is drawn from a locally defined code system. In practice, the code system and value set are likely to be identical.

Drug Accountability Category Type

Value Set	Drug Accountability Category Type
Description	A list of categories used to organize drug accountability information. The code system to be used is defined by the study sponsor.

Drug Accountability Finding Set

Value Set	Drug Accountability Finding Set - C78732
Code System	NCI Thesaurus - 2.16.840.1.113883.3.26.1.1
Source	NCI EVS
Source URL	http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/fda

Description	A list of the different valid drug accountability findings. Is there a defined set?

Drug Accountability Sub-Category

Value Set	Drug Accountability Sub-Category - locally defined
Code System	Drug Accountability Sub-Category Type - locally defined
Description	A record of the list of drug accountability sub-categories that may be reported on within a subject data report. The value set is drawn from a locally defined code system. In practice, the code system and value set are likely to be identical.

Drug Accountability Sub-Category Type

Value Set	Drug Accountability Sub-Category Type
Description	A list of categories used to organize drug accountability information. The code system to be used is defined by the study sponsor.

ECG Lead Location

Value Set	ECG Lead Location - C90013
Code System	NCI Thesaurus - 2.16.840.1.113883.3.26.1.1
Source	NCI EVS
Source URL	http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/fda
Description	A list of possible location types used for ECG leads. Is there a defined set?

ECG Test Method

Value Set	ECG Test Method - C71151
Code System	NCI Thesaurus - 2.16.840.1.113883.3.26.1.1
Source	NCI EVS
Source URL	http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/fda

ECG Test Result Category

Value Set	ECG Test Result Category - locally defined
Code System	ECG Test Result Category Type - locally defined
Description	A record of the list of ECG test result categories that may be reported on within a subject data report. The value set is drawn from a locally defined code system. In practice, the code system and value set are likely to be identical.

ECG Test Result Category Type

Value Set	ECG Test Result Category Type
Description	A list of possible categories used to organize ECT test results. The code system to be used is defined by the study sponsor.

ECG Test Result Sub-Category

Value Set	ECG Test Result Sub-Category - locally defined
Code System	ECG Test Result Sub-Category Type - locally defined
Description	A record of the list of ECG test result sub-categories that may be reported on within a subject data report. The value set is drawn from a locally defined code system. In practice, the code system and value set are likely to be identical.

ECG Test Result Sub-Category Type

Value Set	ECG Test Result Sub-Category Type
Description	A record of the list of ECG test result categories that may be reported on within a subject data report. The value set is drawn from a locally defined code system. In practice, the code system and value set are likely to be identical.

ECG Test Result Type

Value Set	ECG Test Result Type - C71150
Code System	NCI Thesaurus - 2.16.840.1.113883.3.26.1.1
Source	NCI EVS
Source URL	http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/fda
Description	A list of possible test results generated by an ECG. Is there a defined set of categories?

ECG Test Type

Value Set	ECG Test Type - C71153
Code System	NCI Thesaurus - 2.16.840.1.113883.3.26.1.1
Source	ECI EVS
Source URL	http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/fda

Ethnic Group

Value Set	Ethnic Group - C66790

Code System	NCI Thesaurus - 2.16.840.1.113883.3.26.1.1
Source	NCI EVS
Source URL	http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/fda
Description	A list of the valid ethnic groups to be used when categorizing study subjects.

Evaluator Role Type

Value Set	Evaluator Role Type - C76735
Code System	NCI Thesaurus - 2.16.840.1.113883.3.26.1.1
Source	NCI EVS
Source URL	http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/fda
Description	A list of possible study roles played by the evaluator of a result. Is this in EVS?

Event Pattern

Value Set	Event Pattern - CXXXXX
Code System	NCI Thesaurus - 2.16.840.1.113883.3.26.1.1
Source	NCI EVS
Source URL	http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/fda
Description	A list of different patterns that can be assigned to an event. Is this in EVS?

Event Severity

Value Set	Event Severity - C66769
Code System	NCI Thesaurus - 2.16.840.1.113883.3.26.1.1
Source	NCI EVS
Source URL	http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/fda
Description	A list of possible values for event severity. Is there a list in EVS?

Exclusion Reason

Value Set	Exclusion Reason - CXXXXX
Code System	NCI Thesaurus - 2.16.840.1.113883.3.26.1.1
Source	NCI EVS
Source URL	http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/fda
Description	A set of codes that include the different reasons a data item should be excluded from study tabulations.

Exposure Category

Value Set	Exposure Category - locally defined
Code System	Exposure Category Type - locally defined
Description	A record of the list of exposure categories that may be reported on within a subject data report. The value set is drawn from a locally defined code system. In practice, the code system and value set are likely to be identical.

Exposure Category Type

Value Set	Exposure Category Type
Description	A list of categories used for organizing exposures. The code system to be used is defined by the study sponsor.

Exposure Sub-Category

Value Set	Exposure Sub-Category - locally defined
Code System	Exposure Sub-Category Type - locally defined
Description	A record of the list of exposure sub-categories that may be reported on within a subject data report. The value set is drawn from a locally defined code system. In practice, the code system and value set are likely to be identical.

Exposure Sub-Category Type

Value Set	Exposure Sub-Category Type
Description	A list of sub-categories used for organizing exposures. The code system to be used is defined by the study sponsor.

Finding About Category

Value Set	Finding About Category - locally defined
Code System	Finding About Category Type - locally defined
Description	A record of the list of finding about categories that may be reported on within a subject data report. The value set is drawn from a locally defined code system. In practice, the code system and value set are likely to be identical.

Finding About Category Type

Value Set	Finding About Category Type
Description	A list of categories used for organizing finding about results. The code system to be used is defined by the study sponsor.

Finding About Finding Set

Value Set	Finding About Finding Set - C101852
Code System	NCI Thesaurus - 2.16.840.1.113883.3.26.1.1
Source	NCI EVS
Source URL	http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/fda
Description	A list of the different types of findings that may be captured within the SDTM Findings About domain.

Finding About Object

Value Set	Finding About Object - locally defined
Code System	Finding About Object Type - locally defined
Description	A record of the list of finding about objects that may be reported on within a subject data report. The value set is drawn from a locally defined code system. In practice, the code system and value set are likely to be identical.

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. The code system to be used is defined by the study sponsor.

Finding About Sub-Category

Value Set	Finding About Sub-Category - locally defined
Description	A record of the list of finding about sub-categories that may be reported on within a subject data report. The value set is drawn from a locally defined code system. In practice, the code system and value set are likely to be identical.

Finding About Sub-Category Type

Value Set	Finding About Sub-Category Type
Description	A list of sub-categories used for organizing finding about results. The code system to be used is defined by the study sponsor.

Food/Water Consumption Test Type

Value Set	Food/Water Consumption Test Type - CXXXXX
Code System	NCI Thesaurus - 2.16.840.1.113883.3.26.1.1
Source	NCI EVS
Source URL	http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/fda
Description	A set of measurements, tests, or examination that provide information on food and/or water consumption by a study subject.

Inclusion/Exclusion Criteria Category

Value Set	Inclusion/Exclusion Criteria Category - C66797
Code System	NCI Thesaurus - 2.16.840.1.113883.3.26.1.1
Source	NCI EVS
Source URL	http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/fda
Description	A list of categories used for organizing Inclusion/Exclusion criteria. Currently, it indicates whether a criteria is designed to include or exclude possible study subjects.

Inclusion/Exclusion Criteria Sub-Category

Value Set	Inclusion/Exclusion Criteria Sub-Category - locally defined
Code System	Inclusion/Exclusion Criteria Sub-Category Type - locally defined
Description	A record of the list of inclusion/exclusion criteria sub-categories that may be reported on within a subject data report. The value set is drawn from a locally defined code system. In practice, the code system and value set are likely to be identical.

Inclusion/Exclusion Criteria Sub-Category Type

Value Set	Inclusion/Exclusion Criteria Sub-Category Type
Description	A list of sub-categories used for organizing Inclusion/Exclusion criteria. The code system to be used is defined by the study sponsor.

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. Is this defined within EVS?

Inclusion/Exclusion Criterion Set

Value Set	Inclusion/Exclusion Criterion Set - locally defined
Code System	Inclusion/Exclusion Criteria Type - locally defined
Description	A record of the list of inclusion/exclusion criteria that may be reported on within a subject data report. The value set is drawn from a locally defined code system. In practice, the code system and value set are likely to be identical.

Intervention Indication Set

Value Set	Intervention Indication Set - locally defined
Code System	Intervention Indication Type - unknown
Description	A record of the list of intervention indications that may be reported on within a subject data report. The value set is drawn from a locally defined code system. In practice, the code system and value set are likely to be identical.

Intervention Indication Type

Value Set	Intervention Indication Type
Description	A list of possible reasons for a subject's use of a medication item. Is there an EVS reference set?

Laboratory Test Code

Value Set	Laboratory Test Code - C65047
Code System	NCI Thesaurus - 2.16.840.1.113883.3.26.1.1
Source	NCI EVS
Source URL	http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/fda
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. The code system to be used is defined by the study sponsor.

Laboratory Test Result Category

Value Set	Laboratory Test Result Category - locally defined
Code System	Laboratory Test Result Category Type - unknown
Description	A record of the list of laboratory test result categories that may be reported on within a subject data report. The value set is drawn from a locally defined code system. In practice, the code system and value set are likely to be identical.

Laboratory Test Result Category Type

Value Set	Laboratory Test Result Category Type
Description	A list of categories used for organizing laboratory tests. If there is no satisfactory common vocabulary to be employed, the code system to be used will be defined by the study sponsor.

Laboratory Test Result Sub-Category

Value Set	Laboratory Test Result Sub-Category - locally defined
Code System	Laboratory Test Result Sub-Category Type - unknown
Description	A record of the list of laboratory test result sub-categories that may be reported on within a subject data report. The value set is drawn from a locally defined code system. In practice, the code system and value set are likely to be identical.

Laboratory Test Result Sub-Category Type

Value Set	Laboratory Test Result Sub-Category Type
Description	A list of sub-categories used for organizing laboratory tests. If there is no satisfactory common code system to be used, the code system to be used will be defined by the study sponsor.

Macroscopic Examination Set

Value Set	Macroscopic Examination Set - locally defined
Code System	Macroscopic Examination Type - unknown
Description	A record of the list of drug macroscopic examination types that may be reported on within a subject data report. The value set is drawn from a locally defined code system. In practice, the code system and value set are likely to be identical.

Macroscopic Examination Type

Value Set	Macroscopic Examination Type
Description	A collection of the different measurements, tests or examinations whose findings are reported as macroscopic results. Is there a standard code system that could be used for this set of types?

Med DRA

Value Set	MedDRA

Medical History Category

Value Set	Medical History Category - locally defined
Code System	Medical History Category Type - locally defined
Description	A record of the list of medical history categories that may be reported on within a subject data report. The value set is drawn from a locally defined code system. In practice, the code system and value set are likely to be identical.

Medical History Category Type

Value Set	Medical History Category Type
Description	A list of categories used for organizing medical history items. The code system to be used is defined by the study sponsor.

Medical History Item Set

Value Set	Medical History Item Set - locally defined
Code System	Medication Item Type - locally defined
Description	A record of the list of medical history item types that may be reported on within a subject data report. The value set is drawn from a locally defined code system. In practice, the code system and value set are likely to be identical.

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. The set of concepts is defined as a locally defined, sponsor generated code system. However, there would be a strong case for using a generally available clincial vocabulary such as SNOMED.

Medical History Sub-Category

Value Set	Medical History Sub-Category - locally defined
Code System	Medical History Sub-Category Type - locally defined
Description	A record of the list of medical history sub-categories that may be reported on within a subject data report. The value set is drawn from a locally defined code system. In practice, the code system and value set are likely to be identical.

Medical History Sub-Category Type

Value Set	Medical History Sub-Category Type

Description	A list of sub-categories used for organizing medical history items. The code system to be used is defined by the study sponsor.

Medication Class

Value Set	Medication Class - locally defined
Code System	Medication Class Type - unknown
Description	A record of the list of medication classes that may be reported on within a subject data report. The value set is drawn from a locally defined code system. In practice, the code system and value set are likely to be identical.

Medication Class Type

Value Set	Medication Class Type
Description	The set of possible classes that could be used to indicate generally the type of the study substance. The set of concepts is defined as a locally defined, sponsor generated code system. However, there would be a strong case for using a generally available clincial vocabulary such as RXNORM.

Medication Item Set

Value Set	Medication Item Set - locally defined
Code System	Medication Item Type - locally defined
Description	A record of the list of types of medication item that may be reported on within a subject data report. The value set is drawn from a locally defined code system. In practice, the code system and value set are likely to be identical.

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. Is there a standard code set to be advanced?

Method

Value Set	Method - C85492
Code System	NCI Thesaurus - 2.16.840.1.113883.3.26.1.1
Source	NCI EVS
Source URL	http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/fda

Microbiology Finding Category

Value Set	Microbiology Finding Category - locally defined
Code System	Microbiology Finding Category Type - locally defined
Description	A record of the list of microbiology finding categories that may be reported on within a subject data report. The value set is drawn from a locally defined code system. In practice, the code system and value set are likely to be identical.

Microbiology Finding Category Type

Value Set	Microbiology Finding Category Type
Description	A list of categories used for organizing microbiology specimen related tests. The code system to be used is defined by the study sponsor.

Microbiology Finding Set

Value Set	Microbiology Finding Set - locally defined
Code System	Microbiology Finding Type - unknown
Description	A record of the list of types of microbiology finding that may be reported on within a subject data report. The value set is drawn from a locally defined code system. In practice, the code system and value set are likely to be identical.

Microbiology Finding Sub-Category

Value Set	Microbiology Finding Sub-Category - locally defined
Code System	Microbiology Finding Sub-Category Type - locally defined
Description	A record of the list of microbiology finding sub-categories that may be reported on within a subject data report. The value set is drawn from a locally defined code system. In practice, the code system and value set are likely to be identical.

Microbiology Finding Sub-Category Type

Value Set	Microbiology Finding Sub-Category Type
Description	A list of sub-categories used for organizing microbiology specimen related tests. The code system to be used is defined by the study sponsor.

Microbiology Finding Type

Value Set	Microbiology Finding Type

Description	A list of types of microbiology specimen related finding. Is there a standard list? Should LOINC be suggested? Currently, the code system to be used is defined by the study sponsor.

Microbiology Susceptibility Finding Category

Value Set	Microbiology Susceptibility Finding Category - locally defined
Code System	Microbiology Susceptibility Finding Category Type - unknown
Description	A record of the list ofmicrobiology suceptibility finding categories that may be reported on within a subject data report. The value set is drawn from a locally defined code system. In practice, the code system and value set are likely to be identical.

Microbiology Susceptibility Finding Category Type

Value Set	Microbiology Susceptibility Finding Category Type
Description	A list of categories used for organizing microbiology susceptibility tests. These codes could be drawn from a generally acceptable code system such as LOINC. The code system to be used is defined by the study sponsor.

Microbiology Susceptibility Finding Set

Value Set	Microbiology Susceptibility Finding Set - locally defined
Code System	Microbiology Susceptibility Finding Type - locally defined
Description	A record of the list of types of microbiology susceptibility finding that may be reported on within a subject data report. The value set is drawn from a locally defined code system. In practice, the code system and value set are likely to be identical.

Microbiology Susceptibility Finding Sub-Category

Value Set	Microbiology Susceptibility Finding Sub-Category - locally defined
Code System	Microbiology Susceptibility Finding Sub-Category Type - unknown
Description	A record of the list of microbiology susceptibility finding sub-categories that may be reported on within a subject data report. The value set is drawn from a locally defined code system. In practice, the code system and value set are likely to be identical.

Microbiology Susceptibility Finding Sub-Category Type

Value Set	Microbiology Susceptibility Finding Sub-Category Type
Description	A list of sub-categories used for organizing microbiology susceptibility tests. Can these codes be drawn from a generally accepted code system such as LOINC? The code system to be used is defined by the study sponsor.

Microbiology Susceptibility Finding Type

Value Set	Microbiology Susceptibility Finding Type
Description	A list of types of microbiology susceptibility related finding. Is there a standard set? LOINC? Currently, the code system to be used is defined by the study sponsor.

Microbiology Susceptibility Result Category

Value Set	Microbiology Susceptibility Result Category - C85495
Code System	NCI Thesaurus - 2.16.840.1.113883.3.26.1.1
Source	NCI EVS
Source URL	http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/fda
Description	A list of categories used for organizing microbiology susceptibility results. The code system to be used is defined by the study sponsor.

Microscopic Finding Set

Value Set	Microscopic Finding Set - locally defined
Code System	Microscopic Finding Type - unknown
Description	A record of the list of types of microscopic findings that may be reported on within a subject data report. The value set is drawn from a locally defined code system. In practice, the code system and value set are likely to be identical.

Microscopic Finding Type

Value Set	Microscopic Finding Type
Description	A collection of the different measurements, tests or examinations whose findings are reported as microscopic results. If no generally agreeded upon code system can be identified, the code system to be used is defined by the study sponsor.

NCI Thesaurus

Value Set	NCI Thesaurus

Non Performance Reason

Value Set	Non Performance Reason - C66727
Code System	NCI Thesaurus - 2.16.840.1.113883.3.26.1.1
Source	NCI EVS
Source URL	http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/fda

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

Organ Measurement Examination Set

Value Set	Organ Measurement Examination Set - locally defined
Code System	Organ Measurement Examination Type - unknonw
Description	A record of the list of types of organ measurement examination that may be reported on within a subject data report. The value set is drawn from a locally defined code system. In practice, the code system and value set are likely to be identical.

Organ Measurement Examination Type

Value Set	Organ Measurement Examination Type
Description	A collection of the different measurements, tests or examinations whose findings are reported as organ measurement results. If no satisfactory generally accepted code system is recognized, the code system to be used is defined by the study sponsor.

Outcome of Event

Value Set	Outcome of Event - C66768
Code System	NCI Thesaurus - 2.16.840.1.113883.3.26.1.1
Source	NCI EVS
Source URL	http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/fda

Palpable Mass Examination Set

Value Set	Palpable Mass Examination Set - locally defined
Code System	Palpable Mass Examination Type - unknown
Description	A record of the list of types of palpable mass examination that may be reported on within a subject data report. The value set is drawn from a locally defined code system. In practice, the code system and value set are likely to be identical.

Palpable Mass Examination Type

Value Set	Palpable Mass Examination Type
Description	A collection of the different measurements, tests or examinations whose findings are reported as palpable mass results. If no satisfactory generally accepted code system is recognized, the code system to be used is defined by the study sponsor.

Pharmaceutical Dose Form

Value Set	Pharmaceutical Dose Form - C66726
Code System	NCI Thesaurus - 2.16.840.1.113883.3.26.1.1
Source	NCI EVS
Source URL	http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/fda

Pharmacokinetics Concentration Category

Value Set	Pharmacokinetics Concentration Category - locally defined
Code System	Pharmacokinetics Concentration Category Type - locally defined
Description	A record of the list of pharmacokinetic concentration categories that may be reported on within a subject data report. The value set is drawn from a locally defined code system. In practice, the code system and value set are likely to be identical.

Pharmacokinetics Concentration Category Type

Value Set	Pharmacokinetics Concentration Category Type
Description	A list of categories used for organizing pharmacokinetic concentration findings. The code system to be used is defined by the study sponsor.

Pharmacokinetics Concentration Finding Set

Value Set	Pharmacokinetics Concentration Finding Set - locally defined
Code System	Pharmacokinetics Concentration Finding Type - locally defined
Description	A record of the list of types of pharmacokinetic finding that may be reported on within a subject data report. The value set is drawn from a locally defined code system. In practice, the code system and value set are likely to be identical.

Pharmacokinetics Concentration Finding Type

Value Set	Pharmacokinetics Concentration Finding Type
Description	A list of the different types of pharmacokinetics concentration findings. The code system to be used is defined by the study sponsor.

Pharmacokinetics Concentration Sub-Category

Value Set	Pharmacokinetics Concentration Sub-Category - locally defined
Code System	Pharmacokinetics Concentration Sub-Category Type - locally defined

Description	A record of the list of pharmacokinetic concentration categories that may be reported on within a subject data report. The value set is drawn from a locally defined code system. In practice, the code system and value set are likely to be identical.

Pharmacokinetics Concentration Sub-Category Type

Value Set	Pharmacokinetics Concentration Sub-Category Type
Description	A list of sub-categories used for organizing pharmacokinetic concentration findings. The code system to be used is defined by the study sponsor.

Pharmacokinetics Parameter Category

Value Set	Pharmacokinetics Parameter Category - locally defined
Code System	Pharmacokinetics Parameter Category Type - locally defined
Description	A record of the list of pharmacokinetic parameter categories that may be reported on within a subject data report. The value set is drawn from a locally defined code system. In practice, the code system and value set are likely to be identical.

Pharmacokinetics Parameter Category Type

Value Set	Pharmacokinetics Parameter Category Type
Description	A list of the different types of pharmacokinetics parameter findings. The code system to be used is defined by the study sponsor.

Pharmacokinetics Parameter Finding Set

Value Set	Pharmacokinetics Parameter Finding Set - C85839
Code System	NCI Thesaurus - 2.16.840.1.113883.3.26.1.1
Source	NCI EVS
Source URL	http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/fda
Description	A list of categories used for organizing pharmacokinetic parameter findings. The code system to be used is defined by the study sponsor.

Pharmacokinetics Parameter Sub-Category

Value Set	Pharmacokinetics Parameter Sub-Category - locally defined
Code System	Pharmacokinetics Parameter Sub-Category Type - locally defined
Description	A record of the list of pharmacokinetic parameter categories that may be reported on within a subject data report. The value set is drawn from a locally defined code system. In practice, the code system and value set are likely to be identical.

Pharmacokinetics Parameter Sub-Category Type

Value Set	Pharmacokinetics Parameter Sub-Category Type
Description	A list of sub-categories used for organizing pharmacokinetic parameter findings. The code system to be used is defined by the study sponsor.

Physical Exam Finding Category

Value Set	Physical Exam Finding Category - locally defined
Code System	Physical Exam Finding Category Type - unknown
Description	A record of the list of physical exam finding categories that may be reported on within a subject data report. The value set is drawn from a locally defined code system. In practice, the code system and value set are likely to be identical.

Physical Exam Finding Category Type

Value Set	Physical Exam Finding Category Type
Description	A list of categories used for organizing physical exam findings. If no satisfactory generally accepted code system is recognized, the code system to be used is defined by the study sponsor.

Physical Exam Finding Set

Value Set	Physical Exam Finding Set - locally defined
Code System	Physical Exam Finding Type - unknown
Description	A record of the list of types of physical exam finding that may be reported on within a subject data report. The value set is drawn from a locally defined code system. In practice, the code system and value set are likely to be identical.

Physical Exam Finding Sub-Category

Value Set	Physical Exam Finding Sub-Category - locally defined
Code System	Physical Exam Finding Sub-Category Type - unknown
Description	A record of the list of physical exam finding sub-categories that may be reported on within a subject data report. The value set is drawn from a locally defined code system. In practice, the code system and value set are likely to be identical.

Physical Exam Finding Sub-Category Type

Value Set	Physical Exam Finding Sub-Category Type

Description	A list of sub-categories used for organizing physical exam findings. If no satisfactory generally accepted code system is recognized, the code system to be used is defined by the study sponsor.

Physical Exam Finding Type

Value Set	Physical Exam Finding Type
Description	A list of the different types of physical exam finding. Is there a standard set? LOINC? If no satisfactory generally accepted code system is recognized, the code system to be used is defined by the study sponsor.

Portion or Totality Type

Value Set	Portion or Totality Type - CXXXXX
Code System	NCI Thesaurus - 2.16.840.1.113883.3.26.1.1
Source	NCI EVS
Source URL	http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/fda
Description	A listing of the different codes used to indicate the portion or toality of the source anatomic structure that a specimen makes up.

Concept Code	Concept Name	Code System	Description
CA	Involves Cancer	NCI Thesaurus	
BD	Congenital Anomaly or Birth Defect	NCI Thesaurus	
DIS	Persistant or Significant Disability or Incapacity	NCI Thesaurus	
DTH	Results in Death	NCI Thesaurus	
HOSP	Requires or Prolongs Hospitalization	NCI Thesaurus	
LT	Is Life threatening	NCI Thesaurus	
OD	Occurred with Overdose	NCI Thesaurus	
OTH	Other Medically Important Serious Event	NCI Thesaurus	

Question Set

Value Set	Question Set - locally defined
Code System	Question Type - locally defined

Description	A record of different types of question that may be reported on within a subject data report. The value set is drawn from a locally defined code system. In practice, the code system and value set are likely to be identical.

Question Type

Value Set	Question Type
Description	A list of the different questions that may be included on a questionnaire. The code system to be used is defined by the study sponsor.

Questionairre Category

Value Set	Questionairre Category - locally defined
Code System	Questionnaire Category Type - locally defined
Description	A record of the list of questionnaire categories that may be reported on within a subject data report. The value set is drawn from a locally defined code system. In practice, the code system and value set are likely to be identical.

Questionairre Sub-Category

Value Set	Questionairre Sub-Category - locally defined
Code System	Questionnaire Sub-Category Type - locally defined
Description	A record of the list of questionairre sub-categories that may be reported on within a subject data report. The value set is drawn from a locally defined code system. In practice, the code system and value set are likely to be identical.

Questionnaire Category Type

Value Set	Questionnaire Category Type
Description	A list of categories used for organizing questionnaire results. The code system to be used is defined by the study sponsor.

Questionnaire Sub-Category Type

Value Set	Questionnaire Sub-Category Type
Description	A list of sub-categories used for organizing questionnaire results. The code system to be used is defined by the study sponsor.

Race

Value Set	Race - C74457
Code System	NCI Thesaurus - 2.16.840.1.113883.3.26.1.1

Source	NCI EVS
Source URL	http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/fda
Description	A list of the valid race codes to be used when categorizing study subjects.

Reference Period Relationship

Value Set	Reference Period Relationship - C66728
Code System	NCI Thesaurus - 2.16.840.1.113883.3.26.1.1
Source	NCI EVS
Source URL	http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/fda
Description	A collection of values used to describe the relationship between the beginning or end of an event and the reference period defined for the study subject.

Concept Code	Concept Name	Code System	Description
C78802	Abnormal	NCI Thesaurus	
C78800	High	NCI Thesaurus	
78801	Low	NCI Thesaurus	
78727	Normal	NCI Thesaurus	
CXXXXX	Baseline Value	NCI Thesaurus	
CXXXXX	Derived Value	NCI Thesaurus	
CXXXXX	Excluded value	NCI Thesaurus	

Reference Range

Value Set	Reference Range - C78736
Code System	NCI Thesaurus - 2.16.840.1.113883.3.26.1.1
Source	NCI EVS
Source URL	http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/fda
Description	A collection of values used to aid in interpreting subject data laboratory results. It includes statements about the relationship between a laboratory test result, and the reference range defined for the relevant lab test.

Concept Code	Concept Name	Code System	Description
C78802	Abnormal	NCI Thesaurus	

Concept Code	Concept Name	Code System	Description
C78800	High	NCI Thesaurus	
78801	Low	NCI Thesaurus	
78727	Normal	NCI Thesaurus	
CXXXXX	Baseline Value	NCI Thesaurus	
CXXXXX	Derived Value	NCI Thesaurus	
CXXXXX	Excluded value	NCI Thesaurus	

Route of Administration

Value Set	Route of Administration - C66729
Code System	NCI Thesaurus - 2.16.840.1.113883.3.26.1.1
Source	NCI EVS
Source URL	http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/fda
Description	A list of the possible routes of adminstration for a substance. Do we use the CDASH set? If so, how cite? Is this in EVS?

Serious Event Type

Value Set	Serious Event Type - CXXXXX
Code System	NCI Thesaurus - 2.16.840.1.113883.3.26.1.1
Source	NCI EVS
Source URL	http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/fda
Description	A listing of different types of event that are considered to be serious. The codes provided are strictly preliminary.

Concept Code	Concept Name	Code System	Description
CA	Involves Cancer	NCI Thesaurus	
BD	Congenital Anomaly or Birth Defect	NCI Thesaurus	
DIS	Persistant or Significant Disability or Incapacity	NCI Thesaurus	
DTH	Results in Death	NCI Thesaurus	

Concept Code	Concept Name	Code System	Description
HOSP	Requires or Prolongs Hospitalization	NCI Thesaurus	
LT	Is Life threatening	NCI Thesaurus	
OD	Occurred with Overdose	NCI Thesaurus	
OTH	Other Medically Important Serious Event	NCI Thesaurus	

Sex

Value Set	Sex - C66731
Code System	NCI Thesaurus - 2.16.840.1.113883.3.26.1.1
Source	NCI EVS
Source URL	http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/fda
Description	The different relevant values for capturing a study subject's gender.

Species Type

Value Set	Species Type - CXXXXX
Code System	NCI Thesaurus - 2.16.840.1.113883.3.26.1.1
Source	NCI EVS
Source URL	http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/fda
Description	A collection of the different species that could be recorded as a type of study subject. (It is not clear how this collection should intersect with the exisitng microorganism code list.)

Specimen Condition Type

Value Set	Specimen Condition Type - C78733
Code System	NCI Thesaurus - 2.16.840.1.113883.3.26.1.1
Source	NCI EVS
Source URL	http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/fda
Description	A list of different possible values for specimen condition.

Specimen Type

Value Set	Specimen Type - C78734
Code System	NCI Thesaurus - 2.16.840.1.113883.3.26.1.1

Source	NCI EVS
Source URL	http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/fda
Description	A list of different specimen types.

Strain/Substrain Type

Value Set	Strain/Substrain Type - CXXXXX
Code System	NCI Thesaurus - 2.16.840.1.113883.3.26.1.1
Source	NCI EVS
Source URL	http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/fda
Description	A collection of the different strain/substrain designations that can apply to a study subject.

Study Arm Set

Value Set	Study Arm Set - locally defined
Code System	Study Arm Type - locally defined
Description	A record of the types of study arm that may be reported on within a subject data report. The value set is drawn from a locally defined code system. In practice, the code system and value set are likely to be identical.

Study Arm Type

Value Set	Study Arm Type
Description	A list of valid values to be used for categorizing study arms. The code system to be used is defined by the study sponsor.

Study Epoch Set

Value Set	Study Epoch Set - locally defined
Code System	Study Epoch Type - locally defined
Description	A record of the list types of study epoch that may be reported on within a subject data report. The value set is drawn from a locally defined code system. In practice, the code system and value set are likely to be identical.

Study Epoch Type

Value Set	Study Epoch Type
Description	A list of valid values to be used for categorizing study epochs. The code system to be used is defined by the study sponsor.

Study Treatment Causality

Value Set	Study Treatment Causality - CXXXXX
Code System	NCI Thesaurus - 2.16.840.1.113883.3.26.1.1
Description	A list of different levels of causality between an event and the study trreatment.

Subject Characteristic

Value Set	Subject Characteristic - locally defined
Code System	Subject Characteristic Category Type - locally defined
Description	A record of the list of subject characteristic categories that may be reported on within a subject data report. The value set is drawn from a locally defined code system. In practice, the code system and value set are likely to be identical.

Subject Characteristic Category Type

Value Set	Subject Characteristic Category Type
Description	A list of categories used for organizing subject characteristic findings. The code system to be used is defined by the study sponsor.

Subject Characteristic Set

Value Set	Subject Characteristic Set - C74559
Code System	NCI Thesaurus - 2.16.840.1.113883.3.26.1.1
Source	NCI EVS
Source URL	http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/fda
Description	A list of different types of subject characteristic. The code system to be used is defined by the study sponsor.

Subject Characteristic Sub-Category

Value Set	Subject Characteristic Sub-Category - locally defined
Code System	Subject Characteristic Sub-Category Type - locally defined
Description	A record of the list of subject characteristic sub-categories that may be reported on within a subject data report. The value set is drawn from a locally defined code system. In practice, the code system and value set are likely to be identical.

Subject Characteristic Sub-Category Type

Value Set	Subject Characteristic Sub-Category Type

Description	A list of sub-categories used for organizing subject characteristic findings. The code system to be used is defined by the study sponsor.

Subject Data Domain Category Type

Value Set	Subject Data Domain Category Type - CXXXXX
Code System	NCI Thesaurus - 2.16.840.1.113883.3.26.1.1
Source	NCI EVS
Source URL	http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/fda
Description	The collection of the different types of category that are used in subject data reporting. By and large, a single category type has been defined for each SDTM and SEND domain.

Subject Data Domain Result Category Type

Value Set	Subject Data Domain Result Category Type - CXXXXX
Code System	NCI Thesaurus - 2.16.840.1.113883.3.26.1.1
Source	NCI EVS
Source URL	http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/fda
Description	The collection of the different types of result category that are used in subject data reporting. The list corresponds to the rather short list of domains for which result categories are defined.

Subject Data Domain SubCategory Type

Value Set	Subject Data Domain SubCategory Type - CXXXXX
Code System	NCI Thesaurus - 2.16.840.1.113883.3.26.1.1
Source	NCI EVS
Source URL	http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/fda
Description	The collection of the different types of sub-category that are used in subject data reporting. By and large, a single category type has been defined for each SEND and SDTM domain.

Subject Data Interpretation Consolidated Type

Value Set	Subject Data Interpretation Consolidated Type - CXXXXX
Code System	NCI Thesaurus - 2.16.840.1.113883.3.26.1.1
Source	NCI EVS
Source URL	http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/fda
Description	A collection of values used to aid in interpreting subject data laboratory results. It includes values that are defined to indicate that a data item should be excluded from tabulation, treated as a baseline value, or that the item vaue is derived. The value set

	also includes statements about the relationship between a laboratory test result, and the reference range defined for the relevant lab test. Note, this value set consolidates the content of the Refence Range and Subject Data Interpretation value sets.

Concept Code	Concept Name	Code System	Description
C78802	Abnormal	NCI Thesaurus	
C78800	High	NCI Thesaurus	
78801	Low	NCI Thesaurus	
78727	Normal	NCI Thesaurus	
CXXXXX	Baseline Value	NCI Thesaurus	
CXXXXX	Derived Value	NCI Thesaurus	
CXXXXX	Excluded value	NCI Thesaurus	

Subject Data Interpretation Type

Value Set	Subject Data Interpretation Type - CXXXXX
Code System	NCI Thesaurus - 2.16.840.1.113883.3.26.1.1
Source	NCI EVS
Source URL	http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/fda
Description	A collection of values used to aid in interpreting subject data findings. It includes values that are defined to indicate that a data item should be excluded from tabulation, treated as a baseline value, or that the item vaue is derived.

Concept Code	Concept Name	Code System	Description
CXXXXX	Baseline Value	NCI Thesaurus	
CXXXXX	Derived Value	NCI Thesaurus	
CXXXXX	Excluded value	NCI Thesaurus	

Subject Element Set

Value Set	Subject Element Set - locally defined
Code System	Subject Element Type - locally defined

Description	A record of the types of subject element that may be reported on within a subject data report. The value set is drawn from a locally defined code system. In practice, the code system and value set are likely to be identical.

Subject Element Type

Value Set	Subject Element Type
Description	The collection of elements which may be defined to organize the activities within a study. The code system to be used is defined by the study sponsor.

Subject Event Set

Value Set	Subject Event Set - CXXXXX
Code System	NCI Thesaurus - 2.16.840.1.113883.3.26.1.1
Source	NCI EVS
Source URL	http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/fda
Description	A collection of values used to characterize subject events.

Concept Code	Concept Name	Code System	Description
C78802	Abnormal	NCI Thesaurus	
C78800	High	NCI Thesaurus	
78801	Low	NCI Thesaurus	
78727	Normal	NCI Thesaurus	
CXXXXX	Baseline Value	NCI Thesaurus	
CXXXXX	Derived Value	NCI Thesaurus	
CXXXXX	Excluded value	NCI Thesaurus	

Substance Ingredient Set

Value Set	Substance Ingredient Set - locally defined
Code System	Substance Ingredient Type - unknown
Description	A record of different types of substance ingredient that may be reported on within a subject data report. The value set is drawn from a locally defined code system. In practice, the code system and value set are likely to be identical.

Substance Ingredient Type

Value Set	Substance Ingredient Type
Description	The set of possible substances that could be listed as an active or inactive ingredient within the study substance. The set of concepts is defined as a locally defined, sponsor generated code system. However, there would be a strong case for using a generally available clincial vocabulary such as RXNORM.

Substance Use Category

Value Set	Substance Use Category - locally defined
Code System	Substance Use Category Type - locally defined
Description	A record of the list of substance use categories that may be reported on within a subject data report. The value set is drawn from a locally defined code system. In practice, the code system and value set are likely to be identical.

Substance Use Category Type

Value Set	Substance Use Category Type
Description	A list of categories used for organizing substance uses. The code system to be used is defined by the study sponsor. The code system to be used is defined by the study sponsor.

Substance Use Sub-Category

Value Set	Substance Use Sub-Category - locally defined
Code System	Substance Use Sub-Category Type - locally defined
Description	A record of the list of substance use sub-categories that may be reported on within a subject data report. The value set is drawn from a locally defined code system. In practice, the code system and value set are likely to be identical.

Substance Use Sub-Category Type

Value Set	Substance Use Sub-Category Type
Description	A list of sub-categories used for organizing substance uses. The code system to be used is defined by the study sponsor.

Supplemental Value Set

Value Set	Supplemental Value Set - locally defined
Code System	Supplemental Value Type - locally defined

Description	A record of different types of supplemental value that may be reported on within a subject data report. The value set is drawn from a locally defined code system. In practice, the code system and value set are likely to be identical.

Supplemental Value Type

Value Set	Supplemental Value Type
Description	The collection of data item types which are defined to serve as supplemental values. The supplemental values are usd to provide additional data for a finding, event, or intervention that goes beyond existing domain definitions. The code system to be used is defined by the study sponsor.

Test Method Type

Value Set	Test Method Type - C85492
Code System	NCI Thesaurus - 2.16.840.1.113883.3.26.1.1
Source	NCI Thesaurus
Source URL	http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/fda
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 - CXXXXX
Code System	NCI Thesaurus - 2.16.840.1.113883.3.26.1.1
Source	NCI EVS
Source URL	http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/fda
Description	A list of possible values for toxicity grade that is appropriate for a toxicity measure. We need an code that is not domain specific.

Toxicity Measure Type

Value Set	Toxicity Measure Type - CXXXXX
Code System	NCI Thesaurus - 2.16.840.1.113883.3.26.1.1
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. IS this in EVS?

Tumor Examination Set

Value Set	Tumor Examination Set - locally defined
Code System	Tumor Examination Type - unknown

Description	A record of different types of tumor examination that may be reported on within a subject data report. The value set is drawn from a locally defined code system. In practice, the code system and value set are likely to be identical.

Tumor Examination Type

Value Set	Tumor Examination Type
Description	A collection of the different measurements, tests or examinations whose findings are reported as tumor finding results. Is there a standard set? If no satisfactory generally accepted code system is recognized, the code system to be used is defined by the study sponsor.The code system to be used is defined by the study sponsor.

Unit of Measure

Value Set	Unit of Measure - C71620
Code System	NCI Thesaurus - 2.16.840.1.113883.3.26.1.1
Source	NCI EVS
Source URL	http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/fda
Description	A unit that provides meaning to a measurement of a physical quantity.

Visit Classification

Value Set	Visit Classification - CXXXXX
Code System	NCI Thesaurus - 2.16.840.1.113883.3.26.1.1
Source	NCI EVS
Source URL	http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/fda
Description	A collection of the different visit types that may be defined for a study subject.

Concept Code	Concept Name	Code System	Description
C78802	Abnormal	NCI Thesaurus	
C78800	High	NCI Thesaurus	
78801	Low	NCI Thesaurus	
78727	Normal	NCI Thesaurus	
CXXXXX	Baseline Value	NCI Thesaurus	
CXXXXX	Derived Value	NCI Thesaurus	

Concept Code	Concept Name	Code System	Description
CXXXXX	Excluded value	NCI Thesaurus	

Vital Sign

Value Set	Vital Sign - C66741
Code System	NCI Thesaurus - 2.16.840.1.113883.3.26.1.1
Source	NCI EVS
Source URL	http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/fda
Description	A record of different types of supplemental value that may be reported on within a subject data report.

REFERENCES

- Bunker Allyson Weaver, Ramakrishnan, Rama. User Documentation For MDHT Runtime APIs, 2011 Available at: *www.projects.openhealthtools.org*
- CDISC Submission Data Standards Team. Study Data Tabulation Model Implementation Guide: Human Clinical Trials. Available at: *www.CDISC.org*
- CDISC Standard for Exchange of Nonclinical Dat Team. Standard for Exchange of Nonclinical Data Implementation Guide: Nonclinical Studies. 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.*
- 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* .
- *LOINC®* : Logical Observation Identifiers Names and Codes, Regenstrief Institute.
- National Cancer Institute, Enterprise Vocabulary Services *EVS Enterprise Vocabulary Services*
- Extensible Markup Language, *www.w3.org/XML* .