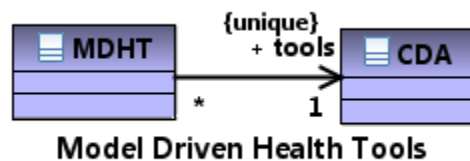


Implementation Guide for CDA Release 2

Subject Study Data

Human Clinical

Non-Human



FDA Draft Document
(Consolidated Developer Documentation)

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Acknowledgments

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

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Revision History

Rev	Date	By Whom	Changes
New	March 2012	Mead Walker	Create a draft document.
New	July 2012	Mead Walker	Update draft to include SDTM and SEND content in a single document.
New	August 2012	Mead Walker	Create independent SDTM and SEND documents. Update the content.

Chapter 1

INTRODUCTION

Topics:

- [Overview](#)
- [Overview](#)
- [Approach](#)
- [Approach](#)
- [Implementation Guide Structure](#)
- [Implementation Guide Structure](#)
- [Implementation Guide Scope](#)
- [Extending CDA](#)
- [Audience](#)
- [Organization of This Guide](#)
- [Use of Templates](#)
- [Use of Templates](#)
- [Conventions Used in This Guide](#)

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.

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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.

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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, and will only contain content associated with other domains if domain data is nested within a containing domain. The content of 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.
- **General Section :** The general section is provided to allow the creation of custom domains. The implementation guide provides Study Subject Event, Study Subject Finding, and Study Subject Intervention templates to be used for the creation of custom 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.

Implementation Guide Structure

The Non-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 SEND Implementation Guide. Each section is rooted in a single SEND domain, and will only contain content associated with other domains if domain data is nested within a containing domain. The content of 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 SEND. There are also entry types that represent data structures within SEND that are reused across the various domains.

Note: In addition to supporting the domains that have been defined for SEND, 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, 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 header for a non-human trial includes identification of the document subject. Within this type of trial, that subject may be an individual subject, or may be a group of subjects identified with a pool ID. When a pool id is used – when the study subject is a group – the Demographics section must contain information that defines the membership of the study pool.

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 SEND Implementation Guide. The reader will

note that, while the SEND and SDTM 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 SEND and SDTM 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. If a pool is listed as the document subject, it also contains a template based on the Pool ID domain.
- **Exposure Section:** Information on use of the study substance. The section contains a template based on the Exposure domain.
- **Disposition Section:** The section draws on the named domain.
- **Body Weight Gain Section:** The section draws on the named domain.
- **Clinical Observation Section:** The section draws on the named domain.
- **Death Diagnosis Section:** The section draws on the named domain.
- **Food and Water Consumption Section:** The section draws on the named domain.
- **Laboratory Test Result Section:** The section draws on the named domain.
- **Microscopic Finding Section:** The section draws on the named domain.
- **Macroscopic Finding Section:** The section draws on the named domain.
- **Organ Measurement Section:** The section draws on the named domain.
- **Palpable Mass Section:** The section draws on the named domain.
- **Pharmacokinetic Concentration Finding Section:** The section draws on the named domain.
- **Pharmacokinetic Parameter Finding Section:** The section draws on the named domain.
- **Subject Characteristic Section:** The section draws on the named domain.
- **Tumor Finding Section:** The section draws on the named domain.
- **Vital Sign Section:** The section draws on the named domain.
- **ECG Test Result 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.
- **General Section :** The general section is provided to allow the creation of custom domains. The implementation guide provides Study Subject Event, Study Subject Finding, and Study Subject Intervention templates to be used for the creation of custom domains.

Review of the Implementation Guide will show a number of templates not based on SEND 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.

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.

Working with the HL7 data structures

Any CDA document – and the subject data report is a CDA document – makes use of data structures defined in the HL7 RIM and in the HL7 data type specifications. Implementing and working with these 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 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.
- 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.
- 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.
- 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.

- 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). Specifics are discussed 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 assignments 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.

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 `templateIds` 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 `templateIds`).

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Within this Implementation Guide, we have created a template data structure corresponding to each of the domains defined within the SEND 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 SEND 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.

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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:

- [*Subject Data Human Clinical Trials*](#)
- [*Subject Data Non-Clinical Trials*](#)

This section those templates used to define documents conformant to the implementation guide. Currently, only a single document type has been defined - the Human Subject Data Report.

Subject Data Human Clinical Trials

[ClinicalDocument: templateId 2.16.840.1.113883.10.20.23.11]

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

1. **SHALL** contain exactly one [1..1] **@classCode**= "DOCCLIN" (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass)
2. **SHALL** contain exactly one [1..1] **@moodCode**= "EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **MAY** contain zero or one [0..1] **realmCode**
 - Identifies a country or other administrative unit that has defined particular rules for the format or content of the clinical document.
4. Contains exactly one [1..1] **typeId** with data type *Infrastructure Root Type Id*
5. **SHALL** contain exactly one [1..1] **id**
 - The identifier assigned to the subject data report. It is needed to uniquely identify a particular report of subject data from a study.
6. **SHALL** contain exactly one [1..1] **code/@code**= "TBD" (CodeSystem: 2.16.840.1.113883.6.1 LOINC)
 - The code value identifies the document as a human clinical subject data report.
7. **SHALL** contain exactly one [1..1] **effectiveTime**
 - The effective date for the contents of the document.
8. **SHOULD** contain exactly one [1..1] **confidentialityCode**, where the **@code** **SHALL** be selected from (CodeSystem: 2.16.840.1.113883.5.25 Confidentiality)
 - Documents the confidentiality level of the document.
9. **MAY** contain zero or one [0..1] **languageCode**
 - The language used for the document. The entry may be left out, if the language used is English.
10. **SHALL** contain exactly one [1..1] **setId**
 - An identifier that remains consistent across all revisions derived from a common original. In the first version of the document - VersionNumber = 1, setId and id will be identical.
11. **SHALL** contain exactly one [1..1] **versionNumber**
 - A unique identifier for a version of a report.
12. Contains exactly one [1..1] **component**, where its type is *Component2*
13. **SHALL** contain exactly one [1..1] **documentationOf**

Identifies the study the subject data report is associated with.

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

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

The identifier of the study. [SDTM: STUDYID]

14. **SHALL** contain exactly one [1..1] **author**

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"**
- b. This author **SHALL** contain exactly one [1..1] **assignedAuthor**
 - a. This assignedAuthor **SHALL** contain exactly one [1..1] **@classCode= "ASSIGNED"**
 - b. This assignedAuthor **SHALL** contain exactly one [1..1] **id**

An identifier for the investigator who is responsible for the document. [SDTM: INVID]

- c. This assignedAuthor **SHALL** contain exactly one [1..1] **assignedPerson**
 - a. This assignedPerson **SHALL** contain exactly one [1..1] **@classCode= "PSN"**
 - b. This assignedPerson **SHALL** contain exactly one [1..1] **@determinerCode= "INSTANCE"**
 - c. This assignedPerson **SHALL** contain exactly one [1..1] **name**

The name of the investigator. [SDTM: INVNAM]

- d. This assignedAuthor **SHALL** contain exactly one [1..1] **representedOrganization**
 - a. This representedOrganization **SHALL** contain exactly one [1..1] **@classCode= "ORG"**
 - b. This representedOrganization **SHALL** contain exactly one [1..1] **@determinerCode= "INSTANCE"**
 - c. This representedOrganization **SHALL** contain exactly one [1..1] **addr**

The only part of the address that is required is the country. This records the country of the investigational site associated with the subject's participation in the study. [SDTM: COUNTRY]

- d. This representedOrganization **SHALL** contain exactly one [1..1] **id**

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

15.SHALL contain exactly one [1..1] **custodian**

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"**
- b. This custodian **SHALL** contain exactly one [1..1] **assignedCustodian**
 - a. This assignedCustodian **SHALL** contain exactly one [1..1] **@classCode= "ASSIGNED"**
 - b. This assignedCustodian **SHALL** contain exactly one [1..1] **representedCustodianOrganization**
 - a. This representedCustodianOrganization **SHALL** contain exactly one [1..1] **@classCode= "ORG"**
 - b. This representedCustodianOrganization **SHALL** contain exactly one [1..1] **@determinerCode= "INSTANCE"**
 - c. This representedCustodianOrganization **SHALL** contain exactly one [1..1] **id**

An identifier for the custodial organization - the study sponsor.

- d. This representedCustodianOrganization **SHALL** contain exactly one [1..1] **name**

The name of the custodial organization - the study sponsor.

16.SHALL contain exactly one [1..1] **recordTarget**

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"**
- b. This recordTarget **SHALL** contain exactly one [1..1] **patientRole**
 - a. This patientRole **SHALL** contain exactly one [1..1] **@classCode= "PAT"**
 - b. This patientRole **SHALL** contain [2..2] **id**

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

- c. This patientRole **SHALL** contain exactly one [1..1] **patient**
 - a. This patient **SHALL** contain exactly one [1..1] **@classCode**= "PSN"
 - b. This patient **SHALL** contain exactly one [1..1] **@determinerCode**= "INSTANCE"
 - c. This patient **SHALL** contain exactly one [1..1] **administrativeGenderCode**, where the @code **SHALL** be selected from ValueSet [Sex](#) C66731 **STATIC**
[SDTM: SEX]
 - d. This patient **MAY** contain zero or one [0..1] **birthTime**
The date of the study subject's birth. [SDTM: BRTHDTC]
 - e. This patient **SHOULD** contain zero or one [0..1] **ethnicGroupCode**, where the @code **SHALL** be selected from ValueSet [Ethnic Group](#) C66790 **STATIC**
[SDTM: ETHNIC]
 - f. This patient **SHOULD** contain zero or one [0..1] **raceCode**, where the @code **SHALL** be selected from ValueSet [Race](#) C74457 **STATIC**
[SDTM: RACE]
- d. This patientRole **SHALL** satisfy: The unique subject ID shall be present. [SDTM, USUBJID].
- e. This patientRole **SHALL** satisfy: Shall include an identifier for the subject within the study. [SDTM, SUBJID].

17. SHALL contain zero or one [0..1] **component**

- a. Contains exactly one [1..1] [Human Clinical Subject Data Document Section](#) (templateId: 2.16.840.1.113883.10.20.23.13)
- Provides an association to the subject of the report.

Subject Data Non-Clinical Trials

[ClinicalDocument: templateId 2.16.840.1.113883.10.20.23.12]

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

1. **SHALL** contain exactly one [1..1] **@classCode**= "DOCCLIN" (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass)
2. **SHALL** contain exactly one [1..1] **@moodCode**= "EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **MAY** contain zero or one [0..1] **realmCode**
 - Identifies a country or other administrative unit that has defined particular rules for the format or content of the clinical document.
4. Contains exactly one [1..1] **typeId** with data type [Infrastructure Root Type Id](#)
5. **SHALL** contain exactly one [1..1] **id**
 - The identifier assigned to the subject data report. It is needed to uniquely identify a particular report of subject data from a study.
6. **SHALL** contain exactly one [1..1] **code/@code**= "TBD" (CodeSystem: 2.16.840.1.113883.6.1 LOINC)
7. **SHALL** contain exactly one [1..1] **effectiveTime**
 - The effective date for the contents of the document.
8. **SHOULD** contain exactly one [1..1] **confidentialityCode**, where the @code **SHALL** be selected from (CodeSystem: 2.16.840.1.113883.5.25 Confidentiality)

- Documents the confidentiality level of the document.
- 9. **MAY** contain zero or one [0..1] **languageCode**
 - The language used for the document. The entry may be left out, if the language used is English.
- 10. **SHALL** contain exactly one [1..1] **setId**
 - An identifier that remains consistent across all revisions derived from a common original. In the first version of the document - VersionNumber = 1, setId and id will be identical.
- 11. **SHALL** contain exactly one [1..1] **versionNumber**
 - A unique identifier for a version of a report.
- 12. Contains exactly one [1..1] **component**, where its type is *Component2*
- 13. **SHALL** contain exactly one [1..1] **documentationOf**

Identifies the study the subject data report is associated with.

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

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

The identifier of the study. [SDTM: STUDYID]

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

A required CDA association - it identifies the non-person living subject, or subject pool, which is the subject of the study data report.

- a. This recordTarget **SHALL** contain exactly one [1..1] **@typeCode="RCT"**
- b. This recordTarget **SHALL** contain exactly one [1..1] **patientRole**
 - a. This patientRole **SHALL** contain exactly one [1..1] **@classCode="PAT"**
 - b. This patientRole **SHALL** contain [2..2] **id**

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

- c. This patientRole **SHALL** contain exactly one [1..1] **patient**
 - a. This patient **SHALL** contain exactly one [1..1] **@classCode="PSN"**
 - b. This patient **SHALL** contain exactly one [1..1] **@determinerCode="INSTANCE"**
 - c. This patient **SHALL** contain exactly one [1..1] **administrativeGenderCode**, where the @code **SHALL** be selected from ValueSet *Sex* C66731 **STATIC**

[SDTM: SEX]

- d. This patient **MAY** contain zero or one [0..1] **birthTime**

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

- e. This patient **SHOULD** contain zero or one [0..1] **ethnicGroupCode**, where the @code **SHALL** be selected from ValueSet *Ethnic Group* C66790 **STATIC**

[SDTM: ETHNIC]

- f. This patient **SHOULD** contain zero or one [0..1] **raceCode**, where the @code **SHALL** be selected from ValueSet *Race* C74457 **STATIC**

[SDTM: RACE]

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

15. SHALL contain at least one [1..*] **component**

- a. Contains exactly one [1..1] *Non-human Subject Data Document Section* (templateId: 2.16.840.1.113883.10.20.23.14)

16. SHALL contain exactly one [1..1] **custodian**

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"
- b. This custodian Contains exactly one [1..1] **assignedCustodian** with data type *Assigned Custodian*

17. SHALL contain exactly one [1..1] **author**

A required CDA association - it identifies the person responsible for the content of the subject data report.

- a. This author **SHALL** contain exactly one [1..1] **@typeCode**= "AUT"
- b. This author **SHALL** contain exactly one [1..1] **assignedAuthor**
 - a. This assignedAuthor **SHALL** contain exactly one [1..1] **@classCode**= "ASSIGNED"
 - b. This assignedAuthor **SHALL** contain exactly one [1..1] **id**

An identifier for the investigator responsible for the document. [SDTM: INVID]

- c. This assignedAuthor **SHALL** contain exactly one [1..1] **assignedPerson**
 - a. This assignedPerson **SHALL** contain exactly one [1..1] **@classCode**= "PSN"
 - b. This assignedPerson **SHALL** contain exactly one [1..1] **@determinerCode**= "INSTANCE"
 - c. This assignedPerson **SHALL** contain zero or one [0..1] **name**

The name of the investigator. [SDTM: INVNAM].

- d. This assignedAuthor **SHALL** contain exactly one [1..1] **representedOrganization**
 - a. This representedOrganization **SHALL** contain zero or one [0..1] **@classCode**= "ORG"
 - b. This representedOrganization **SHALL** contain zero or one [0..1] **@determinerCode**= "INSTANCE"
 - c. This representedOrganization **SHALL** contain exactly one [1..1] **id**

Contains the identifier of the study site for the investigator. [SDTM: SITEID].

- d. This representedOrganization **SHALL** contain exactly one [1..1] **addr**

The only part of the address that is required is the country. This records the country of the investigational site associated with the subject's participation in the study. [SDTM: COUNTRY].

- e. This representedOrganization **SHALL** satisfy: Country shall be valued where addressPartType="country".

Subject Data Non-Clinical Trials example

```
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
  xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <realmCode code="Code forrealmCode"/>
  <typeId root="2.16.840.1.113883.1.3"/>
  <templateId root="2.16.840.1.113883.10.20.23.12"/>
  <id root="832181081" extension="MDHT"/>
  <code code="TBD" codeSystem="2.16.840.1.113883.6.1"/>
  <title>TEXT FOR TITLE</title>
  <effectiveTime/>
  <confidentialityCode codeSystem="2.16.840.1.113883.5.25"
    codeSystemName="Confidentiality"/>
  <languageCode code="Code forlanguageCode"/>
  <setId root="182715b9-d02e-4afd-bac6-c388f55b4511" extension="MDHT"/>
  <versionNumber value="1"/>
```

```
<recordTarget typeCode="RCT">
  <patientRole classCode="PAT"/>
</recordTarget>
<author typeCode="AUT">
  <time/>
  <assignedAuthor classCode="ASSIGNED"/>
</author>
<custodian typeCode="CST"/>
<documentationOf typeCode="DOC">
  <serviceEvent classCode="ACT" moodCode="EVN"/>
</documentationOf>
<component>
  <structuredBody>
    <component>
      <section/>
    </component>
  </structuredBody>
</component>
</ClinicalDocument>
```

Chapter

3

SECTION TEMPLATES

Topics:

- [*Human Clinical Subject Data Document Section*](#)
- [*Non-human Subject Data Document Section*](#)

This section contains templates used to describe the different document sections used within compliant documents. Only a single section type has been defined, the difference between sections is based on the content based, "clinical statement" template that is its primary content.

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 recommended that, with the exception 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)
2. **SHALL** contain zero or one [0..1] **@moodCode**= "EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **code/@code**= "HUSTbd" (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)
 - A code to indicate the nature of the section. This code should indicate the primary domain association for the section.
4. **SHALL** contain exactly one [1..1] **text**
 - A text representation of the structured content within the section.
5. **MAY** contain zero or one [0..1] **entry**
 - a. Contains exactly one [1..1] *Human Clinical Subject Demographics* (templateId: 2.16.840.1.113883.10.20.23.46)
 - The section may include a record based on the defined template. It should also include a record based on the study arm template.
6. **SHOULD** contain zero or more [0..*] **entry**
 - a. Contains exactly one [1..1] *Subject Element* (templateId: 2.16.840.1.113883.10.20.23.93)
 - The section may include one or many records based on the defined template.
7. **SHOULD** contain zero or more [0..*] **entry**
 - a. Contains exactly one [1..1] *Visit* (templateId: 2.16.840.1.113883.10.20.23.100)
 - The section may include one or many records based on the defined template.
8. **MAY** contain zero or more [0..*] **concomitantMedicationAssociation**
 - a. Such concomitantMedicationAssociations **SHALL** contain exactly one [1..1] **@typeCode**= "COMP"
 - b. Such concomitantMedicationAssociations **SHALL** contain exactly one [1..1] **substanceAdministration**, where its type is *Concomitant Medication*
 - a. Contains exactly one [1..1] *Concomitant Medication* (templateId: 2.16.840.1.113883.10.20.25.24)
9. **MAY** contain zero or more [0..*] **entry**

The section may include one or many records based on the defined template.

 - a. Such entries **SHALL** contain exactly one [1..1] **@typeCode**= "COMP"
 - b. Such entries **SHALL** contain exactly one [1..1] **substanceAdministration**, where its type is *Human Clinical Exposure*
 - a. Contains exactly one [1..1] *Human Clinical Exposure* (templateId: 2.16.840.1.113883.10.20.23.44)
10. **MAY** contain zero or more [0..*] **substanceUseAssociation**
 - a. Such substanceUseAssociations **SHALL** contain exactly one [1..1] **@typeCode**= "COMP"

- 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)

11.MAY contain zero or more [0..*] **entry**

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

- The section may include one or many records based on the defined template.

12.SHOULD contain zero or more [0..*] **entry**

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

- The section may include one or many records based on the defined template.

13.SHOULD contain zero or more [0..*] **entry**

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

- The section may include one or many records based on the defined template.

14.MAY contain zero or more [0..*] **entry**

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

- The section may include one or many records based on the defined template.

15.MAY contain zero or more [0..*] **entry**

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

- The section may include one or many records based on the defined template.

16.MAY contain zero or more [0..*] **entry**

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

- The section may include one or many records based on the defined template.

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

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

- The section may include one or many records based on the defined template.

18.MAY contain zero or more [0..*] **entry**

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

- The section may include one or many records based on the defined template.

19.MAY contain zero or more [0..*] **entry**

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

- The section may include one or many records based on the defined template.

20.MAY contain zero or more [0..*] **entry**

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

- The section may include one or many records based on the defined template.

21.MAY contain zero or more [0..*] **entry**

- a. Contains exactly one [1..1] *Comment* (templateId: 2.16.840.1.113883.10.20.23.23)

- The section may include one or many records based on the defined template.

22.MAY contain zero or more [0..*] **entry**

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

- The section may include general findings for the report.

Non-human Subject Data Document Section

[Section: templateId 2.16.840.1.113883.10.20.23.14]

The document is divided into sections as defined by the user. It is recommended that each section contain a single type of the possible listed templates. In the case of pharmacokinetic concentration, this allows for inclusion of data from the pharmacokinetic parameters domain. Comments, related records and supplemental qualifiers may be added to any domain. The user is also free to create custom sections based on use of the included generic templates: Study Subject Finding, Study Subject Event, Study Subject Intervention.

1. **SHALL** contain zero or one [0..1] **@classCode**= "DOCSECT" (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass)
2. **SHALL** contain zero or one [0..1] **@moodCode**= "EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain zero or one [0..1] **code/@code**= "NHStbd" (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)
 - A code to indicate the nature of the section. This code should indicate the primary domain association for the section.
4. **SHALL** contain exactly one [1..1] **text**
 - A text representation of the structured content within the section.
5. **SHALL** contain zero or one [0..1] **entry**
 - a. Contains exactly one [1..1] *Non-human Subject Demographics* (templateId: 2.16.840.1.113883.10.20.23.60)
6. **MAY** contain zero or one [0..1] **entry**
 - a. Contains exactly one [1..1] *Non-human Disposition* (templateId: 2.16.840.1.113883.10.20.23.57)
7. **MAY** contain zero or more [0..*] **entry**
 - a. Contains exactly one [1..1] *Subject Element* (templateId: 2.16.840.1.113883.10.20.23.93)
8. **MAY** contain zero or more [0..*] **entry**
 - a. Contains exactly one [1..1] *Non-human Exposure* (templateId: 2.16.840.1.113883.10.20.23.58)
9. **MAY** contain zero or more [0..*] **entry**
 - a. Contains exactly one [1..1] *Body Weight* (templateId: 2.16.840.1.113883.10.20.23.18)
10. **MAY** contain zero or more [0..*] **entry**
 - a. Contains exactly one [1..1] *Body Weight Gain* (templateId: 2.16.840.1.113883.10.20.23.19)
11. **MAY** contain zero or more [0..*] **entry**
 - a. Contains exactly one [1..1] *Clinical Observation* (templateId: 2.16.840.1.113883.10.20.23.22)
12. **MAY** contain zero or one [0..1] **entry**
 - a. Contains exactly one [1..1] *Death Diagnosis* (templateId: 2.16.840.1.113883.10.20.23.28)
13. **MAY** contain zero or more [0..*] **entry**
 - a. Contains exactly one [1..1] *Food and Water Consumption* (templateId: 2.16.840.1.113883.10.20.23.41)
14. **MAY** contain zero or more [0..*] **entry**
 - a. Contains exactly one [1..1] *Non-human Laboratory Test Result* (templateId: 2.16.840.1.113883.10.20.23.59)
15. **MAY** contain zero or more [0..*] **entry**
 - a. Contains exactly one [1..1] *Macroscopic Finding* (templateId: 2.16.840.1.113883.10.20.23.50)

16. MAY contain zero or more [0..*] **entry**

- a. Contains exactly one [1..1] *Microscopic Finding* (templateId: 2.16.840.1.113883.10.20.23.55)

17. MAY contain zero or more [0..*] **entry**

- a. Contains exactly one [1..1] *Organ Measurement* (templateId: 2.16.840.1.113883.10.20.23.62)

18. MAY contain zero or more [0..*] **entry**

- a. Contains exactly one [1..1] *Palpable Mass* (templateId: 2.16.840.1.113883.10.20.23.64)

19. MAY contain zero or more [0..*] **entry**

- a. Contains exactly one [1..1] *Pharmacokinetic Concentration Finding* (templateId: 2.16.840.1.113883.10.20.23.65)

20. MAY contain zero or more [0..*] **entry**

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

21. MAY contain zero or more [0..*] **entry**

- a. Contains exactly one [1..1] *Tumor Finding* (templateId: 2.16.840.1.113883.10.20.23.99)

22. MAY contain zero or more [0..*] **entry**

- a. Contains exactly one [1..1] *Vital Sign* (templateId: 2.16.840.1.113883.10.20.23.101)

23. MAY contain zero or more [0..*] **entry**

- a. Contains exactly one [1..1] *ECG Test Result* (templateId: 2.16.840.1.113883.10.20.23.33)

24. MAY contain zero or more [0..*] **entry**

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

25. MAY contain zero or more [0..*] **entry**

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

26. MAY contain zero or more [0..*] **entry**

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

27. MAY contain zero or more [0..*] **entry**

- a. Contains exactly one [1..1] *Comment* (templateId: 2.16.840.1.113883.10.20.23.23)

28. MAY contain zero or more [0..*] **entry**

- a. Contains exactly one [1..1] *Pharmacokinetic Parameter Finding* (templateId: 2.16.840.1.113883.10.20.23.66)

29. MAY contain zero or one [0..1] **entry**

- a. Contains exactly one [1..1] *Subject Pool* (templateId: 2.16.840.1.113883.10.20.23.94)
 - Information about the pool which is the subject of the report. The pool identifies the collection of subjects that is the target of the findings, events, and interventions recorded in the report.

Chapter

4

CLINICAL STATEMENT TEMPLATES

Topics:

- [*Adverse Event*](#)
- [*Assay Quantitation*](#)
- [*Body System or Organ Class*](#)
- [*Category*](#)
- [*Clinical Event*](#)
- [*Comment*](#)
- [*Concomitant Medication*](#)
- [*Concomitant Treatment*](#)
- [*Data Collection*](#)
- [*Domain Assignment*](#)
- [*Dose Adjustment Reason*](#)
- [*Drug Accountability*](#)
- [*ECG Test Result*](#)
- [*Event Duration*](#)
- [*Event or Finding Severity*](#)
- [*Event Outcome*](#)
- [*Event Pattern*](#)
- [*Event Study Day*](#)
- [*Fasting Status*](#)
- [*Finding About*](#)
- [*Group Identifier*](#)
- [*Human Clinical Disposition*](#)
- [*Human Clinical Exposure*](#)
- [*Human Clinical Laboratory Test Result*](#)
- [*Human Clinical Subject Demographics*](#)
- [*Inclusion or Exclusion Criteria Not Met*](#)
- [*Indication*](#)
- [*Intended Regimen*](#)
- [*Medical History Item*](#)
- [*Microbiology Specimen Finding*](#)
- [*Microbiology Susceptibility*](#)
- [*Non Performance Reason*](#)

This section of the Implementation Guide details the bulk of the templates used to model document entries those 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*
- *Assay Quantitation*
- *Body System or Organ Class*
- *Body Weight*
- *Body Weight Gain*
- *Category*
- *Clinical Observation*
- *Comment*
- *Data Collection*
- *Death Diagnosis*

- *Death Relationship*
- *Domain Assignment*
- *Dose Adjustment Reason*
- *Drug Accountability*
- *ECG Test Result*
- *Event Duration*
- *Event or Finding Severity*
- *Event Outcome*
- *Event Pattern*
- *Event Study Day*
- *Exclusion Reason*
- *Fasting Status*
- *Finding About*
- *Food and Water Consumption*
- *Group Identifier*
- *Indication*
- *Intended Regimen*
- *Macroscopic Finding*
- *Medical History Item*
- *Microscopic Finding*
- *Non Performance Reason*
- *Non-Study Treatment Relationship*
- *Non-Human Disposition*
- *Non-Human Exposure*
- *Non-Human Laboratory Test Result*
- *Non-human Subject Demographics*
- *Organ Measurement*
- *Other Treatment Action Taken*
- *Palpable Mass*
- *Pharmacokinetic Concentration Finding*
- *Pharmacokinetic Parameter Finding*
- *Physical Examination Finding*
- *Planned Study Day*
- *Position of Subject*
- *Pre-Specified Event*
- *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*
- *Subject Pool*
- *Supplemental Value*
- *Timing Reference*
- *Toxicity*
- *Tumor Finding*
- *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 occurred 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. Contains exactly one [1..1] **@classCode**="OBS" *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass)
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain [1..3] **id**
 - 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/@code**="C49562" *Adverse Event - Reported* (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)
 - The code value indicates that this observation is an adverse event.
5. **SHOULD** contain zero or one [0..1] **effectiveTime**
 - Used to capture the start date/time of the adverse event, its end date/time, and/or its duration. 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 recommended 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
 - The adverse event information. The adverse 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. [SDTM: AETERM, AEMODIFY, AEDECOD]
7. **MAY** contain zero or one [0..1] **targetSiteCode**, where the @code **SHALL** be selected from ValueSet *Anatomical Location* C74456 **STATIC**
 - The anatomic location that is relevant for the adverse event. [SDTM: AELOC]
8. **SHALL** contain exactly one [1..1] **entryRelationship**
 - a. Contains **@typeCode**="REFR" *REFR*
 - b. Contains exactly one [1..1] *Domain Assignment* (templateId: 2.16.840.1.113883.10.20.23.30)
 - Indicates the domain assignment for the event.
9. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode**="COMP" *COMP*
 - b. Contains exactly one [1..1] *Pre-Specified Event* (templateId: 2.16.840.1.113883.10.20.23.70)
 - Indicates whether the type of adverse event that is being reported was prespecified on the CRF.
10. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode**="COMP" *COMP*
 - b. Contains exactly one [1..1] *Group Identifier* (templateId: 2.16.840.1.113883.10.20.23.42)
 - Allows capture of a group identifier for the adverse event.
11. **SHOULD** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode**="COMP" *COMP*

b. Contains exactly one [1..1] *Serious Event* (templateId: 2.16.840.1.113883.10.20.23.77)

- 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.

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

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)

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

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

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

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

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

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

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)

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

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

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)

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

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

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

b. Contains exactly one [1..1] *Study Treatment Causality* (templateId: 2.16.840.1.113883.10.20.23.90)

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

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

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)

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

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

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

b. Contains exactly one [1..1] *Event Pattern* (templateId: 2.16.840.1.113883.10.20.23.36)

- Records the pattern of an adverse event.

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

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

b. Contains exactly one [1..1] *Event Outcome* (templateId: 2.16.840.1.113883.10.20.23.35)

- Information on the outcome of an adverse event.

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

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

- b. Contains exactly one [1..1] *Concomitant Treatment* (templateId: 2.16.840.1.113883.10.20.25.25)
 - A record of whether a treatment (aside from the study treatment) was provided as a result of the adverse event.
- 21. MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Toxicity* (templateId: 2.16.840.1.113883.10.20.23.98)
 - A record of the toxicity of the adverse event.
- 22. MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Event Duration* (templateId: 2.16.840.1.113883.10.20.23.102)
 - Records the duration of an event in cases in which this cannot be derived from existing start and stop information.
- 23. MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="REFR"** *REFR*
 - b. Contains exactly one [1..1] *Study Day Period* (templateId: 2.16.840.1.113883.10.20.23.82)
 - Captures information about the study days coincident with the start and stop of the adverse event.
- 24. MAY** contain zero or one [0..1] **entryRelationship**
 - 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)
 - Allows positioning of the start of the adverse event with relationship to a defined reference time period.
- 25. MAY** contain zero or one [0..1] **entryRelationship**
 - 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)
 - Allows positioning of the end of the adverse event with relationship to a defined reference time period.
- 26. MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Category* (templateId: 2.16.840.1.113883.10.20.23.20)
 - The record of a category to be used in organizing adverse events.
- 27. MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Sub-Category* (templateId: 2.16.840.1.113883.10.20.23.91)
 - The record of a sub-category to be used in organizing adverse events.
- 28. MAY** contain zero or more [0..*] **entryRelationship**
 - a. Contains **@typeCode="REFR"** *REFR*
 - b. Contains exactly one [1..1] *Related Record* (templateId: 2.16.840.1.113883.10.20.23.75)
 - A way to provide a link between the adverse event record and another record situated within this or another domain.
- 29. MAY** contain zero or more [0..*] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Supplemental Value* (templateId: 2.16.840.1.113883.10.20.23.96)
 - Allows the association of a supplemental value - outside of the content specified for the domain - to the record.
- 30. MAY** contain zero or more [0..*] **entryRelationship**

- a. Contains **@typeCode="COMP"** *COMP*
- b. Contains exactly one [1..1] *Comment* (templateId: 2.16.840.1.113883.10.20.23.23)
 - A place to insert comments related to a particular adverse event.

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

- a. Contains **@typeCode="COMP"** *COMP*
- b. Contains exactly one [1..1] *Finding About* (templateId: 2.16.840.1.113883.10.20.23.40)
 - Allows recording of additional findings related to the adverse event.

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="1022502025" 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="2044145414"/>
  <targetSiteCode code="1558638939"/>
  <entryRelationship>
    <act classCode="ACT">
      <templateId root="2.16.840.1.113883.10.20.23.42"/>
      <id root="1697356081" 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/>
  </entryRelationship>
  <entryRelationship>
    <observation>
      <id root="1368489231" extension="MDHT"/>
      <code code="1079685206"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <value xsi:type="IVL_INT" value="1"/>
      <targetSiteCode code="1658101692"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation>
      <templateId root="2.16.840.1.113883.10.20.23.30"/>
      <id root="112788297" 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="800023052"/>
    <targetSiteCode code="1674052636"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <observation classCode="OBS" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.23.23"/>
    <id root="1671362241" 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="2112339319"/>
    <participant/>
    <entryRelationship/>
  </observation>
</entryRelationship>
<entryRelationship>
  <act classCode="ACT">
    <templateId root="2.16.840.1.113883.10.20.23.75"/>
    <id root="1877794352" 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="302207559" extension="MDHT"/>
    <code codeSystem="locally defined" codeSystemName="Supplemental Value
Type"/>
    <effectiveTime>
      <low value="2012"/>
      <high value="2012"/>
    </effectiveTime>
    <targetSiteCode code="1502490252"/>
    <participant/>
    <entryRelationship typeCode="COMP"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <observation/>
</entryRelationship>
<entryRelationship>
  <observation/>
</entryRelationship>
<entryRelationship>
  <observation>
    <id root="191194154" extension="MDHT"/>
    <code code="1745896843"/>
    <effectiveTime>

```

```

        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <value xsi:type="BL"/>
      <targetSiteCode code="1600969818"/>
      <entryRelationship typeCode="COMP"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.89"/>
      <id root="1917715734" 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="1500205302"/>
      <targetSiteCode code="1198682756"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation classCode="OBS">
      <templateId root="2.16.840.1.113883.10.20.23.63"/>
      <id root="928862459" 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="2111144350"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation>
      <id root="1146256313" 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="1569721222"/>
      <targetSiteCode code="1620711978"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation/>
  </entryRelationship>
  <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.36"/>
      <id root="1363201378" 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="501732183"/>
      <targetSiteCode code="269845037"/>
    </observation>
  </entryRelationship>

```

```

</entryRelationship>
<entryRelationship>
  <observation>
    <templateId root="2.16.840.1.113883.10.20.23.35"/>
    <id root="2040817762" 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="1491872682"/>
    <targetSiteCode code="1607351110"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <observation>
    <templateId root="2.16.840.1.113883.10.20.25.25"/>
    <id root="840810238" extension="MDHT"/>
    <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="Adverse Event Concomitant Treatment"/>
    <effectiveTime>
      <low value="2012"/>
      <high value="2012"/>
    </effectiveTime>
    <value xsi:type="BL"/>
    <targetSiteCode code="1057782746"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <observation classCode="OBS" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.23.98"/>
    <id root="81137920" 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="1933491938"/>
    <targetSiteCode code="1788509139"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <observation classCode="OBS" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.23.20"/>
    <id root="1322053071" 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="62918838"/>
    <targetSiteCode code="1637162961"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <observation/>
</entryRelationship>
<entryRelationship>
  <observation>
    <id root="1241944599" extension="MDHT"/>
    <code code="1703764056"/>
  </observation>

```

```

    <effectiveTime>
      <low value="2012"/>
      <high value="2012"/>
    </effectiveTime>
    <targetSiteCode code="641926132"/>
    <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="1337251426" 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="208118093"/>
    <targetSiteCode code="507019618"/>
  </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)
2. **SHALL** contain exactly one [1..1] **@moodCode**="DEF" (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **code/@code**="AQtbdl" (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)
 - The code value identifies this as an assay quantitation observation.
4. **SHALL** contain exactly one [1..1] **value** with data type IVL_PQ
 - Captures the lower limit of assay quantitation. Value as the low property of the IVL data type. The units of measure are expected to match those designated as the standard units for the result. [SDTM: PCLLOQ], [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="2014162191" extension="MDHT"/>
  <code code="53843989"/>
  <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 reusable 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)
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **code/@code**="C88026" *Body System or Organ Class* (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)
 - 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, where the **@code** **SHALL** be selected from ValueSet *Body System/Organ Class* C88026 **STATIC**
 - 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="218550721" 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="1080016604"/>
</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)
2. **SHALL** contain exactly one [1..1] **@moodCode**= "EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **code**, where the **@code** **SHALL** be selected from ValueSet *Subject Data Domain Category Type* CXXXXX **STATIC**
 - 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, where the **@code** **SHALL** be selected from
 - 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="161262686" 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="119426791"/>
</observation>
```

Clinical Event

[Observation: templateId 2.16.840.1.113883.10.20.23.21]

The template is based on the Clinical Event domain. It captures clinical events of interest that are not classified as adverse events. The data 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)
2. **SHALL** contain exactly one [1..1] **@moodCode="EVN"** *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain [1..3] **id**
 - A value that is provided to ensure the uniqueness of clinical event items. [SDTM: CESEQ, CEREFID, CESPID] A single identifier, the sequence number, is required.
4. **SHALL** contain exactly one [1..1] **code**, where the **@code** **SHALL** be selected from (CodeSystem: unknown Clinical Event Type)
 - The code value indicates that this observation records a clinical event.
5. **MAY** contain zero or one [0..1] **statusCode**
 - Used to indicate whether the activity - occurrence of the clinical event - did occur. Use statusCode "Completed" if the event occurred. [SDTM: CEOCCUR]
6. **MAY** contain zero or one [0..1] **effectiveTime**
 - 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]
7. **SHALL** contain exactly one [1..1] **value**
 - 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 text for the event. [SDTM: CETERM, CEDECOD]
8. **SHALL** contain exactly one [1..1] **entryRelationship**
 - a. Contains **@typeCode="REFR"** *REFR*
 - b. Contains exactly one [1..1] *Domain Assignment* (templateId: 2.16.840.1.113883.10.20.23.30)
 - Identifies the SDTM or SEND domain the record is assigned to.
9. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Data Collection* (templateId: 2.16.840.1.113883.10.20.23.27)
 - Carries information regarding the timing of data collection related to the clinical event.
10. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Pre-Specified Event* (templateId: 2.16.840.1.113883.10.20.23.70)
 - Indicates whether or not the event was prespecified on the CRF.
11. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Non Performance Reason* (templateId: 2.16.840.1.113883.10.20.23.56)

- Information on the reason the clinical event was not carried out.
- 12. MAY** contain zero or one [0..1] **entryRelationship**
- a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Body System or Organ Class* (templateId: 2.16.840.1.113883.10.20.23.17)
 - Indicates the body system or organ class associated with the clinical event.
- 13. MAY** contain zero or one [0..1] **entryRelationship**
- 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)
 - Captures information about the severity of the clinical event.
- 14. MAY** contain zero or one [0..1] **entryRelationship**
- 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)
 - Allows positioning of the start of the event with relationship to a defined reference time period.
- 15. MAY** contain zero or one [0..1] **entryRelationship**
- 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)
 - Allows positioning of the termination of the event with relationship to a defined reference time period.
- 16. MAY** contain zero or one [0..1] **entryRelationship**
- a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Category* (templateId: 2.16.840.1.113883.10.20.23.20)
 - The record of a category to be used in organizing information items.
- 17. MAY** contain zero or one [0..1] **entryRelationship**
- a. Contains exactly one [1..1] *Sub- Category* (templateId: 2.16.840.1.113883.10.20.23.91)
 - The record of a sub-category to be used in organizing information items.
- 18. MAY** contain zero or more [0..*] **entryRelationship**
- a. Contains **@typeCode="REFR"** *REFR*
 - b. Contains exactly one [1..1] *Related Record* (templateId: 2.16.840.1.113883.10.20.23.75)
 - Establishes a relationship between this record and another record.
- 19. MAY** contain zero or more [0..*] **entryRelationship**
- a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Supplemental Value* (templateId: 2.16.840.1.113883.10.20.23.96)
 - Allows the association of a supplemental value - outside of the content specified for the domain - to the record.
- 20. MAY** contain zero or more [0..*] **entryRelationship**
- a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Comment* (templateId: 2.16.840.1.113883.10.20.23.23)
 - A place to insert comments related to a particular finding.
- 21. MAY** contain zero or more [0..*] **entryRelationship**
- a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Finding About* (templateId: 2.16.840.1.113883.10.20.23.40)
 - Allows recording of additional findings related to the event.

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="786206417" extension="MDHT"/>
  <code codeSystem="unknown"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <entryRelationship>
    <observation/>
  </entryRelationship>
  <entryRelationship>
    <observation classCode="OBS">
      <templateId root="2.16.840.1.113883.10.20.23.56"/>
      <id root="1618209314" 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="2128209403"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation/>
  </entryRelationship>
  <entryRelationship>
    <act>
      <id root="1534955404" extension="MDHT"/>
      <code code="1290553160"/>
      <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="1361386576" 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>
<entryRelationship>
  <observation>
    <templateId root="2.16.840.1.113883.10.20.23.30"/>
    <id root="1728465528" 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="1205076666"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <act classCode="ACT">
    <templateId root="2.16.840.1.113883.10.20.23.75"/>
    <id root="750516756" 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="422231269" 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="442406294" 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="1571036300"/>
  </observation>
</entryRelationship>
<entryRelationship>

```

```

    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation>
      <id root="1530090926" extension="MDHT" />
      <code code="172844122" />
      <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 separately 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)

2. **SHALL** contain exactly one [1..1] **@moodCode**= "EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **id**
 - A sequence number for the comment. [SDTM: COSEQ], [SEND: COSEQ]
4. **SHOULD** contain exactly one [1..1] **code/@code**= "C49569" (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)
 - The code value indicates that this observation is a comment.
5. **MAY** contain zero or one [0..1] **effectiveTime**
 - The date time of the comment. [SDTM: CODTC], [SEND: CODTC]
6. **SHALL** contain exactly one [1..1] **value** with data type ED
 - The comment text. [SDTM: COVAL], [SEND: COVAL]
7. **SHOULD** contain zero or one [0..1] **participant**
 - a. Contains exactly one [1..1] *Study Finding Evaluator* (templateId: 2.16.840.1.113883.10.20.23.84)
 - The author of the comment.
8. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. This entryRelationship Contains exactly one [1..1] **@typeCode**
 - b. This entryRelationship Contains zero or one [0..1] **act**, where its type is CDA Act
 - c. This entryRelationship **SHALL** contain exactly one [1..1] **act**
 - a. This act **SHALL** contain exactly one [1..1] **@classCode**= "ACT" *Act* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass)
 - b. This act **SHALL** contain exactly one [1..1] **@moodCode**= "EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
 - c. This act **SHALL** contain exactly one [1..1] **code**

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="659673567" 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 concomitant and prior medications or therapies used by the study subject. Examples are concomitant 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)
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain [1..2] **id**
 - A sponsor supplied reference number for the concomitant medication. [SDTM: CMSEQ, CMSPID] A sequence number is required.
4. **MAY** contain zero or one [0..1] **text**
 - 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 insufficient to capture the dosing frequency. [SDTM: CMDOSTXT]
5. **SHOULD** contain zero or one [0..1] **statusCode**
 - Used to indicate whether the activity - use of a particular medication - did occur. Use statusCode "Completed" if the use occurred. [SDTM: CMOCCUR]
6. **MAY** contain zero or one [0..1] **effectiveTime**
 - Information on when and how often the concomitant 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 frequency. 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 effective time attribute is used to capture information regarding the start, stop, duration and frequency of use for the concomitant medication. There shall be Two SXPR components created. The first will be an interval of time stamps (IVL_TS) to address 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] **routeCode**
 - The route by which the medication is administered. [SDTM: CMROUTE]
8. **MAY** contain zero or one [0..1] **doseQuantity**
 - 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 quantities) to allow the entry of dose ranges instead of a single value. In the case where only a single value is needed, the instance can use PQ instead of IVL_PQ. [SDTM: CMDOSE, CMDOSU]
9. **MAY** contain zero or one [0..1] **maxDoseQuantity**
 - Information on the total daily dose of the medication. The structure also accommodates periods other than a day. Therefore 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.
10. **SHALL** contain exactly one [1..1] **entryRelationship**
 - a. Contains **@typeCode**="REFR" *REFR*

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

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

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

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

b. Contains exactly one [1..1] *Group Identifier* (templateId: 2.16.840.1.113883.10.20.23.42)

- Allows capture of a group identifier for the concomitant medication information.

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

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

b. Contains exactly one [1..1] *Data Collection* (templateId: 2.16.840.1.113883.10.20.23.27)

- 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.

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

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

b. Contains exactly one [1..1] *Non Performance Reason* (templateId: 2.16.840.1.113883.10.20.23.56)

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

14.SHALL contain exactly one [1..1] **consumable**

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

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

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

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

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

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

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

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

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

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

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

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

b. Contains exactly one [1..1] *Pre-Specified Event* (templateId: 2.16.840.1.113883.10.20.23.70)

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

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

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

b. Contains exactly one [1..1] *Event Duration* (templateId: 2.16.840.1.113883.10.20.23.102)

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

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

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

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

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

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

- a. Contains **@typeCode="REFR"** *REFR*
- b. Contains exactly one [1..1] *Timing Reference* (templateId: 2.16.840.1.113883.10.20.23.97)
 - Creates an association between the timing of an activity and a defined reference time point.

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

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

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

- 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)
 - Allows positioning of the termination of the event with relationship to a defined reference time period.

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

- a. Contains **@typeCode="COMP"** *COMP*
- b. Contains exactly one [1..1] *Category* (templateId: 2.16.840.1.113883.10.20.23.20)
 - The record of a category to be used in organizing information items.

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

- a. Contains **@typeCode="COMP"** *COMP*
- b. Contains exactly one [1..1] *Sub- Category* (templateId: 2.16.840.1.113883.10.20.23.91)
 - The record of a sub-category to be used in organizing information items.

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

- a. Contains **@typeCode="REFR"** *REFR*
- b. Contains exactly one [1..1] *Related Record* (templateId: 2.16.840.1.113883.10.20.23.75)
 - Establishes a relationship between this record and another record.

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

- a. Contains **@typeCode="COMP"** *COMP*
- b. Contains exactly one [1..1] *Supplemental Value* (templateId: 2.16.840.1.113883.10.20.23.96)
 - Allows the association of a supplemental value - outside of the content specified for the domain - to the record.

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

- a. Contains **@typeCode="COMP"** *COMP*
- b. Contains exactly one [1..1] *Comment* (templateId: 2.16.840.1.113883.10.20.23.23)
 - A place to insert comments related to a particular intervention.

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

- a. Contains **@typeCode="COMP"** *COMP*
- b. Contains exactly one [1..1] *Finding About* (templateId: 2.16.840.1.113883.10.20.23.40)
 - Allows recording of additional findings related to the concomitant medication.

29. Contains zero or one [0..1] **ageAssociation**

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

- b. This observation **SHALL** contain exactly one [1..1] **@moodCode**= "EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
- c. This observation **SHALL** contain exactly one [1..1] **code/@code**= "C25150" *Reported Age* (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)

The code value indicates this is an age observation.

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

The recorded age of the study subject. Note, in some cases age will be available while date of birth is either not known or withheld. [SDTM: AGE, AGEU], [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="1549123286" extension="MDHT"/>
  <text>Text Value</text>
  <statusCode code="completed"/>
  <effectiveTime value="20120907"/>
  <routeCode code="1751777926"/>
  <doseQuantity/>
  <maxDoseQuantity/>
  <consumable>
    <manufacturedProduct classCode="MANU"/>
  </consumable>
  <entryRelationship>
    <act classCode="ACT">
      <templateId root="2.16.840.1.113883.10.20.23.42"/>
      <id root="225625319" 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="213607451" 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="56631162" extension="MDHT"/>
      <code code="964560510"/>
      <text>Text Value</text>
      <statusCode code="completed"/>
      <effectiveTime>
```

```

        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <entryRelationship>
        <observation/>
      </entryRelationship>
    </act>
  </entryRelationship>
  <entryRelationship>
    <observation>
      <id root="1149857245" extension="MDHT"/>
      <code code="651252808"/>
      <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="1743026800" 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="81341794" 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="1402547553" 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="1387679940" 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="1575974516" 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="791272914" 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="170375621" 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="478553677" 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="1906945892" extension="MDHT"/>
    <code code="1687034018"/>
    <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>
  <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="202236995" 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)
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **code/@code**="C83199" *Adverse Event Concomitant Treatment* (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)
 - The code value indicates the observation contains concomitant or additional treatment information.
4. **SHALL** contain exactly one [1..1] **value** with data type BL
 - Indicate whether or not concomitant or additional treatment was given because of the occurrence of the 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="210080078" extension="MDHT"/>
  <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus"
displayName="Adverse Event Concomitant 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 performance 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)
2. **SHALL** contain exactly one [1..1] **@moodCode="EVN"** *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **MAY** contain zero or one [0..1] **@negationInd**
 - When information about an event or activity is pre-specified, the negation indicator may be used to state that the information was not collected. Value the indicator as TRUE if the information item was not elicited. [SDTM: CMSTAT, SUSTAT, MHSTAT, CESTAT, MSSTAT], [Study Data Tabulation Model: -STAT]
4. **SHALL** contain exactly one [1..1] **code/@code="Dctbd"** (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)
 - The code value indicates the information relates to the collection of data regarding an event or activity.
5. **MAY** contain zero or one [0..1] **effectiveTime** with data type TS
 - The date/time of data collection. [SDTM: DMDTC, SUDTC, DSDTC, MHDTC, PEDTC, CEDTC, IEDTC, QSDTC, SCDTC, MSDTC] [SEND: BWDTC, CLDTC, DDDTC, MADTC, MIDTC, OMDTC, PMDTC, SCDTC]
6. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="REFR"** *REFR*
 - b. Contains exactly one [1..1] *Event Study Day* (templateId: 2.16.840.1.113883.10.20.23.37)
 - Used to record the study day associated with the data collection.

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="1427236647" extension="MDHT"/>
  <code code="1171904604"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <entryRelationship>
    <observation>
      <id root="1148555718" extension="MDHT"/>
      <code code="2102208792"/>
      <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 possibility 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)

2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **code/@code**="C66734" (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)
 - 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**

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="1152547432" 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)
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/@code**="DARTbd" (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)
 - The code value indicates this is a dose adjustment observation.
4. **SHALL** contain exactly one [1..1] **value** with data type ED
 - 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="255716637" extension="MDHT"/>
  <code code="2107886247"/>
  <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 of 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)
2. **SHALL** contain exactly one [1..1] **@moodCode="EVN"** *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain [1..3] **id**
 - A value that is provided to ensure the uniqueness of drug accountability items. [SDTM: DASEQ, DAREFID, DASPID] A single identifier, the sequence number, is required.
4. **SHALL** contain exactly one [1..1] **code**, where the **@code** **SHALL** be selected from ValueSet *Drug Accountability Finding Type* C78732 **STATIC**
 - A coded value that identifies 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**
 - 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
 - The date/time of the accountability assessment. [SDTM: DADTC]
7. **SHOULD** contain zero or one [0..1] **value**
 - Captures the drug accountability value. The finding may be recorded as a coded value - if the result is character based - or as a physical quantity - if the result is numeric. [SDTM: DAORRES, DAORRESU, DASTRESC, DASTRESN, DASTRESU]
8. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Domain Assignment* (templateId: 2.16.840.1.113883.10.20.23.30)
 - Identifies the SDTM or SEND domain the record is assigned to.
9. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Group Identifier* (templateId: 2.16.840.1.113883.10.20.23.42)
 - Allows capture of a group identifier for the drug accountability item.
10. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Non Performance Reason* (templateId: 2.16.840.1.113883.10.20.23.56)
 - Provides a reason for not capturing information for the drug accountability item.
11. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="REFR"** *REFR*
 - b. Contains exactly one [1..1] *Event Study Day* (templateId: 2.16.840.1.113883.10.20.23.37)
 - Used to record the study day associated with an activity taking place during a single day.
12. **MAY** contain zero or one [0..1] **entryRelationship**

- a. Contains **@typeCode="COMP"** *COMP*
- b. Contains exactly one [1..1] *Category* (templateId: 2.16.840.1.113883.10.20.23.20)
 - The record of a category to be used in organizing information items.

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

- a. Contains **@typeCode="COMP"** *COMP*
- b. Contains exactly one [1..1] *Sub- Category* (templateId: 2.16.840.1.113883.10.20.23.91)
 - The record of a sub-category to be used in organizing information items.

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

- a. Contains **@typeCode="REFR"** *REFR*
- b. Contains exactly one [1..1] *Related Record* (templateId: 2.16.840.1.113883.10.20.23.75)
 - Establishes a relationship between this record and another record.

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

- a. Contains **@typeCode="COMP"** *COMP*
- b. Contains exactly one [1..1] *Supplemental Value* (templateId: 2.16.840.1.113883.10.20.23.96)
 - Allows the association of a supplemental value - outside of the content specified for the domain - to the record.

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

- a. Contains **@typeCode="COMP"** *COMP*
- b. Contains exactly one [1..1] *Comment* (templateId: 2.16.840.1.113883.10.20.23.23)
 - A place to insert comments related to a particular finding.

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

- a. Contains **@typeCode="COMP"** *COMP*
- b. Contains exactly one [1..1] *Finding About* (templateId: 2.16.840.1.113883.10.20.23.40)
 - Allows recording of additional findings related to the event.

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="1709799765" extension="MDHT"/>
  <code code="1129427173"/>
  <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="1550708220" 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="857477595" 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="1101127052"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <observation>
    <id root="783700447" extension="MDHT"/>
    <code code="1031435682"/>
    <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="842255249" 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="355213451"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <observation/>
</entryRelationship>
<entryRelationship>
  <observation classCode="OBS" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.23.23"/>
    <id root="1427329608" 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/>
  </observation>
</entryRelationship>
<entryRelationship>
  <observation>
    <templateId root="2.16.840.1.113883.10.20.23.30"/>
    <id root="488127061" 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="876017257"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <act classCode="ACT">
      <templateId root="2.16.840.1.113883.10.20.23.75"/>
      <id root="615222533" 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="405342855" 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="1258068297" extension="MDHT"/>
      <code code="1425921679"/>
      <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>
    </observation>
  </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)
2. **SHALL** contain exactly one [1..1] **@moodCode**= "EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain [1..3] **id**
 - 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**, where the @code **SHALL** be selected from ValueSet [ECG Test Type](#) C71153 **STATIC**
 - A coded value that identifies 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**
 - 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**
 - 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**
 - The performance date of the ECG test. [SDTM: EGDTC], [SEND: EGDTC, EGENDTC]
8. **SHOULD** contain zero or one [0..1] **value**
 - Captures the ECG measurement or finding. The finding may be recorded as a coded value - if the result is character based - or as a physical quantity - if the result is numeric. 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. **SHOULD** contain [0..3] **interpretationCode**, where the @code **SHALL** be selected from ValueSet [Subject Data Interpretation Type](#) CXXXXX **STATIC**
 - 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]

10. MAY contain zero or one [0..1] **methodCode**, where the @code **SHALL** be selected from ValueSet [ECG Test Method](#) C71151 **STATIC**

- Capture the method of the ECG test. [SDTM: EGMETHOD], [SEND: EGMETHOD]

11. SHALL contain exactly one [1..1] **entryRelationship**

- Contains **@typeCode="REFR"** [REFR](#)
 - Contains exactly one [1..1] [Domain Assignment](#) (templateId: 2.16.840.1.113883.10.20.23.30)
- Identifies the SDTM or SEND domain the record is assigned to.

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

- Contains **@typeCode="COMP"** [COMP](#)
 - Contains exactly one [1..1] [Group Identifier](#) (templateId: 2.16.840.1.113883.10.20.23.42)
- Allows capture of a group identifier for the ECG result.

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

- Contains **@typeCode="COMP"** [COMP](#)
 - Contains exactly one [1..1] [Non Performance Reason](#) (templateId: 2.16.840.1.113883.10.20.23.56)
- Provides a reason for not capturing information for the ECG test result.

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

Captures the location - on the subject's body - of a lead used for collecting ECG information.

- This entryRelationship **SHALL** contain zero or one [0..1] **@typeCode="COMP"**
- This entryRelationship **SHALL** contain exactly one [1..1] **observation**

An observation of the actual lead location.

- This observation **SHALL** contain exactly one [1..1] **@classCode="OBS"** [Observation](#) (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass)
- This observation **SHALL** contain exactly one [1..1] **@moodCode="EVN"** [Event](#) (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
- This observation **SHALL** contain exactly one [1..1] **code/@code="C87881"** (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)

A code that indicates the observation contains information regarding the ECG lead that the result relates to.

- This observation **SHALL** contain zero or more [0..*] **value** with data type CD, where the @code **SHALL** be selected from ValueSet [ECG Lead Location](#) C90013 **STATIC**

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

An observation of the actual lead location.

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

- Contains exactly one [1..1] [Study Test Organization](#) (templateId: 2.16.840.1.113883.10.20.23.88)
- Used to record the organization performing the test.

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

- Contains exactly one [1..1] [Study Finding Evaluator](#) (templateId: 2.16.840.1.113883.10.20.23.84)
- Used to record the role played by the person providing the value of a subjective finding.

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

- Contains **@typeCode="COMP"** [COMP](#)
 - Contains exactly one [1..1] [Position of Subject](#) (templateId: 2.16.840.1.113883.10.20.23.69)
- Records the position of the subject at the time of measurement.

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

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

An observation of the state of consciousness.

- a. This observation **SHALL** contain exactly one [1..1] **@classCode**
- b. This observation **SHALL** contain exactly one [1..1] **@moodCode**
- c. This observation **SHALL** contain exactly one [1..1] **code/@code="CStbd"** (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)

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, where the **@code** **SHALL** be selected from ValueSet *Consciousness State* CXXXXXX **STATIC**

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.

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

- a. Contains **@typeCode="REFR"** *REFR*
- b. Contains exactly one [1..1] *Planned Study Day* (templateId: 2.16.840.1.113883.10.20.23.68)
 - Captures the planned study day for making an observation or recording a finding.

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

- a. Contains **@typeCode="REFR"** *REFR*
- b. Contains exactly one [1..1] *Study Day Period* (templateId: 2.16.840.1.113883.10.20.23.82)
 - A reference to the study days corresponding to the time period of the observation.

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

- a. Contains **@typeCode="REFR"** *REFR*
- b. Contains exactly one [1..1] *Timing Reference* (templateId: 2.16.840.1.113883.10.20.23.97)
 - Orients the performance of the ECG test with respect to a study defined timepoint.

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

- a. Contains **@typeCode="COMP"** *COMP*
- b. Contains exactly one [1..1] *Category* (templateId: 2.16.840.1.113883.10.20.23.20)
 - The record of a category to be used in organizing information items.

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

- a. Contains **@typeCode="COMP"** *COMP*
- b. Contains exactly one [1..1] *Sub- Category* (templateId: 2.16.840.1.113883.10.20.23.91)
 - The record of a sub-category to be used in organizing information items.

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

- a. Contains **@typeCode="REFR"** *REFR*
- b. Contains exactly one [1..1] *Related Record* (templateId: 2.16.840.1.113883.10.20.23.75)
 - Establishes a relationship between this record and another record.

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

- a. Contains **@typeCode="COMP"** *COMP*
- b. Contains exactly one [1..1] *Supplemental Value* (templateId: 2.16.840.1.113883.10.20.23.96)
 - Allows the association of a supplemental value - outside of the content specified for the domain - to the record.

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

- a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Comment* (templateId: 2.16.840.1.113883.10.20.23.23)
 - A place to insert comments related to a particular finding.
- 27. MAY** contain zero or more [0..*] **entryRelationship**
- a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Finding About* (templateId: 2.16.840.1.113883.10.20.23.40)
 - Allows recording of additional findings related to the finding.
- 28. SHALL** satisfy: Use the PQR type. Capture the numeric result in standard units as value and unit, capture the numeric result in the original units as a translation. Note, this is only necessary if the original result does not use the standard units.
- 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 original units as a translation. Note, this is only necessary if the original result does not use the standard format.

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="1000225396" 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="666774876"/>
  <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="96199084" extension="MDHT"/>
      <code code="C83204" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
    </act>
  </entryRelationship>
</observation>
```

```

    <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="1205086007" 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="1320047615"/>
    <interpretationCode code="627942153"/>
    <methodCode code="1334394419"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <act>
    <templateId root="2.16.840.1.113883.10.20.23.97"/>
    <id root="1291502648" 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="1568931986" extension="MDHT"/>
    <code code="853570673"/>
    <text>Text Value</text>
    <statusCode code="completed"/>
    <effectiveTime>
      <low value="2012"/>
      <high value="2012"/>
    </effectiveTime>
    <value xsi:type="INT" value="1"/>
    <interpretationCode code="1544635112"/>
    <methodCode code="1271370770"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <observation>
    <id root="846773767" extension="MDHT"/>
    <code code="2084788689"/>
    <text>Text Value</text>
    <statusCode code="completed"/>
    <effectiveTime>
      <low value="2012"/>
      <high value="2012"/>
    </effectiveTime>
  </observation>

```

```

        <value xsi:type="IVL_INT" value="1"/>
        <interpretationCode code="218729489"/>
        <methodCode code="186533094"/>
    </observation>
</entryRelationship>
<entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
        <templateId root="2.16.840.1.113883.10.20.23.23"/>
        <id root="803750732" 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="1754194493"/>
        <methodCode code="183922519"/>
        <participant/>
    </observation>
</entryRelationship>
<entryRelationship>
    <observation>
        <templateId root="2.16.840.1.113883.10.20.23.30"/>
        <id root="435705319" 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="443118356"/>
        <interpretationCode code="1306866431"/>
        <methodCode code="1332255564"/>
    </observation>
</entryRelationship>
<entryRelationship>
    <act classCode="ACT">
        <templateId root="2.16.840.1.113883.10.20.23.75"/>
        <id root="1491444625" 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="752038742" 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="1703496207"/>
      <methodCode code="122625605"/>
      <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="1579778559" 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="1642517814"/>
      <interpretationCode code="866244649"/>
      <methodCode code="817232170"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation/>
  </entryRelationship>
  <entryRelationship>
    <observation/>
  </entryRelationship>
  <entryRelationship>
    <observation>
      <id root="956047837" extension="MDHT"/>
      <code code="1512244723"/>
      <text>Text Value</text>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <interpretationCode code="1289563843"/>
      <methodCode code="645670851"/>
      <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>
    <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>

```

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 presense 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)
2. **SHALL** contain exactly one [1..1] **@moodCode="EVN"** *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **code/@code="EDtbd"** (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)
 - A code that indicates the observation records the duration of an event.
4. **SHALL** contain exactly one [1..1] **value** with data type PQR
 - Captures the duration of an event.

sdtn::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		ALRT
moodCode	@moodCode	1..1	SHALL	NO	x_ActMoodDocumentObservation		DEF
negationInd	@negationInd	0..1		NO	Boolean		
nullFlavor	@nullFlavor	0..1		NO	NullFlavor		ASKU
code	code	1..1	SHALL	YES	CD		NCI Thesaurus 2.16.840.1.113883.3.26.1.1 EDtbd
derivationExpr	derivationExpr	0..1		YES	ST		
effectiveTime	effectiveTime	0..1		YES	IVL_TS		
id	id	0..*		YES	II		
interpretationCode	interpretationCode	0..*		YES	CE		

sdtn::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)
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		
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="203923884" 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="1336851209"/>
</observation>
```

Event or Finding Severity

[Observation: templateId 2.16.840.1.113883.10.20.23.34]

The template provides a reusable structure 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)
2. **SHALL** contain exactly one [1..1] **@moodCode**= "EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **code/@code**= "C66769" (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)
 - The code value indicates this is a severity observation.
4. **SHALL** contain exactly one [1..1] **value** with data type CD, where the **@code** **SHALL** be selected from ValueSet *Event Severity* C66769 **STATIC**
 - 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="889180991" 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="1649051055"/>
</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)
2. **SHALL** contain exactly one [1..1] **@moodCode**= "EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **code/@code**= "C49489" *Adverse Event Outcome* (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)
 - A code that indicates this observation contains adverse event outcome information.
4. **SHALL** contain exactly one [1..1] **value** with data type CD, where the **@code** **SHALL** be selected from ValueSet *Outcome of Event* C66768 **STATIC**
 - 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="647971857" 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="2059037919"/>
</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)
2. **SHALL** contain exactly one [1..1] **@moodCode**= "EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **code/@code**= "C83208" *Adverse Event Pattern* (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)
 - A code that indicates the observation contains information regarding the pattern of the adverse event over time.
4. **SHALL** contain exactly one [1..1] **value** with data type CD, where the @code **SHALL** be selected from ValueSet *Event Pattern* CXXXXX STATIC
 - 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="1479009936" 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="1731564816"/>
</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)
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **code/@code**="ESDtbd" (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)
 - A fixed value that indicates the observation captures the actual study day for an event.
4. **SHALL** contain exactly one [1..1] **value** with data type INT
 - The applicable study day value. [SDTM: DMDY, MHDY, CEDY, 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="610963371" extension="MDHT"/>
  <code code="1293206804"/>
  <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)
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **code/@code**="FStbd" (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)
 - The code value indicates the observation concerns the subject's fasting status.
4. **SHALL** contain exactly one [1..1] **value** with data type BL
 - A Boolean indicator to provide information 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="1871235385" 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-clinical trial reporting.

1. **SHALL** contain exactly one [1..1] **@classCode="OBS"** *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass)
2. **SHALL** contain exactly one [1..1] **@moodCode="EVN"** *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain [1..2] **id**
 - A value that is provided to ensure the uniqueness of the findings about result. [SDTM: FASEQ, FASPID] A single identifier, the sequence number, is required.
4. **SHALL** contain exactly one [1..1] **code**, where the @code **SHALL** be selected from ValueSet [Finding About Finding Type](#) C101852 **STATIC**
 - 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]
5. **MAY** contain zero or one [0..1] **statusCode**
 - Used to indicate whether or not a measurement has been performed. [SDTM: FASTAT]
6. **MAY** contain zero or one [0..1] **effectiveTime**
7. **SHALL** contain exactly one [1..1] **value**
 - The findings about result, using both original units and a standard format or set of units. [SDTM: FAORRES, FAORRESU, FASTRESC, FASTRESN, FASTRESU]
8. **MAY** contain zero or one [0..1] **interpretationCode**, where the @code **SHALL** be selected from ValueSet [Subject Data Interpretation Type](#) CXXXXXX **STATIC**
 - Includes information used to better interpret the observation value (result). [SDTM: FABLFL]
9. **MAY** contain zero or one [0..1] **targetSiteCode**, where the @code **SHALL** be selected from ValueSet [Anatomical Location](#) C74456 **STATIC**
 - Used to specify the location of a clinical evaluation. [SDTM: FALOC]
10. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] [Domain Assignment](#) (templateId: 2.16.840.1.113883.10.20.23.30)
 - Identifies the SDTM or SEND domain the record is assigned to.
11. **SHALL** contain zero or one [0..1] **entryRelationship**

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

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

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

- a. Contains **@typeCode="COMP"** *COMP*
- b. Contains exactly one [1..1] *Group Identifier* (templateId: 2.16.840.1.113883.10.20.23.42)
 - Allows capture of a group identifier for the finding.

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

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

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

- a. Contains **@typeCode="COMP"** *COMP*
- b. Contains exactly one [1..1] *Non Performance Reason* (templateId: 2.16.840.1.113883.10.20.23.56)
 - Provides a reason for not capturing information for the finding.

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

- a. Contains exactly one [1..1] *Study Finding Evaluator* (templateId: 2.16.840.1.113883.10.20.23.84)
 - Used to record the role played by the person providing the value of a subjective finding.

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

- a. Contains **@typeCode="COMP"** *COMP*
- b. Contains exactly one [1..1] *Category* (templateId: 2.16.840.1.113883.10.20.23.20)
 - The record of a category to be used in organizing information items.

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

- a. Contains **@typeCode="COMP"** *COMP*
- b. Contains exactly one [1..1] *Sub- Category* (templateId: 2.16.840.1.113883.10.20.23.91)
 - The record of a sub-category to be used in organizing information items.

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="426876246" extension="MDHT"/>
  <code code="781748172"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <interpretationCode code="480840319"/>
  <targetSiteCode code="1979564089"/>
  <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>
</observation>
```

```

    </observation>
  </entryRelationship>
  <entryRelationship>
    <act classCode="ACT">
      <templateId root="2.16.840.1.113883.10.20.23.42"/>
      <id root="1049331736" 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="525269834" 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="2011177234"/>
      <interpretationCode code="1467945760"/>
      <targetSiteCode code="418474761"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <act>
      <id root="889472407" extension="MDHT"/>
      <code code="435729060"/>
      <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="50280819" 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="550398664"/>
      <interpretationCode code="871679891"/>
      <targetSiteCode code="1166880958"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation/>
  </entryRelationship>

```

```

<entryRelationship>
  <observation>
    <templateId root="2.16.840.1.113883.10.20.23.30"/>
    <id root="1680255218" 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="608791172"/>
    <interpretationCode code="1152324015"/>
    <targetSiteCode code="83218596"/>
  </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 concomitant 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)
2. **SHALL** contain exactly one [1..1] **@moodCode="EVN"** *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **id**
 - 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/@code="C83204"** (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)
 - 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="875966162" 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]

This template supports the contents 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)
2. **SHALL** contain exactly one [1..1] **@moodCode="EVN"** *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain [1..2] **id**
 - An identifier that is used to ensure the uniqueness of subject records within the substance use domain. [SDTM: DSSEQ, DSREFID] Note, the Sequence Number is required.
4. **SHALL** contain exactly one [1..1] **code**, where the **@code** **SHALL** be selected from ValueSet [Disposition Item Type](#) CXXXXX **STATIC**
 - 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]
5. **SHOULD** contain zero or one [0..1] **effectiveTime**
 - 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]
6. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="REFR"** *REFR*
 - b. Contains exactly one [1..1] [Study Epoch](#) (templateId: 2.16.840.1.113883.10.20.23.83)
 - Records the study epoch during which the information was collected.
7. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] [Group Identifier](#) (templateId: 2.16.840.1.113883.10.20.23.42)
 - Allows capture of a group identifier for the disposition item.
8. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="REFR"** *REFR*
 - b. Contains exactly one [1..1] [Study Day Period](#) (templateId: 2.16.840.1.113883.10.20.23.82)
 - Used to record the study days associated with the beginning and end points of an activity that may extend over a period of time.
9. **MAY** contain zero or more [0..*] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] [Comment](#) (templateId: 2.16.840.1.113883.10.20.23.23)
 - A place to insert comments related to a particular finding.
10. **SHALL** contain exactly one [1..1] **entryRelationship**
 - a. Contains **@typeCode="REFR"** *REFR*
 - b. Contains exactly one [1..1] [Domain Assignment](#) (templateId: 2.16.840.1.113883.10.20.23.30)
 - Identifies the SDTM or SEND domain the record is assigned to.
11. **MAY** contain zero or more [0..*] **entryRelationship**
 - a. Contains **@typeCode="REFR"** *REFR*
 - b. Contains exactly one [1..1] [Related Record](#) (templateId: 2.16.840.1.113883.10.20.23.75)

- Establishes a relationship between this record and another record.
- 12. MAY** contain zero or more [0..*] **entryRelationship**
- Contains **@typeCode="COMP" COMP**
 - Contains exactly one [1..1] **Supplemental Value** (templateId: 2.16.840.1.113883.10.20.23.96)
 - Allows the association of a supplemental value - outside of the content specified for the domain - to the record.
- 13. MAY** contain zero or one [0..1] **entryRelationship**
- Contains **@typeCode="COMP" COMP**
 - Contains exactly one [1..1] **Category** (templateId: 2.16.840.1.113883.10.20.23.20)
 - The record of a category to be used in organizing information items.
- 14. MAY** contain zero or one [0..1] **entryRelationship**
- Contains **@typeCode="COMP" COMP**
 - Contains exactly one [1..1] **Sub- Category** (templateId: 2.16.840.1.113883.10.20.23.91)
 - The record of a sub-category to be used in organizing information items.
- 15. MAY** contain zero or more [0..*] **entryRelationship**
- Contains **@typeCode="COMP" COMP**
 - Contains exactly one [1..1] **Finding About** (templateId: 2.16.840.1.113883.10.20.23.40)
 - Allows recording of additional findings related to the event.

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="1581893756" extension="MDHT"/>
  <code code="1400168958"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <entryRelationship>
    <act>
      <templateId root="2.16.840.1.113883.10.20.23.83"/>
      <id root="2060640806" 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="1590946795" 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="1801337271" extension="MDHT"/>
    <code code="1267921932"/>
    <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="1033897853" 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="292114522" 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="2072064598" extension="MDHT"/>
    <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus"/>
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      <high value="2012"/>
    </effectiveTime>
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Type"/>
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</entryRelationship>
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  <observation classCode="OBS" moodCode="EVN">
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    <id root="2004922929" extension="MDHT"/>

```

```

    <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
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  <observation/>
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  <observation>
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    </effectiveTime>
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    <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"/>
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      </observation>
    </entryRelationship>
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      <act/>
    </entryRelationship>
    <entryRelationship>
      <observation classCode="OBS" moodCode="EVN">
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Thesaurus"/>
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    </entryRelationship>
    <entryRelationship>
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      <observation>
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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)
2. **SHALL** contain exactly one [1..1] **@moodCode="EVN"** *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain [1..2] **id**
 - A sponsor supplied reference number for the study treatment. [SDTM: EXSEQ, EXSPID] A sequence number is required.
4. **MAY** contain zero or one [0..1] **text**
 - A text description of the dosing. [SDTM: EXDOSTXT]
5. **SHOULD** contain zero or one [0..1] **effectiveTime**
 - 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 requery. 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 effective time attribute is used to capture information regarding the start, stop, duration and frequency of use for the concomitant medication. There shall be Two SXPR components created. The first will be an interval of time stamps (IVL_TS) to address 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]
6. **MAY** contain zero or one [0..1] **routeCode**
 - The route by which the treatment is administered. [SDTM: EXROUTE]
7. **MAY** contain zero or one [0..1] **approachSiteCode** with data type CE, where the @code **SHALL** be selected from ValueSet *Anatomical Location* C74456 **STATIC**
 - An indication of the location, e.g. left arm, where the substance was administered. [SDTM: EXLOC]
8. **SHOULD** contain zero or one [0..1] **doseQuantity**
 - 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]
9. **MAY** contain zero or one [0..1] **maxDoseQuantity**
 - Information on the total daily dose of the study treatment. The structure also accommodates periods other than a day. Therefore 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.
10. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Group Identifier* (templateId: 2.16.840.1.113883.10.20.23.42)
 - Allows capture of a group identifier for the exposure information.
11. **SHALL** contain exactly one [1..1] **consumable**
 - a. Contains exactly one [1..1] *Consumable Material* (templateId: 2.16.840.1.113883.10.20.23.26)

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

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

- Contains **@typeCode="REFR"** *REFR*
- Contains exactly one [1..1] *Study Epoch* (templateId: 2.16.840.1.113883.10.20.23.83)

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

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

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.

- This entryRelationship **SHALL** contain exactly one [1..1] **@typeCode="REFR"**
- This entryRelationship **SHALL** contain exactly one [1..1] **observation**
 - This observation **SHALL** contain exactly one [1..1] **@classCode="OBS"** *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass)
 - This observation **SHALL** contain exactly one [1..1] **@moodCode="EVN"** *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
 - This observation **SHALL** contain exactly one [1..1] **code**, where the **@code** **SHALL** be selected from (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)

The code value indicates the observation captures an element's order within a trial arm.

- This observation **SHALL** contain exactly one [1..1] **value** with data type ED

A value that gives the order of an element within the trial arm. Since this order could be hierarchically 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**

- Contains **@typeCode="COMP"** *COMP*
 - Contains exactly one [1..1] *Event Duration* (templateId: 2.16.840.1.113883.10.20.23.102)
- Records the duration of an event in cases in which this cannot be derived from existing start and stop information.

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

- Contains **@typeCode="REFR"** *REFR*
 - Contains exactly one [1..1] *Timing Reference* (templateId: 2.16.840.1.113883.10.20.23.97)
- Orients the consumption of the study drug with respect to a study defined timepoint.

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

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

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

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

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

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

18.SHALL contain exactly one [1..1] **entryRelationship**

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

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

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

- a. Contains **@typeCode="REFR"** *REFR*
 - b. Contains exactly one [1..1] *Related Record* (templateId: 2.16.840.1.113883.10.20.23.75)
 - Establishes a relationship between this record and another record.
- 20.MAY** contain zero or more [0..*] **entryRelationship**
- a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Supplemental Value* (templateId: 2.16.840.1.113883.10.20.23.96)
 - Allows the association of a supplemental value - outside of the content specified for the domain - to the record.
- 21.MAY** contain zero or one [0..1] **entryRelationship**
- a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Intended Regimen* (templateId: 2.16.840.1.113883.10.20.23.49)
 - Information on the intended dose regimen of the medication. It supplements the frequency information provided within the effectiveTime element.
- 22.MAY** contain zero or one [0..1] **entryRelationship**
- a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Dose Adjustment Reason* (templateId: 2.16.840.1.113883.10.20.23.31)
 - 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.
- 23.MAY** contain zero or one [0..1] **entryRelationship**
- a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Category* (templateId: 2.16.840.1.113883.10.20.23.20)
 - The record of a category to be used in organizing information items.
- 24.MAY** contain zero or one [0..1] **entryRelationship**
- a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Sub- Category* (templateId: 2.16.840.1.113883.10.20.23.91)
 - The record of a sub-category to be used in organizing information items.
- 25.MAY** contain zero or more [0..*] **entryRelationship**
- a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Finding About* (templateId: 2.16.840.1.113883.10.20.23.40)
 - Allows recording of additional findings related to the event.

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="20120907"/>
  <routeCode code="2027521625"/>
  <approachSiteCode xsi:type="CE" code="446847705"/>
  <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>
</substanceadministration>
```

```

    </observation>
  </entryRelationship>
  <entryRelationship>
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codeSystemName="NCI Thesaurus"/>
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codeSystemName="NCI Thesaurus"/>
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      <effectiveTime>
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    </observation>
  </entryRelationship>

```

```

    </observation>
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    </act>
  </entryRelationship>
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Type"/>
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```

```

    </effectiveTime>
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    <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus"/>
    <text>Text Value</text>
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    <id root="805662284" extension="MDHT"/>
    <code code="609285318"/>
    <text>Text Value</text>
    <effectiveTime>
      <low value="2012"/>
      <high value="2012"/>
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      <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"/>
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  <act/>
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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>
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    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.102"/>
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codeSystemName="NCI Thesaurus"/>
      <text>Text Value</text>
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  </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)
2. **SHALL** contain exactly one [1..1] **@moodCode="EVN"** *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain [1..2] **id**
 - A value that is provided to ensure the uniqueness of the laboratory result. [SDTM: LBSEQ, LBSPID] A single identifier, the sequence number, is required.
4. **SHALL** contain exactly one [1..1] **code**, where the **@code** **SHALL** be selected from ValueSet *Laboratory Test Type* C65047 **STATIC**
 - 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**
 - Used to indicate whether or not an exam has been performed. [SDTM: LBSTAT]
6. **SHOULD** contain zero or one [0..1] **value** with data type CD
 - The laboratory result, using both original units and a standard format or set of units. [SDTM: LBORRES, LBORRESU, LBSTRESC, LBSTRESN, LBSTRESU]
7. **SHOULD** contain [0..3] **interpretationCode**, where the **@code** **SHALL** be selected from ValueSet *Subject Data Interpretation Consolidated Type* CXXXXXX **STATIC**
 - 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: LBBFL, LBDRVFL, LBNRIND]
8. **MAY** contain zero or one [0..1] **methodCode**, where the **@code** **SHALL** be selected from ValueSet *Method* C85492 **STATIC**
 - Indicates the method of the test or examination. [SDTM: LBMETHOD]
9. **MAY** contain zero or more [0..*] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Comment* (templateId: 2.16.840.1.113883.10.20.23.23)
 - A place to insert comments related to a particular finding.
10. **SHALL** contain exactly one [1..1] **entryRelationship**

- a. Contains **@typeCode="REFR"** *REFR*
- b. Contains exactly one [1..1] *Domain Assignment* (templateId: 2.16.840.1.113883.10.20.23.30)
 - Identifies the SDTM or SEND domain the record is assigned to.
- 11. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Group Identifier* (templateId: 2.16.840.1.113883.10.20.23.42)
 - Allows capture of a group identifier for the test result.
- 12. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Non Performance Reason* (templateId: 2.16.840.1.113883.10.20.23.56)
 - Information on the reason a scheduled activity was not carried out.
- 13. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Specimen Information* (templateId: 2.16.840.1.113883.10.20.23.78)
 - 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.
- 14. **SHOULD** contain zero or one [0..1] **reference Range**
 - a. Contains exactly one [1..1] *Reference Range* (templateId: 2.16.840.1.113883.10.20.23.74)
 - Information on the reference range defined for a test. It is used to support interpretation of the test result.
- 15. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Fasting Status* (templateId: 2.16.840.1.113883.10.20.23.39)
 - Used to indicate the fasting status - time since consumption of food - for the study subject.
- 16. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Toxicity* (templateId: 2.16.840.1.113883.10.20.23.98)
 - A record of the toxicity measured by the test.
- 17. **MAY** contain zero or one [0..1] **participant**
 - a. Contains exactly one [1..1] *Study Test Organization* (templateId: 2.16.840.1.113883.10.20.23.88)
 - Used to identify the organization that performed the test.
- 18. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="REFR"** *REFR*
 - b. Contains exactly one [1..1] *Timing Reference* (templateId: 2.16.840.1.113883.10.20.23.97)
 - Creates an association between the timing of an activity and a defined reference time point.
- 19. **SHOULD** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Category* (templateId: 2.16.840.1.113883.10.20.23.20)
 - The record of a category to be used in organizing information items.
- 20. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Sub- Category* (templateId: 2.16.840.1.113883.10.20.23.91)
 - The record of a sub-category to be used in organizing information items.

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

- a. Contains **@typeCode="REFR"** *REFR*
- b. Contains exactly one [1..1] *Related Record* (templateId: 2.16.840.1.113883.10.20.23.75)
 - Establishes a relationship between this record and another record.

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

- a. Contains **@typeCode="COMP"** *COMP*
- b. Contains exactly one [1..1] *Supplemental Value* (templateId: 2.16.840.1.113883.10.20.23.96)
 - Allows the association of a supplemental value - outside of the content specified for the domain - to the record.

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

- a. Contains **@typeCode="COMP"** *COMP*
- b. Contains exactly one [1..1] *Finding About* (templateId: 2.16.840.1.113883.10.20.23.40)
 - Allows recording of additional findings related to the event.

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="689638697" extension="MDHT"/>
  <code code="96735437"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <value xsi:type="CD" code="1039554210"/>
  <interpretationCode codeSystemName="NCI Thesaurus"/>
  <methodCode code="1275938107"/>
  <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="2023049099" 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="1020800405" extension="MDHT"/>
      <code code="334894701"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <methodCode code="1801202679"/>
      <specimen typeCode="SPC">
        <templateId root="null"/>
      </specimen>
    </procedure>
  </entryRelationship>
</observation>
```

```

    </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="477919262" 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="591413746"/>
    <interpretationCode code="1460762051"/>
    <methodCode code="1192885046"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <act>
    <templateId root="2.16.840.1.113883.10.20.23.97"/>
    <id root="583439208" 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="303776883" 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="527002297"/>
    <methodCode code="463188428"/>
    <participant/>
  </observation>
</entryRelationship>
<entryRelationship>
  <observation>

```

```

    <templateId root="2.16.840.1.113883.10.20.23.30"/>
    <id root="1165155297" 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="1703125101"/>
    <interpretationCode code="1525281370"/>
    <methodCode code="1709194436"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <act classCode="ACT">
    <templateId root="2.16.840.1.113883.10.20.23.75"/>
    <id root="1454360111" 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="1325286675" extension="MDHT"/>
    <code codeSystem="locally defined" codeSystemName="Supplemental Value
Type"/>
    <statusCode code="completed"/>
    <effectiveTime>
      <low value="2012"/>
      <high value="2012"/>
    </effectiveTime>
    <interpretationCode code="1641440886"/>
    <methodCode code="821221220"/>
    <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="545902988" 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="1496762722"/>
    <interpretationCode code="317897230"/>
    <methodCode code="1212318714"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <observation classCode="OBS" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.23.20"/>
    <id root="74022789" 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="1972307830"/>
    <interpretationCode code="556663284"/>
    <methodCode code="1868334521"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <observation/>
</entryRelationship>
<entryRelationship>
  <observation classCode="OBS">
    <templateId root="2.16.840.1.113883.10.20.23.39"/>
    <id root="360215790" 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="1786861165"/>
    <methodCode code="1446811948"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <observation>
    <id root="1665259914" extension="MDHT"/>
    <code code="1051491312"/>
    <statusCode code="completed"/>
    <effectiveTime>
      <low value="2012"/>
      <high value="2012"/>
    </effectiveTime>
    <interpretationCode code="1158626810"/>
    <methodCode code="668257274"/>
    <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)
3. **SHALL** contain exactly one [1..1] **code/@code="DMGtbd"** (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)
 - Indicates that the contained information includes subject demographic data that is not accommodated by the record target participation.
4. **SHOULD** contain zero or one [0..1] **ageAssociation**

Used to record the age of the subject.

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

The code value indicates this is an age observation.

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

The recorded age of the study subject. Note, in some cases age will be available while date of birth is either not known or withheld. [SDTM: AGE, AGEU], [SEND: AGE, AGEU]

5. **SHOULD** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Data Collection* (templateId: 2.16.840.1.113883.10.20.23.27)
 - 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.
6. **SHALL** contain [2..2] **entryRelationship**

- a. Contains **@typeCode="REFR"** *REFR*
 - b. Contains exactly one [1..1] *Study Arm* (templateId: 2.16.840.1.113883.10.20.23.81)
 - Information may be collected on both the Planned Study Arm, and the Actual Study Arm. The Planned Study Arm must be provided.
7. **SHALL** contain exactly one [1..1] **participant**
- 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"**
 - b. This participant Contains exactly one [1..1] **participantRole**
 - a. This participantRole **SHALL** contain zero or one [0..1] **@classCode="SDLOC"**
 - b. This participantRole **SHALL** contain exactly one [1..1] **addr**

Use the country property of the address data type to capture the country of the study site. [SDTM: COUNTRY]
8. **MAY** contain zero or more [0..*] **entryRelationship**
- a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Comment* (templateId: 2.16.840.1.113883.10.20.23.23)
 - A place to insert comments related to a particular finding.
9. **SHALL** contain exactly one [1..1] **entryRelationship**
- a. Contains **@typeCode="REFR"** *REFR*
 - b. Contains exactly one [1..1] *Domain Assignment* (templateId: 2.16.840.1.113883.10.20.23.30)
 - Identifies the SDTM domain the record is assigned to.
10. **MAY** contain zero or more [0..*] **entryRelationship**
- a. Contains **@typeCode="REFR"** *REFR*
 - b. Contains exactly one [1..1] *Related Record* (templateId: 2.16.840.1.113883.10.20.23.75)
 - Establishes a relationship between this record and another record.
11. **MAY** contain zero or more [0..*] **entryRelationship**
- a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Supplemental Value* (templateId: 2.16.840.1.113883.10.20.23.96)
 - Allows the association of a supplemental value - outside of the content specified for the domain - to the record.
12. **SHALL** contain exactly one [1..1] **entryRelationship**
- a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Reference Period* (templateId: 2.16.840.1.113883.10.20.23.73)
 - Provides information on the reference period that has been defined for the subject's participation in the study.
13. **MAY** contain zero or more [0..*] **entryRelationship**
- a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Finding About* (templateId: 2.16.840.1.113883.10.20.23.40)
 - Allows recording of additional findings related to the event.

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="155131966" extension="MDHT"/>
  <code code="791076149"/>
  <effectiveTime>
```



```

    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <participant typeCode="LOC">
    <participantRole classCode="SDLOC"/>
  </participant>
  <entryRelationship>
    <act>
      <id root="1328131953" extension="MDHT"/>
      <code code="1626985062"/>
      <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="1194335234" 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="1652444301" 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="1446167977" 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="110654781" 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="851305532" 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>
    <act>
      <id root="497759964" extension="MDHT"/>
      <code code="55823908"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
    </act>
  </entryRelationship>
  <entryRelationship>
    <observation>
      <id root="392776394" extension="MDHT"/>
      <code code="2030551139"/>
      <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>
    <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>
  <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>
    <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>

```

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 criteria at the time that eligibility for study entry is determined - at the end of a run in period or immediately before randomization.

1. **SHALL** contain exactly one [1..1] **@classCode="OBS"** *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass)
2. **SHALL** contain exactly one [1..1] **@moodCode="EVN"** *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain [1..2] **id**
 - A value that is provided to ensure the uniqueness of the inclusion/exclusion exception. [SDTM: IESEQ, IESPID] A single identifier, the sequence number, is required.
4. **SHALL** contain exactly one [1..1] **code**, where the **@code** **SHALL** be selected from (CodeSystem: locally defined Inclusion/Exclusion Criteria Type)
 - A coded value that identifies 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
 - The response to the question - was the inclusion or exclusion criteria met? [SDTM: IEORES, IESTRESC]
6. **SHALL** contain exactly one [1..1] **entryRelationship**
 - a. Contains **@typeCode="REFR"** *REFR*
 - b. Contains exactly one [1..1] *Domain Assignment* (templateId: 2.16.840.1.113883.10.20.23.30)
 - Identifies the SDTM domain the record is assigned to.
7. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Data Collection* (templateId: 2.16.840.1.113883.10.20.23.27)
 - 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.
8. **SHALL** contain exactly one [1..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Category* (templateId: 2.16.840.1.113883.10.20.23.20)
 - The record of a category to be used in organizing information items.
9. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Sub-Category* (templateId: 2.16.840.1.113883.10.20.23.91)

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

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="446302260" extension="MDHT"/>
  <code code="433365135"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <value xsi:type="BL"/>
  <entryRelationship>
    <act>
      <id root="90962377" extension="MDHT"/>
      <code code="1591295083"/>
      <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="292052296" 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/>
    </observation>
  </entryRelationship>
</observation>
```

```

    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation>
      <templateId root="2.16.840.1.113883.10.20.23.30"/>
      <id root="1970510890" 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="211848036"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <act classCode="ACT">
      <templateId root="2.16.840.1.113883.10.20.23.75"/>
      <id root="1839186911" 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="1488214170" 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="584160204" 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="1044641762"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation/>
  </entryRelationship>
  <entryRelationship>
    <observation>
      <id root="1616527861" extension="MDHT"/>
      <code code="1355983491"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
    </observation>
  </entryRelationship>

```

```

    </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 intervention.

1. **SHALL** contain exactly one [1..1] **@classCode="OBS"** *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass)
2. **SHALL** contain exactly one [1..1] **@moodCode="EVN"** *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **code/@code="C83085"** *Concomitant Medication Indication* (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)
 - A code value to indicate the observation contains indication information.
4. **SHALL** contain exactly one [1..1] **value** with data type CD, where the @code **SHALL** be selected from (CodeSystem: locally defined Intervention Indication Type)
 - 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="1979503225" 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="739637234"/>
</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)
2. **SHALL** contain exactly one [1..1] **@moodCode**= "EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **code/@code**= "IRtbd" (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)
 - 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
 - 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="347881491" 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)
2. **SHALL** contain exactly one [1..1] **@moodCode**= "EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)

3. SHALL contain [1..3] **id**

- A value that is provided to ensure the uniqueness of medical history items. [SDTM: MHSEQ, MHREFID, MHSPID] A single identifier, the sequence number, is required.

4. SHALL contain exactly one [1..1] **code/@code="MHItd"** (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)

- The code value indicates that this observation is a medical history item.

5. MAY contain zero or one [0..1] **statusCode**

- 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**

- 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, where the @code **SHALL** be selected from (CodeSystem: unknown Medical History Item Type)

- A code value and descriptive text to provide information on the nature of the medical condition or event. [SDTM: MHTERM, MHMODIFY, MHDECOD]

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

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

9. MAY contain zero or one [0..1] **entryRelationship****a.** Contains **@typeCode="COMP"** *COMP***b.** Contains exactly one [1..1] *Group Identifier* (templateId: 2.16.840.1.113883.10.20.23.42)

- Allows capture of a group identifier for the medical history item.

10. MAY contain zero or one [0..1] **entryRelationship****a.** Contains **@typeCode="COMP"** *COMP***b.** Contains exactly one [1..1] *Data Collection* (templateId: 2.16.840.1.113883.10.20.23.27)

- 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.

11. SHALL contain zero or one [0..1] **entryRelationship****a.** Contains **@typeCode="COMP"** *COMP***b.** Contains exactly one [1..1] *Pre-Specified Event* (templateId: 2.16.840.1.113883.10.20.23.70)

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

12. MAY contain zero or one [0..1] **entryRelationship****a.** Contains **@typeCode="COMP"** *COMP***b.** Contains exactly one [1..1] *Non Performance Reason* (templateId: 2.16.840.1.113883.10.20.23.56)

- Provides a reason for not capturing information for the medical history item.

13. MAY contain zero or one [0..1] **entryRelationship****a.** Contains **@typeCode="COMP"** *COMP***b.** Contains exactly one [1..1] *Body System or Organ Class* (templateId: 2.16.840.1.113883.10.20.23.17)

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

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

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="1799199574" 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="1583137098"/>
</observation>
```

```

<entryRelationship>
  <act classCode="ACT">
    <templateId root="2.16.840.1.113883.10.20.23.42"/>
    <id root="2009549608" 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="1122322441" 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="2080258596"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <observation/>
</entryRelationship>
<entryRelationship>
  <act>
    <id root="1093320793" extension="MDHT"/>
    <code code="248396019"/>
    <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="452798932" 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="392024077" 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="936309891"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <act classCode="ACT">
      <templateId root="2.16.840.1.113883.10.20.23.75"/>
      <id root="579823633" 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="76069236" 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="1989904567" 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="1422536088"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation/>
  </entryRelationship>

```

[Observation: templateId 2.16.840.1.113883.10.20.23.53]

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

- 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**, where the @code **SHALL** be selected from (CodeSystem: locally defined Microbiology Finding Type)
 - 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**
 - Used to indicate whether or not an exam has been performed. [SDTM: MBSTAT]
- 6. **SHOULD** contain zero or more [0..*] **value**
 - The microbiology specimen result, using both original units and a standard format or set of units. [SDTM: MBORRES, MBORRESU, MBSTRESC, MBSTRESN, MBSTRESU]
- 7. **MAY** contain [0..2] **interpretationCode**, where the @code **SHALL** be selected from ValueSet *Subject Data Interpretation Type* CXXXXX **STATIC**
 - 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]
- 8. **SHOULD** contain zero or one [0..1] **methodCode**, where the @code **SHALL** be selected from ValueSet *Method* C85492 **STATIC**
 - Indicates the method of the test or examination. [SDTM: MBMETHOD]
- 9. **SHALL** contain exactly one [1..1] **entryRelationship**
 - a. Contains @typeCode="REFR" *REFR*
 - b. Contains exactly one [1..1] *Domain Assignment* (templateId: 2.16.840.1.113883.10.20.23.30)
 - Identifies the SDTM or SEND domain the record is assigned to.
- 10. **SHOULD** contain zero or one [0..1] **entryRelationship**
 - a. Contains @typeCode="COMP" *COMP*
 - b. Contains exactly one [1..1] *Group Identifier* (templateId: 2.16.840.1.113883.10.20.23.42)
 - Allows capture of a group identifier for the finding.
- 11. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains @typeCode="COMP" *COMP*
 - b. Contains exactly one [1..1] *Non Performance Reason* (templateId: 2.16.840.1.113883.10.20.23.56)
 - Provides a reason for not capturing information for the finding.
- 12. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains @typeCode="COMP" *COMP*
 - b. Contains exactly one [1..1] *Specimen Information* (templateId: 2.16.840.1.113883.10.20.23.78)
 - 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.
- 13. **MAY** contain zero or one [0..1] **participant**
 - a. Contains exactly one [1..1] *Study Test Organization* (templateId: 2.16.840.1.113883.10.20.23.88)
 - Used to identify the organization that performed the test.
- 14. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains @typeCode="COMP" *COMP*
 - b. Contains exactly one [1..1] *Category* (templateId: 2.16.840.1.113883.10.20.23.20)
 - The record of a category to be used in organizing information items.
- 15. **MAY** contain zero or one [0..1] **entryRelationship**

- a. Contains @typeCode="COMP" *COMP*
- b. Contains exactly one [1..1] *Sub- Category* (templateId: 2.16.840.1.113883.10.20.23.91)
 - The record of a sub-category to be used in organizing information items.

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

- a. Contains @typeCode="COMP" *COMP*
- b. Contains exactly one [1..1] *Result Category* (templateId: 2.16.840.1.113883.10.20.23.76)
 - The record of a category to be used in organizing finding or observation results.

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

- a. Contains @typeCode="REFR" *REFR*
- b. Contains exactly one [1..1] *Related Record* (templateId: 2.16.840.1.113883.10.20.23.75)
 - Establishes a relationship between this record and another record.

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

- a. Contains @typeCode="COMP" *COMP*
- b. Contains exactly one [1..1] *Supplemental Value* (templateId: 2.16.840.1.113883.10.20.23.96)
 - Allows the association of a supplemental value - outside of the content specified for the domain - to the record.

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

- a. Contains @typeCode="COMP" *COMP*
- b. Contains exactly one [1..1] *Comment* (templateId: 2.16.840.1.113883.10.20.23.23)
 - A place to insert comments related to a particular finding.

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

- a. Contains @typeCode="COMP" *COMP*
- b. Contains exactly one [1..1] *Finding About* (templateId: 2.16.840.1.113883.10.20.23.40)
 - Allows recording of additional findings related to the event.

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="1859155953" extension="MDHT"/>
  <code codeSystem="locally defined"/>
  <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="1622398670" extension="MDHT"/>
      <code code="C83204" codeSystem="2.16.840.1.113883.3.26.1.1"
      codeSystemName="NCI Thesaurus"/>
      <statusCode code="completed"/>
    </act>
  </entryRelationship>
</observation>
```

```

    <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="1186714231" 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="1323327353"/>
    <interpretationCode code="1816230755"/>
    <methodCode code="661616163"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <procedure>
    <id root="1459975797" extension="MDHT"/>
    <code code="289746815"/>
    <statusCode code="completed"/>
    <effectiveTime>
      <low value="2012"/>
      <high value="2012"/>
    </effectiveTime>
    <methodCode code="406595457"/>
    <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="911280179" 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="2022651294"/>
    <methodCode code="161301260"/>
  </observation>
</entryRelationship>

```

```

    <entryRelationship/>
  </observation>
</entryRelationship>
<entryRelationship>
  <observation>
    <templateId root="2.16.840.1.113883.10.20.23.30"/>
    <id root="1798570260" 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="2026129166"/>
    <interpretationCode code="321806262"/>
    <methodCode code="1707381688"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <act classCode="ACT">
    <templateId root="2.16.840.1.113883.10.20.23.75"/>
    <id root="202548437" 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="402370322" extension="MDHT"/>
    <code codeSystem="locally defined" codeSystemName="Supplemental Value
Type"/>
    <statusCode code="completed"/>
    <effectiveTime>
      <low value="2012"/>
      <high value="2012"/>
    </effectiveTime>
    <interpretationCode code="1291263569"/>
    <methodCode code="964727660"/>
    <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="151542289" 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="483235629"/>
    <interpretationCode code="788906516"/>
    <methodCode code="1786655588"/>
  </observation>

```



```

</entryRelationship>
<entryRelationship>
  <observation/>
</entryRelationship>
<entryRelationship>
  <observation>
    <templateId root="2.16.840.1.113883.10.20.23.76"/>
    <id root="416328288" 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="1842263806"/>
    <interpretationCode code="224564708"/>
    <methodCode code="1432599088"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <observation>
    <id root="1018573818" extension="MDHT"/>
    <code code="2097889106"/>
    <statusCode code="completed"/>
    <effectiveTime>
      <low value="2012"/>
      <high value="2012"/>
    </effectiveTime>
    <interpretationCode code="879633393"/>
    <methodCode code="1210489241"/>
    <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>
  </observation>
  <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>
</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)
2. **SHALL** contain exactly one [1..1] **@moodCode="EVN"** *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain [1..3] **id**
 - A value that is provided to ensure the uniqueness of the microbiology finding. [SDTM: MSSEQ, MSREFID, MSSPID] A single identifier, the sequence number, is required.
4. **SHALL** contain exactly one [1..1] **code**, where the **@code** **SHALL** be selected from (CodeSystem: locally defined Microbiology Susceptibility Finding Type)
 - 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**
 - 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
 - The date/time that the test was performed. [SDTM: MSDTC]
7. **SHOULD** contain zero or more [0..*] **value**
 - The microbiology specimen result, using both original units and a standard format or set of units. [SDTM: MSORRES, MSORRESU, MSSTRESC, MSSTRESN, MSSTRESU]
8. **MAY** contain [0..2] **interpretationCode**, where the **@code** **SHALL** be selected from ValueSet [Subject Data Interpretation Type](#) CXXXXX **STATIC**
 - 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]
9. **SHOULD** contain zero or one [0..1] **methodCode**, where the **@code** **SHALL** be selected from ValueSet [Method](#) C85492 **STATIC**
 - Indicates the method of the test or examination. [SDTM: MSMETHOD]
10. **SHALL** contain exactly one [1..1] **entryRelationship**
 - a. Contains **@typeCode="REFR"** *REFR*
 - b. Contains exactly one [1..1] [Domain Assignment](#) (templateId: 2.16.840.1.113883.10.20.23.30)
 - Identifies the SDTM or SEND domain the record is assigned to.
11. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] [Group Identifier](#) (templateId: 2.16.840.1.113883.10.20.23.42)
 - Allows capture of a group identifier for the finding.
12. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*

- b. Contains exactly one [1..1] *Non Performance Reason* (templateId: 2.16.840.1.113883.10.20.23.56)
 - Provides a reason for not capturing information for the finding.
- 13.MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="REFR"** *REFR*
 - b. Contains exactly one [1..1] *Event Study Day* (templateId: 2.16.840.1.113883.10.20.23.37)
 - Used to record the study day associated with an activity taking place during a single day.
- 14.MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="REFR"** *REFR*
 - b. Contains exactly one [1..1] *Timing Reference* (templateId: 2.16.840.1.113883.10.20.23.97)
 - Orients the performance of the susceptibility test with respect to a study defined timepoint.
- 15.MAY** contain zero or one [0..1] **participant**
 - a. Contains exactly one [1..1] *Study Test Organization* (templateId: 2.16.840.1.113883.10.20.23.88)
 - Used to record the organization performing the test.
- 16.MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Category* (templateId: 2.16.840.1.113883.10.20.23.20)
 - The record of a category to be used in organizing information items.
- 17.MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Sub- Category* (templateId: 2.16.840.1.113883.10.20.23.91)
 - The record of a sub-category to be used in organizing information items.
- 18.SHOULD** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Result Category* (templateId: 2.16.840.1.113883.10.20.23.76)
 - The record of a category to be used in organizing finding or observation results.
- 19.MAY** contain zero or more [0..*] **entryRelationship**
 - a. Contains **@typeCode="REFR"** *REFR*
 - b. Contains exactly one [1..1] *Related Record* (templateId: 2.16.840.1.113883.10.20.23.75)
 - Establishes a relationship between this record and another record.
- 20.MAY** contain zero or more [0..*] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Supplemental Value* (templateId: 2.16.840.1.113883.10.20.23.96)
 - Allows the association of a supplemental value - outside of the content specified for the domain - to the record.
- 21.MAY** contain zero or more [0..*] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Comment* (templateId: 2.16.840.1.113883.10.20.23.23)
 - A place to insert comments related to a particular finding.
- 22.MAY** contain zero or more [0..*] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Finding About* (templateId: 2.16.840.1.113883.10.20.23.40)
 - Allows recording of additional findings related to the event.

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="3964627" extension="MDHT"/>
  <code code="810143015"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <interpretationCode codeSystemName="NCI Thesaurus"/>
  <methodCode code="621161795"/>
  <participant>
    <participantRole classCode="ASSIGNED">
      <templateId root="null"/>
    </participantRole>
  </participant>
  <entryRelationship>
    <observation>
      <id root="442809525" extension="MDHT"/>
      <code code="1898669805"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <value xsi:type="INT" value="1"/>
      <interpretationCode code="177385098"/>
      <methodCode code="1555282114"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <act>
      <templateId root="2.16.840.1.113883.10.20.23.97"/>
      <id root="2024543139" 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="1934894439" 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="1339765738" 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="1804257873"/>
    <interpretationCode code="1319926940"/>
    <methodCode code="1469801997"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <observation classCode="OBS" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.23.23"/>
    <id root="1037127119" 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="423371432"/>
    <methodCode code="7959011"/>
    <participant/>
  </observation>
</entryRelationship>
<entryRelationship>
  <observation>
    <templateId root="2.16.840.1.113883.10.20.23.30"/>
    <id root="2046698950" 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="1533050366"/>
    <interpretationCode code="149409796"/>
    <methodCode code="876358909"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <act classCode="ACT">
    <templateId root="2.16.840.1.113883.10.20.23.75"/>
    <id root="1489902792" 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="772236369" extension="MDHT"/>

```

```

    <code codeSystem="locally defined" codeSystemName="Supplemental Value
Type"/>
    <statusCode code="completed"/>
    <effectiveTime>
      <low value="2012"/>
      <high value="2012"/>
    </effectiveTime>
    <interpretationCode code="74717766"/>
    <methodCode code="338082050"/>
    <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="404101516" 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="1837485306"/>
    <interpretationCode code="1407068477"/>
    <methodCode code="1969564984"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <observation/>
</entryRelationship>
<entryRelationship>
  <observation>
    <templateId root="2.16.840.1.113883.10.20.23.76"/>
    <id root="1840720794" 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="1339454186"/>
    <interpretationCode code="377004032"/>
    <methodCode code="1235176975"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <observation>
    <id root="1486238779" extension="MDHT"/>
    <code code="752643188"/>
    <statusCode code="completed"/>
    <effectiveTime>
      <low value="2012"/>
      <high value="2012"/>
    </effectiveTime>
    <interpretationCode code="1222296984"/>
    <methodCode code="2072102595"/>
    <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>
</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)
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **code/@code**="C66727" *Reason for non completion* (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)
 - The code value identifies this observation as a non-performance reason.
4. **SHALL** contain exactly one [1..1] **value** with data type CD, where the @code **SHALL** be selected from ValueSet [Non Performance Reason](#) C66727 **STATIC**
 - A coded indication of the reason that information relating to the intended activity or measure was not collected. [SDTM: CMREASND, SUREASND, MHREASND, CERASND, 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 Tabulation 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="1198369465" 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="1868770328"/>
</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)
2. **SHALL** contain exactly one [1..1] **@moodCode="EVN"** *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **code/@code="NSTtbd"** (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)
 - A value to indicate that the observation provides the investigator's opinion regarding the causality of the event to a non-study treatment.
4. **SHALL** contain exactly one [1..1] **value** with data type ED
 - 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="1291483250" 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)
2. **SHALL** contain exactly one [1..1] **@moodCode**= "EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **code/@code**= "OATtbd" (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)
 - 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
 - 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="1598925456" 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 analytes(usually study drugs and/or their metabolites) as a function of time after dosing the study drug.

1. **SHALL** contain exactly one [1..1] **@classCode**= "OBS" *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass)
2. **SHALL** contain exactly one [1..1] **@moodCode**= "EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain [1..3] **id**
 - A value that is provided to ensure the uniqueness of the pharmacokinetics 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**, where the **@code** **SHALL** be selected from (CodeSystem: locally defined Pharmacokinetics Concentration Finding Type)
 - 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**
 - 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
 - The pharmacokinetics result, using both original units and a standard format or set of units. [SDTM: PCORRES, PCORRESU, PCSTRESC, PCSTRESN, PCSTRESU], [SEND: PCORRES, PCORRESU, PCSTRESC, PCSTRESN, PCSTRESU]
7. **SHOULD** contain [0..3] **interpretationCode**, where the **@code** **SHALL** be selected from ValueSet *Subject Data Interpretation Type* CXXXXX **STATIC**

- Includes information used to better interpret the observation value (result). [SDTM: PCDRVFL]. [SEND: PCBLFL, PCDRVFL, PCEXCLFL]
- 8. **MAY** contain zero or one [0..1] **methodCode**, where the @code **SHALL** be selected from ValueSet [Method C85492](#) **STATIC**
 - Indicates the method of the test or examination. [SDTM: PCMETHOD], [SEND: PCMETHOD]
- 9. **SHALL** contain exactly one [1..1] **entryRelationship**
 - a. Contains @typeCode="REFR" *REFR*
 - b. Contains exactly one [1..1] [Domain Assignment](#) (templateId: 2.16.840.1.113883.10.20.23.30)
 - Identifies the SDTM or SEND domain the record is assigned to.
- 10. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains @typeCode="COMP" *COMP*
 - b. Contains exactly one [1..1] [Group Identifier](#) (templateId: 2.16.840.1.113883.10.20.23.42)
 - Allows capture of a group identifier for the finding.
- 11. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains @typeCode="COMP" *COMP*
 - b. Contains exactly one [1..1] [Non Performance Reason](#) (templateId: 2.16.840.1.113883.10.20.23.56)
 - Provides a reason for not capturing information for the finding.
- 12. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains @typeCode="COMP" *COMP*
 - b. Contains exactly one [1..1] [Exclusion Reason](#) (templateId: 2.16.840.1.113883.10.20.23.38)
 - Information on the reason that a data item is to be excluded from tabulation.
- 13. **SHALL** contain zero or one [0..1] **entryRelationship**
 - a. Contains @typeCode="COMP" *COMP*
 - b. Contains exactly one [1..1] [Specimen Information](#) (templateId: 2.16.840.1.113883.10.20.23.78)
 - 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.
- 14. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains @typeCode="COMP" *COMP*
 - b. Contains exactly one [1..1] [Fasting Status](#) (templateId: 2.16.840.1.113883.10.20.23.39)
 - Used to indicate the fasting status - time since consumption of food - for the study subject.
- 15. **SHOULD** contain zero or one [0..1] **entryRelationship**
 - a. Contains @typeCode="COMP" *COMP*
 - b. Contains exactly one [1..1] [Assay Quantitation](#) (templateId: 2.16.840.1.113883.10.20.23.16)
 - Records the lower limit of quantitation for an assay.
- 16. **MAY** contain zero or one [0..1] **participant**
 - a. Contains exactly one [1..1] [Study Test Organization](#) (templateId: 2.16.840.1.113883.10.20.23.88)
 - Used to record the organization performing the test.
- 17. **SHOULD** contain zero or one [0..1] **entryRelationship**
 - a. Contains @typeCode="REFR" *REFR*
 - b. Contains exactly one [1..1] [Planned Study Day](#) (templateId: 2.16.840.1.113883.10.20.23.68)
 - Captures the planned study day for making an observation or recording a finding.
- 18. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains @typeCode="COMP" *COMP*

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

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

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

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

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

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

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

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

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

- Establishes a relationship between this record and another record.

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

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

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

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

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

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

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

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

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

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

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

- Allows recording of additional findings related to the finding.

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="827589405" extension="MDHT"/>
  <code code="450286793"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <value xsi:type="CD" code="561002747"/>
  <interpretationCode code="496134862"/>
  <methodCode code="1848231931"/>
  <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="1389967675" 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>
</observation>
```

```

    </effectiveTime>
  </act>
</entryRelationship>
<entryRelationship>
  <procedure>
    <id root="1735800366" extension="MDHT"/>
    <code code="1914688073"/>
    <statusCode code="completed"/>
    <effectiveTime>
      <low value="2012"/>
      <high value="2012"/>
    </effectiveTime>
    <methodCode code="1369846376"/>
    <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="387190398" 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="498592669"/>
    <interpretationCode code="691893496"/>
    <methodCode code="1921656822"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <observation>
    <id root="1378043939" extension="MDHT"/>
    <code code="820514948"/>
    <statusCode code="completed"/>
    <effectiveTime>
      <low value="2012"/>
      <high value="2012"/>
    </effectiveTime>
    <value xsi:type="INT" value="1"/>
    <interpretationCode code="36336351"/>
    <methodCode code="242619119"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <observation classCode="OBS">
    <templateId root="2.16.840.1.113883.10.20.23.38"/>
    <id root="1510187247" 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>
      <low value="2012"/>
      <high value="2012"/>
    </effectiveTime>
    <value xsi:type="CD" code="1139839662"/>
    <interpretationCode code="1930769724"/>
    <methodCode code="2114513459"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <observation classCode="OBS" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.23.23"/>
    <id root="1163829888" 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="2094203554"/>
    <methodCode code="1805700513"/>
    <participant/>
  </observation>
</entryRelationship>
<entryRelationship>
  <observation>
    <templateId root="2.16.840.1.113883.10.20.23.30"/>
    <id root="34773949" 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="198641127"/>
    <interpretationCode code="684619635"/>
    <methodCode code="580809203"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <act classCode="ACT">
    <templateId root="2.16.840.1.113883.10.20.23.75"/>
    <id root="140732596" 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="1830483184" extension="MDHT"/>

```

```

    <code codeSystem="locally defined" codeSystemName="Supplemental Value
Type"/>
    <statusCode code="completed"/>
    <effectiveTime>
      <low value="2012"/>
      <high value="2012"/>
    </effectiveTime>
    <interpretationCode code="784928441"/>
    <methodCode code="1997311726"/>
    <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="1910885405" 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="1123913352"/>
    <interpretationCode code="899788165"/>
    <methodCode code="890499793"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <observation/>
</entryRelationship>
<entryRelationship>
  <observation classCode="OBS">
    <templateId root="2.16.840.1.113883.10.20.23.39"/>
    <id root="1858391228" 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="1001813518"/>
    <methodCode code="1042341018"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <observation>
    <id root="83883357" extension="MDHT"/>
    <code code="852291155"/>
    <statusCode code="completed"/>
    <effectiveTime>
      <low value="2012"/>
      <high value="2012"/>
    </effectiveTime>
    <value xsi:type="IVL_PQ"/>
    <interpretationCode code="2119095894"/>
    <methodCode code="1401034375"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <observation>

```

```

<id root="548141915" extension="MDHT"/>
<code code="379446390"/>
<statusCode code="completed"/>
<effectiveTime>
  <low value="2012"/>
  <high value="2012"/>
</effectiveTime>
<interpretationCode code="1481839631"/>
<methodCode code="1374989940"/>
<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>

```

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 analytes.

1. **SHALL** contain exactly one [1..1] **@classCode="OBS"** *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass)
2. **SHALL** contain exactly one [1..1] **@moodCode="EVN"** *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **id**
 - A value that is provided to ensure the uniqueness of the pharmacokinetics parameter result. [SDTM: PPSEQ], [SEND: PPSEQ]

4. **SHALL** contain exactly one [1..1] **code**, where the @code **SHALL** be selected from ValueSet *Pharmacokinetics Parameter Finding Type* C85839 **STATIC**
 - 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**
 - Used to indicate whether or not an exam has been performed. [SDTM: PPSTAT], [SEND: PPSTAT]
6. **SHOULD** contain zero or one [0..1] **value**
 - The pharmacokinetics parameter result, using both original units and a standard format or set of units. [SDTM: PPORRES, PPORRESU, PPSTRESC, PPSTRESN, PPSTRESU], [SEND: PPORRES, PPORRESU, PPSTRESC, PPSTRESN, PPSTRESU]
7. **SHALL** contain exactly one [1..1] **entryRelationship**
 - a. Contains @typeCode="REFR" *REFR*
 - b. Contains exactly one [1..1] *Domain Assignment* (templateId: 2.16.840.1.113883.10.20.23.30)
 - Identifies the SDTM or SEND domain the record is assigned to.
8. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains @typeCode="COMP" *COMP*
 - b. Contains exactly one [1..1] *Group Identifier* (templateId: 2.16.840.1.113883.10.20.23.42)
 - Allows capture of a group identifier for the finding.
9. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains @typeCode="COMP" *COMP*
 - b. Contains exactly one [1..1] *Non Performance Reason* (templateId: 2.16.840.1.113883.10.20.23.56)
 - Provides a reason for not capturing information for the finding.
10. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains @typeCode="COMP" *COMP*
 - b. Contains exactly one [1..1] *Specimen Information* (templateId: 2.16.840.1.113883.10.20.23.78)
 - 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.
11. **SHOULD** contain zero or one [0..1] **entryRelationship**
 - a. Contains @typeCode="COMP" *COMP*
 - b. Contains exactly one [1..1] *Timing Reference* (templateId: 2.16.840.1.113883.10.20.23.97)
 - Orients the performance of the test leading to the pharmacokinetic parameter with respect to a study defined timepoint.
12. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains @typeCode="COMP" *COMP*
 - b. Contains exactly one [1..1] *Category* (templateId: 2.16.840.1.113883.10.20.23.20)
 - The record of a category to be used in organizing information items.
13. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains @typeCode="COMP" *COMP*
 - b. Contains exactly one [1..1] *Sub- Category* (templateId: 2.16.840.1.113883.10.20.23.91)
 - The record of a sub-category to be used in organizing information items.
14. **MAY** contain zero or more [0..*] **entryRelationship**
 - a. Contains @typeCode="REFR" *REFR*
 - b. Contains exactly one [1..1] *Related Record* (templateId: 2.16.840.1.113883.10.20.23.75)
 - Establishes a relationship between this record and another record.

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

- a. Contains **@typeCode="COMP"** *COMP*
- b. Contains exactly one [1..1] *Supplemental Value* (templateId: 2.16.840.1.113883.10.20.23.96)
 - Allows the association of a supplemental value - outside of the content specified for the domain - to the record.

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

- a. Contains **@typeCode="COMP"** *COMP*
- b. Contains exactly one [1..1] *Comment* (templateId: 2.16.840.1.113883.10.20.23.23)
 - A place to insert comments related to a particular finding.

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

- a. Contains **@typeCode="COMP"** *COMP*
- b. Contains exactly one [1..1] *Finding About* (templateId: 2.16.840.1.113883.10.20.23.40)
 - Allows recording of additional findings related to the finding.

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="1164164821" extension="MDHT"/>
  <code code="1403587617"/>
  <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="477788972" 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="148147042" extension="MDHT"/>
      <code code="848354097"/>
      <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>
  </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="1345834660" 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="905044602"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <act>
    <templateId root="2.16.840.1.113883.10.20.23.97"/>
    <id root="512595192" 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="1376685168" 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="1789907322" 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="1910106438"/>
  </observation>
</entryRelationship>
<entryRelationship>

```

```

    <act classCode="ACT">
      <templateId root="2.16.840.1.113883.10.20.23.75"/>
      <id root="1984596391" 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="1021114323" 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="1989215028" 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="491531631"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation/>
  </entryRelationship>
  <entryRelationship>
    <observation>
      <id root="1036518858" extension="MDHT"/>
      <code code="1189578491"/>
      <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>

```

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)
2. **SHALL** contain exactly one [1..1] **@moodCode**= "EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain [1..2] **id**
 - A value that is provided to ensure the uniqueness of the physical exam finding. [SDTM: PESEQ, PESPID] A single identifier, the sequence number, is required.
4. **SHALL** contain exactly one [1..1] **code**, where the **@code** **SHALL** be selected from (CodeSystem: locally defined Physical Exam Finding Type)
 - 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**
 - Used to indicate whether or not the specified physical exam has been performed. [SDTM: PESTAT]
6. **SHOULD** contain zero or one [0..1] **value**
 - The result of the component of the physical exam indicated by the code value. Verbatim findings are captured in original 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, PEORESUS, PESTRESC]
7. **MAY** contain zero or one [0..1] **methodCode**, where the **@code** **SHALL** be selected from ValueSet [Method C85492](#) **STATIC**
 - The method used for conducting the test or examination. [SDTM: PEMETHOD]

8. **MAY** contain zero or one [0..1] **targetSiteCode**, where the @code **SHALL** be selected from ValueSet *Anatomical Location* C74456 **STATIC**
 - Can be used to specify where a physical exam finding occurred. [SDTM: PELOC]
9. **SHALL** contain exactly one [1..1] **entryRelationship**
 - a. Contains @typeCode="REFR" *REFR*
 - b. Contains exactly one [1..1] *Domain Assignment* (templateId: 2.16.840.1.113883.10.20.23.30)
 - Identifies the SDTM or SEND domain the record is assigned to.
10. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains @typeCode="COMP" *COMP*
 - b. Contains exactly one [1..1] *Group Identifier* (templateId: 2.16.840.1.113883.10.20.23.42)
 - Allows capture of a group identifier for the finding.
11. **SHOULD** contain zero or one [0..1] **entryRelationship**
 - a. Contains @typeCode="COMP" *COMP*
 - b. Contains exactly one [1..1] *Data Collection* (templateId: 2.16.840.1.113883.10.20.23.27)
 - Information on whether a predefined data item was collected, and the timing of collection.
12. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains @typeCode="COMP" *COMP*
 - b. Contains exactly one [1..1] *Non Performance Reason* (templateId: 2.16.840.1.113883.10.20.23.56)
 - Provides a reason for not capturing information for the finding.
13. **MAY** contain zero or one [0..1] **participant**
 - a. Contains exactly one [1..1] *Study Finding Evaluator* (templateId: 2.16.840.1.113883.10.20.23.84)
 - Used to record the role played by the person providing the value of a subjective finding.
14. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains @typeCode="COMP" *COMP*
 - b. Contains exactly one [1..1] *Body System or Organ Class* (templateId: 2.16.840.1.113883.10.20.23.17)
 - Allows identification of the relevant body system or organ class.
15. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains @typeCode="COMP" *COMP*
 - b. Contains exactly one [1..1] *Category* (templateId: 2.16.840.1.113883.10.20.23.20)
 - The record of a category to be used in organizing information items.
16. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains @typeCode="COMP" *COMP*
 - b. Contains exactly one [1..1] *Sub- Category* (templateId: 2.16.840.1.113883.10.20.23.91)
 - The record of a sub-category to be used in organizing information items.
17. **MAY** contain zero or more [0..*] **entryRelationship**
 - a. Contains @typeCode="REFR" *REFR*
 - b. Contains exactly one [1..1] *Related Record* (templateId: 2.16.840.1.113883.10.20.23.75)
 - Establishes a relationship between this record and another record.
18. **MAY** contain zero or more [0..*] **entryRelationship**
 - a. Contains @typeCode="COMP" *COMP*
 - b. Contains exactly one [1..1] *Supplemental Value* (templateId: 2.16.840.1.113883.10.20.23.96)
 - Allows the association of a supplemental value - outside of the content specified for the domain - to the record.

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

- a. Contains **@typeCode="COMP"** *COMP*
- b. Contains exactly one [1..1] *Comment* (templateId: 2.16.840.1.113883.10.20.23.23)
 - A place to insert comments related to a particular finding.

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

- a. Contains **@typeCode="COMP"** *COMP*
- b. Contains exactly one [1..1] *Finding About* (templateId: 2.16.840.1.113883.10.20.23.40)
 - Allows recording of additional findings related to the finding.

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="1570962274" extension="MDHT"/>
  <code code="1212485387"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <methodCode code="1888318932"/>
  <targetSiteCode code="1611529967"/>
  <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="163524329" 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="1686621156" 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="846897116"/>
      <methodCode code="1161450130"/>
      <targetSiteCode code="1738366838"/>
    </observation>
  </entryRelationship>
</observation>
```

```

    </observation>
  </entryRelationship>
  <entryRelationship>
    <act>
      <id root="990622381" extension="MDHT"/>
      <code code="302207700"/>
      <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="1925689071" 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="1772558268"/>
      <targetSiteCode code="1861280800"/>
      <participant/>
      <entryRelationship/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation>
      <templateId root="2.16.840.1.113883.10.20.23.30"/>
      <id root="1367887099" 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="497560558"/>
      <methodCode code="238273663"/>
      <targetSiteCode code="368183068"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <act classCode="ACT">
      <templateId root="2.16.840.1.113883.10.20.23.75"/>
      <id root="418691540" 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="1540692708" extension="MDHT"/>
      <code codeSystem="locally defined" codeSystemName="Supplemental Value
Type"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <methodCode code="1639679591"/>
      <targetSiteCode code="587331924"/>
      <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="1579786196" 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="834863419"/>
      <methodCode code="746143349"/>
      <targetSiteCode code="1000343560"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation/>
  </entryRelationship>
  <entryRelationship>
    <observation>
      <id root="139236536" extension="MDHT"/>
      <code code="565016693"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <methodCode code="187772605"/>
      <targetSiteCode code="953201799"/>
      <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>
    <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)
2. **SHALL** contain exactly one [1..1] **@moodCode**= "INT" (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **code/@code**= "C83450" *Planned Study Day of Visit* (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)
 - A fixed value that indicates the observation captures the planned study day for an event.
4. **SHALL** contain exactly one [1..1] **value** with data type INT
 - 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="27792652" extension="MDHT"/>
  <code code="1287591491"/>
  <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**
2. **SHALL** contain exactly one [1..1] **@moodCode**
3. **SHALL** contain exactly one [1..1] **code/@code="C71148"** (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)
 - A code value that indicates that the observation is that of body position.
4. **SHALL** contain exactly one [1..1] **value** with data type CD, where the **@code** **SHALL** be selected from ValueSet *Body Position* C71148 **STATIC**
 - 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="179668063" 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="2132463751" />
</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)
2. **SHALL** contain exactly one [1..1] **@moodCode="EVN"** *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **code/@code="PSEtbd"** (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)
 - 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
 - Indicate whether or not the the indicated activity or event was prespecified on the CRF. [SDTM: CMPRESP, SUPRESP, AEPRESP, MHPRESP, CEPHRESP], [Study Data Tabulation 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="2045735316" 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**
2. **SHALL** contain exactly one [1..1] **@moodCode**
3. **SHALL** contain [1..3] **id**
 - A value that is provided to ensure the uniqueness of protocol deviation items. [SDTM: DVSEQ, DVREFID, DVSPID] A single identifier, the sequence number, is required.
4. **SHALL** contain exactly one [1..1] **code/@code="PDtbd"** (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)
 - A fixed value that indicates the observation carries protocol deviation information.
5. **MAY** contain zero or one [0..1] **effectiveTime**
 - 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
 - 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**
 - a. Contains **@typeCode="REFR"** *REFR*
 - b. Contains exactly one [1..1] *Study Epoch* (templateId: 2.16.840.1.113883.10.20.23.83)
 - Records the study epoch during which the information was collected.
8. **SHALL** contain exactly one [1..1] **entryRelationship**
 - a. Contains **@typeCode="REFR"** *REFR*
 - b. Contains exactly one [1..1] *Domain Assignment* (templateId: 2.16.840.1.113883.10.20.23.30)
 - Identifies the SDTM or SEND domain the record is assigned to.
9. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Category* (templateId: 2.16.840.1.113883.10.20.23.20)
 - The record of a category to be used in organizing information items.
10. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Sub- Category* (templateId: 2.16.840.1.113883.10.20.23.91)
 - The record of a sub-category to be used in organizing information items.
11. **MAY** contain zero or more [0..*] **entryRelationship**
 - a. Contains **@typeCode="REFR"** *REFR*
 - b. Contains exactly one [1..1] *Related Record* (templateId: 2.16.840.1.113883.10.20.23.75)

- Establishes a relationship between this record and another record.

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

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

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

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

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

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

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

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

- Allows recording of additional findings related to the finding.

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="536396832" 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="1780181671"/>
  <entryRelationship>
    <act>
      <templateId root="2.16.840.1.113883.10.20.23.83"/>
      <id root="483757897" 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="142834192" 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="831764449" 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="1206256039"/>
    </observation>
</entryRelationship>
<entryRelationship>
    <act classCode="ACT">
        <templateId root="2.16.840.1.113883.10.20.23.75"/>
        <id root="89706770" 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="1569226159" 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="463872506" 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="208795557"/>
    </observation>
</entryRelationship>
<entryRelationship>
    <observation/>
</entryRelationship>
<entryRelationship>
    <observation>
        <id root="490715883" extension="MDHT"/>
        <code code="1233151845"/>
        <effectiveTime>
            <low value="2012"/>
            <high value="2012"/>
        </effectiveTime>
        <participant/>
        <entryRelationship typeCode="REFR"/>
    </observation>
    <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>
</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)
2. **SHALL** contain exactly one [1..1] **@moodCode="EVN"** *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain [1..2] **id**
 - A value that is provided to ensure the uniqueness of the questionnaire finding. [SDTM: QSSEQ, QSSPID] A single identifier, the sequence number, is required.
4. **SHALL** contain exactly one [1..1] **code**, where the **@code** **SHALL** be selected from (CodeSystem: locally defined Question Type)
 - 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**
 - Used to indicate whether or not the specified questionnaire response was elicited. [SDTM: QSSTAT]
6. **MAY** contain zero or one [0..1] **effectiveTime**

- Used to capture the evaluation interval associated with the questionnaire finding. E.g., "Have you experienced any episodes in the last two years?" [SDTM: QSEVLINT]
- 7. **SHOULD** contain zero or one [0..1] **value**
 - The response to the questionnaire item indicated by the code value. A result or finding in standard format should be recorded as a base value - either code or physical quantity. A modified reported term is included as a translation. [SDTM: QSORRES, QSORRESU, QSSTRESC, QSSTRESN, QSSTRESU]
- 8. **SHOULD** contain [0..2] **interpretationCode**, where the @code **SHALL** be selected from ValueSet *Subject Data Interpretation Type* CXXXXXX STATIC
 - 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]
- 9. **SHALL** contain exactly one [1..1] **entryRelationship**
 - a. Contains @typeCode="REFR" *REFR*
 - b. Contains exactly one [1..1] *Domain Assignment* (templateId: 2.16.840.1.113883.10.20.23.30)
 - Identifies the SDTM or SEND domain the record is assigned to.
- 10. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains exactly one [1..1] *Group Identifier* (templateId: 2.16.840.1.113883.10.20.23.42)
 - Allows capture of a group identifier for the response to the question.
- 11. **SHOULD** contain zero or one [0..1] **entryRelationship**
 - a. Contains @typeCode="COMP" *COMP*
 - b. Contains exactly one [1..1] *Data Collection* (templateId: 2.16.840.1.113883.10.20.23.27)
 - 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.
- 12. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains @typeCode="COMP" *COMP*
 - b. Contains exactly one [1..1] *Non Performance Reason* (templateId: 2.16.840.1.113883.10.20.23.56)
 - Provides a reason for not capturing information for the question.
- 13. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains @typeCode="REFR" *REFR*
 - b. Contains exactly one [1..1] *Timing Reference* (templateId: 2.16.840.1.113883.10.20.23.97)
 - Orients the timing of the question and response with respect to a study defined timepoint.
- 14. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains @typeCode="COMP" *COMP*
 - b. Contains exactly one [1..1] *Category* (templateId: 2.16.840.1.113883.10.20.23.20)
 - The record of a category to be used in organizing information items.
- 15. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains @typeCode="COMP" *COMP*
 - b. Contains exactly one [1..1] *Sub- Category* (templateId: 2.16.840.1.113883.10.20.23.91)
 - The record of a sub-category to be used in organizing information items.
- 16. **MAY** contain zero or more [0..*] **entryRelationship**
 - a. Contains @typeCode="REFR" *REFR*
 - b. Contains exactly one [1..1] *Related Record* (templateId: 2.16.840.1.113883.10.20.23.75)
 - Establishes a relationship between this record and another record.
- 17. **MAY** contain zero or more [0..*] **entryRelationship**
 - a. Contains @typeCode="COMP" *COMP*

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

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

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

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

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

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

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

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

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

- Allows recording of additional findings related to the finding.

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="338111849" extension="MDHT"/>
  <code code="1536594434"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <interpretationCode code="784573425"/>
  <entryRelationship>
    <act classCode="ACT">
      <templateId root="2.16.840.1.113883.10.20.23.42"/>
      <id root="145136317" 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="1721664499" 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="1895090012"/>
      <interpretationCode code="1217027115"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <act>
      <templateId root="2.16.840.1.113883.10.20.23.97"/>
      <id root="2099566730" 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="343452613" extension="MDHT"/>
      <code code="760565418"/>
      <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="1031012327" 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="150482994"/>
      <participant/>
      <entryRelationship/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation>
      <templateId root="2.16.840.1.113883.10.20.23.30"/>
      <id root="2015615730" 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="984226917"/>
      <interpretationCode code="511726217"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <act classCode="ACT">
      <templateId root="2.16.840.1.113883.10.20.23.75"/>
      <id root="356952634" 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>
<entryRelationship>
  <observation classCode="OBS" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.23.96"/>
    <id root="1694875800" extension="MDHT"/>
    <code codeSystem="locally defined" codeSystemName="Supplemental Value
Type"/>
    <statusCode code="completed"/>
    <effectiveTime>
      <low value="2012"/>
      <high value="2012"/>
    </effectiveTime>
    <interpretationCode code="921414383"/>
    <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="1558973295" 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="715358060"/>
    <interpretationCode code="231301002"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <observation/>
</entryRelationship>
<entryRelationship>
  <observation>
    <id root="700185514" extension="MDHT"/>
    <code code="42575163"/>
    <statusCode code="completed"/>
    <effectiveTime>
      <low value="2012"/>
      <high value="2012"/>
    </effectiveTime>
    <interpretationCode code="1652516511"/>
    <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>
  </observation>
  <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 participation 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 reuse 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)
2. **SHALL** contain exactly one [1..1] **@moodCode="EVN"** *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **code/@code="Rptbd"** (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)
 - A code value that indicates that the act captures reference period information.
4. **SHALL** contain exactly one [1..1] **effectiveTime**
 - The reference start and stop time for the subject's participation 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="278465745" extension="MDHT"/>
  <code code="870442102"/>
  <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)
2. **SHALL** contain exactly one [1..1] **@moodCode="EVN"** *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **id**
 - 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/@code="RRtbd"** (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)
 - 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="1535514511" 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)
2. **SHALL** contain exactly one [1..1] **@moodCode="EVN"** *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **code**, where the @code **SHALL** be selected from ValueSet [Subject Data Domain Result Category Type](#) CXXXXX **STATIC**
 - 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
 - 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="1591400031" 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="1900660588"/>
</observation>
```

Serious Event

[Observation: templateId 2.16.840.1.113883.10.20.23.77]

The template is used to record information 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 captured as a template to facilitate its reuse as a characteristic of different types of event within clinical and non-clinical trial reporting.

[SDTM: J. [Study Data Tabulation Model; -SER]

1. **SHALL** contain exactly one [1..1] **@classCode**= "OBS" *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass)
2. **SHALL** contain exactly one [1..1] **@moodCode**= "EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **code/@code**= "SETbd" *Serious Event* (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)
 - A code value that indicates that the observation captures event seriousness information.
4. **SHALL** contain exactly one [1..1] **value** with data type BL
 - 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**
 - a. Such entryRelationships **SHALL** contain exactly one [1..1] **@typeCode**= "COMP"
 - b. Such entryRelationships **SHALL** contain exactly one [1..1] **observation**
 - a. This observation **SHALL** contain exactly one [1..1] **@classCode**
 - b. This observation **SHALL** contain exactly one [1..1] **@moodCode**= "EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
 - c. This observation **SHALL** contain exactly one [1..1] **code/@code**= "SETbd" (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)

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

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, ASEDISAB, 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="2074394825" extension="MDHT"/>
  <code code="1670112001"/>
  <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)
2. **SHALL** contain exactly one [1..1] **@moodCode="EVN"** *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **code/@code="SCLtbd"** (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)
 - A fixed code value to indicate the act is one of specimen collection.
4. **SHOULD** contain zero or one [0..1] **effectiveTime**
 - 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] **targetSiteCode**, where the @code **SHALL** be selected from ValueSet [Anatomical Location](#) C74456 **STATIC**
 - Information about the anatomic region from which the specimen was extracted. {SEND: MAANTREG}
6. **SHOULD** contain zero or one [0..1] **specimen**

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

- a. This specimen **SHALL** contain zero or one [0..1] **@typeCode="SPC"**
- b. This specimen **SHOULD** contain zero or one [0..1] **specimenRole**
 - a. This specimenRole **SHALL** contain zero or one [0..1] **@classCode="SPEC"**
 - b. This specimenRole **MAY** contain zero or one [0..1] **id**

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

- c. This specimenRole **SHOULD** contain zero or one [0..1] **specimenEntity**
 - a. This specimenEntity **SHALL** contain exactly one [1..1] **@classCode="ENT"**
 - b. This specimenEntity **SHALL** contain exactly one [1..1] **@determinerCode="INSTANCE"**
 - c. This specimenEntity **SHALL** contain exactly one [1..1] **code**, where the @code **SHALL** be selected from ValueSet [Specimen Type](#) C78734 **STATIC**

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

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

Characterizes the relationship of the specimen to the anatomic 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"
- b. This entryRelationship **SHALL** contain exactly one [1..1] **observation**
 - a. This observation Contains exactly one [1..1] **@classCode**="OBS" *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass)
 - b. This observation **SHALL** contain exactly one [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
 - c. This observation **SHALL** contain exactly one [1..1] **code/@code**="POTtbd" (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)

A fixed value that indicates the nature of the observation. It provides information on the relationship of the specimen to the anatomic structure it was drawn from..

- d. This observation **SHALL** contain exactly one [1..1] **value** with data type CD, where the **@code** **SHALL** be selected from ValueSet *Portion or Totality Type* CXXXXX **STATIC**

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

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

Records information regarding the usability of the specimen.

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

The value indicates the nature of the observation. It provides information on the usability of the specimen.

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

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

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

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

- a. This entryRelationship **SHALL** contain exactly one [1..1] **@typeCode**="COMP"
- b. This entryRelationship **SHALL** contain exactly one [1..1] **observation**
 - a. This observation Contains exactly one [1..1] **@classCode**="OBS" *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass)
 - b. This observation **SHALL** contain exactly one [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
 - c. This observation **SHALL** contain exactly one [1..1] **code/@code**="C78733" (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)

The value indicates the nature of the observation. It provides information on the specimen condition.

- d. This observation **SHALL** contain exactly one [1..1] **value** with data type CD, where the **@code** **SHALL** be selected from ValueSet *Specimen Condition Type* C78733 **STATIC**

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

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

- a. Contains **@typeCode="REFR"** *REFR*
- b. Contains exactly one [1..1] *Event Study Day* (templateId: 2.16.840.1.113883.10.20.23.37)
 - Used to record the study day associated with an activity taking place during a single day.

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

- a. Contains **@typeCode="REFR"** *REFR*
- b. Contains exactly one [1..1] *Timing Reference* (templateId: 2.16.840.1.113883.10.20.23.97)
 - Orients the performance of the test on the specimen with respect to a study defined timepoint.

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="1581650660" extension="MDHT"/>
  <code code="331092688"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <targetSiteCode code="1644417297"/>
  <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="1117069097" extension="MDHT"/>
      <code code="302211436"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <targetSiteCode code="1047167213"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <act>
      <templateId root="2.16.840.1.113883.10.20.23.97"/>
      <id root="58902449" 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)
2. **SHALL** contain exactly one [1..1] **@moodCode**= "EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **code/@code**= "STRPtbd" (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)
 - 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, where the **@code** **SHALL** be selected from ValueSet [Reference Period Relationship](#) C66728 **STATIC**
 - 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="1355770578" 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="2033013560"/>
</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)
2. **SHALL** contain exactly one [1..1] **@moodCode**= "EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **code/@code**= "ENRPtbd" (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)

- 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, where the @code **SHALL** be selected from ValueSet [Reference Period Relationship](#) C66728 **STATIC**
 - 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="1831012600" 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="401492119"/>
</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)
2. **SHALL** contain exactly one [1..1] @moodCode="INT" (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
 - 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**, where the @code **SHALL** be selected from (CodeSystem: locally defined Study Arm Type)
 - The fixed value includes the code for the study arm. [SDTM: ARMCD]
4. **SHALL** contain zero or one [0..1] **text**
 - Provide the description of the planned arm for the subject. [SDTM, ARM].
5. **SHOULD** contain zero or one [0..1] **effectiveTime**
 - The reference period for the subject's participation in the study. It is usually equivalent to an interval that begins on the date/time when the person was first exposed to study treatment, and ends when the subject was determined to have ended the trial. The end date is often equivalent to the date/time of last exposure to study treatment. [SDTM: RFSTDTC, RFENDTC].

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="148728013" 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 labeled 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)
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **code/@code**="STPtbd" (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)
 - A fixed value that indicates the observation captures the actual study day for an event.
4. **SHALL** contain exactly one [1..1] **value** with data type IVL_INT
 - The applicable study day 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="1115151980" extension="MDHT"/>
  <code code="847746811"/>
  <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)
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **code**, where the **@code** **SHALL** be selected from (CodeSystem: locally defined Study Epoch Type)

- A code value for the epoch.
4. **SHALL** contain zero or one [0..1] **text**
 - 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="394618528" 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)
3. **SHALL** contain [1..3] **id**
 - 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**
 - The code value indicates the nature of the observation. The verbatim term is captured as original text. A modified term is represented 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. **MAY** contain zero or one [0..1] **statusCode**
 - Used to indicate whether the event did occur. Use statusCode "Completed" if the event in question occurred. [Study Data Tabulation Model: -OCCUR]
6. **SHOULD** contain zero or one [0..1] **effectiveTime**
 - 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 recommended 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]
7. **SHALL** contain exactly one [1..1] **value** with data type CD
 - 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**, where the @code **SHALL** be selected from ValueSet [Anatomical Location](#) C74456 **STATIC**

- The anatomic location that is relevant for the event. [Study Data Tabulation Model: -LOC]

9. SHALL contain exactly one [1..1] **entryRelationship**

- Contains **@typeCode="REFR"** *REFR*
 - Contains exactly one [1..1] *Domain Assignment* (templateId: 2.16.840.1.113883.10.20.23.30)
- Identifies the SDTM or SEND domain the record is assigned to.

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

- Contains **@typeCode="COMP"** *COMP*
 - Contains exactly one [1..1] *Data Collection* (templateId: 2.16.840.1.113883.10.20.23.27)
- Information on whether a predefined data item was collected, and the timing of collection.

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

- Contains **@typeCode="COMP"** *COMP*
 - Contains exactly one [1..1] *Non Performance Reason* (templateId: 2.16.840.1.113883.10.20.23.56)
- Information on the reason a scheduled activity was not carried out.

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

- Contains **@typeCode="COMP"** *COMP*
 - Contains exactly one [1..1] *Group Identifier* (templateId: 2.16.840.1.113883.10.20.23.42)
- Indicates an identifier that is used to group associated events.

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

- Contains **@typeCode="COMP"** *COMP*
 - Contains exactly one [1..1] *Event or Finding Severity* (templateId: 2.16.840.1.113883.10.20.23.34)
- A record of the severity or intensity of the finding.

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

- Contains **@typeCode="COMP"** *COMP*
 - Contains exactly one [1..1] *Pre-Specified Event* (templateId: 2.16.840.1.113883.10.20.23.70)
- Indicates whether or not the event was prespecified on the CRF.

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

- Contains **@typeCode="COMP"** *COMP*
 - Contains exactly one [1..1] *Body System or Organ Class* (templateId: 2.16.840.1.113883.10.20.23.17)
- Allows identification of the relevant body system or organ class for the event.

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

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

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

- Contains **@typeCode="COMP"** *COMP*
 - Contains exactly one [1..1] *Study Treatment Action Taken* (templateId: 2.16.840.1.113883.10.20.23.89)
- Information on whether adjustments were made to the study treatment as a result of the event.

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

- Contains **@typeCode="COMP"** *COMP*

- b. Contains exactly one [1..1] *Other Treatment Action Taken* (templateId: 2.16.840.1.113883.10.20.23.63)

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

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

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

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

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

- 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)

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

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

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

- Records the pattern of an event.

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

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

- Records the outcome of an event.

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

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

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

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

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

- A record of the toxicity of the event.

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

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

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

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

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

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

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

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

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

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

- a. Contains **@typeCode="REFR"** *REFR*
- b. Contains exactly one [1..1] *Related Record* (templateId: 2.16.840.1.113883.10.20.23.75)
 - Establishes a relationship between this record and another record.

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

- a. Contains **@typeCode="COMP"** *COMP*
- b. Contains exactly one [1..1] *Supplemental Value* (templateId: 2.16.840.1.113883.10.20.23.96)
 - Allows the association of a supplemental value - outside of the content specified for the domain - to the record.

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

- a. Contains **@typeCode="COMP"** *COMP*
- b. Contains exactly one [1..1] *Comment* (templateId: 2.16.840.1.113883.10.20.23.23)
 - A place to insert comments related to a particular finding.

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

- a. Contains **@typeCode="COMP"** *COMP*
- b. Contains exactly one [1..1] *Finding About* (templateId: 2.16.840.1.113883.10.20.23.40)
 - Allows recording of additional findings related to the finding.

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

- a. Contains **@typeCode="COMP"** *COMP*
- b. Contains exactly one [1..1] *Event Duration* (templateId: 2.16.840.1.113883.10.20.23.102)
 - Records the duration of an event in cases in which this cannot be derived from existing start and stop information.

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="1588920547" extension="MDHT"/>
  <code code="1346159022"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <value xsi:type="CD" code="548524319"/>
  <targetSiteCode code="991809943"/>
  <entryRelationship>
    <act classCode="ACT">
      <templateId root="2.16.840.1.113883.10.20.23.42"/>
      <id root="682887289" 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>
<entryRelationship>
  <observation>
    <id root="993949552" extension="MDHT"/>
    <code code="895127332"/>
    <statusCode code="completed"/>
    <effectiveTime>
      <low value="2012"/>
      <high value="2012"/>
    </effectiveTime>
    <value xsi:type="IVL_INT" value="1"/>
    <targetSiteCode code="500333429"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <observation/>
</entryRelationship>
<entryRelationship>
  <observation classCode="OBS" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.23.23"/>
    <id root="1055017128" 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="973741690"/>
    <participant/>
    <entryRelationship/>
  </observation>
</entryRelationship>
<entryRelationship>
  <observation>
    <templateId root="2.16.840.1.113883.10.20.23.30"/>
    <id root="1761336469" 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="1740112662"/>
    <targetSiteCode code="1301735412"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <act classCode="ACT">
    <templateId root="2.16.840.1.113883.10.20.23.75"/>
    <id root="1136394113" 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="2126854109" extension="MDHT"/>
    <code codeSystem="locally defined" codeSystemName="Supplemental Value
Type"/>
    <statusCode code="completed"/>
    <effectiveTime>
      <low value="2012"/>
      <high value="2012"/>
    </effectiveTime>
    <targetSiteCode code="1301179222"/>
    <participant/>
    <entryRelationship typeCode="COMP"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <act>
    <id root="1000488558" extension="MDHT"/>
    <code code="1594910846"/>
    <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="1437511250" 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="1066499005"/>
    <targetSiteCode code="1444128589"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <observation>
    <id root="1545823090" extension="MDHT"/>
    <code code="1251449"/>
    <statusCode code="completed"/>
    <effectiveTime>
      <low value="2012"/>
      <high value="2012"/>
    </effectiveTime>
    <value xsi:type="BL"/>
    <targetSiteCode code="1022419152"/>
    <entryRelationship typeCode="COMP"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <observation classCode="OBS" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.23.89"/>
    <id root="997873286" 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="31244219"/>
    <targetSiteCode code="1750747737"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <observation classCode="OBS">
    <templateId root="2.16.840.1.113883.10.20.23.63"/>
    <id root="919919384" 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="1473053299"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <observation>
    <id root="1148851583" 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="294116992"/>
    <targetSiteCode code="163257980"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <observation/>
</entryRelationship>
<entryRelationship>
  <observation classCode="OBS" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.23.36"/>
    <id root="1649577575" extension="MDHT"/>
    <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"/>
      <high value="2012"/>
    </effectiveTime>
    <value xsi:type="CD" code="91190877"/>
    <targetSiteCode code="1738525668"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <observation>
    <templateId root="2.16.840.1.113883.10.20.23.35"/>
    <id root="1105582492" 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>
  </observation>
</entryRelationship>

```

```

        </effectiveTime>
        <value xsi:type="CD" code="923241653"/>
        <targetSiteCode code="691017532"/>
    </observation>
</entryRelationship>
<entryRelationship>
    <observation>
        <templateId root="2.16.840.1.113883.10.20.25.25"/>
        <id root="864254556" extension="MDHT"/>
        <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus" displayName="Adverse Event Concomitant Treatment"/>
        <statusCode code="completed"/>
        <effectiveTime>
            <low value="2012"/>
            <high value="2012"/>
        </effectiveTime>
        <value xsi:type="BL"/>
        <targetSiteCode code="2043740681"/>
    </observation>
</entryRelationship>
<entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
        <templateId root="2.16.840.1.113883.10.20.23.98"/>
        <id root="2076461940" 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="711555832"/>
        <targetSiteCode code="543115148"/>
    </observation>
</entryRelationship>
<entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
        <templateId root="2.16.840.1.113883.10.20.23.20"/>
        <id root="425531794" 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="1996947379"/>
        <targetSiteCode code="47487842"/>
    </observation>
</entryRelationship>
<entryRelationship>
    <observation/>
</entryRelationship>
<entryRelationship>
    <observation>
        <id root="1571882180" extension="MDHT"/>
        <code code="1502237075"/>
        <statusCode code="completed"/>
        <effectiveTime>
            <low value="2012"/>
            <high value="2012"/>
        </effectiveTime>
        <targetSiteCode code="1906275570"/>
    </observation>
</entryRelationship>

```

```

    <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="746557446" 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="121461002"/>
    <targetSiteCode code="706659206"/>
  </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.

1. **SHALL** contain exactly one [1..1] **@classCode="OBS"** *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass)
2. **SHALL** contain exactly one [1..1] **@moodCode="EVN"** *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain [1..2] **id**
 - 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**
 - 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.
5. **MAY** contain zero or one [0..1] **text**
 - The reference property of the ED data type is used to capture the file name and path for an external file. [Study Data Tabulation Model: -XFN]
6. **MAY** contain zero or one [0..1] **statusCode**
 - Used to indicate whether or not an exam has been performed. [Study Data Tabulation Model: -STAT]
7. **SHOULD** contain zero or one [0..1] **value**
 - The finding result, using both original units and a standard format or set of units. [Study Data Tabulation Model: -ORRES, ORRESU, STRESC, STRESN, STRESU] 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.
8. **MAY** contain [0..3] **interpretationCode**
 - 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.
9. **MAY** contain zero or one [0..1] **methodCode**, where the @code **SHALL** be selected from ValueSet [Method C85492](#) **STATIC**
 - Indicates the method of the test or examination. [Study Data Tabulation Model: = METHOD]
10. **MAY** contain zero or more [0..*] **targetSiteCode**, where the @code **SHALL** be selected from ValueSet [Anatomical Location C74456](#) **STATIC**
 - 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 target location, target site code - which can repeat - is used.
11. **SHALL** contain exactly one [1..1] **entryRelationship**
 - a. Contains **@typeCode="REFR"** *REFR*
 - b. Contains exactly one [1..1] [Domain Assignment](#) (templateId: 2.16.840.1.113883.10.20.23.30)
 - Identifies the SDTM or SEND domain the record is assigned to.
12. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] [Group Identifier](#) (templateId: 2.16.840.1.113883.10.20.23.42)
 - Indicates an identifier that is used to group associated findings.
13. **MAY** contain zero or one [0..1] **entryRelationship**

- a. Contains @typeCode="COMP" *COMP*
- b. Contains exactly one [1..1] *Non Performance Reason* (templateId: 2.16.840.1.113883.10.20.23.56)
 - Information on the reason a scheduled activity was not carried out.
- 14.MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains @typeCode="COMP" *COMP*
 - b. Contains exactly one [1..1] *Specimen Information* (templateId: 2.16.840.1.113883.10.20.23.78)
- 15.MAY** contain zero or one [0..1] **participant**
 - a. Contains exactly one [1..1] *Study Test Organization* (templateId: 2.16.840.1.113883.10.20.23.88)
 - Used to identify the organization that performed the test.
- 16.MAY** contain zero or one [0..1] **participant**
 - a. Contains exactly one [1..1] *Study Finding Evaluator* (templateId: 2.16.840.1.113883.10.20.23.84)
 - Records the role of the person evaluating the finding.
- 17.MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains @typeCode="COMP" *COMP*
 - b. Contains exactly one [1..1] *Toxicity* (templateId: 2.16.840.1.113883.10.20.23.98)
 - A record of the toxicity associated with the finding.
- 18.MAY** contain zero or one [0..1] **entryRelationship**
 - 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**
 - 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)
 - Allows identification of the relevant body system or organ class for the observation.
- 20.MAY** contain zero or one [0..1] **reference Range**
 - a. Contains exactly one [1..1] *Reference Range* (templateId: 2.16.840.1.113883.10.20.23.74)
 - Information on the reference range defined for a test. It is used to support interpretation of the test result.
- 21.MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains @typeCode="COMP" *COMP*
 - b. Contains exactly one [1..1] *Fasting Status* (templateId: 2.16.840.1.113883.10.20.23.39)
 - Used to indicate the fasting status - time since consumption of food - for the study subject.
- 22.MAY** contain zero or one [0..1] **entryRelationship**
 - 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)
 - Carries information about the severity or intensity associated with the finding.
- 23.MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains @typeCode="COMP" *COMP*
 - b. Contains exactly one [1..1] *Death Relationship* (templateId: 2.16.840.1.113883.10.20.23.29)
 - Records the relationship of the finding to the death of the subject.
- 24.MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains @typeCode="COMP" *COMP*
 - b. Contains exactly one [1..1] *Assay Quantitation* (templateId: 2.16.840.1.113883.10.20.23.16)

- Records the lower limit of quantitation for an assay.
- 25. MAY** contain zero or one [0..1] **entryRelationship**
- a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Category* (templateId: 2.16.840.1.113883.10.20.23.20)
 - The record of a category to be used in organizing information items.
- 26. MAY** contain zero or one [0..1] **entryRelationship**
- a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Sub- Category* (templateId: 2.16.840.1.113883.10.20.23.91)
 - The record of a sub-category to be used in organizing information items.
- 27. MAY** contain zero or more [0..*] **entryRelationship**
- a. Contains **@typeCode="REFR"** *REFR*
 - b. Contains exactly one [1..1] *Related Record* (templateId: 2.16.840.1.113883.10.20.23.75)
 - Establishes a relationship between this record and another record.
- 28. MAY** contain zero or more [0..*] **entryRelationship**
- a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Supplemental Value* (templateId: 2.16.840.1.113883.10.20.23.96)
 - Allows the association of a supplemental value - outside of the content specified for the domain - to the record.
- 29. MAY** contain zero or more [0..*] **entryRelationship**
- a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Comment* (templateId: 2.16.840.1.113883.10.20.23.23)
 - A place to insert comments related to a particular finding.
- 30. MAY** contain zero or more [0..*] **entryRelationship**
- a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Finding About* (templateId: 2.16.840.1.113883.10.20.23.40)
 - Allows recording of additional findings related to the finding.

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"
  classCode="OBS">
  <templateId root="2.16.840.1.113883.10.20.23.86"/>
  <id root="1490674225" extension="MDHT"/>
  <code code="688661998"/>
  <text>Text Value</text>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <interpretationCode code="1891654073"/>
  <methodCode codeSystemName="NCI Thesaurus"/>
  <targetSiteCode codeSystem="2.16.840.1.113883.3.26.1.1"/>
  <participant>
    <participantRole classCode="ASSIGNED">
      <templateId root="null"/>
    </participantRole>
  </participant>
  <participant>
    <participantRole classCode="ASSIGNED">
      <templateId root="null"/>
    </participantRole>
  </participant>
</observation>
```

```

    <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus"/>
  </participantRole>
</participant>
<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"/>
    <text>Text Value</text>
    <statusCode code="completed"/>
    <effectiveTime>
      <low value="2012"/>
      <high value="2012"/>
    </effectiveTime>
    <value xsi:type="CD" code="2029511583"/>
    <interpretationCode code="493900009"/>
    <methodCode code="1005458572"/>
    <targetSiteCode code="1497033706"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <act classCode="ACT">
    <templateId root="2.16.840.1.113883.10.20.23.42"/>
    <id root="692172634" 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"/>
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    </effectiveTime>
  </act>
</entryRelationship>
<entryRelationship>
  <procedure>
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    <statusCode code="completed"/>
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      <low value="2012"/>
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    </effectiveTime>
    <methodCode code="1341862066"/>
    <targetSiteCode code="1065515298"/>
    <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="1851235806" 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="1556122405"/>
    <methodCode code="1096335050"/>
    <targetSiteCode code="1290284532"/>
    <participant/>
  </entryRelationship>
</observation>
</entryRelationship>
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  <observation>
    <templateId root="2.16.840.1.113883.10.20.23.30"/>
    <id root="680294595" 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="406442751"/>
    <interpretationCode code="281804153"/>
    <methodCode code="2044771909"/>
    <targetSiteCode code="922121827"/>
  </observation>
</entryRelationship>
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  <act classCode="ACT">
    <templateId root="2.16.840.1.113883.10.20.23.75"/>
    <id root="331680623" 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="1017838267" 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>
  </observation>
</entryRelationship>

```

```

        </effectiveTime>
        <interpretationCode code="757235468"/>
        <methodCode code="548914881"/>
        <targetSiteCode code="960775388"/>
        <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="519927269" extension="MDHT"/>
        <code code="T0tbd" 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="209456917"/>
        <interpretationCode code="80173387"/>
        <methodCode code="350853596"/>
        <targetSiteCode code="737230489"/>
    </observation>
</entryRelationship>
<entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
        <templateId root="2.16.840.1.113883.10.20.23.20"/>
        <id root="1135221077" 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="1840863185"/>
        <interpretationCode code="1892415498"/>
        <methodCode code="748942224"/>
        <targetSiteCode code="1599961329"/>
    </observation>
</entryRelationship>
<entryRelationship>
    <observation/>
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<entryRelationship>
    <observation classCode="OBS">
        <templateId root="2.16.840.1.113883.10.20.23.39"/>
        <id root="1798961034" 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>
    </observation>
</entryRelationship>

```

```

    </effectiveTime>
    <value xsi:type="BL"/>
    <interpretationCode code="754522578"/>
    <methodCode code="1003565244"/>
    <targetSiteCode code="174507172"/>
  </observation>
</entryRelationship>
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  <observation/>
</entryRelationship>
<entryRelationship>
  <observation classCode="OBS" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.23.29"/>
    <id root="592531202" extension="MDHT"/>
    <code code="C95087" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
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    <statusCode code="completed"/>
    <effectiveTime>
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    </effectiveTime>
    <value xsi:type="CD" code="1747312731"/>
    <interpretationCode code="406357045"/>
    <methodCode code="1145511772"/>
    <targetSiteCode code="920005681"/>
  </observation>
</entryRelationship>
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  <observation>
    <id root="226420889" extension="MDHT"/>
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    <statusCode code="completed"/>
    <effectiveTime>
      <low value="2012"/>
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    </effectiveTime>
    <value xsi:type="IVL_PQ"/>
    <interpretationCode code="1606648056"/>
    <methodCode code="2059527328"/>
    <targetSiteCode code="2025767234"/>
  </observation>
</entryRelationship>
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    <id root="937305606" extension="MDHT"/>
    <code code="1806881663"/>
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    <effectiveTime>
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    </effectiveTime>
    <interpretationCode code="1055407066"/>
    <methodCode code="1432836350"/>
    <targetSiteCode code="202925859"/>
    <participant/>
    <entryRelationship typeCode="REFR"/>
  </observation>
  <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
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    </observation>
  </entryRelationship>
  <entryRelationship>
    <act/>
  </entryRelationship>
  <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.20"/>
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Thesaurus"/>
    </observation>
  </entryRelationship>
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      <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)
2. **SHALL** contain exactly one [1..1] **@moodCode**= "EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain [1..2] **id**
 - A sponsor supplied reference number for the treatment. A sequence number is required.
4. **MAY** contain zero or one [0..1] **text**
 - A text description of the intervention or dosing. [Study Data Tabulation Model: -DOSTXT]
5. **MAY** contain zero or one [0..1] **statusCode**
 - Used to indicate whether the activity - use of a particular medication or treatment - did occur. Use statusCode "Completed" if the use occurred. [Study Data Tabulation Model: -OCCUR]
6. **MAY** contain zero or one [0..1] **effectiveTime**
 - Information on when and how often 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 frequency. 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 effective time attribute is used to capture information regarding the start, stop, duration and frequency of use for the concomitant medication. There shall be Two SXPR components created. The first will be an interval of time stamps (IVL_TS) to address 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 Tabulation Model: -DOSFRQ,]

7. **MAY** contain zero or one [0..1] **routeCode**, where the @code **SHALL** be selected from ValueSet *Route of Administration* C66729 **STATIC**

- The route by which the treatment is administered. [Study Data Tabulation Model: -ROUTE]

8. **MAY** contain zero or one [0..1] **approachSiteCode** with data type CE, where the @code **SHALL** be selected from ValueSet *Anatomical Location* C74456 **STATIC**

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

9. **SHOULD** contain zero or one [0..1] **doseQuantity**

- The amount of a treatment taken at a single administration. The physical quantity data type is used. Dose units go into the units property of the datatype. [Study Data Tabulation Model: -DOSE, DOSU]

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

- Information on the total daily dose of the medication or treatment. The structure also accommodates periods other than a day. Therefore 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 Tabulation Model: -DOSTOT]

11. Contains exactly one [1..1] **consumable**, where its type is *Consumable*

12. **SHALL** contain exactly one [1..1] **entryRelationship**

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

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

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

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

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

b. Contains exactly one [1..1] *Study Epoch* (templateId: 2.16.840.1.113883.10.20.23.83)

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

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

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

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

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

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

The code value indicates the observation captures an element's order within a trial arm.

d. This observation **SHALL** contain zero or more [0..*] **value** with data type INT

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

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

- a. Contains **@typeCode="COMP"** *COMP*
- b. Contains exactly one [1..1] *Group Identifier* (templateId: 2.16.840.1.113883.10.20.23.42)
 - Indicates an identifier that is used to group associated interventions.
- 16. MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Data Collection* (templateId: 2.16.840.1.113883.10.20.23.27)
 - Information on whether a predefined data item was collected, and the timing of collection.
- 17. MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Non Performance Reason* (templateId: 2.16.840.1.113883.10.20.23.56)
 - Information on the reason a scheduled activity was not carried out.
- 18. MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Pre-Specified Event* (templateId: 2.16.840.1.113883.10.20.23.70)
 - Indicates whether or not the event was prespecified on the CRF.
- 19. SHOULD** contain zero or one [0..1] **consumable**
 - Identifies and carries information for the consumable item that is being referred to.
- 20. MAY** contain zero or one [0..1] **entryRelationship**
 - 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**
 - 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**
 - 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**
 - a. Contains **@typeCode="REFR"** *REFR*
 - b. Contains exactly one [1..1] *Timing Reference* (templateId: 2.16.840.1.113883.10.20.23.97)
 - Creates an association between the timing of an activity and a defined reference time point.
- 24. MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="REFR"** *REFR*
 - b. Contains exactly one [1..1] *Study Day Period* (templateId: 2.16.840.1.113883.10.20.23.82)
 - A reference to the study days corresponding to the time period of the observation.
- 25. MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Category* (templateId: 2.16.840.1.113883.10.20.23.20)
 - The record of a category to be used in organizing information items.
- 26. MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Sub- Category* (templateId: 2.16.840.1.113883.10.20.23.91)
 - The record of a sub-category to be used in organizing information items.
- 27. MAY** contain zero or more [0..*] **entryRelationship**

- a. Contains **@typeCode="REFR"** *REFR*
- b. Contains exactly one [1..1] *Related Record* (templateId: 2.16.840.1.113883.10.20.23.75)
 - Establishes a relationship between this record and another record.

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

- a. Contains **@typeCode="COMP"** *COMP*
- b. Contains exactly one [1..1] *Supplemental Value* (templateId: 2.16.840.1.113883.10.20.23.96)
 - Allows the association of a supplemental value - outside of the content specified for the domain - to the record.

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

- a. Contains **@typeCode="COMP"** *COMP*
- b. Contains exactly one [1..1] *Comment* (templateId: 2.16.840.1.113883.10.20.23.23)
 - A place to insert comments related to a particular finding.

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

- a. Contains **@typeCode="COMP"** *COMP*
- b. Contains exactly one [1..1] *Finding About* (templateId: 2.16.840.1.113883.10.20.23.40)
 - Allows recording of additional findings related to the intervention.

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

- a. Contains **@typeCode="COMP"** *COMP*
- b. Contains exactly one [1..1] *Event Duration* (templateId: 2.16.840.1.113883.10.20.23.102)
 - Records the duration of an intervention in cases in which this cannot be derived from existing start and stop information.

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="1649391315" extension="MDHT"/>
  <text>Text Value</text>
  <statusCode code="completed"/>
  <effectiveTime value="20120907"/>
  <routeCode code="970867267"/>
  <approachSiteCode xsi:type="CE" code="777739112"/>
  <doseQuantity/>
  <maxDoseQuantity/>
  <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="35868679" 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>
</substanceadministration>
```

```

    </act>
  </entryRelationship>
  <entryRelationship>
    <act>
      <templateId root="2.16.840.1.113883.10.20.23.83"/>
      <id root="1933493095" 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="1508474919" 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="1289607980" extension="MDHT"/>
      <code code="1605703254"/>
      <text>Text Value</text>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation/>
  </entryRelationship>
  <entryRelationship>
    <act>
      <id root="564820537" extension="MDHT"/>
      <code code="2044234947"/>
      <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="1012159274" 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="274323919" 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="186571563" 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="1397550450" 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="1989093407" 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="669027257" 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="29596397" 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="1889945732" extension="MDHT"/>
    <code code="412982733"/>
    <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="805999773" 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="2023657516" extension="MDHT"/>
    <code code="1684271324"/>
    <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="125860860" 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)
2. **SHALL** contain exactly one [1..1] **@moodCode**= "EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **code/@code**= "C66767" (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)
 - 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, where the @code **SHALL** be selected from ValueSet *Action Taken with Study Treatment* C66767 **STATIC**
 - 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="204578668" 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="870136055"/>
</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)
2. **SHALL** contain exactly one [1..1] **@moodCode**= "EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **code/@code**= "STCtbd" (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)
 - A value to indicate that the observation provides the investigator's opinion regarding the causality of the event to the treatment.
4. **SHALL** contain exactly one [1..1] **value** with data type CD, where the @code **SHALL** be selected from ValueSet *Study Treatment Causality* CXXXXX **STATIC**
 - 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="1485092930" 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="2039018672"/>
</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**
2. **SHALL** contain exactly one [1..1] **@moodCode**
3. **SHALL** contain exactly one [1..1] **code**, where the **@code** **SHALL** be selected from ValueSet [Subject Data Domain SubCategory Type](#) CXXXXX **STATIC**
 - 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
 - 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="373903422" 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="1816421971"/>
</observation>
```

Subject Characteristic

[Observation: templateId 2.16.840.1.113883.10.20.23.92]

The template is used 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)
2. **SHALL** contain exactly one [1..1] **@moodCode="EVN"** *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain [1..2] **id**
 - 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**, where the **@code** **SHALL** be selected from ValueSet *Subject Characteristic Type* C74559 **STATIC**
 - A coded value that identifies the subject characteristic. 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**
 - Used to indicate whether or not the specified study characteristic response was elicited. [SDTM: SCSTAT]
6. **SHOULD** contain zero or one [0..1] **value**
 - The response to the study characteristic item indicated by the code value. A result or finding in standard format should be recorded as a base value - either code or physical quantity. A modified reported term is included as a translation. [SDTM: SCORRES, SCORRESU, SCSTRESC, SCSTRESN, SCSTRESU], [SEND: SCORRES, SCORRESU, SCSTRESC, SCSTRESN, SCSTRESU]
7. **SHALL** contain exactly one [1..1] **entryRelationship**
 - a. Contains **@typeCode="REFR"** *REFR*
 - b. Contains exactly one [1..1] *Domain Assignment* (templateId: 2.16.840.1.113883.10.20.23.30)
 - Identifies the SDTM or SEND domain the record is assigned to.
8. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Group Identifier* (templateId: 2.16.840.1.113883.10.20.23.42)
 - Allows capture of a group identifier for the subject characteristics.
9. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="REFR"** *REFR*
 - b. Contains exactly one [1..1] *Data Collection* (templateId: 2.16.840.1.113883.10.20.23.27)
 - 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.
10. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Non Performance Reason* (templateId: 2.16.840.1.113883.10.20.23.56)
 - Provides a reason for not capturing information for the subject characteristic.
11. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Category* (templateId: 2.16.840.1.113883.10.20.23.20)
 - The record of a category to be used in organizing information items.
12. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Sub- Category* (templateId: 2.16.840.1.113883.10.20.23.91)
 - The record of a sub-category to be used in organizing information items.
13. **MAY** contain zero or more [0..*] **entryRelationship**
 - a. Contains **@typeCode="REFR"** *REFR*

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

- Establishes a relationship between this record and another record.

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

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

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

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

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

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

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

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

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

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

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

- Allows recording of additional findings related to the subject characteristic.

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="1480602253" 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="583590505" extension="MDHT"/>
      <code code="829097025"/>
      <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="117461222" 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="699919817"/>
    </observation>
  </entryRelationship>
</observation>
```

```

</entryRelationship>
<entryRelationship>
  <act classCode="ACT">
    <templateId root="2.16.840.1.113883.10.20.23.42"/>
    <id root="1039125892" 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="1838692174" 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/>
  </observation>
</entryRelationship>
<entryRelationship>
  <observation>
    <templateId root="2.16.840.1.113883.10.20.23.30"/>
    <id root="1370506160" 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="1507164087"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <act classCode="ACT">
    <templateId root="2.16.840.1.113883.10.20.23.75"/>
    <id root="64632986" 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="828544624" 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="1113225120" 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="772276755"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <observation/>
</entryRelationship>
<entryRelationship>
  <observation>
    <id root="963835719" extension="MDHT"/>
    <code code="238240259"/>
    <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)
2. **SHALL** contain exactly one [1..1] **@moodCode="EVN"** *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **id**
 - The identifier is assigned to ensure uniqueness of the subject records within the domain. [SDTM: SESEQ]
4. **SHALL** contain exactly one [1..1] **code**, where the **@code** **SHALL** be selected from (CodeSystem: locally defined Subject Element Type)
 - The code value indicates the nature of the element. If the element is unplanned, the code value should indicate this. Use original text to provide the verbatim content of the element - whether planned or unplanned. [SDTM: ETCDD, ELEMENT, SEUPDES], [SEND: ETCDD, ELEMENT, SEUPDES]
5. **SHALL** contain exactly one [1..1] **effectiveTime**
 - Information that records the start and stop dates of the element. A value for the start date - interval lower bound is required. [SDTM: SESDTC, SEENDTC], [SEND: SESDTC, SEENDTC]
6. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="REFR"** *REFR*
 - b. Contains exactly one [1..1] *Study Epoch* (templateId: 2.16.840.1.113883.10.20.23.83)
 - Records the study epoch during which the information was collected.
7. **MAY** contain zero or one [0..1] **entryRelationship**

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

The code value indicates the observation captures an element's order within a trial arm.

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

A value that gives the order of an element within the trial arm. Since this order could be hierarchically 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**

- a. Contains **@typeCode="REFR"** *REFR*
- b. Contains exactly one [1..1] *Domain Assignment* (templateId: 2.16.840.1.113883.10.20.23.30)
 - Identifies the SDTM or SEND domain the record is assigned to.

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

- a. Contains **@typeCode="REFR"** *REFR*
- b. Contains exactly one [1..1] *Related Record* (templateId: 2.16.840.1.113883.10.20.23.75)
 - Establishes a relationship between this record and another record.

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

- a. Contains **@typeCode="COMP"** *COMP*
- b. Contains exactly one [1..1] *Supplemental Value* (templateId: 2.16.840.1.113883.10.20.23.96)
 - Allows the association of a supplemental value - outside of the content specified for the domain - to the record.

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

- a. Contains **@typeCode="COMP"** *COMP*
- b. Contains exactly one [1..1] *Comment* (templateId: 2.16.840.1.113883.10.20.23.23)
 - A place to insert comments related to a particular finding.

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

- a. Contains **@typeCode="COMP"** *COMP*
- b. Contains exactly one [1..1] *Finding About* (templateId: 2.16.840.1.113883.10.20.23.40)
 - Allows recording of additional findings related to the element.

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="1202760205" 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="1298111729" 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="236023898" 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="1660091660" 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="926095507" 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="749919324" 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="1641276517" extension="MDHT"/>
    <code code="1978831402"/>
    <effectiveTime>
      <low value="2012"/>
      <high value="2012"/>
    </effectiveTime>
    <participant/>
    <entryRelationship typeCode="REFR"/>
  </observation>
  <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>

```

```

    </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)
2. **SHALL** contain exactly one [1..1] **@moodCode="EVN"** *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain [1..2] **id**
 - An identifier that is used to ensure the uniqueness of subject records within the substance use domain. [SDTM: SUSEQ, SUSPID] The sequence number is required.
4. **MAY** contain zero or one [0..1] **text**
 - Used to capture textual information about the use of the substance. [SDTM: SUDOSTXT]
5. **MAY** contain zero or one [0..1] **statusCode**
 - Used to indicate whether the activity - use of a particular substance - did occur. Use statusCode "Completed" if the use occurred. [SDTM: SUOCCUR]
6. **MAY** contain zero or one [0..1] **effectiveTime**
 - Information on when and how often 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 requery. 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 effective time attribute is used to capture information regarding the start, stop, duration and frequency of use for the concomitant medication. There shall be Two SXPR components created. The first will be an interval of time stamps (IVL_TS) to address 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] **routeCode**, where the @code **SHALL** be selected from ValueSet *Route of Administration* C66729 **STATIC**
 - The route by which the substance is administered, applied or ingested. [SDTM: SUROUTE]
8. **MAY** contain zero or one [0..1] **doseQuantity**
 - Information on the dosage of the substance that was consumed. [SDTM: SUDOSE, SUDOSU]
9. **MAY** contain zero or one [0..1] **maxDoseQuantity**
 - Information on the total daily dose of the substance. The structure also accommodates periods other than a day. Therefore 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.
10. **SHALL** contain exactly one [1..1] **entryRelationship**
 - a. Contains @typeCode="REFR" *REFR*
 - b. Contains exactly one [1..1] *Domain Assignment* (templateId: 2.16.840.1.113883.10.20.23.30)
 - Identifies the SDTM or SEND domain the record is assigned to.
11. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains @typeCode="COMP" *COMP*
 - b. Contains exactly one [1..1] *Data Collection* (templateId: 2.16.840.1.113883.10.20.23.27)
 - 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.
12. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains @typeCode="COMP" *COMP*
 - b. Contains exactly one [1..1] *Pre-Specified Event* (templateId: 2.16.840.1.113883.10.20.23.70)
 - Used to indicate whether collection of data regarding an event of this type has been pre-specified, usually on a reporting form.
13. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains @typeCode="COMP" *COMP*
 - b. Contains exactly one [1..1] *Non Performance Reason* (templateId: 2.16.840.1.113883.10.20.23.56)
 - Provides a reason for not capturing information for the substance use.
14. **SHALL** contain exactly one [1..1] **consumable**
 - a. Contains exactly one [1..1] *Consumable Material* (templateId: 2.16.840.1.113883.10.20.23.26)
 - Identifies and carries information for the consumable item that is being referred to.
15. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains @typeCode="REFR" *REFR*
 - b. Contains exactly one [1..1] *Study Day Period* (templateId: 2.16.840.1.113883.10.20.23.82)
 - Used to record the study days associated with the beginning and end points of an activity that may extend over a period of time.
16. **MAY** contain zero or one [0..1] **entryRelationship**
 - 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)

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

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

- 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)

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

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

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

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

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

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

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

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

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

- Establishes a relationship between this record and another record.

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

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

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

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

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

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

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

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

- Allows recording of additional findings related to the event.

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

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

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

- 25.SHALL** satisfy: The effective time attribute is used to capture information regarding the start, stop, duration and frequency of use for the concomitant medication. There shall be Two SXP components created. The first will be an interval of time stamps (IVL_TS) to address 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 SXP 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.

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="1086668301" extension="MDHT"/>
  <text>Text Value</text>
  <statusCode code="completed"/>
  <effectiveTime value="20120907"/>
  <routeCode code="1760008495"/>
  <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="2082747377" 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="381894198" extension="MDHT"/>
      <code code="1407990383"/>
      <text>Text Value</text>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <entryRelationship>
        <observation/>
      </entryRelationship>
    </act>
  </entryRelationship>
  <entryRelationship>
    <observation>
      <id root="552806271" extension="MDHT"/>
      <code code="1687908271"/>
      <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="453355908" 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="981137846" 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="1314734221" 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="911035823" 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="313334659" 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="1899571618" extension="MDHT"/>
    <code code="5160482"/>
    <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="1531222449" 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 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)
2. **SHALL** contain exactly one [1..1] **@moodCode="EVN"** *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **code**, where the @code **SHALL** be selected from (CodeSystem: locally defined Supplemental Value Type)
 - A code that indicates the type of information being provided. [SDTM: QNAM, QLABEL], [SEND: QNAM, QLABEL]
4. **SHALL** contain exactly one [1..1] **value**
 - 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**

Information on the source of the supplemental information.

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

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

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

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

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

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, where the @code **SHALL** be selected from ValueSet *Data Origin Type* CXXXXXX **STATIC**

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**

- a. Contains exactly one [1..1] *Study Finding Evaluator* (templateId: 2.16.840.1.113883.10.20.23.84)

- Identification of the party responsible for (author of) the supplemental information.

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="542801336" 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)
2. **SHALL** contain exactly one [1..1] **@moodCode="EVN"** *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **MAY** contain zero or one [0..1] **id**
 - 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/@code="TRtbd"** (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)
 - A fixed code value to indicate the observation contains timing reference information.
5. **MAY** contain zero or one [0..1] **text**
 - 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]
6. **MAY** contain zero or one [0..1] **effectiveTime**

- The planned elapsed time - a duration - at which the event or measurement is to take place with reference to the anchoring time point. The width property of the IVL_TS data type is used. [SDTM: LBELTM, VSELTM], [SEND: EXELTM, BGELM, CLELTM, VSELTM, EGELTM]

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

Indicates the reference point associated with a timing offset.

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

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

- This act **SHALL** contain exactly one [1..1] **@classCode= "ACT"** Act (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass)
- This act **SHALL** contain exactly one [1..1] **@moodCode**
- This act **SHALL** contain exactly one [1..1] **code/@code= "ATPtbd"** (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)

A code that indicates the nature of the fixed reference point that is referred to by the timing reference. If a suitable value set has not been defined, the original text property of the coded type is used. [SDTM: LBPTREF, VSTPTREF]. [SEND: EXPTREF, BGPTREF, CLPTREF, LBPTREF, VSTPTREF, EGPTREF]

- This act **MAY** contain zero or one [0..1] **effectiveTime**

The date time of the anchor time point. [SDTM: LBRFTDTC, VSRFTDTC], [SEND: EXRFTDTC, 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 timing is indicated as an offset from the time point reference.

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="1799425635" 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.

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

2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **code/@code**="TOTbd" (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)
 - The code value indicates that toxicity information is being provided.
4. **SHALL** contain exactly one [1..1] **value** with data type CD, where the @code **SHALL** be selected from ValueSet *Toxicity Measure Type* CXXXXX **STATIC**
 - 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="927721815" 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="50157404"/>
</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)
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **id**
 - The clinical encounter number. It is a numeric value that is used for sorting. [SDTM, VISITNUM].
4. **SHALL** contain exactly one [1..1] **code**, where the @code **SHALL** be selected from ValueSet *Visit Type* CXXXXX **STATIC**
 - A coded value that indicates the type or name of the visit. If this information is not formally codified, the value may be placed in the original text property of the coded data type. [SDTM: VISIT].
5. **MAY** contain zero or one [0..1] **text**
 - A text block to be used for description of an unplanned visit. [SDTM: SVUPDES]
6. **SHOULD** contain exactly one [1..1] **effectiveTime**
 - The interval data type allows entry of the start date/time of the visit and of the end/date time. [SDTM: SVSTDTC, SVENDTC]
7. **SHALL** contain exactly one [1..1] **entryRelationship**
 - a. Contains **@typeCode**="REFR" *REFR*

- b. Contains exactly one [1..1] [Domain Assignment](#) (templateId: 2.16.840.1.113883.10.20.23.30)
 - Identifies the SDTM or SEND domain the record is assigned to.
- 8. **MAY** contain zero or more [0..*] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] [ECG Test Result](#) (templateId: 2.16.840.1.113883.10.20.23.33)
- 9. **MAY** contain zero or more [0..*] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] [Human Clinical Laboratory Test Result](#) (templateId: 2.16.840.1.113883.10.20.23.45)
- 10. **MAY** contain zero or more [0..*] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] [Physical Examination Finding](#) (templateId: 2.16.840.1.113883.10.20.23.67)
- 11. **MAY** contain zero or more [0..*] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] [Questionnaire Finding](#) (templateId: 2.16.840.1.113883.10.20.23.72)
- 12. **MAY** contain zero or more [0..*] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] [Vital Sign](#) (templateId: 2.16.840.1.113883.10.20.23.101)
- 13. **MAY** contain zero or one [0..1] **entryRelationship**
 - 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**
 - 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**
 - 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**
 - 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**
 - 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**
 - a. Contains **@typeCode="REFR"** *REFR*
 - b. Contains exactly one [1..1] [Planned Study Day](#) (templateId: 2.16.840.1.113883.10.20.23.68)
 - Records the study day on which collection of the information was originally scheduled.
- 19. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="REFR"** *REFR*
 - b. Contains exactly one [1..1] [Study Day Period](#) (templateId: 2.16.840.1.113883.10.20.23.82)

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

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

- Contains **@typeCode="REFR"** *REFR*
 - Contains exactly one [1..1] *Related Record* (templateId: 2.16.840.1.113883.10.20.23.75)
- Establishes a relationship between this record and another record.

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

- Contains **@typeCode="COMP"** *COMP*
 - Contains exactly one [1..1] *Supplemental Value* (templateId: 2.16.840.1.113883.10.20.23.96)
- Allows the association of a supplemental value - outside of the content specified for the domain - to the record.

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

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

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

- Contains **@typeCode="COMP"** *COMP*
 - Contains exactly one [1..1] *Finding About* (templateId: 2.16.840.1.113883.10.20.23.40)
- Allows recording of additional findings related to the visit.

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="1899955115" 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="468605368" 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"/>
    </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"/>
```



```

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codeSystemName="NCI Thesaurus"/>
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  </entryRelationship>

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</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)
2. **SHALL** contain exactly one [1..1] **@moodCode**= "EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **id**
 - 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 Type](#) C66741 **STATIC**
 - 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**
 - 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**
 - 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 zero or more [0..*] **value**
 - The result of the observation. Note, if the observation was not performed, the value will not be present. Observation values may be provided as text, as coded data, or as physical quantities. 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**, where the @code **SHALL** be selected from ValueSet *Subject Data Interpretation Type* CXXXXXX **STATIC**

- 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**, where the @code **SHALL** be selected from ValueSet *Anatomical Location* C74456 **STATIC**

- The body location relevant to the vital sign measurement. [SDTM: VSLOC], [SEND: VSLOC]

10. **SHALL** contain exactly one [1..1] **entryRelationship**

- Contains @typeCode="REFR" *REFR*
 - Contains exactly one [1..1] *Domain Assignment* (templateId: 2.16.840.1.113883.10.20.23.30)
- Identifies the SDTM or SEND domain the record is assigned to.

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

- Contains @typeCode="COMP" *COMP*
 - Contains exactly one [1..1] *Group Identifier* (templateId: 2.16.840.1.113883.10.20.23.42)
- Indicates an identifier that is used to group associated findings.

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

- Contains @typeCode="COMP" *COMP*
 - Contains exactly one [1..1] *Non Performance Reason* (templateId: 2.16.840.1.113883.10.20.23.56)
- Provides a reason for not capturing information for the vital sign.

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

- Contains @typeCode="COMP" *COMP*
 - Contains exactly one [1..1] *Exclusion Reason* (templateId: 2.16.840.1.113883.10.20.23.38)
- Information on the reason that a data item is to be excluded from tabulation.

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

- Contains @typeCode="COMP" *COMP*
- 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**

A record of the consciousness state of the subject at the time of measurement. It is not used for SDTM associated reporting.

- This entryRelationship **SHALL** contain exactly one [1..1] **@classCode**
- This entryRelationship **SHALL** contain exactly one [1..1] **@moodCode**
- This entryRelationship **SHALL** contain exactly one [1..1] **code/@code="CStbd"** (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)

A code value that indicates that the observation records information regarding the subject's level of consciousness.

- This entryRelationship **SHALL** contain exactly one [1..1] **value** with data type CD, where the @code **SHALL** be selected from ValueSet *Consciousness State* CXXXXXX **STATIC**

A coded value that indicates the state of consciousness of the subject when the vital sign measurement was recorded. [SEND: VSCSTATE]

- Contains @typeCode="COMP" *COMP*

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

- a. Contains **@typeCode="REFR"** *REFR*
- b. Contains exactly one [1..1] *Event Study Day* (templateId: 2.16.840.1.113883.10.20.23.37)
 - Used to record the study day associated with an activity taking place during a single day.
- 17.MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="REFR"** *REFR*
 - b. Contains exactly one [1..1] *Timing Reference* (templateId: 2.16.840.1.113883.10.20.23.97)
 - Orients the collection of the vital sign information with respect to a study defined timepoint.
- 18.SHOULD** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="REFR"** *REFR*
 - b. Contains exactly one [1..1] *Planned Study Day* (templateId: 2.16.840.1.113883.10.20.23.68)
 - A record of the study day on which the vital statistics observation was planned for.
- 19.MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="REFR"** *REFR*
 - b. Contains exactly one [1..1] *Study Day Period* (templateId: 2.16.840.1.113883.10.20.23.82)
 - A record of the study date/time on which an activity took place. If relevant, both starting and stopping time points can be recorded.
- 20.MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Category* (templateId: 2.16.840.1.113883.10.20.23.20)
 - The record of a category to be used in organizing information items.
- 21.MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Sub- Category* (templateId: 2.16.840.1.113883.10.20.23.91)
 - The record of a sub-category to be used in organizing information items.
- 22.MAY** contain zero or more [0..*] **entryRelationship**
 - a. Contains **@typeCode="REFR"** *REFR*
 - b. Contains exactly one [1..1] *Related Record* (templateId: 2.16.840.1.113883.10.20.23.75)
 - Establishes a relationship between this record and another record.
- 23.MAY** contain zero or more [0..*] **entryRelationship**
 - a. Contains **@typeCode="REFR"** *REFR*
 - b. Contains exactly one [1..1] *Supplemental Value* (templateId: 2.16.840.1.113883.10.20.23.96)
 - Allows the association of a supplemental value - outside of the content specified for the domain - to the record.
- 24.MAY** contain zero or more [0..*] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Comment* (templateId: 2.16.840.1.113883.10.20.23.23)
 - A place to insert comments related to a particular finding.
- 25.MAY** contain zero or more [0..*] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Finding About* (templateId: 2.16.840.1.113883.10.20.23.40)
 - Allows recording of additional findings related to the finding.

Vital Sign example

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

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  xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
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      <value xsi:type="ED">Text Value</value>
      <interpretationCode code="1042540331"/>
    </observation>
  </entryRelationship>

```

```

        <targetSiteCode code="277095829"/>
        <participant/>
        <entryRelationship/>
    </observation>
</entryRelationship>
<entryRelationship>
    <observation>
        <templateId root="2.16.840.1.113883.10.20.23.30"/>
        <id root="1129205827" 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="2023872226"/>
        <interpretationCode code="828685992"/>
        <targetSiteCode code="1126293446"/>
    </observation>
</entryRelationship>
<entryRelationship>
    <act classCode="ACT">
        <templateId root="2.16.840.1.113883.10.20.23.75"/>
        <id root="1210184931" 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="343897937" extension="MDHT"/>
        <code codeSystem="locally defined" codeSystemName="Supplemental Value
Type"/>
        <statusCode code="completed"/>
        <effectiveTime>
            <low value="2012"/>
            <high value="2012"/>
        </effectiveTime>
        <interpretationCode code="606182180"/>
        <targetSiteCode code="1455319374"/>
        <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="223101894" 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="594266988"/>
        <interpretationCode code="272628932"/>
    </observation>
</entryRelationship>

```

```

        <targetSiteCode code="2073307056"/>
      </observation>
    </entryRelationship>
    <entryRelationship>
      <observation/>
    </entryRelationship>
    <entryRelationship>
      <observation/>
    </entryRelationship>
    <entryRelationship>
      <observation>
        <id root="238040069" extension="MDHT"/>
        <code code="239128787"/>
        <statusCode code="completed"/>
        <effectiveTime>
          <low value="2012"/>
          <high value="2012"/>
        </effectiveTime>
        <interpretationCode code="2031283702"/>
        <targetSiteCode code="245399647"/>
        <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>

```

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)
2. **SHALL** contain exactly one [1..1] **@moodCode**="DEF" (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **code/@code**="AQtbdt" (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)
 - The code value identifies this as an assay quantitation observation.
4. **SHALL** contain exactly one [1..1] **value** with data type IVL_PQ
 - Captures the lower limit of assay quantitation. Value as the low property of the IVL data type. The units of measure are expected to match those designated as the standard units for the result. [SDTM: PCLLOQ], [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="2014162191" extension="MDHT"/>
  <code code="53843989"/>
  <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 reusable 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)
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **code/@code**="C88026" *Body System or Organ Class* (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)
 - 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, where the **@code** **SHALL** be selected from ValueSet *Body System/Organ Class* C88026 **STATIC**
 - 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="218550721" 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="1080016604"/>
</observation>
```

Body Weight

[Observation: templateId 2.16.840.1.113883.10.20.23.18]

The template captures information that SEND organizes into the body weight domain. It supports collecting the weight of a study subject at different points during a study.

1. **SHALL** contain exactly one [1..1] **@classCode="OBS"** *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass)
2. **SHALL** contain exactly one [1..1] **@moodCode="EVN"** *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **id**
 - A sequence number that is used to identify the subject record. [SEND: BWSEQ]
4. **SHALL** contain exactly one [1..1] **code**, where the **@code** **SHALL** be selected from ValueSet [Body Weight Measurement](#) CXXXXXX **STATIC**
 - A value to indicate the nature of the observation recording the subject's body weight. Use the code property of the CD type to capture the test code, and the original text property to capture a verbatim description of the test. [SEND: BWTESTCD, BWTEST]
5. **MAY** contain zero or one [0..1] **statusCode**
 - Used to indicate whether or not a measurement has been performed. [SEND: BWSTAT]
6. **SHOULD** contain zero or one [0..1] **value**
 - The recorded test result. Use several observations if needed. Use of standard or non-standard units of measure is indicated by the OID provided for the PQR -physical quantity representation - type supporting physical quantities. Character data is sent using the ED - encapsulated data - type. [SEND: BWORRES, BWORRESU, BWSTRESC, BWSTRESN, BWSTRESU]
7. **MAY** contain [0..2] **interpretationCode**, where the **@code** **SHALL** be selected from ValueSet [Subject Data Interpretation Type](#) CXXXXXX **STATIC**
 - Includes information used to better interpret the observation value (result). Namely, whether it is a baseline value, and whether the result should be excluded from tabulations. [SEND: BWBLFL, BWEXCLFL]
8. **SHALL** contain exactly one [1..1] **entryRelationship**
 - a. Contains **@typeCode="REFR"** *REFR*
 - b. Contains exactly one [1..1] [Domain Assignment](#) (templateId: 2.16.840.1.113883.10.20.23.30)
 - Identifies the SDTM or SEND domain the record is assigned to.
9. **SHOULD** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] [Data Collection](#) (templateId: 2.16.840.1.113883.10.20.23.27)
10. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] [Non Performance Reason](#) (templateId: 2.16.840.1.113883.10.20.23.56)

- Information on the reason a scheduled activity was not carried out.
11. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Exclusion Reason* (templateId: 2.16.840.1.113883.10.20.23.38)
 - Information on the reason that a data item is to be excluded from tabulation.
 12. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Fasting Status* (templateId: 2.16.840.1.113883.10.20.23.39)
 - Used to indicate the fasting status - time since consumption of food - for the study subject.
 13. **MAY** contain zero or more [0..*] **entryRelationship**
 - a. Contains **@typeCode="REFR"** *REFR*
 - b. Contains exactly one [1..1] *Related Record* (templateId: 2.16.840.1.113883.10.20.23.75)
 - Establishes a relationship between this record and another record.
 14. **MAY** contain zero or more [0..*] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Supplemental Value* (templateId: 2.16.840.1.113883.10.20.23.96)
 - Allows the association of a supplemental value - outside of the content specified for the domain - to the record.
 15. **SHOULD** contain zero or more [0..*] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Comment* (templateId: 2.16.840.1.113883.10.20.23.23)
 - A place to insert comments related to a particular finding.

Body Weight 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="2.16.840.1.113883.10.20.23.18"/>
  <id root="333075075" 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"/>
  <entryRelationship>
    <observation classCode="OBS">
      <templateId root="2.16.840.1.113883.10.20.23.56"/>
      <id root="1475695615" 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="214430015"/>
      <interpretationCode code="1142408452"/>
    </observation>
  </entryRelationship>
</entryRelationship>
<act>
  <id root="393438476" extension="MDHT"/>
```



```

<code code="343546374"/>
<statusCode code="completed"/>
<effectiveTime>
  <low value="2012"/>
  <high value="2012"/>
</effectiveTime>
<entryRelationship>
  <observation/>
</entryRelationship>
</act>
</entryRelationship>
<entryRelationship>
  <observation classCode="OBS">
    <templateId root="2.16.840.1.113883.10.20.23.38"/>
    <id root="898653875" 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>
      <low value="2012"/>
      <high value="2012"/>
    </effectiveTime>
    <value xsi:type="CD" code="1400092777"/>
    <interpretationCode code="122272257"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <observation classCode="OBS" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.23.23"/>
    <id root="258892079" 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="782283477"/>
    <participant/>
    <entryRelationship/>
  </observation>
</entryRelationship>
<entryRelationship>
  <observation>
    <templateId root="2.16.840.1.113883.10.20.23.30"/>
    <id root="2027203379" 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="1793603424"/>
    <interpretationCode code="1476194015"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <act classCode="ACT">
    <templateId root="2.16.840.1.113883.10.20.23.75"/>
    <id root="1965527110" 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="1073634140" extension="MDHT"/>
        <code codeSystem="locally defined" codeSystemName="Supplemental Value
Type"/>
        <statusCode code="completed"/>
        <effectiveTime>
          <low value="2012"/>
          <high value="2012"/>
        </effectiveTime>
        <interpretationCode code="1095085830"/>
        <participant/>
        <entryRelationship typeCode="COMP"/>
      </observation>
    </entryRelationship>
    <entryRelationship>
      <observation classCode="OBS">
        <templateId root="2.16.840.1.113883.10.20.23.39"/>
        <id root="1154317989" 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="840590442"/>
      </observation>
    </entryRelationship>
  </observation>

```

Body Weight Gain

[Observation: templateId 2.16.840.1.113883.10.20.23.19]

The template captures information for the SEND Body Weight Gain domain. It is used to record changes in the body weight of a study subject.

1. **SHALL** contain exactly one [1..1] **@classCode="OBS"** *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass)
2. **SHALL** contain exactly one [1..1] **@moodCode="EVN"** *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **id**
 - A sequence number used to identify the body weight change observation. [SEND: BGSEQ]
4. **SHALL** contain exactly one [1..1] **code**, where the @code **SHALL** be selected from ValueSet [Body Weight Gain](#) CXXXXX **STATIC**
 - A value to indicate the nature of the observation recording the subject's the subject's change in weight. Use the code property of the CD type to capture the test code, and the original text property to capture a verbatim description of the test. [SEND: BGTESTCD, BGTEST]
5. **MAY** contain zero or one [0..1] **statusCode**

- Used to indicate whether or not a measurement has been performed. [SEND: BGSTAT]
6. **SHOULD** contain zero or one [0..1] **effectiveTime**
 - Date/times that the subject was weighed which are captured as a time interval. This should include both the starting and ending points for the measure of weight change. [SEND: BGDTC, BGENDTC]
 7. **SHOULD** contain zero or one [0..1] **value**
 - The recorded test result. Use several observations if needed. Use of standard or non-standard units of measure is indicated by the OID provided for the PQR -physical quantity representation - type supporting physical quantities. Character data is sent using the ED - encapsulated data - type. [SEND: BGORRES, BGORRESU, BGSTRESC, BGSTRESN, BGSTRESU]
 8. **SHOULD** contain zero or one [0..1] **interpretationCode**, where the @code **SHALL** be selected from ValueSet *Subject Data Interpretation Type* CXXXXX **STATIC**
 - Includes information used to better interpret the observation value (result). Includes information used to better interpret the observation value (result). Namely, whether the result should be excluded from tabulations. [SEND: BGEXCLFL]
 9. **SHALL** contain exactly one [1..1] **entryRelationship**
 - 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**
 - a. Contains @typeCode="COMP" *COMP*
 - b. Contains exactly one [1..1] *Non Performance Reason* (templateId: 2.16.840.1.113883.10.20.23.56)
 - Information on the reason a scheduled activity was not carried out.
 11. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains @typeCode="COMP" *COMP*
 - b. Contains exactly one [1..1] *Exclusion Reason* (templateId: 2.16.840.1.113883.10.20.23.38)
 - Information on the reason that a data item is to be excluded from tabulation.
 12. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains @typeCode="REFR" *REFR*
 - b. Contains exactly one [1..1] *Study Day Period* (templateId: 2.16.840.1.113883.10.20.23.82)
 - A reference to the study days corresponding to the time period of the observation.
 13. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains @typeCode="REFR" *REFR*
 - b. Contains exactly one [1..1] *Timing Reference* (templateId: 2.16.840.1.113883.10.20.23.97)
 - Creates an association between the timing of an activity and a defined reference time point.
 14. **MAY** contain zero or more [0..*] **entryRelationship**
 - a. Contains @typeCode="REFR" *REFR*
 - b. Contains exactly one [1..1] *Related Record* (templateId: 2.16.840.1.113883.10.20.23.75)
 - Establishes a relationship between this record and another record.
 15. **MAY** contain zero or more [0..*] **entryRelationship**
 - a. Contains @typeCode="COMP" *COMP*
 - b. Contains exactly one [1..1] *Supplemental Value* (templateId: 2.16.840.1.113883.10.20.23.96)
 - Allows the association of a supplemental value - outside of the content specified for the domain - to the record.
 16. **MAY** contain zero or more [0..*] **entryRelationship**
 - a. Contains @typeCode="COMP" *COMP*
 - b. Contains exactly one [1..1] *Comment* (templateId: 2.16.840.1.113883.10.20.23.23)

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

Body Weight Gain 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="2.16.840.1.113883.10.20.23.19"/>
  <id root="700545194" 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"/>
  <entryRelationship>
    <observation classCode="OBS">
      <templateId root="2.16.840.1.113883.10.20.23.56"/>
      <id root="263146608" 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="65689579"/>
      <interpretationCode code="1758409411"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation>
      <id root="481934442" extension="MDHT"/>
      <code code="1702898310"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <value xsi:type="IVL_INT" value="1"/>
      <interpretationCode code="1808657550"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <act>
      <templateId root="2.16.840.1.113883.10.20.23.97"/>
      <id root="1571982903" 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">
      <templateId root="2.16.840.1.113883.10.20.23.38"/>
      <id root="1578070472" 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>
            <low value="2012"/>
            <high value="2012"/>
        </effectiveTime>
        <value xsi:type="CD" code="1245021998"/>
        <interpretationCode code="609635657"/>
    </observation>
</entryRelationship>
<entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
        <templateId root="2.16.840.1.113883.10.20.23.23"/>
        <id root="250068897" 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="1238973168"/>
        <participant/>
        <entryRelationship/>
    </observation>
</entryRelationship>
<entryRelationship>
    <observation>
        <templateId root="2.16.840.1.113883.10.20.23.30"/>
        <id root="385480673" 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="1924119398"/>
        <interpretationCode code="1494359286"/>
    </observation>
</entryRelationship>
<entryRelationship>
    <act classCode="ACT">
        <templateId root="2.16.840.1.113883.10.20.23.75"/>
        <id root="1801022843" 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="525952659" extension="MDHT"/>
        <code codeSystem="locally defined" codeSystemName="Supplemental Value
Type"/>
        <statusCode code="completed"/>
        <effectiveTime>
            <low value="2012"/>
            <high value="2012"/>

```

```

    </effectiveTime>
    <interpretationCode code="1342066521"/>
    <participant/>
    <entryRelationship typeCode="COMP"/>
  </observation>
</entryRelationship>
</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)
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **code**, where the **@code** **SHALL** be selected from ValueSet *Subject Data Domain Category Type* CXXXXX **STATIC**
 - 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, where the **@code** **SHALL** be selected from
 - 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="161262686" 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="119426791"/>
</observation>

```

Clinical Observation

[Observation: templateId 2.16.840.1.113883.10.20.23.22]

The template supports content of the clinical observation domain. This includes the capture of clinical observations, not more specifically defined and assigned to a particular domain, that are associated with a study subject.

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

3. **SHALL** contain exactly one [1..1] **id**
 - A sequence number for the observation. [SEND: CLSEQ]
4. **SHALL** contain exactly one [1..1] **code**, where the @code **SHALL** be selected from (CodeSystem: unknown Clinical Observation Type)
 - A value to indicate the nature of the observation being recorded. Use the code property of the CD type to support the test code, and the original text property for descriptive text. [SEND: CLTESTCD, CLTEST]
5. **MAY** contain zero or one [0..1] **statusCode**
 - Used to indicate whether or not a measurement has been performed. [SEND: CLSTAT]
6. **SHOULD** contain zero or one [0..1] **value** with data type CD
 - The recorded test result. Use of the CD type allows the original text result to be captured within the original text property, while the code property records the standardized result. [SEND: CLORRES, CLSTRESC]
7. **MAY** contain zero or one [0..1] **interpretationCode**
 - Includes information used to better interpret the observation value (result). In particular, it captures whether a result should be excluded from tabulations. [SEND: CLEXCLFL]
8. **MAY** contain zero or more [0..*] **targetSiteCode**, where the @code **SHALL** be selected from ValueSet [Anatomical Location](#) C74456 **STATIC**
 - Used to capture the relevant body site location for a clinical sign. [CLLOC]
9. **SHALL** contain exactly one [1..1] **entryRelationship**
 - a. Contains @typeCode="REFR" *REFR*
 - b. Contains exactly one [1..1] [Domain Assignment](#) (templateId: 2.16.840.1.113883.10.20.23.30)
 - Identifies the SDTM or SEND domain the record is assigned to.
10. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains @typeCode="COMP" *COMP*
 - b. Contains exactly one [1..1] [Group Identifier](#) (templateId: 2.16.840.1.113883.10.20.23.42)
 - Indicates an identifier that is used to group associated findings.
11. **SHOULD** contain zero or one [0..1] **entryRelationship**
 - a. Contains @typeCode="COMP" *COMP*
 - b. Contains exactly one [1..1] [Data Collection](#) (templateId: 2.16.840.1.113883.10.20.23.27)
 - Information on whether a predefined data item was collected, and the timing of collection.
12. **MAY** contain zero or one [0..1] **participant**
 - a. Contains exactly one [1..1] [Mass Identification](#) (templateId: 2.16.840.1.113883.10.20.23.51)
 - Records the identifier of a body mass associated with the observation.
13. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains @typeCode="COMP" *COMP*
 - b. Contains exactly one [1..1] [Non Performance Reason](#) (templateId: 2.16.840.1.113883.10.20.23.56)
 - Information on the reason a scheduled activity was not carried out.
14. **MAY** contain zero or one [0..1] **participant**
 - a. Contains exactly one [1..1] [Study Finding Evaluator](#) (templateId: 2.16.840.1.113883.10.20.23.84)
 - Records the role of the person evaluating the finding.
15. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains @typeCode="COMP" *COMP*
 - b. Contains exactly one [1..1] [Body System or Organ Class](#) (templateId: 2.16.840.1.113883.10.20.23.17)
 - Allows identification of the relevant body system or organ class for the observation.

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

- 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)
 - Allows recording of the severity of the event being observed.

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

- a. Contains **@typeCode="REFR"** *REFR*
- b. Contains exactly one [1..1] *Planned Study Day* (templateId: 2.16.840.1.113883.10.20.23.68)
 - Captures the planned study day for making an observation or recording a finding.

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

- a. Contains **@typeCode="REFR"** *REFR*
- b. Contains exactly one [1..1] *Timing Reference* (templateId: 2.16.840.1.113883.10.20.23.97)
 - Creates an association between the timing of an activity and a defined reference time point.

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

- a. Contains **@typeCode="COMP"** *COMP*
- b. Contains exactly one [1..1] *Exclusion Reason* (templateId: 2.16.840.1.113883.10.20.23.38)
 - Documents the reason for excluding a finding from the tabulation of results.

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

- a. Contains **@typeCode="COMP"** *COMP*
- b. Contains exactly one [1..1] *Category* (templateId: 2.16.840.1.113883.10.20.23.20)
 - The record of a category to be used in organizing information items.

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

- a. Contains **@typeCode="COMP"** *COMP*
- b. Contains exactly one [1..1] *Sub- Category* (templateId: 2.16.840.1.113883.10.20.23.91)
 - The record of a sub-category to be used in organizing information items.

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

- a. Contains **@typeCode="COMP"** *COMP*
- b. Contains exactly one [1..1] *Result Category* (templateId: 2.16.840.1.113883.10.20.23.76)
 - The record of a category to be used in organizing finding or observation results.

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

- a. Contains **@typeCode="REFR"** *REFR*
- b. Contains exactly one [1..1] *Related Record* (templateId: 2.16.840.1.113883.10.20.23.75)
 - Establishes a relationship between this record and another record.

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

- a. Contains **@typeCode="COMP"** *COMP*
- b. Contains exactly one [1..1] *Supplemental Value* (templateId: 2.16.840.1.113883.10.20.23.96)
 - Allows the association of a supplemental value - outside of the content specified for the domain - to the record.

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

- a. Contains **@typeCode="COMP"** *COMP*
- b. Contains exactly one [1..1] *Comment* (templateId: 2.16.840.1.113883.10.20.23.23)
 - A place to insert comments related to a particular finding.

Clinical Observation 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="2.16.840.1.113883.10.20.23.22"/>
  <id root="260481156" extension="MDHT"/>
  <code codeSystem="unknown" codeSystemName="Clinical Observation Type"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <value xsi:type="CD" code="1974627356"/>
  <interpretationCode code="1818319819"/>
  <targetSiteCode codeSystem="2.16.840.1.113883.3.26.1.1"/>
  <participant>
    <participantRole classCode="ASSIGNED">
      <templateId root="null"/>
      <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus"/>
    </participantRole>
  </participant>
  <participant>
    <participantRole classCode="ROL"/>
  </participant>
  <entryRelationship>
    <act classCode="ACT">
      <templateId root="2.16.840.1.113883.10.20.23.42"/>
      <id root="1480683274" 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="548966224" 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="1726352155"/>
      <interpretationCode code="2130832030"/>
      <targetSiteCode code="1761785688"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation/>
  </entryRelationship>
  <entryRelationship>
    <observation>
      <id root="1509720495" extension="MDHT"/>
      <code code="1474625609"/>
      <statusCode code="completed"/>
    </observation>
  </entryRelationship>

```

```

    <effectiveTime>
      <low value="2012"/>
      <high value="2012"/>
    </effectiveTime>
    <value xsi:type="INT" value="1"/>
    <interpretationCode code="1336432218"/>
    <targetSiteCode code="1151207305"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <act>
    <id root="1380043871" extension="MDHT"/>
    <code code="1210321169"/>
    <statusCode code="completed"/>
    <effectiveTime>
      <low value="2012"/>
      <high value="2012"/>
    </effectiveTime>
    <entryRelationship>
      <observation/>
    </entryRelationship>
  </act>
</entryRelationship>
<entryRelationship>
  <act>
    <templateId root="2.16.840.1.113883.10.20.23.97"/>
    <id root="1101784556" 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">
    <templateId root="2.16.840.1.113883.10.20.23.38"/>
    <id root="1536409348" 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>
      <low value="2012"/>
      <high value="2012"/>
    </effectiveTime>
    <value xsi:type="CD" code="646559989"/>
    <interpretationCode code="1017380908"/>
    <targetSiteCode code="61688478"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <observation classCode="OBS" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.23.23"/>
    <id root="807063536" 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>
  </observation>
</entryRelationship>

```

```

        <interpretationCode code="1634003240"/>
        <targetSiteCode code="256398138"/>
        <participant/>
        <entryRelationship/>
    </observation>
</entryRelationship>
<entryRelationship>
    <observation>
        <templateId root="2.16.840.1.113883.10.20.23.30"/>
        <id root="145340981" 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="2109565289"/>
        <interpretationCode code="2011688322"/>
        <targetSiteCode code="1011742903"/>
    </observation>
</entryRelationship>
<entryRelationship>
    <act classCode="ACT">
        <templateId root="2.16.840.1.113883.10.20.23.75"/>
        <id root="580460154" 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="413775605" extension="MDHT"/>
        <code codeSystem="locally defined" codeSystemName="Supplemental Value
Type"/>
        <statusCode code="completed"/>
        <effectiveTime>
            <low value="2012"/>
            <high value="2012"/>
        </effectiveTime>
        <interpretationCode code="21460422"/>
        <targetSiteCode code="1752019471"/>
        <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="1204326446" 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="600878457"/>

```

```

        <interpretationCode code="2106100945"/>
        <targetSiteCode code="2076362021"/>
      </observation>
    </entryRelationship>
    <entryRelationship>
      <observation/>
    </entryRelationship>
    <entryRelationship>
      <observation>
        <templateId root="2.16.840.1.113883.10.20.23.76"/>
        <id root="1549247834" 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="1655333420"/>
        <interpretationCode code="1179660106"/>
        <targetSiteCode code="1045780531"/>
      </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 separately 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)
2. **SHALL** contain exactly one [1..1] **@moodCode**= "EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **id**
 - A sequence number for the comment. [SDTM: COSEQ], [SEND: COSEQ]
4. **SHOULD** contain exactly one [1..1] **code/@code**= "C49569" (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)
 - The code value indicates that this observation is a comment.
5. **MAY** contain zero or one [0..1] **effectiveTime**
 - The date time of the comment. [SDTM: CODTC], [SEND: CODTC]
6. **SHALL** contain exactly one [1..1] **value** with data type ED
 - The comment text. [SDTM: COVAL], [SEND: COVAL]
7. **SHOULD** contain zero or one [0..1] **participant**
 - a. Contains exactly one [1..1] *Study Finding Evaluator* (templateId: 2.16.840.1.113883.10.20.23.84)
 - The author of the comment.
8. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. This entryRelationship Contains exactly one [1..1] **@typeCode**
 - b. This entryRelationship Contains zero or one [0..1] **act**, where its type is CDA Act
 - c. This entryRelationship **SHALL** contain exactly one [1..1] **act**

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

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="659673567" 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>
```

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 performance 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)
2. **SHALL** contain exactly one [1..1] **@moodCode**= "EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **MAY** contain zero or one [0..1] **@negationInd**
 - When information about an event or activity is pre-specified, the negation indicator may be used to state that the information was not collected. Value the indicator as TRUE if the information item was not elicited. [SDTM: CMSTAT, SUSTAT, MHSTAT, CESTAT, MSSTAT], [Study Data Tabulation Model: -STAT]
4. **SHALL** contain exactly one [1..1] **code/@code**= "Dctbd" (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)
 - The code value indicates the information relates to the collection of data regarding an event or activity.
5. **MAY** contain zero or one [0..1] **effectiveTime** with data type TS

- The date/time of data collection. [SDTM: DMDTC, SUDTC, DSDTC, MHDTC, PEDTC, CEDTC, IEDTC, QSDTC, SCDTC, MSDTC] [SEND: BWDTC, CLDTC, DDDTC, MADTC, MIDTC, OMDTC, PMDTC, SCDTC]

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

- Contains **@typeCode="REFR"** *REFR*
 - Contains exactly one [1..1] *Event Study Day* (templateId: 2.16.840.1.113883.10.20.23.37)
- Used to record the study day associated with the data collection.

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="1427236647" extension="MDHT"/>
  <code code="1171904604"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <entryRelationship>
    <observation>
      <id root="1148555718" extension="MDHT"/>
      <code code="2102208792"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
    </observation>
  </entryRelationship>
</act>
```

Death Diagnosis

[Observation: templateId 2.16.840.1.113883.10.20.23.28]

The template captures the content of the Death Diagnosis Domain. It includes diagnostic information linked to the death of a study subject.

- SHALL** contain exactly one [1..1] **@classCode="OBS"** *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass)
- SHALL** contain exactly one [1..1] **@moodCode="EVN"** *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
- SHALL** contain exactly one [1..1] **id**
 - A sequence number for the observation. [SEND: DDSEQ]
- SHALL** contain exactly one [1..1] **code/@code="C95087"** (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)
 - A value to indicate the observation records diagnosis information associated with the subject's death. Note, the SEND instruction is for the value to always equal "death diagnosis". [SEND: DDTESTCD, DDTEST]
- SHALL** contain exactly one [1..1] **value** with data type CD, where the **@code** **SHALL** be selected from (CodeSystem: unknown Death Diagnosis)
 - The recorded death diagnosis. [SEND: DDORRES, DDSTRESC]
- SHALL** contain exactly one [1..1] **entryRelationship**
 - Contains **@typeCode="REFR"** *REFR*
 - Contains exactly one [1..1] *Domain Assignment* (templateId: 2.16.840.1.113883.10.20.23.30)
 - Identifies the SDTM or SEND domain the record is assigned to.

7. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Data Collection* (templateId: 2.16.840.1.113883.10.20.23.27)
 - Information on whether a predefined data item was collected, and the timing of collection.
8. **MAY** contain zero or one [0..1] **participant**
 - a. Contains exactly one [1..1] *Study Finding Evaluator* (templateId: 2.16.840.1.113883.10.20.23.84)
 - Records the role of the person evaluating the finding.
9. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Result Category* (templateId: 2.16.840.1.113883.10.20.23.76)
 - The record of a category to be used in organizing finding or observation results.
10. **MAY** contain zero or more [0..*] **entryRelationship**
 - a. Contains **@typeCode="REFR"** *REFR*
 - b. Contains exactly one [1..1] *Related Record* (templateId: 2.16.840.1.113883.10.20.23.75)
 - Establishes a relationship between this record and another record.
11. **MAY** contain zero or more [0..*] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Supplemental Value* (templateId: 2.16.840.1.113883.10.20.23.96)
 - Allows the association of a supplemental value - outside of the content specified for the domain - to the record.
12. **MAY** contain zero or more [0..*] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Comment* (templateId: 2.16.840.1.113883.10.20.23.23)
 - A place to insert comments related to a particular finding.

Death Diagnosis 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="2.16.840.1.113883.10.20.23.28"/>
  <id root="271114213" 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="1787769923"/>
  <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>
      <id root="737713408" extension="MDHT"/>
      <code code="1591489438"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
    </act>
  </entryRelationship>
</observation>
```

```

        </observation>
      </entryRelationship>
    </act>
  </entryRelationship>
  <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.23"/>
      <id root="701230553" 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/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation>
      <templateId root="2.16.840.1.113883.10.20.23.30"/>
      <id root="638273928" 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="467644841"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <act classCode="ACT">
      <templateId root="2.16.840.1.113883.10.20.23.75"/>
      <id root="965317763" 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="138426070" extension="MDHT"/>
      <code codeSystem="locally defined" codeSystemName="Supplemental Value
Type"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <participant/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation>
      <templateId root="2.16.840.1.113883.10.20.23.76"/>
      <id root="303134981" 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="2069627563"/>
    </observation>
  </entryRelationship>
</observation>

```

Death Relationship

[Observation: templateId 2.16.840.1.113883.10.20.23.29]

The template provides a reusable structure to describe the relationship of a particular finding to the death of a study subject.

1. **SHALL** contain exactly one [1..1] **@classCode**= "OBS" *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass)
2. **SHALL** contain exactly one [1..1] **@moodCode**= "EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **code/@code**= "C95087" (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)
 - The code value indicates this is a death relationship observation.
4. **SHALL** contain exactly one [1..1] **value** with data type CD
 - An indication of the relationship of the finding to the death of the subject. [SEND: MADTHREL, MIDTHREL, TFDTHREL], [Study Data Tabulation Model: -DTHREL]

Death 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" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.23.29"/>
  <id root="602273429" extension="MDHT"/>
  <code code="C95087" 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="1681432356"/>
</observation>

```

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 possibility 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)
2. **SHALL** contain exactly one [1..1] **@moodCode**= "EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **code/@code**= "C66734" (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)

- 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**

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="1152547432" 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)
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/@code="DARtbd" (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)
 - The code value indicates this is a dose adjustment observation.
4. **SHALL** contain exactly one [1..1] **value** with data type ED
 - 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="255716637" extension="MDHT"/>
  <code code="2107886247"/>
  <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 of 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)
2. **SHALL** contain exactly one [1..1] **@moodCode="EVN"** *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain [1..3] **id**
 - A value that is provided to ensure the uniqueness of drug accountability items. [SDTM: DASEQ, DAREFID, DASPID] A single identifier, the sequence number, is required.
4. **SHALL** contain exactly one [1..1] **code**, where the **@code** **SHALL** be selected from ValueSet *Drug Accountability Finding Type* C78732 **STATIC**
 - A coded value that identifies 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**
 - 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
 - The date/time of the accountability assessment. [SDTM: DADTC]
7. **SHOULD** contain zero or one [0..1] **value**
 - Captures the drug accountability value. The finding may be recorded as a coded value - if the result is character based - or as a physical quantity - if the result is numeric. [SDTM: DAORRES, DAORRESU, DASTRESC, DASTRESN, DASTRESU]
8. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Domain Assignment* (templateId: 2.16.840.1.113883.10.20.23.30)
 - Identifies the SDTM or SEND domain the record is assigned to.
9. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Group Identifier* (templateId: 2.16.840.1.113883.10.20.23.42)
 - Allows capture of a group identifier for the drug accountability item.
10. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Non Performance Reason* (templateId: 2.16.840.1.113883.10.20.23.56)
 - Provides a reason for not capturing information for the drug accountability item.
11. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="REFR"** *REFR*
 - b. Contains exactly one [1..1] *Event Study Day* (templateId: 2.16.840.1.113883.10.20.23.37)
 - Used to record the study day associated with an activity taking place during a single day.
12. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Category* (templateId: 2.16.840.1.113883.10.20.23.20)
 - The record of a category to be used in organizing information items.
13. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Sub- Category* (templateId: 2.16.840.1.113883.10.20.23.91)
 - The record of a sub-category to be used in organizing information items.
14. **MAY** contain zero or more [0..*] **entryRelationship**

- a. Contains **@typeCode="REFR"** *REFR*
- b. Contains exactly one [1..1] *Related Record* (templateId: 2.16.840.1.113883.10.20.23.75)
 - Establishes a relationship between this record and another record.

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

- a. Contains **@typeCode="COMP"** *COMP*
- b. Contains exactly one [1..1] *Supplemental Value* (templateId: 2.16.840.1.113883.10.20.23.96)
 - Allows the association of a supplemental value - outside of the content specified for the domain - to the record.

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

- a. Contains **@typeCode="COMP"** *COMP*
- b. Contains exactly one [1..1] *Comment* (templateId: 2.16.840.1.113883.10.20.23.23)
 - A place to insert comments related to a particular finding.

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

- a. Contains **@typeCode="COMP"** *COMP*
- b. Contains exactly one [1..1] *Finding About* (templateId: 2.16.840.1.113883.10.20.23.40)
 - Allows recording of additional findings related to the event.

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="1709799765" extension="MDHT"/>
  <code code="1129427173"/>
  <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="1550708220" 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="857477595" 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="1101127052"/>
    </observation>
  </entryRelationship>
</entryRelationship>
```

```

<observation>
  <id root="783700447" extension="MDHT"/>
  <code code="1031435682"/>
  <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="842255249" 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="355213451"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <observation/>
</entryRelationship>
<entryRelationship>
  <observation classCode="OBS" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.23.23"/>
    <id root="1427329608" 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>
  </observation>
</entryRelationship>
<entryRelationship>
  <observation>
    <templateId root="2.16.840.1.113883.10.20.23.30"/>
    <id root="488127061" 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="876017257"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <act classCode="ACT">
    <templateId root="2.16.840.1.113883.10.20.23.75"/>
    <id root="615222533" 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="405342855" 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="1258068297" extension="MDHT"/>
        <code code="1425921679"/>
        <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>
    <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)
2. **SHALL** contain exactly one [1..1] **@moodCode="EVN"** *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain [1..3] **id**
 - 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**, where the @code **SHALL** be selected from ValueSet [ECG Test Type](#) C71153 **STATIC**
 - A coded value that identifies 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**
 - 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**
 - 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**
 - The performance date of the ECG test. [SDTM: EGDTC], [SEND: EGDTC, EGENDTC]
8. **SHOULD** contain zero or one [0..1] **value**
 - Captures the ECG measurement or finding. The finding may be recorded as a coded value - if the result is character based - or as a physical quantity - if the result is numeric. 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. **SHOULD** contain [0..3] **interpretationCode**, where the @code **SHALL** be selected from ValueSet [Subject Data Interpretation Type](#) CXXXXX **STATIC**
 - 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]
10. **MAY** contain zero or one [0..1] **methodCode**, where the @code **SHALL** be selected from ValueSet [ECG Test Method](#) C71151 **STATIC**
 - Capture the method of the ECG test. [SDTM: EGMETHOD], [SEND: EGMETHOD]
11. **SHALL** contain exactly one [1..1] **entryRelationship**
 - a. Contains **@typeCode="REFR"** *REFR*
 - b. Contains exactly one [1..1] [Domain Assignment](#) (templateId: 2.16.840.1.113883.10.20.23.30)
 - Identifies the SDTM or SEND domain the record is assigned to.

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

- a. Contains **@typeCode="COMP"** *COMP*
- b. Contains exactly one [1..1] *Group Identifier* (templateId: 2.16.840.1.113883.10.20.23.42)
 - Allows capture of a group identifier for the ECG result.

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

- a. Contains **@typeCode="COMP"** *COMP*
- b. Contains exactly one [1..1] *Non Performance Reason* (templateId: 2.16.840.1.113883.10.20.23.56)
 - Provides a reason for not capturing information for the ECG test result.

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

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

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)
- b. This observation **SHALL** contain exactly one [1..1] **@moodCode="EVN"** *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
- c. This observation **SHALL** contain exactly one [1..1] **code/@code="C87881"** (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)

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, where the **@code** **SHALL** be selected from ValueSet *ECG Lead Location* C90013 **STATIC**

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

An observation of the actual lead location.

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

- a. Contains exactly one [1..1] *Study Test Organization* (templateId: 2.16.840.1.113883.10.20.23.88)
 - Used to record the organization performing the test.

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

- a. Contains exactly one [1..1] *Study Finding Evaluator* (templateId: 2.16.840.1.113883.10.20.23.84)
 - Used to record the role played by the person providing the value of a subjective finding.

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

- a. Contains **@typeCode="COMP"** *COMP*
- b. Contains exactly one [1..1] *Position of Subject* (templateId: 2.16.840.1.113883.10.20.23.69)
 - Records the position of the subject at the time of measurement.

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

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

An observation of the state of consciousness.

- a. This observation **SHALL** contain exactly one [1..1] **@classCode**
- b. This observation **SHALL** contain exactly one [1..1] **@moodCode**

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

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, where the @code **SHALL** be selected from ValueSet *Consciousness State* CXXXXX **STATIC**

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.

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

- a. Contains **@typeCode="REFR"** *REFR*
- b. Contains exactly one [1..1] *Planned Study Day* (templateId: 2.16.840.1.113883.10.20.23.68)
 - Captures the planned study day for making an observation or recording a finding.

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

- a. Contains **@typeCode="REFR"** *REFR*
- b. Contains exactly one [1..1] *Study Day Period* (templateId: 2.16.840.1.113883.10.20.23.82)
 - A reference to the study days corresponding to the time period of the observation.

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

- a. Contains **@typeCode="REFR"** *REFR*
- b. Contains exactly one [1..1] *Timing Reference* (templateId: 2.16.840.1.113883.10.20.23.97)
 - Orients the performance of the ECG test with respect to a study defined timepoint.

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

- a. Contains **@typeCode="COMP"** *COMP*
- b. Contains exactly one [1..1] *Category* (templateId: 2.16.840.1.113883.10.20.23.20)
 - The record of a category to be used in organizing information items.

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

- a. Contains **@typeCode="COMP"** *COMP*
- b. Contains exactly one [1..1] *Sub- Category* (templateId: 2.16.840.1.113883.10.20.23.91)
 - The record of a sub-category to be used in organizing information items.

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

- a. Contains **@typeCode="REFR"** *REFR*
- b. Contains exactly one [1..1] *Related Record* (templateId: 2.16.840.1.113883.10.20.23.75)
 - Establishes a relationship between this record and another record.

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

- a. Contains **@typeCode="COMP"** *COMP*
- b. Contains exactly one [1..1] *Supplemental Value* (templateId: 2.16.840.1.113883.10.20.23.96)
 - Allows the association of a supplemental value - outside of the content specified for the domain - to the record.

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

- a. Contains **@typeCode="COMP"** *COMP*
- b. Contains exactly one [1..1] *Comment* (templateId: 2.16.840.1.113883.10.20.23.23)
 - A place to insert comments related to a particular finding.

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

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

- Allows recording of additional findings related to the finding.

28. SHALL satisfy: Use the PQR type. Capture the numeric result in standard units as value and unit, capture the numeric result in the original units as a translation. Note, this is only necessary if the original result does not use the standard units.

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 original units as a translation. Note, this is only necessary if the original result does not use the standard format.

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="1000225396" 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="666774876"/>
  <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="96199084" 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="1205086007" 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="1320047615"/>
      <interpretationCode code="627942153"/>
      <methodCode code="1334394419"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <act>
      <templateId root="2.16.840.1.113883.10.20.23.97"/>
      <id root="1291502648" 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="1568931986" extension="MDHT"/>
      <code code="853570673"/>
      <text>Text Value</text>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <value xsi:type="INT" value="1"/>
      <interpretationCode code="1544635112"/>
      <methodCode code="1271370770"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation>
      <id root="846773767" extension="MDHT"/>
      <code code="2084788689"/>
      <text>Text Value</text>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <value xsi:type="IVL_INT" value="1"/>
      <interpretationCode code="218729489"/>
      <methodCode code="186533094"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.23"/>
      <id root="803750732" 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="1754194493"/>
    <methodCode code="183922519"/>
    <participant/>
    <entryRelationship/>
  </observation>
</entryRelationship>
<entryRelationship>
  <observation>
    <templateId root="2.16.840.1.113883.10.20.23.30"/>
    <id root="435705319" 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="443118356"/>
    <interpretationCode code="1306866431"/>
    <methodCode code="1332255564"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <act classCode="ACT">
    <templateId root="2.16.840.1.113883.10.20.23.75"/>
    <id root="1491444625" 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="752038742" 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="1703496207"/>
    <methodCode code="122625605"/>
    <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="1579778559" 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="1642517814"/>
    <interpretationCode code="866244649"/>
    <methodCode code="817232170"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <observation/>
</entryRelationship>
<entryRelationship>
  <observation/>
</entryRelationship>
<entryRelationship>
  <observation>
    <id root="956047837" extension="MDHT"/>
    <code code="1512244723"/>
    <text>Text Value</text>
    <statusCode code="completed"/>
    <effectiveTime>
      <low value="2012"/>
      <high value="2012"/>
    </effectiveTime>
    <interpretationCode code="1289563843"/>
    <methodCode code="645670851"/>
    <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>
  </observation>
</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 presense 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)
2. **SHALL** contain exactly one [1..1] **@moodCode**= "EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **code/@code**= "EDtbd" (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)
 - A code that indicates the observation records the duration of an event.
4. **SHALL** contain exactly one [1..1] **value** with data type PQR
 - Captures the duration of an event.

sdm::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		ALRT
moodCode	@moodCode	1..1	SHALL	NO	x_ActMoodDocumentObservation		DEF
negationInd	@negationInd	0..1		NO	Boolean		
nullFlavor	@nullFlavor	0..1		NO	NullFlavor		ASKU
code	code	1..1	SHALL	YES	CD		NCI Thesaurus 2.16.840.1.113883.3.26.1.1 EDtbd
derivationExpr	derivationExpr	0..1		YES	ST		
effectiveTime	effectiveTime	0..1		YES	IVL_TS		
id	id	0..*		YES	II		
interpretationCode	interpretationCode	0..*		YES	CE		
languageCode	languageCode	0..1		YES	CS		
methodCode	methodCode	0..*		YES	CE		
priorityCode	priorityCode	0..1		YES	CE		
realmCode	realmCode	0..*		YES	CS		
repeatNumber	repeatNumber	0..1		YES	IVL_INT		

sdtn::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)
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		
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="203923884" 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="1336851209"/>
</observation>
```

Event or Finding Severity

[Observation: templateId 2.16.840.1.113883.10.20.23.34]

The template provides a reusable structure 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)

2. **SHALL** contain exactly one [1..1] **@moodCode**= "EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **code/@code**= "C66769" (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)
 - The code value indicates this is a severity observation.
4. **SHALL** contain exactly one [1..1] **value** with data type CD, where the @code **SHALL** be selected from ValueSet *Event Severity* C66769 **STATIC**
 - 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="889180991" 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="1649051055" />
</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)
2. **SHALL** contain exactly one [1..1] **@moodCode**= "EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **code/@code**= "C49489" *Adverse Event Outcome* (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)
 - A code that indicates this observation contains adverse event outcome information.
4. **SHALL** contain exactly one [1..1] **value** with data type CD, where the @code **SHALL** be selected from ValueSet *Outcome of Event* C66768 **STATIC**
 - 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="647971857" 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="2059037919" />
</observation>
```



```
</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)
2. **SHALL** contain exactly one [1..1] **@moodCode**= "EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **code/@code**= "C83208" *Adverse Event Pattern* (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)
 - A code that indicates the observation contains information regarding the pattern of the adverse event over time.
4. **SHALL** contain exactly one [1..1] **value** with data type CD, where the **@code** **SHALL** be selected from ValueSet *Event Pattern* CXXXXX **STATIC**
 - 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="1479009936" 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="1731564816"/>
</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)
2. **SHALL** contain exactly one [1..1] **@moodCode**= "EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **code/@code**= "ESDtbdb" (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)
 - A fixed value that indicates the observation captures the actual study day for an event.
4. **SHALL** contain exactly one [1..1] **value** with data type INT

- The applicable study day value. [SDTM: DMDY, MHDY, CEDY, 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="610963371" extension="MDHT"/>
  <code code="1293206804"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <value xsi:type="INT" value="1"/>
</observation>
```

Exclusion Reason

[Observation: templateId 2.16.840.1.113883.10.20.23.38]

A reusable structure that indicates the reason for excluding a reported value from calculations. 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. Contains exactly one [1..1] **@classCode**="OBS" *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass)
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **code/@code**="EXCtbd" *Baseline Indicator* (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)
 - A code value that indicates the observation indicates the reason for excluding a value from calculations.
4. **SHALL** contain exactly one [1..1] **value** with data type CD, where the @code **SHALL** be selected from ValueSet [Exclusion Reason](#) CXXXXX **STATIC**
 - A coded value to indicate the reason for excluding a coded value from calculations. [SEND: BWEXCLFL, BGEXCLFL, CLEXCLFL, FWEXCLFL, LBEXCLFL, OMEXCLFL, PCEXCLFL, VSEXCLFL, EGEXCLFL]

Exclusion 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="2.16.840.1.113883.10.20.23.38"/>
  <id root="1819921991" extension="MDHT"/>
  <code code="EXCtbd" codeSystem="2.16.840.1.113883.3.26.1.1"
  codeSystemName="NCI Thesaurus" displayName="Baseline Indicator"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <value xsi:type="CD" code="364455138"/>
</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)
2. **SHALL** contain exactly one [1..1] **@moodCode**= "EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **code/@code**= "FStbd" (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)
 - The code value indicates the observation concerns the subject's fasting status.
4. **SHALL** contain exactly one [1..1] **value** with data type BL
 - A Boolean indicator to provide information 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="1871235385" 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-clinical trial reporting.

1. **SHALL** contain exactly one [1..1] **@classCode**= "OBS" *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass)
2. **SHALL** contain exactly one [1..1] **@moodCode**= "EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain [1..2] **id**
 - A value that is provided to ensure the uniqueness of the findings about result. [SDTM: FASEQ, FASPID] A single identifier, the sequence number, is required.
4. **SHALL** contain exactly one [1..1] **code**, where the **@code** **SHALL** be selected from ValueSet [Finding About Finding Type](#) C101852 **STATIC**
 - 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]
5. **MAY** contain zero or one [0..1] **statusCode**

- Used to indicate whether or not a measurement has been performed. [SDTM: FASTAT]
- 6. **MAY** contain zero or one [0..1] **effectiveTime**
- 7. **SHALL** contain exactly one [1..1] **value**
 - The findings about result, using both original units and a standard format or set of units. [SDTM: FAORRES, FAORRESU, FASTRESC, FASTRESN, FASTRESU]
- 8. **MAY** contain zero or one [0..1] **interpretationCode**, where the @code **SHALL** be selected from ValueSet *Subject Data Interpretation Type* CXXXXX **STATIC**
 - Includes information used to better interpret the observation value (result). [SDTM: FABLFL]
- 9. **MAY** contain zero or one [0..1] **targetSiteCode**, where the @code **SHALL** be selected from ValueSet *Anatomical Location* C74456 **STATIC**
 - Used to specify the location of a clinical evaluation. [SDTM: FALOC]
- 10. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains @typeCode="COMP" *COMP*
 - b. Contains exactly one [1..1] *Domain Assignment* (templateId: 2.16.840.1.113883.10.20.23.30)
 - Identifies the SDTM or SEND domain the record is assigned to.
- 11. **SHALL** contain zero or one [0..1] **entryRelationship**

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

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

12. **SHALL** contain zero or one [0..1] **entryRelationship**
 - a. Contains @typeCode="COMP" *COMP*
 - b. Contains exactly one [1..1] *Group Identifier* (templateId: 2.16.840.1.113883.10.20.23.42)
 - Allows capture of a group identifier for the finding.
13. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains @typeCode="COMP" *COMP*
 - b. Contains exactly one [1..1] *Data Collection* (templateId: 2.16.840.1.113883.10.20.23.27)
 - 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.
14. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains @typeCode="COMP" *COMP*
 - b. Contains exactly one [1..1] *Non Performance Reason* (templateId: 2.16.840.1.113883.10.20.23.56)
 - Provides a reason for not capturing information for the finding.
15. **MAY** contain zero or one [0..1] **participant**
 - a. Contains exactly one [1..1] *Study Finding Evaluator* (templateId: 2.16.840.1.113883.10.20.23.84)
 - Used to record the role played by the person providing the value of a subjective finding.

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

- a. Contains **@typeCode="COMP"** *COMP*
- b. Contains exactly one [1..1] *Category* (templateId: 2.16.840.1.113883.10.20.23.20)
 - The record of a category to be used in organizing information items.

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

- a. Contains **@typeCode="COMP"** *COMP*
- b. Contains exactly one [1..1] *Sub- Category* (templateId: 2.16.840.1.113883.10.20.23.91)
 - The record of a sub-category to be used in organizing information items.

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="426876246" extension="MDHT"/>
  <code code="781748172"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <interpretationCode code="480840319"/>
  <targetSiteCode code="1979564089"/>
  <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="1049331736" 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="525269834" 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>
    </observation>
  </entryRelationship>
</observation>
```

```

        <value xsi:type="CD" code="2011177234"/>
        <interpretationCode code="1467945760"/>
        <targetSiteCode code="418474761"/>
    </observation>
</entryRelationship>
<entryRelationship>
    <act>
        <id root="889472407" extension="MDHT"/>
        <code code="435729060"/>
        <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="50280819" 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="550398664"/>
        <interpretationCode code="871679891"/>
        <targetSiteCode code="1166880958"/>
    </observation>
</entryRelationship>
<entryRelationship>
    <observation/>
</entryRelationship>
<entryRelationship>
    <observation>
        <templateId root="2.16.840.1.113883.10.20.23.30"/>
        <id root="1680255218" 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="608791172"/>
        <interpretationCode code="1152324015"/>
        <targetSiteCode code="83218596"/>
    </observation>
</entryRelationship>
</observation>

```

Food and Water Consumption

[Observation: templateId 2.16.840.1.113883.10.20.23.41]

The templated is used to capture information stored in the Food and Wather Consumption Domain. It includes information on the study subject's consumption of food and/or water.

1. **SHALL** contain exactly one [1..1] **@classCode="OBS"** *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass)
2. **SHALL** contain exactly one [1..1] **@moodCode="EVN"** *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **id**
 - A sequence number for the observation. [SEND: FWSEQ]
4. **SHALL** contain exactly one [1..1] **code**, where the @code **SHALL** be selected from ValueSet *Food/Water Consumption Test Type* CXXXXX **STATIC**
 - A value to indicate the particular food and water consumption related observation. [SEND: FWTESTCD, FWTEST]
5. **MAY** contain zero or one [0..1] **statusCode**
 - Used to indicate whether or not a measurement has been performed. [SEND: FWSTAT]
6. **SHOULD** contain zero or one [0..1] **effectiveTime**
 - Information on the date/time of the observation. It is expected this will be captured as a time interval to record the time period for which the consumption is relevant. [SEND: FWDTC, FWENDTC]
7. **SHOULD** contain exactly one [1..1] **value**
 - The recorded food or water consumption observation. [SEND: FWORRES, FWORRESU, FWSTRESC, FWSTRESCN FWSTRESCU]
8. **MAY** contain zero or one [0..1] **interpretationCode**, where the @code **SHALL** be selected from ValueSet *Subject Data Interpretation Type* CXXXXX **STATIC**
 - Includes information used to better interpret the observation value (result), namely whether it should be excluded from tabulation of results. [SEND: FWEXCLFL]
9. **SHALL** contain exactly one [1..1] **entryRelationship**
 - a. Contains **@typeCode="REFR"** *REFR*
 - b. Contains exactly one [1..1] *Domain Assignment* (templateId: 2.16.840.1.113883.10.20.23.30)
 - Identifies the SDTM or SEND domain the record is assigned to.
10. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Group Identifier* (templateId: 2.16.840.1.113883.10.20.23.42)
 - Indicates an identifier that is used to group associated findings.
11. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Non Performance Reason* (templateId: 2.16.840.1.113883.10.20.23.56)
 - Information on the reason a scheduled activity was not carried out.
12. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Exclusion Reason* (templateId: 2.16.840.1.113883.10.20.23.38)
 - Information on the reason that a data item is to be excluded from tabulation.
13. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="REFR"** *REFR*
 - b. Contains exactly one [1..1] *Study Day Period* (templateId: 2.16.840.1.113883.10.20.23.82)
 - A reference to the study days corresponding to the time period of the observation.
14. **MAY** contain zero or more [0..*] **entryRelationship**
 - a. Contains **@typeCode="REFR"** *REFR*
 - b. Contains exactly one [1..1] *Related Record* (templateId: 2.16.840.1.113883.10.20.23.75)

- Establishes a relationship between this record and another record.

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

- Contains **@typeCode="COMP"** *COMP*
 - Contains exactly one [1..1] *Supplemental Value* (templateId: 2.16.840.1.113883.10.20.23.96)
- Allows the association of a supplemental value - outside of the content specified for the domain - to the record.

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

- Contains **@typeCode="COMP"** *COMP*
 - Contains exactly one [1..1] *Comment* (templateId: 2.16.840.1.113883.10.20.23.23)
- A place to insert comments related to a particular finding.

Food and Water Consumption 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="1882465027" extension="MDHT"/>
  <code code="2094389184"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <interpretationCode code="52498493"/>
  <entryRelationship>
    <observation classCode="OBS">
      <templateId root="2.16.840.1.113883.10.20.23.56"/>
      <id root="474680142" 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="663717857"/>
      <interpretationCode code="1607155968"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation>
      <id root="1874953067" extension="MDHT"/>
      <code code="800367713"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <value xsi:type="IVL_INT" value="1"/>
      <interpretationCode code="1663080268"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation classCode="OBS">
      <templateId root="2.16.840.1.113883.10.20.23.38"/>
      <id root="958019" 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>
```



```

        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <value xsi:type="CD" code="929603606"/>
      <interpretationCode code="1033803855"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <act classCode="ACT">
      <templateId root="2.16.840.1.113883.10.20.23.42"/>
      <id root="56218731" 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="1526213311" 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="351869920"/>
      <participant/>
      <entryRelationship/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation>
      <templateId root="2.16.840.1.113883.10.20.23.30"/>
      <id root="622651789" 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="1857776738"/>
      <interpretationCode code="663771733"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <act classCode="ACT">
      <templateId root="2.16.840.1.113883.10.20.23.75"/>
      <id root="489039192" 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="2062293407" extension="MDHT"/>
    <code codeSystem="locally defined" codeSystemName="Supplemental Value
Type"/>
    <statusCode code="completed"/>
    <effectiveTime>
      <low value="2012"/>
      <high value="2012"/>
    </effectiveTime>
    <interpretationCode code="204761193"/>
    <participant/>
    <entryRelationship typeCode="COMP"/>
  </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 concomitant 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)
2. **SHALL** contain exactly one [1..1] **@moodCode="EVN"** *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **id**
 - 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/@code="C83204"** (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)
 - 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="875966162" 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>

```

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 intervention.

1. **SHALL** contain exactly one [1..1] **@classCode**="OBS" *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass)
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **code/@code**="C83085" *Concomitant Medication Indication* (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)
 - A code value to indicate the observation contains indication information.
4. **SHALL** contain exactly one [1..1] **value** with data type CD, where the **@code** **SHALL** be selected from (CodeSystem: locally defined Intervention Indication Type)
 - 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="1979503225" 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="739637234"/>
</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)
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **code/@code**="IRtbd" (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)
 - 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
 - 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="347881491" 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>

```

Macroscopic Finding

[Observation: templateId 2.16.840.1.113883.10.20.23.50]

The template is used to record macroscopic findings for a study subject

1. **SHALL** contain exactly one [1..1] **@classCode="OBS"** *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass)
2. **SHALL** contain exactly one [1..1] **@moodCode="EVN"** *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **id**
 - A sequence number for the observation. [SEND: MASEQ]
4. **SHALL** contain exactly one [1..1] **code**, where the **@code SHALL** be selected from (CodeSystem: locally defined Macroscopic Examination Type)
 - A value to indicate the particular macroscopic finding observation. [SEND: MATESTCD, MATEST]
5. **MAY** contain zero or one [0..1] **statusCode**
 - Used to indicate whether or not a measurement has been performed. [SEND: MASTAT]
6. **SHOULD** contain zero or more [0..*] **value**
 - The recorded macroscopic finding. [SEND: MAORRES, MASTRESC]
7. **SHALL** contain exactly one [1..1] **entryRelationship**
 - a. Contains **@typeCode="REFR"** *REFR*
 - b. Contains exactly one [1..1] *Domain Assignment* (templateId: 2.16.840.1.113883.10.20.23.30)
 - Identifies the SDTM or SEND domain the record is assigned to.
8. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Group Identifier* (templateId: 2.16.840.1.113883.10.20.23.42)
 - Indicates an identifier that is used to group associated findings.
9. **MAY** contain zero or one [0..1] **participant**
 - a. Contains exactly one [1..1] *Mass Identification* (templateId: 2.16.840.1.113883.10.20.23.51)
 - Records an identifier for a mass discovered within the subject.
10. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Data Collection* (templateId: 2.16.840.1.113883.10.20.23.27)
 - Information on whether a predefined data item was collected, and the timing of collection.
11. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Non Performance Reason* (templateId: 2.16.840.1.113883.10.20.23.56)
 - Information on the reason a scheduled activity was not carried out.

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

- a. Contains **@typeCode="COMP"** *COMP*
- b. Contains exactly one [1..1] *Specimen Information* (templateId: 2.16.840.1.113883.10.20.23.78)
 - 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.

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

- 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)
 - A record of the severity or intensity of the finding.

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

- a. Contains **@typeCode="COMP"** *COMP*
- b. Contains exactly one [1..1] *Death Relationship* (templateId: 2.16.840.1.113883.10.20.23.29)
 - Records the relationship of the finding to the death of the subject.

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

- a. Contains **@typeCode="COMP"** *COMP*
- b. Contains exactly one [1..1] *Body System or Organ Class* (templateId: 2.16.840.1.113883.10.20.23.17)
 - Allows identification of the relevant body system or organ class for the observation.

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

- a. Contains exactly one [1..1] *Study Test Organization* (templateId: 2.16.840.1.113883.10.20.23.88)
 - Used to identify the organization that performed the test.

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

- a. Contains exactly one [1..1] *Study Finding Evaluator* (templateId: 2.16.840.1.113883.10.20.23.84)
 - Records the role of the person evaluating the finding.

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

- a. Contains **@typeCode="REFR"** *REFR*
- b. Contains exactly one [1..1] *Related Record* (templateId: 2.16.840.1.113883.10.20.23.75)
 - Establishes a relationship between this record and another record.

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

- a. Contains **@typeCode="COMP"** *COMP*
- b. Contains exactly one [1..1] *Supplemental Value* (templateId: 2.16.840.1.113883.10.20.23.96)
 - Allows the association of a supplemental value - outside of the content specified for the domain - to the record.

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

- a. Contains **@typeCode="COMP"** *COMP*
- b. Contains exactly one [1..1] *Comment* (templateId: 2.16.840.1.113883.10.20.23.23)
 - A place to insert comments related to a particular finding.

Macroscopic 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="1637615591" extension="MDHT"/>
  <code codeSystem="locally defined"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2012"/>
  </effectiveTime>
</observation>
```

```

    <high value="2012"/>
  </effectiveTime>
  <participant>
    <participantRole classCode="ROL"/>
  </participant>
  <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>
    <act classCode="ACT">
      <templateId root="2.16.840.1.113883.10.20.23.42"/>
      <id root="367884445" 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="725277289" extension="MDHT"/>
      <code code="744220835"/>
      <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>
    <observation/>
  </entryRelationship>
  <entryRelationship>
    <observation classCode="OBS">
      <templateId root="2.16.840.1.113883.10.20.23.56"/>
      <id root="538002034" extension="MDHT"/>
    </observation>
  </entryRelationship>

```

```

    <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="2002526497"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <observation/>
</entryRelationship>
<entryRelationship>
  <act>
    <id root="1249997615" extension="MDHT"/>
    <code code="101967852"/>
    <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="148896315" 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="199218653" 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="588159689"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <act classCode="ACT">
    <templateId root="2.16.840.1.113883.10.20.23.75"/>
    <id root="377481530" 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="1182360871" 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="2.16.840.1.113883.10.20.23.29"/>
        <id root="18574989" extension="MDHT"/>
        <code code="C95087" 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="1146657542"/>
      </observation>
    </entryRelationship>
  </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)
2. **SHALL** contain exactly one [1..1] **@moodCode="EVN"** *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain [1..3] **id**
 - A value that is provided to ensure the uniqueness of medical history items. [SDTM: MHSEQ, MHREFID, MHSPID] A single identifier, the sequence number, is required.
4. **SHALL** contain exactly one [1..1] **code/@code="MHItbd"** (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)
 - The code value indicates that this observation is a medical history item.
5. **MAY** contain zero or one [0..1] **statusCode**
 - 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**
 - 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, where the @code **SHALL** be selected from (CodeSystem: unknown Medical History Item Type)
 - A code value and descriptive text to provide information on the nature of the medical condition or event. [SDTM: MHTERM, MHMODIFY, MHDECOD]
8. **SHALL** contain exactly one [1..1] **entryRelationship**
 - a. Contains @typeCode="REFR" *REFR*
 - b. Contains exactly one [1..1] *Domain Assignment* (templateId: 2.16.840.1.113883.10.20.23.30)
 - Identifies the SDTM or SEND domain the record is assigned to.
9. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains @typeCode="COMP" *COMP*
 - b. Contains exactly one [1..1] *Group Identifier* (templateId: 2.16.840.1.113883.10.20.23.42)
 - Allows capture of a group identifier for the medical history item.
10. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains @typeCode="COMP" *COMP*
 - b. Contains exactly one [1..1] *Data Collection* (templateId: 2.16.840.1.113883.10.20.23.27)
 - 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.
11. **SHALL** contain zero or one [0..1] **entryRelationship**
 - a. Contains @typeCode="COMP" *COMP*
 - b. Contains exactly one [1..1] *Pre-Specified Event* (templateId: 2.16.840.1.113883.10.20.23.70)
 - Used to indicate whether collection of data regarding an event of this type has been pre-specified, usually on a reporting form.
12. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains @typeCode="COMP" *COMP*
 - b. Contains exactly one [1..1] *Non Performance Reason* (templateId: 2.16.840.1.113883.10.20.23.56)
 - Provides a reason for not capturing information for the medical history item.
13. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains @typeCode="COMP" *COMP*
 - b. Contains exactly one [1..1] *Body System or Organ Class* (templateId: 2.16.840.1.113883.10.20.23.17)
 - Allows identification of the relevant body system or organ class.
14. **MAY** contain zero or one [0..1] **entryRelationship**
 - 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)
 - Allows positioning of the start of the event with relationship to a defined reference time period.
15. **MAY** contain zero or one [0..1] **entryRelationship**
 - 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)
 - Allows positioning of the termination of the event with relationship to a defined reference time period.
16. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains @typeCode="COMP" *COMP*
 - b. Contains exactly one [1..1] *Category* (templateId: 2.16.840.1.113883.10.20.23.20)

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

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="1799199574" 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="1583137098"/>
  <entryRelationship>
    <act classCode="ACT">
      <templateId root="2.16.840.1.113883.10.20.23.42"/>
      <id root="2009549608" 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="1122322441" 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="2080258596"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <observation/>
</entryRelationship>
<entryRelationship>
  <act>
    <id root="1093320793" extension="MDHT"/>
    <code code="248396019"/>
    <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="452798932" 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="392024077" 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="936309891"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <act classCode="ACT">
    <templateId root="2.16.840.1.113883.10.20.23.75"/>

```

```

        <id root="579823633" 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="76069236" 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="1989904567" 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="1422536088"/>
    </observation>
</entryRelationship>
<entryRelationship>
    <observation/>
</entryRelationship>
<entryRelationship>
    <observation>
        <id root="316678493" extension="MDHT"/>
        <code code="1461562470"/>
        <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>

```

Microscopic Finding

[Observation: templateId 2.16.840.1.113883.10.20.23.55]

The template provides a structure to record microscopic findings for a study subject.

1. **SHALL** contain exactly one [1..1] **@classCode**= "OBS" *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass)
2. **SHALL** contain exactly one [1..1] **@moodCode**= "EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **id**
 - A sequence number for the observation. [SEND: MISEQ]
4. **SHALL** contain exactly one [1..1] **code**, where the **@code** **SHALL** be selected from (CodeSystem: locally defined Microscopic Finding Type)
 - A value to indicate the particular microscopic finding observation. [SEND: MITESTCD, MITEST]
5. **MAY** contain zero or one [0..1] **statusCode**
 - Used to indicate whether or not a measurement has been performed. [SEND: MISTAT]
6. **SHOULD** contain zero or one [0..1] **value** with data type CD
 - The recorded microscopic finding. [SEND: MIORRES, MISTRESC]
7. **MAY** contain zero or one [0..1] **methodCode**, where the **@code** **SHALL** be selected from ValueSet [Method C85492 STATIC](#)
 - Indicates the method of the test or examination. [SEND: MIMETHOD]
8. **SHALL** contain exactly one [1..1] **entryRelationship**
 - a. Contains **@typeCode**= "REFR" *REFR*

- b. Contains exactly one [1..1] *Domain Assignment* (templateId: 2.16.840.1.113883.10.20.23.30)
 - Identifies the SDTM or SEND domain the record is assigned to.
- 9. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Group Identifier* (templateId: 2.16.840.1.113883.10.20.23.42)
 - Indicates an identifier that is used to group associated findings.
- 10. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Data Collection* (templateId: 2.16.840.1.113883.10.20.23.27)
 - Information on whether a predefined data item was collected, and the timing of collection.
- 11. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Non Performance Reason* (templateId: 2.16.840.1.113883.10.20.23.56)
 - Information on the reason a scheduled activity was not carried out.
- 12. **MAY** contain zero or one [0..1] **participant**
 - a. Contains exactly one [1..1] *Mass Identification* (templateId: 2.16.840.1.113883.10.20.23.51)
 - Records an identifier for a mass discovered within the subject.
- 13. **SHALL** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Specimen Information* (templateId: 2.16.840.1.113883.10.20.23.78)
 - 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.
- 14. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Body System or Organ Class* (templateId: 2.16.840.1.113883.10.20.23.17)
 - Allows identification of the relevant body system or organ class for the observation.
- 15. **SHOULD** contain zero or one [0..1] **entryRelationship**
 - 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)
 - A record of the severity or intensity of the finding.
- 16. **MAY** contain zero or more [0..*] **entryRelationship**
 - a. Contains **@typeCode="REFR"** *REFR*
 - b. Contains exactly one [1..1] *Related Record* (templateId: 2.16.840.1.113883.10.20.23.75)
 - Establishes a relationship between this record and another record.
- 17. **MAY** contain zero or one [0..1] **participant**
 - a. Contains exactly one [1..1] *Study Test Organization* (templateId: 2.16.840.1.113883.10.20.23.88)
 - Used to identify the organization that performed the test.
- 18. **MAY** contain zero or one [0..1] **participant**
 - a. Contains exactly one [1..1] *Study Finding Evaluator* (templateId: 2.16.840.1.113883.10.20.23.84)
 - Records the role of the person evaluating the finding.
- 19. **MAY** contain zero or one [0..1] **entryRelationship**

- a. Contains **@typeCode="COMP"** *COMP*
- b. Contains exactly one [1..1] *Result Category* (templateId: 2.16.840.1.113883.10.20.23.76)
 - The record of a category to be used in organizing finding or observation results.

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

- a. Contains **@typeCode="COMP"** *COMP*
- b. Contains exactly one [1..1] *Death Relationship* (templateId: 2.16.840.1.113883.10.20.23.29)
 - Records the relationship of the finding to the death of the subject.

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

- a. Contains **@typeCode="COMP"** *COMP*
- b. Contains exactly one [1..1] *Supplemental Value* (templateId: 2.16.840.1.113883.10.20.23.96)
 - Allows the association of a supplemental value - outside of the content specified for the domain - to the record.

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

- a. Contains **@typeCode="COMP"** *COMP*
- b. Contains exactly one [1..1] *Comment* (templateId: 2.16.840.1.113883.10.20.23.23)
 - A place to insert comments related to a particular finding.

Microscopic Finding example

```
<?xml version="1.0" encoding="UTF-8"?>
<observation xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
  xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd"
  classCode="OBS">
  <templateId root="2.16.840.1.113883.10.20.23.55"/>
  <id root="46941122" extension="MDHT"/>
  <code codeSystem="locally defined" codeSystemName="Microscopic Finding
  Type"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <value xsi:type="CD" code="1175823223"/>
  <methodCode codeSystemName="NCI Thesaurus"/>
  <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>
  <participant>
    <participantRole classCode="ROL"/>
  </participant>
  <entryRelationship>
    <observation classCode="OBS">
      <templateId root="2.16.840.1.113883.10.20.23.56"/>
      <id root="183041043" 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="1759460226"/>
      <methodCode code="246561555"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <procedure>
      <id root="381282865" extension="MDHT"/>
      <code code="795874433"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <methodCode code="1133921034"/>
      <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/>
</entryRelationship>
<entryRelationship>
  <act>
    <id root="945823271" extension="MDHT"/>
    <code code="1545853123"/>
    <statusCode code="completed"/>
    <effectiveTime>
      <low value="2012"/>
      <high value="2012"/>
    </effectiveTime>
    <entryRelationship>
      <observation/>
    </entryRelationship>
  </act>
</entryRelationship>
<entryRelationship>
  <act classCode="ACT">
    <templateId root="2.16.840.1.113883.10.20.23.42"/>
    <id root="1917621697" 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" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.23.23"/>
    <id root="746591583" 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="277871330"/>
    <participant/>
    <entryRelationship/>
  </observation>
</entryRelationship>
<entryRelationship>
  <observation>
    <templateId root="2.16.840.1.113883.10.20.23.30"/>
    <id root="1857306523" 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="1260166571"/>
    <methodCode code="481804233"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <act classCode="ACT">
    <templateId root="2.16.840.1.113883.10.20.23.75"/>
    <id root="1882583917" 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="683448198" extension="MDHT"/>
    <code codeSystem="locally defined" codeSystemName="Supplemental Value
Type"/>
    <statusCode code="completed"/>
    <effectiveTime>
      <low value="2012"/>
      <high value="2012"/>
    </effectiveTime>
    <methodCode code="1880799427"/>
    <participant/>
    <entryRelationship typeCode="COMP"/>
  </observation>
</entryRelationship>

```

```

<entryRelationship>
  <observation>
    <templateId root="2.16.840.1.113883.10.20.23.76"/>
    <id root="1734591067" 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="766486123"/>
    <methodCode code="310704771"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <observation classCode="OBS" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.23.29"/>
    <id root="1685417847" extension="MDHT"/>
    <code code="C95087" 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="603071230"/>
    <methodCode code="96102800"/>
  </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)
2. **SHALL** contain exactly one [1..1] **@moodCode="EVN"** *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **code/@code="C66727"** *Reason for non completion* (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)
 - The code value identifies this observation as a non-performance reason.
4. **SHALL** contain exactly one [1..1] **value** with data type CD, where the **@code** **SHALL** be selected from ValueSet *Non Performance Reason* C66727 **STATIC**
 - 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 Tabulation 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="1198369465" 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="1868770328"/>
</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)
2. **SHALL** contain exactly one [1..1] **@moodCode**= "EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **code/@code**= "NSTtbd" (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)
 - A value to indicate that the observation provides the investigator's opinion regarding the causality of the event to a non-study treatment.
4. **SHALL** contain exactly one [1..1] **value** with data type ED
 - 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="1291483250" 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>

```

Non-Human Disposition

[Act: templateId 2.16.840.1.113883.10.20.23.57]

The template provides a structure to capture disposition information in non-clinical trials. Disposition information provides an accounting for all subjects who entered the study and may include protocol milestones, such as randomization, as well as the subject's completion status or reason for discontinuation for the entire study or each phase or segment of the study, including screening and post-treatment follow-up.

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

3. **SHALL** contain exactly one [1..1] **id**
 - An identifier that is used to ensure the uniqueness of the disposition record. [SEND: DSSEQ]
4. **SHALL** contain exactly one [1..1] **code**, where the @code **SHALL** be selected from ValueSet [Disposition Item Type](#) CXXXXX **STATIC**
 - A code drawn from a controlled terminology for the event or protocol milestone. The verbatim name for the term must be captured as well. [SEND: DSTERM; DSDECOD]
5. **SHALL** contain exactly one [1..1] **effectiveTime** with data type TS
 - The date/time of the disposition event. [SEND: DSSTDTC]
6. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains @typeCode="REFR" *REFR*
 - b. Contains exactly one [1..1] [Study Day Period](#) (templateId: 2.16.840.1.113883.10.20.23.82)
 - A reference to the study day corresponding to the time of the observation.
7. **SHOULD** contain zero or one [0..1] **entryRelationship**
 - a. Contains @typeCode="REFR" *REFR*
 - b. Contains exactly one [1..1] [Planned Study Day](#) (templateId: 2.16.840.1.113883.10.20.23.68)
 - Captures the planned study day for making an observation or recording a finding.
8. **MAY** contain zero or more [0..*] **entryRelationship**
 - a. Contains @typeCode="COMP" *COMP*
 - b. Contains exactly one [1..1] [Comment](#) (templateId: 2.16.840.1.113883.10.20.23.23)
 - A place to insert comments related to a particular finding.
9. **SHALL** contain exactly one [1..1] **entryRelationship**
 - a. Contains @typeCode="REFR" *REFR*
 - b. Contains exactly one [1..1] [Domain Assignment](#) (templateId: 2.16.840.1.113883.10.20.23.30)
 - Identifies the SEND domain the record is assigned to.
10. **MAY** contain zero or more [0..*] **entryRelationship**
 - a. Contains @typeCode="REFR" *REFR*
 - b. Contains exactly one [1..1] [Related Record](#) (templateId: 2.16.840.1.113883.10.20.23.75)
 - Establishes a relationship between this record and another record.
11. **MAY** contain zero or more [0..*] **entryRelationship**
 - a. Contains @typeCode="COMP" *COMP*
 - b. Contains exactly one [1..1] [Supplemental Value](#) (templateId: 2.16.840.1.113883.10.20.23.96)
 - Allows the association of a supplemental value - outside of the content specified for the domain - to the record.

Non-Human 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="2.16.840.1.113883.10.20.23.57"/>
  <id root="942036011" extension="MDHT"/>
  <code code="728341420"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <entryRelationship>
    <observation>
      <id root="1024488531" extension="MDHT"/>
    </observation>
  </entryRelationship>
</act>
```

```

        <code code="685294129"/>
        <effectiveTime>
            <low value="2012"/>
            <high value="2012"/>
        </effectiveTime>
    </observation>
</entryRelationship>
<entryRelationship>
    <observation>
        <id root="1866089754" extension="MDHT"/>
        <code code="1928859406"/>
        <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="1916099271" 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="1336441984" 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="1694476120" 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="409115132" extension="MDHT"/>
        <code codeSystem="locally defined" codeSystemName="Supplemental Value
Type"/>
        <effectiveTime>
            <low value="2012"/>
            <high value="2012"/>

```

```

    </effectiveTime>
    <participant/>
    <entryRelationship typeCode="COMP" />
  </observation>
</entryRelationship>
</act>

```

Non-Human Exposure

[SubstanceAdministration: templateId 2.16.840.1.113883.10.20.23.58]

The template captures details of a non-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, and is typically but not always supplied to the subject.

1. **SHALL** contain exactly one [1..1] **@classCode**= "SBADM" (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass)
2. **SHALL** contain exactly one [1..1] **@moodCode**= "EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **id**
 - A sponsor supplied reference number for the study treatment. [SEND: EXSEQ]
4. **MAY** contain zero or one [0..1] **text**
 - A text description of the dosing. [SEND: EXDOSTXT]
5. **MAY** contain zero or one [0..1] **effectiveTime**
 - 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 frequency. 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 effective time attribute is used to capture information regarding the start, stop, duration and frequency of use for the concomitant medication. There shall be Two SXPR components created. The first will be an interval of time stamps (IVL_TS) to address 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. [SEND: EXSTDTC, EXENDTC, EXDUR, EXDOSFRQ]
6. **SHALL** contain exactly one [1..1] **routeCode**, where the @code **SHALL** be selected from ValueSet [Route of Administration](#) C66729 **STATIC**
 - The route by which the treatment is administered. [SEND: EXROUTE]
7. **MAY** contain zero or one [0..1] **approachSiteCode** with data type CE, where the @code **SHALL** be selected from ValueSet [Anatomical Location](#) C74456 **STATIC**
 - An indication of the location, e.g. left arm, where the substance was administered. [SEND: EXLOC]
8. **SHOULD** contain zero or one [0..1] **doseQuantity**
 - The amount of study treatment taken at a single administration. The physical quantity type captures both dose amount and unit of measure. [SEND: EXDOSE, EXDOSU]
9. **MAY** contain zero or one [0..1] **maxDoseQuantity**
 - Information on the total daily dose of the study treatment. The structure also accommodates periods other than a day. Therefore 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.
10. **SHALL** contain exactly one [1..1] **consumable**
 - a. Contains exactly one [1..1] [Consumable Material](#) (templateId: 2.16.840.1.113883.10.20.23.26)

- Identifies and carries information for the consumable item that is being referred to.
11. **SHOULD** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="REFR"** *REFR*
 - b. Contains exactly one [1..1] *Timing Reference* (templateId: 2.16.840.1.113883.10.20.23.97)
 - Creates an association between the timing of an activity and a defined reference time point.
 12. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="REFR"** *REFR*
 - b. Contains exactly one [1..1] *Study Day Period* (templateId: 2.16.840.1.113883.10.20.23.82)
 - A reference to the study days corresponding to the time period of the observation.
 13. **MAY** contain zero or more [0..*] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Comment* (templateId: 2.16.840.1.113883.10.20.23.23)
 - A place to insert comments related to a particular finding.
 14. **SHALL** contain exactly one [1..1] **entryRelationship**
 - a. Contains **@typeCode="REFR"** *REFR*
 - b. Contains exactly one [1..1] *Domain Assignment* (templateId: 2.16.840.1.113883.10.20.23.30)
 - Identifies the SEND domain the record is assigned to.
 15. **MAY** contain zero or more [0..*] **entryRelationship**
 - a. Contains **@typeCode="REFR"** *REFR*
 - b. Contains exactly one [1..1] *Related Record* (templateId: 2.16.840.1.113883.10.20.23.75)
 - Establishes a relationship between this record and another record.
 16. **MAY** contain zero or more [0..*] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Supplemental Value* (templateId: 2.16.840.1.113883.10.20.23.96)
 - Allows the association of a supplemental value - outside of the content specified for the domain - to the record.
 17. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Dose Adjustment Reason* (templateId: 2.16.840.1.113883.10.20.23.31)
 - 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.
 18. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Category* (templateId: 2.16.840.1.113883.10.20.23.20)
 - The record of a category to be used in organizing information items.
 19. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Sub- Category* (templateId: 2.16.840.1.113883.10.20.23.91)
 - The record of a sub-category to be used in organizing information items.
 20. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Event Duration* (templateId: 2.16.840.1.113883.10.20.23.102)
 - Records the duration of an event in cases in which this cannot be derived from existing start and stop information.

Non-Human 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"
classCode="SBADM" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.23.58"/>
  <id root="42618004" extension="MDHT"/>
  <text>Text Value</text>
  <effectiveTime value="20120907"/>
  <routeCode codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus"/>
  <approachSiteCode codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
  <doseQuantity/>
  <maxDoseQuantity/>
  <consumable>
    <manufacturedProduct classCode="MANU"/>
  </consumable>
  <entryRelationship>
    <act>
      <templateId root="2.16.840.1.113883.10.20.23.97"/>
      <id root="2090025854" 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>
  </entryRelationship>
  <entryRelationship>
    <observation>
      <id root="1206118907" extension="MDHT"/>
      <code code="127305926"/>
      <text>Text Value</text>
      <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="1702419164" extension="MDHT"/>
      <code code="C49569" 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>
      <participant/>
      <entryRelationship/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation>
      <templateId root="2.16.840.1.113883.10.20.23.30"/>
      <id root="645286587" extension="MDHT"/>
      <code code="C66734" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>

```



```

    <text>Text Value</text>
    <effectiveTime>
      <low value="2012"/>
      <high value="2012"/>
    </effectiveTime>
  </observation>
</entryRelationship>
<entryRelationship>
  <act classCode="ACT">
    <templateId root="2.16.840.1.113883.10.20.23.75"/>
    <id root="607666308" extension="MDHT"/>
    <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus"/>
    <text>Text Value</text>
    <effectiveTime>
      <low value="2012"/>
      <high value="2012"/>
    </effectiveTime>
  </act>
</entryRelationship>
<entryRelationship>
  <observation classCode="OBS" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.23.96"/>
    <id root="371614880" extension="MDHT"/>
    <code codeSystem="locally defined" codeSystemName="Supplemental Value
Type"/>
    <text>Text Value</text>
    <effectiveTime>
      <low value="2012"/>
      <high value="2012"/>
    </effectiveTime>
    <participant/>
    <entryRelationship typeCode="COMP"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <observation>
    <id root="516718793" extension="MDHT"/>
    <code code="805959930"/>
    <text>Text Value</text>
    <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="344069895" extension="MDHT"/>
    <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus"/>
    <text>Text Value</text>
    <effectiveTime>
      <low value="2012"/>
      <high value="2012"/>
    </effectiveTime>
  </observation>
</entryRelationship>
<entryRelationship>
  <observation/>
</entryRelationship>
<entryRelationship>
  <observation classCode="OBS" moodCode="EVN">

```

```

<templateId root="2.16.840.1.113883.10.20.23.102"/>
<id root="1434495830" 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>

```

Non-Human Laboratory Test Result

[Observation: templateId 2.16.840.1.113883.10.20.23.59]

The template is used to collect information on laboratory data collected on a reporting form or received from a central provider or vendor.

1. **SHALL** contain exactly one [1..1] **@classCode="OBS"** *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass)
2. **SHALL** contain exactly one [1..1] **@moodCode="EVN"** *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain [1..2] **id**
 - A value that is provided to ensure the uniqueness of the laboratory result. [SEND: LBSEQ, LBSPID] A single identifier, the sequence number, is required.
4. **SHALL** contain exactly one [1..1] **code**, where the @code **SHALL** be selected from ValueSet *Laboratory Test Type* C65047 **STATIC**
 - A coded value that identifies the laboratory test result. The verbatim text is placed within the original text property of the CD data type. [SEND: LBTESTCD, LBTEST]
5. **MAY** contain zero or one [0..1] **statusCode**
 - Used to indicate whether or not an exam has been performed. [SDTM: LBSTAT]
6. **SHOULD** contain zero or more [0..*] **value** with data type CD
 - The laboratory result, using both original units and a standard format or set of units. [SEND: LBORRES, LBORRESU, LBSTRESC, LBSTRESN, LBSTRESU]
7. **SHOULD** contain [0..4] **interpretationCode**, where the @code **SHALL** be selected from ValueSet *Subject Data Interpretation Consolidated Type* CXXXXX **STATIC**
 - 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, whether it should be excluded from tabulations, and/or its relationship to the reference range defined for the test. [SEND: LBBFL, LBDRVFL, LBEXCLFL, LBNRIND]
8. **SHOULD** contain zero or one [0..1] **methodCode**, where the @code **SHALL** be selected from ValueSet *Method* C85492 **STATIC**
 - Indicates the method of the test or examination. [SEND: LBMETHOD]
9. **SHALL** contain exactly one [1..1] **entryRelationship**
 - a. Contains **@typeCode="REFR"** *REFR*
 - b. Contains exactly one [1..1] *Domain Assignment* (templateId: 2.16.840.1.113883.10.20.23.30)
 - Identifies the SDTM or SEND domain the record is assigned to.
10. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Group Identifier* (templateId: 2.16.840.1.113883.10.20.23.42)

- Allows capture of a group identifier for the laboratory result.
11. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Exclusion Reason* (templateId: 2.16.840.1.113883.10.20.23.38)
 - Information on the reason that a data item is to be excluded from tabulation.
 12. **SHOULD** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Specimen Information* (templateId: 2.16.840.1.113883.10.20.23.78)
 - 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.
 13. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Non Performance Reason* (templateId: 2.16.840.1.113883.10.20.23.56)
 - Captures the reason for not performing the indicated test.
 14. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Fasting Status* (templateId: 2.16.840.1.113883.10.20.23.39)
 - Used to indicate the fasting status - time since consumption of food - for the study subject.
 15. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Toxicity* (templateId: 2.16.840.1.113883.10.20.23.98)
 - A record of the toxicity measured by the text.
 16. **MAY** contain zero or one [0..1] **participant**
 - a. Contains exactly one [1..1] *Study Test Organization* (templateId: 2.16.840.1.113883.10.20.23.88)
 - Used to capture the organization performing the test.
 17. **SHOULD** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="REFR"** *REFR*
 - b. Contains exactly one [1..1] *Planned Study Day* (templateId: 2.16.840.1.113883.10.20.23.68)
 - Captures the planned study day for making an observation or recording a finding.
 18. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="REFR"** *REFR*
 - b. Contains exactly one [1..1] *Study Day Period* (templateId: 2.16.840.1.113883.10.20.23.82)
 - A reference to the study days corresponding to the time period of the observation.
 19. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="REFR"** *REFR*
 - b. Contains exactly one [1..1] *Timing Reference* (templateId: 2.16.840.1.113883.10.20.23.97)
 - Creates an association between the timing of an activity and a defined reference time point.
 20. **MAY** contain zero or one [0..1] **entryRelationship**
 - 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**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Sub- Category* (templateId: 2.16.840.1.113883.10.20.23.91)

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

22. SHOULD contain zero or one [0..1] **reference Range**

- Contains exactly one [1..1] *Reference Range* (templateId: 2.16.840.1.113883.10.20.23.74)
- Information on the reference range defined for a test. It is used to support interpretation of the test result.

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

- Contains **@typeCode="REFR"** *REFR*
- Contains exactly one [1..1] *Related Record* (templateId: 2.16.840.1.113883.10.20.23.75)
- Establishes a relationship between this record and another record.

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

- Contains **@typeCode="COMP"** *COMP*
- Contains exactly one [1..1] *Supplemental Value* (templateId: 2.16.840.1.113883.10.20.23.96)
- Allows the association of a supplemental value - outside of the content specified for the domain - to the record.

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

- Contains **@typeCode="COMP"** *COMP*
- Contains exactly one [1..1] *Comment* (templateId: 2.16.840.1.113883.10.20.23.23)
- A place to insert comments related to a particular finding.

Non-Human 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="792774276" extension="MDHT"/>
  <code code="76750076"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <value xsi:type="CD" code="1226921627"/>
  <interpretationCode code="1077588699"/>
  <methodCode code="1694661546"/>
  <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="899328747" 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="299181952" extension="MDHT"/>
      <code code="364327679"/>
      <statusCode code="completed"/>
      <effectiveTime>
```

```

        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <methodCode code="444770589"/>
      <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="1657526045" 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="712423330"/>
      <interpretationCode code="1200908533"/>
      <methodCode code="945693034"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation classCode="OBS">
      <templateId root="2.16.840.1.113883.10.20.23.38"/>
      <id root="311203484" 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>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <value xsi:type="CD" code="1381308219"/>
      <interpretationCode code="532060326"/>
      <methodCode code="1021713128"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation>
      <id root="1982098466" extension="MDHT"/>
      <code code="780109362"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <value xsi:type="INT" value="1"/>
      <interpretationCode code="2019650335"/>
    </observation>
  </entryRelationship>

```

```

    <methodCode code="1027287681"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <observation>
    <id root="1608747771" extension="MDHT"/>
    <code code="2073340169"/>
    <statusCode code="completed"/>
    <effectiveTime>
      <low value="2012"/>
      <high value="2012"/>
    </effectiveTime>
    <value xsi:type="IVL_INT" value="1"/>
    <interpretationCode code="545128072"/>
    <methodCode code="1479887084"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <act>
    <templateId root="2.16.840.1.113883.10.20.23.97"/>
    <id root="847057950" 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="1449061048" 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="698034280"/>
    <methodCode code="1240010351"/>
    <participant/>
    <entryRelationship/>
  </observation>
</entryRelationship>
<entryRelationship>
  <observation>
    <templateId root="2.16.840.1.113883.10.20.23.30"/>
    <id root="741081834" 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="1134372335"/>
    <interpretationCode code="2116287896"/>
    <methodCode code="554470615"/>
  </observation>
</entryRelationship>

```

```

<entryRelationship>
  <act classCode="ACT">
    <templateId root="2.16.840.1.113883.10.20.23.75"/>
    <id root="609651736" 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="1361373463" extension="MDHT"/>
    <code codeSystem="locally defined" codeSystemName="Supplemental Value
Type"/>
    <statusCode code="completed"/>
    <effectiveTime>
      <low value="2012"/>
      <high value="2012"/>
    </effectiveTime>
    <interpretationCode code="1835789418"/>
    <methodCode code="385910668"/>
    <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="1789559749" extension="MDHT"/>
    <code code="T0tbd" 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="744502495"/>
    <interpretationCode code="1351998739"/>
    <methodCode code="633306924"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <observation classCode="OBS" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.23.20"/>
    <id root="1869177989" 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="557180602"/>
    <interpretationCode code="28190601"/>
    <methodCode code="70006209"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <observation/>
</entryRelationship>

```

```

</entryRelationship>
<entryRelationship>
  <observation classCode="OBS">
    <templateId root="2.16.840.1.113883.10.20.23.39"/>
    <id root="277398443" 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="493049908"/>
    <methodCode code="700025376"/>
  </observation>
</entryRelationship>
</observation>

```

Non-human Subject Demographics

[Act: templateId 2.16.840.1.113883.10.20.23.60]

The template is used to record demographic information for a non-human study subject. The section includes that data which is not accommodated within the recordTarget structure.

1. **SHALL** contain exactly one [1..1] **@classCode="ACT"** *Act* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass)
2. **SHALL** contain exactly one [1..1] **@moodCode="EVN"** *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **code/@code="DMGtbd"** (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)

- Indicates that the contained information includes subject demographic data that is not accommodated by the record target participation.

4. **MAY** contain zero or one [0..1] **strainAssociation**

Information on the strain/substrain designation for the subject.

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

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

The code value indicates the observation records the applicable strain for the study subject.

- d. This observation **SHALL** contain exactly one [1..1] **value** with data type CD, where the **@code** **SHALL** be selected from ValueSet [Strain/Substrain Type](#) CXXXXX **STATIC**

Used to identify the vendor-supplied strain/substrain designation for the subject (i.e., test system) under study. When applicable, it combines the root strain, substrain, and associated genetic modifications as supplied by the vendor. It is extensible to accommodate strains not listed and genetically modified substrains. If this variable is excluded in the DM domain, the information must be present at a higher level (Trial Summary). [SEND: STRAIN]

- e. This observation **MAY** contain zero or one [0..1] **text**

A text description that provides additional details regarding the subject. [SEND: SUBTRAIN]

5. MAY contain zero or one [0..1] **ageAssociation**

Used to record the age of the subject.

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

The code value indicates this is an age observation.

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

The recorded age of the study subject. Note, in some cases age will be available while date of birth is either not known or withheld. [SDTM: AGE, AGEU]

6. SHALL contain [2..2] **entryRelationship**

- a. Contains **@typeCode="REFR"** *REFR*
- b. Contains exactly one [1..1] *Study Arm* (templateId: 2.16.840.1.113883.10.20.23.81)
 - Information may be collected on both the Planned Study Arm, and the Actual Study Arm. The Planned Study Arm must be provided.

7. SHOULD contain zero or one [0..1] **speciesAssociation**

Information on the study species.

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

The code value indicates this is an age observation.

- d. This observation **SHALL** contain exactly one [1..1] **value** with data type CD, where the **@code** **SHALL** be selected from ValueSet *Species Type* CXXXXX **STATIC**

The species of the subject. If no value is present, it must be provided within the trial summary. [SEND: SPECIES]

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

- a. Contains **@typeCode="COMP"** *COMP*
- b. Contains exactly one [1..1] *Comment* (templateId: 2.16.840.1.113883.10.20.23.23)
 - A place to insert comments related to a particular finding.

9. SHALL contain exactly one [1..1] **entryRelationship**

- a. Contains **@typeCode="REFR"** *REFR*
- b. Contains exactly one [1..1] *Domain Assignment* (templateId: 2.16.840.1.113883.10.20.23.30)
 - Identifies the SDTM or SEND domain the record is assigned to.

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

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

- Establishes a relationship between this record and another record.

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

- Contains **@typeCode="COMP"** *COMP*
 - Contains exactly one [1..1] *Supplemental Value* (templateId: 2.16.840.1.113883.10.20.23.96)
- Allows the association of a supplemental value - outside of the content specified for the domain - to the record.

12. SHALL contain exactly one [1..1] **entryRelationship**

- Contains **@typeCode="COMP"** *COMP*
 - Contains exactly one [1..1] *Reference Period* (templateId: 2.16.840.1.113883.10.20.23.73)
- Provides information on the reference period that has been defined for the subject's participation in the study.

13. SHALL contain exactly one [1..1] **setMembershipAssociation**

A record of the trial set that the subject has been assigned to.

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

The code value indicates this is a set membership observation.

- This observation **SHALL** contain exactly one [1..1] **value** with data type CD

A code that identifies the trial set the subject has been assigned to. The list of valid trial sets is submitted as part of study design. [SEND: SETCD]

Non-human 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="1420941260" extension="MDHT"/>
  <code code="1606638171"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <entryRelationship>
    <act>
      <templateId root="2.16.840.1.113883.10.20.23.81"/>
      <id root="1170742721" 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="1210830979" 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="1814943091" 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="995335427" 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="896250177" extension="MDHT"/>
        <code codeSystem="locally defined" codeSystemName="Supplemental Value
Type"/>
        <effectiveTime>
          <low value="2012"/>
          <high value="2012"/>
        </effectiveTime>
      </observation>
    </entryRelationship>
    <entryRelationship>
      <act>
        <id root="1068921274" extension="MDHT"/>
        <code code="2053310071"/>
        <effectiveTime>
          <low value="2012"/>
          <high value="2012"/>
        </effectiveTime>
      </act>
    </entryRelationship>
  </act>

```

Organ Measurement

[Observation: templateId 2.16.840.1.113883.10.20.23.62]

The template is used to record measurements of organs belonging to the study subject

1. **SHALL** contain exactly one [1..1] **@classCode="OBS"** *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass)
2. **SHALL** contain exactly one [1..1] **@moodCode="EVN"** *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **id**
 - A sequence number for the observation. [SEND: OMSEQ]
4. **SHALL** contain exactly one [1..1] **code**, where the @code **SHALL** be selected from (CodeSystem: locally defined Organ Measurement Examination Type)
 - A value to indicate the particular organ measurement observation. [SEND: OMTESTCD, OMTEST]
5. **MAY** contain zero or one [0..1] **statusCode**
 - Used to indicate whether or not a measurement has been performed. [SEND: OMSTAT]
6. **SHOULD** contain zero or one [0..1] **value**
 - The recorded organ measurement finding. [SEND: OMORRES, OMORRESU, OMSTRESC, OMSTRESN, OMSTRESU]
7. **MAY** contain zero or one [0..1] **interpretationCode**, where the @code **SHALL** be selected from ValueSet *Subject Data Interpretation Type* CXXXXX **STATIC**
 - Includes information used to better interpret the observation value (result). It is used to record observations to be excluded from tabulation. [SEND: OMEXCLFL]
8. Contains zero or one [0..1] **entryRelationship**
 - a. 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**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Data Collection* (templateId: 2.16.840.1.113883.10.20.23.27)
 - Information on whether a predefined data item was collected, and the timing of collection.
10. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Non Performance Reason* (templateId: 2.16.840.1.113883.10.20.23.56)
 - Information on the reason a scheduled activity was not carried out.
11. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Exclusion Reason* (templateId: 2.16.840.1.113883.10.20.23.38)
 - Information on the reason that a data item is to be excluded from tabulation.
12. **SHALL** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Specimen Information* (templateId: 2.16.840.1.113883.10.20.23.78)
 - 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.
13. **MAY** contain zero or more [0..*] **entryRelationship**
 - a. Contains **@typeCode="REFR"** *REFR*
 - b. Contains exactly one [1..1] *Related Record* (templateId: 2.16.840.1.113883.10.20.23.75)
 - Establishes a relationship between this record and another record.
14. **MAY** contain zero or more [0..*] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Supplemental Value* (templateId: 2.16.840.1.113883.10.20.23.96)
 - Allows the association of a supplemental value - outside of the content specified for the domain - to the record.

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

- a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Comment* (templateId: 2.16.840.1.113883.10.20.23.23)
- A place to insert comments related to a particular finding.

Organ Measurement 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="2.16.840.1.113883.10.20.23.62"/>
  <id root="417154161" extension="MDHT"/>
  <code codeSystem="locally defined"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <interpretationCode codeSystemName="NCI Thesaurus"/>
  <entryRelationship>
    <observation classCode="OBS">
      <templateId root="2.16.840.1.113883.10.20.23.56"/>
      <id root="1509542382" 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="1838547830"/>
      <interpretationCode code="1873653895"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <procedure>
      <id root="173245499" extension="MDHT"/>
      <code code="174974240"/>
      <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>
    <act>
```

```

    <id root="750935131" extension="MDHT"/>
    <code code="979128397"/>
    <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="974197478" 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="792829091"/>
    <participant/>
    <entryRelationship/>
  </observation>
</entryRelationship>
<entryRelationship>
  <observation>
    <templateId root="2.16.840.1.113883.10.20.23.30"/>
    <id root="2025660537" 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="643493241"/>
    <interpretationCode code="571281832"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <observation classCode="OBS">
    <templateId root="2.16.840.1.113883.10.20.23.38"/>
    <id root="1940137080" 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>
      <low value="2012"/>
      <high value="2012"/>
    </effectiveTime>
    <value xsi:type="CD" code="1381984682"/>
    <interpretationCode code="171577485"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <act classCode="ACT">
    <templateId root="2.16.840.1.113883.10.20.23.75"/>
    <id root="695178110" 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="1425460324" extension="MDHT"/>
    <code codeSystem="locally defined" codeSystemName="Supplemental Value
Type"/>
    <statusCode code="completed"/>
    <effectiveTime>
      <low value="2012"/>
      <high value="2012"/>
    </effectiveTime>
    <interpretationCode code="112498028"/>
    <participant/>
    <entryRelationship typeCode="COMP"/>
  </observation>
</entryRelationship>
</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)
2. **SHALL** contain exactly one [1..1] **@moodCode="EVN"** *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **code/@code="OATtbd"** (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)
 - 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
 - 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="1598925456" 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>
```

Palpable Mass

[Observation: templateId 2.16.840.1.113883.10.20.23.64]

The template is used to record information for palpable masses which are detected during the study.

1. **SHALL** contain exactly one [1..1] **@classCode="OBS"** *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass)
2. **SHALL** contain exactly one [1..1] **@moodCode="EVN"** *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **id**
 - A sequence number for the observation. [SEND: PMSEQ]
4. **SHALL** contain exactly one [1..1] **code**, where the @code **SHALL** be selected from (CodeSystem: locally defined Palpable Mass Examination Type)
 - A value to indicate the particular palpable observation. [SEND: PMTESTCD, PMTEST]
5. **MAY** contain zero or one [0..1] **statusCode**
 - Used to indicate whether or not a measurement has been performed. [SEND: PMSTAT]
6. **SHOULD** contain zero or one [0..1] **value**
 - The recorded palpable mass finding. [SEND: PMORRES, PMORRESU, PMSTRESC, PMSTRESN, PMSTRESU]
7. **SHOULD** contain zero or one [0..1] **targetSiteCode**, where the @code **SHALL** be selected from ValueSet *Anatomical Location* C74456 **STATIC**
 - The body site for the palpable mass finding. [SEND: PMLOC]
8. **SHALL** contain exactly one [1..1] **entryRelationship**
 - a. Contains **@typeCode="REFR"** *REFR*
 - b. Contains exactly one [1..1] *Domain Assignment* (templateId: 2.16.840.1.113883.10.20.23.30)
 - Identifies the SDTM or SEND domain the record is assigned to.
9. **SHOULD** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Data Collection* (templateId: 2.16.840.1.113883.10.20.23.27)
 - Information on whether a predefined data item was collected, and the timing of collection.
10. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Non Performance Reason* (templateId: 2.16.840.1.113883.10.20.23.56)
 - Information on the reason a scheduled activity was not carried out.
11. **MAY** contain zero or one [0..1] **participant**
 - a. Contains exactly one [1..1] *Study Finding Evaluator* (templateId: 2.16.840.1.113883.10.20.23.84)
 - Records the role of the person evaluating the finding.
12. **SHOULD** contain zero or one [0..1] **participant**
 - a. Contains exactly one [1..1] *Mass Identification* (templateId: 2.16.840.1.113883.10.20.23.51)
 - Records the identifier of a body mass associated with the observation.
13. **SHOULD** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="REFR"** *REFR*
 - b. Contains exactly one [1..1] *Planned Study Day* (templateId: 2.16.840.1.113883.10.20.23.68)

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

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

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

- Establishes a relationship between this record and another record.

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

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

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

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

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

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

Palpable Mass 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="2.16.840.1.113883.10.20.23.64"/>
  <id root="1059909265" extension="MDHT"/>
  <code codeSystem="locally defined" codeSystemName="Palpable Mass Examination
Type"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <targetSiteCode code="1581527120"/>
  <participant>
    <participantRole classCode="ASSIGNED">
      <templateId root="null"/>
      <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus"/>
    </participantRole>
  </participant>
  <participant>
    <participantRole classCode="ROL"/>
  </participant>
  <entryRelationship>
    <observation classCode="OBS">
      <templateId root="2.16.840.1.113883.10.20.23.56"/>
      <id root="1539072896" 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="775068849"/>
      <targetSiteCode code="1334446578"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation>
      <id root="1680890147" extension="MDHT"/>
```

```

    <code code="1722387357"/>
    <statusCode code="completed"/>
    <effectiveTime>
      <low value="2012"/>
      <high value="2012"/>
    </effectiveTime>
    <value xsi:type="INT" value="1"/>
    <targetSiteCode code="1068975562"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <act>
    <id root="582755804" extension="MDHT"/>
    <code code="2127127818"/>
    <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="259105153" 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="1118318323"/>
    <participant/>
    <entryRelationship/>
  </observation>
</entryRelationship>
<entryRelationship>
  <observation>
    <templateId root="2.16.840.1.113883.10.20.23.30"/>
    <id root="475193536" 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="1336627410"/>
    <targetSiteCode code="207987585"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <act classCode="ACT">
    <templateId root="2.16.840.1.113883.10.20.23.75"/>
    <id root="1000304298" 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="1800099893" extension="MDHT"/>
      <code codeSystem="locally defined" codeSystemName="Supplemental Value
Type"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <targetSiteCode code="717628129"/>
      <participant/>
      <entryRelationship typeCode="COMP"/>
    </observation>
  </entryRelationship>
</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)
2. **SHALL** contain exactly one [1..1] **@moodCode= "EVN"** *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain [1..3] **id**
 - A value that is provided to ensure the uniqueness of the pharmacokinetics 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**, where the **@code SHALL** be selected from (CodeSystem: locally defined Pharmacokinetics Concentration Finding Type)
 - 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**
 - 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
 - The pharmacokinetics result, using both original units and a standard format or set of units. [SDTM: PCORRES, PCORRESU, PCSTRESC, PCSTRESN, PCSTRESU], [SEND: PCORRES, PCORRESU, PCSTRESC, PCSTRESN, PCSTRESU]
7. **SHOULD** contain [0..3] **interpretationCode**, where the **@code SHALL** be selected from ValueSet *Subject Data Interpretation Type* CXXXXX **STATIC**
 - Includes information used to better interpret the observation value (result). [SDTM: PCDRVFL]. [SEND: PCBLFL, PCDRVFL, PCEXCLFL]
8. **MAY** contain zero or one [0..1] **methodCode**, where the **@code SHALL** be selected from ValueSet *Method* C85492 **STATIC**
 - Indicates the method of the test or examination. [SDTM: PCMETHOD], [SEND: PCMETHOD]
9. **SHALL** contain exactly one [1..1] **entryRelationship**

- a. Contains **@typeCode="REFR"** *REFR*
 - b. Contains exactly one [1..1] *Domain Assignment* (templateId: 2.16.840.1.113883.10.20.23.30)
 - Identifies the SDTM or SEND domain the record is assigned to.
- 10.MAY** contain zero or one [0..1] **entryRelationship**
- a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Group Identifier* (templateId: 2.16.840.1.113883.10.20.23.42)
 - Allows capture of a group identifier for the finding.
- 11.MAY** contain zero or one [0..1] **entryRelationship**
- a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Non Performance Reason* (templateId: 2.16.840.1.113883.10.20.23.56)
 - Provides a reason for not capturing information for the finding.
- 12.MAY** contain zero or one [0..1] **entryRelationship**
- a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Exclusion Reason* (templateId: 2.16.840.1.113883.10.20.23.38)
 - Information on the reason that a data item is to be excluded from tabulation.
- 13.SHALL** contain zero or one [0..1] **entryRelationship**
- a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Specimen Information* (templateId: 2.16.840.1.113883.10.20.23.78)
 - 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.
- 14.MAY** contain zero or one [0..1] **entryRelationship**
- a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Fasting Status* (templateId: 2.16.840.1.113883.10.20.23.39)
 - Used to indicate the fasting status - time since consumption of food - for the study subject.
- 15.SHOULD** contain zero or one [0..1] **entryRelationship**
- a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Assay Quantitation* (templateId: 2.16.840.1.113883.10.20.23.16)
 - Records the lower limit of quantitation for an assay.
- 16.MAY** contain zero or one [0..1] **participant**
- a. Contains exactly one [1..1] *Study Test Organization* (templateId: 2.16.840.1.113883.10.20.23.88)
 - Used to record the organization performing the test.
- 17.SHOULD** contain zero or one [0..1] **entryRelationship**
- a. Contains **@typeCode="REFR"** *REFR*
 - b. Contains exactly one [1..1] *Planned Study Day* (templateId: 2.16.840.1.113883.10.20.23.68)
 - Captures the planned study day for making an observation or recording a finding.
- 18.MAY** contain zero or one [0..1] **entryRelationship**
- a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Category* (templateId: 2.16.840.1.113883.10.20.23.20)
 - The record of a category to be used in organizing information items.
- 19.MAY** contain zero or one [0..1] **entryRelationship**
- a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Sub- Category* (templateId: 2.16.840.1.113883.10.20.23.91)

- The record of a sub-category to be used in organizing information items.
- 20. MAY** contain zero or more [0..*] **entryRelationship**
- Contains **@typeCode="REFR"** *REFR*
 - Contains exactly one [1..1] *Related Record* (templateId: 2.16.840.1.113883.10.20.23.75)
 - Establishes a relationship between this record and another record.
- 21. MAY** contain zero or more [0..*] **entryRelationship**
- Contains **@typeCode="COMP"** *COMP*
 - Contains exactly one [1..1] *Supplemental Value* (templateId: 2.16.840.1.113883.10.20.23.96)
 - Allows the association of a supplemental value - outside of the content specified for the domain - to the record.
- 22. MAY** contain zero or more [0..*] **entryRelationship**
- Contains **@typeCode="COMP"** *COMP*
 - Contains exactly one [1..1] *Comment* (templateId: 2.16.840.1.113883.10.20.23.23)
 - A place to insert comments related to a particular finding.
- 23. MAY** contain zero or more [0..*] **entryRelationship**
- Contains **@typeCode="COMP"** *COMP*
 - Contains exactly one [1..1] *Finding About* (templateId: 2.16.840.1.113883.10.20.23.40)
 - Allows recording of additional findings related to the finding.

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="827589405" extension="MDHT"/>
  <code code="450286793"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <value xsi:type="CD" code="561002747"/>
  <interpretationCode code="496134862"/>
  <methodCode code="1848231931"/>
  <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="1389967675" 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="1735800366" extension="MDHT"/>
      <code code="1914688073"/>
      <statusCode code="completed"/>
    </procedure>
  </entryRelationship>
</observation>
```

```

    <effectiveTime>
      <low value="2012"/>
      <high value="2012"/>
    </effectiveTime>
    <methodCode code="1369846376"/>
    <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="387190398" 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="498592669"/>
    <interpretationCode code="691893496"/>
    <methodCode code="1921656822"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <observation>
    <id root="1378043939" extension="MDHT"/>
    <code code="820514948"/>
    <statusCode code="completed"/>
    <effectiveTime>
      <low value="2012"/>
      <high value="2012"/>
    </effectiveTime>
    <value xsi:type="INT" value="1"/>
    <interpretationCode code="36336351"/>
    <methodCode code="242619119"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <observation classCode="OBS">
    <templateId root="2.16.840.1.113883.10.20.23.38"/>
    <id root="1510187247" 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>
      <low value="2012"/>
      <high value="2012"/>
    </effectiveTime>
    <value xsi:type="CD" code="1139839662"/>

```

```

        <interpretationCode code="1930769724"/>
        <methodCode code="2114513459"/>
    </observation>
</entryRelationship>
<entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
        <templateId root="2.16.840.1.113883.10.20.23.23"/>
        <id root="1163829888" 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="2094203554"/>
        <methodCode code="1805700513"/>
        <participant/>
    </observation>
</entryRelationship>
<entryRelationship>
    <observation>
        <templateId root="2.16.840.1.113883.10.20.23.30"/>
        <id root="34773949" 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="198641127"/>
        <interpretationCode code="684619635"/>
        <methodCode code="580809203"/>
    </observation>
</entryRelationship>
<entryRelationship>
    <act classCode="ACT">
        <templateId root="2.16.840.1.113883.10.20.23.75"/>
        <id root="140732596" 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="1830483184" extension="MDHT"/>
        <code codeSystem="locally defined" codeSystemName="Supplemental Value
Type"/>
        <statusCode code="completed"/>
        <effectiveTime>
            <low value="2012"/>
            <high value="2012"/>
        </effectiveTime>
        <interpretationCode code="784928441"/>
        <methodCode code="1997311726"/>
    </observation>
</entryRelationship>

```

```

    <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="1910885405" 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="1123913352"/>
    <interpretationCode code="899788165"/>
    <methodCode code="890499793"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <observation/>
</entryRelationship>
<entryRelationship>
  <observation classCode="OBS">
    <templateId root="2.16.840.1.113883.10.20.23.39"/>
    <id root="1858391228" 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="1001813518"/>
    <methodCode code="1042341018"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <observation>
    <id root="83883357" extension="MDHT"/>
    <code code="852291155"/>
    <statusCode code="completed"/>
    <effectiveTime>
      <low value="2012"/>
      <high value="2012"/>
    </effectiveTime>
    <value xsi:type="IVL_PQ"/>
    <interpretationCode code="2119095894"/>
    <methodCode code="1401034375"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <observation>
    <id root="548141915" extension="MDHT"/>
    <code code="379446390"/>
    <statusCode code="completed"/>
    <effectiveTime>
      <low value="2012"/>
      <high value="2012"/>
    </effectiveTime>
    <interpretationCode code="1481839631"/>
    <methodCode code="1374989940"/>
  </observation>
</entryRelationship>

```



```

<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>

```

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)
2. **SHALL** contain exactly one [1..1] **@moodCode="EVN"** *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **id**
 - A value that is provided to ensure the uniqueness of the pharmacokinetics parameter result. [SDTM: PPSEQ], [SEND: PPSEQ]
4. **SHALL** contain exactly one [1..1] **code**, where the **@code** **SHALL** be selected from ValueSet *Pharmacokinetics Parameter Finding Type* C85839 **STATIC**
 - 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**
 - Used to indicate whether or not an exam has been performed. [SDTM: PPSTAT], [SEND: PPSTAT]

6. SHOULD contain zero or one [0..1] **value**

- The pharmacokinetics parameter result, using both original units and a standard format or set of units. [SDTM: PPORRES, PPORRESU, PPSTRESC, PPSTRESN, PPSTRESU], [SEND: PPORRES, PPORRESU, PPSTRESC, PPSTRESN, PPSTRESU]

7. SHALL contain exactly one [1..1] **entryRelationship**

- Contains **@typeCode="REFR"** *REFR*
 - Contains exactly one [1..1] *Domain Assignment* (templateId: 2.16.840.1.113883.10.20.23.30)
- Identifies the SDTM or SEND domain the record is assigned to.

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

- Contains **@typeCode="COMP"** *COMP*
 - Contains exactly one [1..1] *Group Identifier* (templateId: 2.16.840.1.113883.10.20.23.42)
- Allows capture of a group identifier for the finding.

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

- Contains **@typeCode="COMP"** *COMP*
 - Contains exactly one [1..1] *Non Performance Reason* (templateId: 2.16.840.1.113883.10.20.23.56)
- Provides a reason for not capturing information for the finding.

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

- Contains **@typeCode="COMP"** *COMP*
 - Contains exactly one [1..1] *Specimen Information* (templateId: 2.16.840.1.113883.10.20.23.78)
- 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.

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

- Contains **@typeCode="COMP"** *COMP*
 - Contains exactly one [1..1] *Timing Reference* (templateId: 2.16.840.1.113883.10.20.23.97)
- Orients the performance of the test leading to the pharmacokinetic parameter with respect to a study defined timepoint.

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

- Contains **@typeCode="COMP"** *COMP*
 - Contains exactly one [1..1] *Category* (templateId: 2.16.840.1.113883.10.20.23.20)
- The record of a category to be used in organizing information items.

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

- Contains **@typeCode="COMP"** *COMP*
 - Contains exactly one [1..1] *Sub- Category* (templateId: 2.16.840.1.113883.10.20.23.91)
- The record of a sub-category to be used in organizing information items.

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

- Contains **@typeCode="REFR"** *REFR*
 - Contains exactly one [1..1] *Related Record* (templateId: 2.16.840.1.113883.10.20.23.75)
- Establishes a relationship between this record and another record.

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

- Contains **@typeCode="COMP"** *COMP*
 - Contains exactly one [1..1] *Supplemental Value* (templateId: 2.16.840.1.113883.10.20.23.96)
- Allows the association of a supplemental value - outside of the content specified for the domain - to the record.

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

- a. Contains **@typeCode="COMP"** *COMP*
- b. Contains exactly one [1..1] *Comment* (templateId: 2.16.840.1.113883.10.20.23.23)
 - A place to insert comments related to a particular finding.

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

- a. Contains **@typeCode="COMP"** *COMP*
- b. Contains exactly one [1..1] *Finding About* (templateId: 2.16.840.1.113883.10.20.23.40)
 - Allows recording of additional findings related to the finding.

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="1164164821" extension="MDHT"/>
  <code code="1403587617"/>
  <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="477788972" 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="148147042" extension="MDHT"/>
      <code code="848354097"/>
      <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>
```

```

    <observation classCode="OBS">
      <templateId root="2.16.840.1.113883.10.20.23.56"/>
      <id root="1345834660" 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="905044602"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <act>
      <templateId root="2.16.840.1.113883.10.20.23.97"/>
      <id root="512595192" 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="1376685168" 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="1789907322" 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="1910106438"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <act classCode="ACT">
      <templateId root="2.16.840.1.113883.10.20.23.75"/>
      <id root="1984596391" 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="1021114323" 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="1989215028" 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="491531631"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation/>
  </entryRelationship>
  <entryRelationship>
    <observation>
      <id root="1036518858" extension="MDHT"/>
      <code code="1189578491"/>
      <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>
    <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)
2. **SHALL** contain exactly one [1..1] **@moodCode="EVN"** *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain [1..2] **id**
 - A value that is provided to ensure the uniqueness of the physical exam finding. [SDTM: PESEQ, PESPID] A single identifier, the sequence number, is required.
4. **SHALL** contain exactly one [1..1] **code**, where the **@code** **SHALL** be selected from (CodeSystem: locally defined Physical Exam Finding Type)
 - 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**
 - Used to indicate whether or not the specified physical exam has been performed. [SDTM: PESTAT]
6. **SHOULD** contain zero or one [0..1] **value**
 - The result of the component of the physical exam indicated by the code value. Verbatim findings are captured in original 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, PEORESUS, PESTRESC]
7. **MAY** contain zero or one [0..1] **methodCode**, where the **@code** **SHALL** be selected from ValueSet [Method C85492](#) **STATIC**
 - The method used for conducting the test or examination. [SDTM: PEMETHOD]
8. **MAY** contain zero or one [0..1] **targetSiteCode**, where the **@code** **SHALL** be selected from ValueSet [Anatomical Location C74456](#) **STATIC**
 - Can be used to specify where a physical exam finding occurred. [SDTM: PELOC]
9. **SHALL** contain exactly one [1..1] **entryRelationship**
 - a. Contains **@typeCode="REFR"** *REFR*
 - b. Contains exactly one [1..1] [Domain Assignment](#) (templateId: 2.16.840.1.113883.10.20.23.30)

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

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

- Contains **@typeCode="COMP"** *COMP*
 - Contains exactly one [1..1] *Group Identifier* (templateId: 2.16.840.1.113883.10.20.23.42)
- Allows capture of a group identifier for the finding.

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

- Contains **@typeCode="COMP"** *COMP*
 - Contains exactly one [1..1] *Data Collection* (templateId: 2.16.840.1.113883.10.20.23.27)
- Information on whether a predefined data item was collected, and the timing of collection.

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

- Contains **@typeCode="COMP"** *COMP*
 - Contains exactly one [1..1] *Non Performance Reason* (templateId: 2.16.840.1.113883.10.20.23.56)
- Provides a reason for not capturing information for the finding.

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

- Contains exactly one [1..1] *Study Finding Evaluator* (templateId: 2.16.840.1.113883.10.20.23.84)
- Used to record the role played by the person providing the value of a subjective finding.

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

- Contains **@typeCode="COMP"** *COMP*
 - Contains exactly one [1..1] *Body System or Organ Class* (templateId: 2.16.840.1.113883.10.20.23.17)
- Allows identification of the relevant body system or organ class.

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

- Contains **@typeCode="COMP"** *COMP*
 - Contains exactly one [1..1] *Category* (templateId: 2.16.840.1.113883.10.20.23.20)
- The record of a category to be used in organizing information items.

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

- Contains **@typeCode="COMP"** *COMP*
 - Contains exactly one [1..1] *Sub- Category* (templateId: 2.16.840.1.113883.10.20.23.91)
- The record of a sub-category to be used in organizing information items.

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

- Contains **@typeCode="REFR"** *REFR*
 - Contains exactly one [1..1] *Related Record* (templateId: 2.16.840.1.113883.10.20.23.75)
- Establishes a relationship between this record and another record.

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

- Contains **@typeCode="COMP"** *COMP*
 - Contains exactly one [1..1] *Supplemental Value* (templateId: 2.16.840.1.113883.10.20.23.96)
- Allows the association of a supplemental value - outside of the content specified for the domain - to the record.

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

- Contains **@typeCode="COMP"** *COMP*
 - Contains exactly one [1..1] *Comment* (templateId: 2.16.840.1.113883.10.20.23.23)
- A place to insert comments related to a particular finding.

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

- a. Contains `@typeCode="COMP"` *COMP*
- b. Contains exactly one [1..1] *Finding About* (templateId: 2.16.840.1.113883.10.20.23.40)
 - Allows recording of additional findings related to the finding.

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="1570962274" extension="MDHT"/>
  <code code="1212485387"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <methodCode code="1888318932"/>
  <targetSiteCode code="1611529967"/>
  <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="163524329" 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="1686621156" 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="846897116"/>
      <methodCode code="1161450130"/>
      <targetSiteCode code="1738366838"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <act>
      <id root="990622381" extension="MDHT"/>
      <code code="302207700"/>
      <statusCode code="completed"/>
    </act>
  </entryRelationship>
</observation>
```



```

    <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="1925689071" 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="1772558268"/>
    <targetSiteCode code="1861280800"/>
    <participant/>
    <entryRelationship/>
  </observation>
</entryRelationship>
<entryRelationship>
  <observation>
    <templateId root="2.16.840.1.113883.10.20.23.30"/>
    <id root="1367887099" 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="497560558"/>
    <methodCode code="238273663"/>
    <targetSiteCode code="368183068"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <act classCode="ACT">
    <templateId root="2.16.840.1.113883.10.20.23.75"/>
    <id root="418691540" 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="1540692708" extension="MDHT"/>
    <code codeSystem="locally defined" codeSystemName="Supplemental Value
Type"/>
    <statusCode code="completed"/>
    <effectiveTime>

```

```

        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <methodCode code="1639679591"/>
      <targetSiteCode code="587331924"/>
      <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="1579786196" 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="834863419"/>
      <methodCode code="746143349"/>
      <targetSiteCode code="1000343560"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation/>
  </entryRelationship>
  <entryRelationship>
    <observation>
      <id root="139236536" extension="MDHT"/>
      <code code="565016693"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <methodCode code="187772605"/>
      <targetSiteCode code="953201799"/>
      <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>
    </observation>
  </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>
    <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)
2. **SHALL** contain exactly one [1..1] **@moodCode**="INT" (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **code/@code**="C83450" *Planned Study Day of Visit* (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)
 - A fixed value that indicates the observation captures the planned study day for an event.
4. **SHALL** contain exactly one [1..1] **value** with data type INT
 - 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="27792652" extension="MDHT"/>
  <code code="1287591491"/>
  <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**
2. **SHALL** contain exactly one [1..1] **@moodCode**
3. **SHALL** contain exactly one [1..1] **code/@code**="C71148" (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)

- A code value that indicates that the observation is that of body position.
4. **SHALL** contain exactly one [1..1] **value** with data type CD, where the @code **SHALL** be selected from ValueSet *Body Position* C71148 **STATIC**
 - 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="179668063" 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="2132463751"/>
</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)
2. **SHALL** contain exactly one [1..1] @moodCode="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] code/@code="PSEtbd" (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)
 - 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
 - Indicate whether or not the indicated activity or event was prespecified on the CRF. [SDTM: CMPRESP, SUPRESP, AEPRESP, MHPRESP, CEPHRESP], [Study Data Tabulation 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="2045735316" 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>
```

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 participation 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 reuse 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)
2. **SHALL** contain exactly one [1..1] **@moodCode="EVN"** *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **code/@code="Rptbd"** (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)
 - A code value that indicates that the act captures reference period information.
4. **SHALL** contain exactly one [1..1] **effectiveTime**
 - The reference start and stop time for the subject's participation 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="278465745" extension="MDHT"/>
  <code code="870442102"/>
  <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)
2. **SHALL** contain exactly one [1..1] **@moodCode="EVN"** *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **id**
 - 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/@code="RRtbd"** (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)
 - 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="1535514511" 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)
2. **SHALL** contain exactly one [1..1] **@moodCode**= "EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **code**, where the **@code** **SHALL** be selected from ValueSet [Subject Data Domain Result Category Type CXXXXX STATIC](#)
 - 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
 - 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="1591400031" 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="1900660588"/>
</observation>
```

Serious Event

[Observation: templateId 2.16.840.1.113883.10.20.23.77]

The template is used to record information 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 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)
2. **SHALL** contain exactly one [1..1] **@moodCode**= "EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **code/@code**= "SEtbd" *Serious Event* (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)

- A code value that indicates that the observation captures event seriousness information.
4. **SHALL** contain exactly one [1..1] **value** with data type BL
- 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**
- a. Such entryRelationships **SHALL** contain exactly one [1..1] **@typeCode="COMP"**
 - b. Such entryRelationships **SHALL** contain exactly one [1..1] **observation**
 - a. This observation **SHALL** contain exactly one [1..1] **@classCode**
 - b. This observation **SHALL** contain exactly one [1..1] **@moodCode="EVN"** *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
 - c. This observation **SHALL** contain exactly one [1..1] **code/@code="SETtbd"** (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)

The code value indicates the observation conveys information on the nature of the seriousness of the adverse event.
 - d. This observation **SHALL** contain exactly one [1..1] **value** with data type CD, where the @code **SHALL** be selected from ValueSet *Serious Event Type* CXXXXXX **STATIC**
- 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, ASEDISAB, 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="2074394825" extension="MDHT"/>
  <code code="1670112001"/>
  <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)
2. **SHALL** contain exactly one [1..1] **@moodCode="EVN"** *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **code/@code="SCLtbd"** (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)

- A fixed code value to indicate the act is one of specimen collection.

4. SHOULD contain zero or one [0..1] **effectiveTime**

- 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] **targetSiteCode**, where the @code **SHALL** be selected from ValueSet *Anatomical Location* C74456 **STATIC**

- Information about the anatomic region from which the specimen was extracted. {SEND: MAANTREG}

6. SHOULD contain zero or one [0..1] **specimen**

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

- a.** This specimen **SHALL** contain zero or one [0..1] **@typeCode= "SPC"**

- b.** This specimen **SHOULD** contain zero or one [0..1] **specimenRole**

- a.** This specimenRole **SHALL** contain zero or one [0..1] **@classCode= "SPEC"**

- b.** This specimenRole **MAY** contain zero or one [0..1] **id**

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

- c.** This specimenRole **SHOULD** contain zero or one [0..1] **specimenEntity**

- a.** This specimenEntity **SHALL** contain exactly one [1..1] **@classCode= "ENT"**

- b.** This specimenEntity **SHALL** contain exactly one [1..1] **@determinerCode= "INSTANCE"**

- c.** This specimenEntity **SHALL** contain exactly one [1..1] **code**, where the @code **SHALL** be selected from ValueSet *Specimen Type* C78734 **STATIC**

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

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

Characterizes the relationship of the specimen to the anatomic 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"**

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

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

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

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

A fixed value that indicates the nature of the observation. It provides information on the relationship of the specimen to the anatomic structure it was drawn from..

- d.** This observation **SHALL** contain exactly one [1..1] **value** with data type CD, where the @code **SHALL** be selected from ValueSet *Portion or Totality Type* CXXXXX **STATIC**

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

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

Records information regarding the usability of the specimen.

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

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

The value indicates the nature of the observation. It provides information on the usability of the specimen.

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

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

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

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

- a. This entryRelationship **SHALL** contain exactly one [1..1] **@typeCode="COMP"**
- b. This entryRelationship **SHALL** contain exactly one [1..1] **observation**
 - a. This observation Contains exactly one [1..1] **@classCode="OBS"** *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass)
 - b. This observation **SHALL** contain exactly one [1..1] **@moodCode="EVN"** *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
 - c. This observation **SHALL** contain exactly one [1..1] **code/@code="C78733"** (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)

The value indicates the nature of the observation. It provides information on the specimen condition.

- d. This observation **SHALL** contain exactly one [1..1] **value** with data type CD, where the **@code** **SHALL** be selected from ValueSet *Specimen Condition Type* C78733 **STATIC**

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

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

- a. Contains **@typeCode="REFR"** *REFR*
- b. Contains exactly one [1..1] *Event Study Day* (templateId: 2.16.840.1.113883.10.20.23.37)
 - Used to record the study day associated with an activity taking place during a single day.

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

- a. Contains **@typeCode="REFR"** *REFR*
- b. Contains exactly one [1..1] *Timing Reference* (templateId: 2.16.840.1.113883.10.20.23.97)
 - Orients the performance of the test on the specimen with respect to a study defined timepoint.

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="1581650660" extension="MDHT"/>
  <code code="331092688"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <targetSiteCode code="1644417297"/>
  <specimen typeCode="SPC">
    <templateId root="null"/>
    <specimenRole classCode="SPEC"/>
  </specimen>
</procedure>
```

```

</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="1117069097" extension="MDHT"/>
    <code code="302211436"/>
    <effectiveTime>
      <low value="2012"/>
      <high value="2012"/>
    </effectiveTime>
    <targetSiteCode code="1047167213"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <act>
    <templateId root="2.16.840.1.113883.10.20.23.97"/>
    <id root="58902449" 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)
2. **SHALL** contain exactly one [1..1] **@moodCode="EVN"** *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **code/@code="STRPtbd"** (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)
 - 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, where the @code **SHALL** be selected from ValueSet [Reference Period Relationship](#) C66728 **STATIC**
 - 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="1355770578" 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="2033013560"/>
</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)
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **code/@code**="ENRPtbd" (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)
 - 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, where the @code **SHALL** be selected from ValueSet [Reference Period Relationship](#) C66728 **STATIC**
 - 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="1831012600" 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="401492119"/>
</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)
2. **SHALL** contain exactly one [1..1] **@moodCode="INT"** (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
 - 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**, where the @code **SHALL** be selected from (CodeSystem: locally defined Study Arm Type)
 - The fixed value includes the code for the study arm. [SDTM: ARMCD]
4. **SHALL** contain zero or one [0..1] **text**
 - Provide the description of the planned arm for the subject. [SDTM, ARM].
5. **SHOULD** contain zero or one [0..1] **effectiveTime**
 - The reference period for the subject's participation in the study. It is usually equivalent to an interval that begins on the date/time when the person was first exposed to study treatment, and ends when the subject was determined to have ended the trial. The end date is often equivalent to the date/time of last exposure to study treatment. [SDTM: RFSTDTC, RFENDTC].

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="148728013" 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 labeled 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)
2. **SHALL** contain exactly one [1..1] **@moodCode="EVN"** *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)

3. **SHALL** contain exactly one [1..1] **code/@code**="STPtbd" (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)

- A fixed value that indicates the observation captures the actual study day for an event.

4. **SHALL** contain exactly one [1..1] **value** with data type IVL_INT

- The applicable study day 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="1115151980" extension="MDHT"/>
  <code code="847746811"/>
  <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)
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **code**, where the **@code** **SHALL** be selected from (CodeSystem: locally defined Study Epoch Type)
 - A code value for the epoch.
4. **SHALL** contain zero or one [0..1] **text**
 - 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="394618528" 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)
3. **SHALL** contain [1..3] **id**
 - 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**
 - The code value indicates the nature of the observation. The verbatim term is captured as original text. A modified term is represented 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. **MAY** contain zero or one [0..1] **statusCode**
 - Used to indicate whether the event did occur. Use statusCode "Completed" if the event in question occurred. [Study Data Tabulation Model: -OCCUR]
6. **SHOULD** contain zero or one [0..1] **effectiveTime**
 - 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 recommended 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]
7. **SHALL** contain exactly one [1..1] **value** with data type CD
 - 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**, where the @code **SHALL** be selected from ValueSet [Anatomical Location](#) C74456 **STATIC**
 - The anatomic location that is relevant for the event. [Study Data Tabulation Model: -LOC]
9. **SHALL** contain exactly one [1..1] **entryRelationship**
 - a. Contains **@typeCode="REFR"** *REFR*
 - b. Contains exactly one [1..1] [Domain Assignment](#) (templateId: 2.16.840.1.113883.10.20.23.30)
 - Identifies the SDTM or SEND domain the record is assigned to.
10. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] [Data Collection](#) (templateId: 2.16.840.1.113883.10.20.23.27)
 - Information on whether a predefined data item was collected, and the timing of collection.
11. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] [Non Performance Reason](#) (templateId: 2.16.840.1.113883.10.20.23.56)

- Information on the reason a scheduled activity was not carried out.
- 12. MAY** contain zero or one [0..1] **entryRelationship**
- a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Group Identifier* (templateId: 2.16.840.1.113883.10.20.23.42)
 - Indicates an identifier that is used to group associated events.
- 13. MAY** contain zero or one [0..1] **entryRelationship**
- 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)
 - A record of the severity or intensity of the finding.
- 14. MAY** contain zero or one [0..1] **entryRelationship**
- a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Pre-Specified Event* (templateId: 2.16.840.1.113883.10.20.23.70)
 - Indicates whether or not the event was prespecified on the CRF.
- 15. MAY** contain zero or one [0..1] **entryRelationship**
- a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Body System or Organ Class* (templateId: 2.16.840.1.113883.10.20.23.17)
 - Allows identification of the relevant body system or organ class for the event.
- 16. MAY** contain zero or one [0..1] **entryRelationship**
- a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Serious Event* (templateId: 2.16.840.1.113883.10.20.23.77)
 - 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.
- 17. MAY** contain zero or one [0..1] **entryRelationship**
- 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)
 - Information on whether adjustments were made to the study treatment as a result of the event.
- 18. MAY** contain zero or one [0..1] **entryRelationship**
- 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)
 - Information on whether action other than adjustment to the study treatment was taken as a result of the event.
- 19. MAY** contain zero or one [0..1] **entryRelationship**
- a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Study Treatment Causality* (templateId: 2.16.840.1.113883.10.20.23.90)
 - Captures the investigator's opinion of the causal relationship between the event and study treatment.
- 20. MAY** contain zero or one [0..1] **entryRelationship**
- 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)
 - Captures the investigator's opinion of the causal relationship between the event and some event other than the study treatment.

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

- a. Contains **@typeCode="COMP"** *COMP*
- b. Contains exactly one [1..1] *Event Pattern* (templateId: 2.16.840.1.113883.10.20.23.36)
 - Records the pattern of an event.

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

- a. Contains **@typeCode="COMP"** *COMP*
- b. Contains exactly one [1..1] *Event Outcome* (templateId: 2.16.840.1.113883.10.20.23.35)
 - Records the outcome of an event.

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

- a. Contains **@typeCode="COMP"** *COMP*
- b. Contains exactly one [1..1] *Concomitant Treatment* (templateId: 2.16.840.1.113883.10.20.25.25)
 - A record of whether a treatment (aside from the study treatment) was provided as a result of the event.

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

- a. Contains **@typeCode="COMP"** *COMP*
- b. Contains exactly one [1..1] *Toxicity* (templateId: 2.16.840.1.113883.10.20.23.98)
 - A record of the toxicity of the event.

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

- a. Contains **@typeCode="REFR"** *REFR*
- b. Contains exactly one [1..1] *Study Day Period* (templateId: 2.16.840.1.113883.10.20.23.82)
 - A reference to the study days corresponding to the time period of the observation.

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

- a. Contains **@typeCode="COMP"** *COMP*
- b. Contains exactly one [1..1] *Category* (templateId: 2.16.840.1.113883.10.20.23.20)
 - The record of a category to be used in organizing information items.

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

- a. Contains **@typeCode="COMP"** *COMP*
- b. Contains exactly one [1..1] *Sub- Category* (templateId: 2.16.840.1.113883.10.20.23.91)
 - The record of a sub-category to be used in organizing information items.

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

- a. Contains **@typeCode="REFR"** *REFR*
- b. Contains exactly one [1..1] *Related Record* (templateId: 2.16.840.1.113883.10.20.23.75)
 - Establishes a relationship between this record and another record.

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

- a. Contains **@typeCode="COMP"** *COMP*
- b. Contains exactly one [1..1] *Supplemental Value* (templateId: 2.16.840.1.113883.10.20.23.96)
 - Allows the association of a supplemental value - outside of the content specified for the domain - to the record.

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

- a. Contains **@typeCode="COMP"** *COMP*
- b. Contains exactly one [1..1] *Comment* (templateId: 2.16.840.1.113883.10.20.23.23)
 - A place to insert comments related to a particular finding.

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

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

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

- Allows recording of additional findings related to the finding.

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

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

b. Contains exactly one [1..1] *Event Duration* (templateId: 2.16.840.1.113883.10.20.23.102)

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

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="1588920547" extension="MDHT"/>
  <code code="1346159022"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <value xsi:type="CD" code="548524319"/>
  <targetSiteCode code="991809943"/>
  <entryRelationship>
    <act classCode="ACT">
      <templateId root="2.16.840.1.113883.10.20.23.42"/>
      <id root="682887289" 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="993949552" extension="MDHT"/>
      <code code="895127332"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <value xsi:type="IVL_INT" value="1"/>
      <targetSiteCode code="500333429"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation/>
  </entryRelationship>
  <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.23"/>
```

```

    <id root="1055017128" 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="973741690"/>
    <participant/>
    <entryRelationship/>
  </observation>
</entryRelationship>
<entryRelationship>
  <observation>
    <templateId root="2.16.840.1.113883.10.20.23.30"/>
    <id root="1761336469" extension="MDHT"/>
    <code code="C66734" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
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    <targetSiteCode code="1301735412"/>
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    <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
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    <statusCode code="completed"/>
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    </effectiveTime>
  </act>
</entryRelationship>
<entryRelationship>
  <observation classCode="OBS" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.23.96"/>
    <id root="2126854109" extension="MDHT"/>
    <code codeSystem="locally defined" codeSystemName="Supplemental Value
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    <statusCode code="completed"/>
    <effectiveTime>
      <low value="2012"/>
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  </observation>
</entryRelationship>
<entryRelationship>
  <act>
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    <code code="1594910846"/>
    <statusCode code="completed"/>
    <effectiveTime>

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      </entryRelationship>
    </act>
  </entryRelationship>
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      <id root="1437511250" extension="MDHT"/>
      <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus" displayName="Reason for non completion"/>
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      </effectiveTime>
      <value xsi:type="BL"/>
      <targetSiteCode code="1022419152"/>
      <entryRelationship typeCode="COMP"/>
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  </entryRelationship>
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    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.89"/>
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codeSystemName="NCI Thesaurus"/>
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    </observation>
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  <entryRelationship>
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codeSystemName="NCI Thesaurus"/>
      <statusCode code="completed"/>
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        <high value="2012"/>
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    </observation>
  </entryRelationship>

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    <targetSiteCode code="1473053299"/>
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    </effectiveTime>
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codeSystemName="NCI Thesaurus" displayName="Adverse Event Pattern"/>
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    <effectiveTime>
      <low value="2012"/>
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    <value xsi:type="CD" code="91190877"/>
    <targetSiteCode code="1738525668"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <observation>
    <templateId root="2.16.840.1.113883.10.20.23.35"/>
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Outcome"/>
    <statusCode code="completed"/>
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</entryRelationship>
<entryRelationship>
  <observation>
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Thesaurus" displayName="Adverse Event Concomitant Treatment"/>
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    <targetSiteCode code="2043740681"/>
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</entryRelationship>

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codeSystemName="NCI Thesaurus"/>
    <statusCode code="completed"/>
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Thesaurus"/>
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</entryRelationship>
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  <observation/>
</entryRelationship>
<entryRelationship>
  <observation>
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    <statusCode code="completed"/>
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    </effectiveTime>
    <targetSiteCode code="1906275570"/>
    <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"/>
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  </observation>
  <entryRelationship>
    <observation classCode="OBS">
      <templateId root="2.16.840.1.113883.10.20.23.56"/>
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Thesaurus" displayName="Reason for non completion"/>
    </observation>
  </entryRelationship>
</entryRelationship>
  <act/>
</entryRelationship>
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```

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Thesaurus"/>
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codeSystemName="NCI Thesaurus"/>
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  </observation>
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    <id root="746557446" extension="MDHT"/>
    <code code="EDtbd" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
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    <effectiveTime>
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    <value xsi:type="PQR" code="121461002"/>
    <targetSiteCode code="706659206"/>
  </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.

1. **SHALL** contain exactly one [1..1] **@classCode="OBS"** *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass)
2. **SHALL** contain exactly one [1..1] **@moodCode="EVN"** *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain [1..2] **id**
 - 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**
 - 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.
5. **MAY** contain zero or one [0..1] **text**
 - The reference property of the ED data type is used to capture the file name and path for an external file. [Study Data Tabulation Model: -XFN]
6. **MAY** contain zero or one [0..1] **statusCode**

- Used to indicate whether or not an exam has been performed. [Study Data Tabulation Model: -STAT]
- 7. SHOULD** contain zero or one [0..1] **value**
- The finding result, using both original units and a standard format or set of units. [Study Data Tabulation Model: -ORRES, ORRESU, STRESC, STRESN, STRESU] 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.
- 8. MAY** contain [0..3] **interpretationCode**
- 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.
- 9. MAY** contain zero or one [0..1] **methodCode**, where the @code **SHALL** be selected from ValueSet [Method C85492](#) **STATIC**
- Indicates the method of the test or examination. [Study Data Tabulation Model: = METHOD]
- 10. MAY** contain zero or more [0..*] **targetSiteCode**, where the @code **SHALL** be selected from ValueSet [Anatomical Location C74456](#) **STATIC**
- 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 target location, target site code - which can repeat - is used.
- 11. SHALL** contain exactly one [1..1] **entryRelationship**
- a. Contains @typeCode="REFR" *REFR*
 - b. Contains exactly one [1..1] [Domain Assignment](#) (templateId: 2.16.840.1.113883.10.20.23.30)
 - Identifies the SDTM or SEND domain the record is assigned to.
- 12. MAY** contain zero or one [0..1] **entryRelationship**
- a. Contains @typeCode="COMP" *COMP*
 - b. Contains exactly one [1..1] [Group Identifier](#) (templateId: 2.16.840.1.113883.10.20.23.42)
 - Indicates an identifier that is used to group associated findings.
- 13. MAY** contain zero or one [0..1] **entryRelationship**
- a. Contains @typeCode="COMP" *COMP*
 - b. Contains exactly one [1..1] [Non Performance Reason](#) (templateId: 2.16.840.1.113883.10.20.23.56)
 - Information on the reason a scheduled activity was not carried out.
- 14. MAY** contain zero or one [0..1] **entryRelationship**
- a. Contains @typeCode="COMP" *COMP*
 - b. Contains exactly one [1..1] [Specimen Information](#) (templateId: 2.16.840.1.113883.10.20.23.78)
- 15. MAY** contain zero or one [0..1] **participant**
- a. Contains exactly one [1..1] [Study Test Organization](#) (templateId: 2.16.840.1.113883.10.20.23.88)
 - Used to identify the organization that performed the test.
- 16. MAY** contain zero or one [0..1] **participant**
- a. Contains exactly one [1..1] [Study Finding Evaluator](#) (templateId: 2.16.840.1.113883.10.20.23.84)
 - Records the role of the person evaluating the finding.
- 17. MAY** contain zero or one [0..1] **entryRelationship**
- a. Contains @typeCode="COMP" *COMP*

- b. Contains exactly one [1..1] *Toxicity* (templateId: 2.16.840.1.113883.10.20.23.98)
 - A record of the toxicity associated with the finding.
- 18. **MAY** contain zero or one [0..1] **entryRelationship**
 - 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**
 - 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)
 - Allows identification of the relevant body system or organ class for the observation.
- 20. **MAY** contain zero or one [0..1] **reference Range**
 - a. Contains exactly one [1..1] *Reference Range* (templateId: 2.16.840.1.113883.10.20.23.74)
 - Information on the reference range defined for a test. It is used to support interpretation of the test result.
- 21. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains @typeCode="COMP" *COMP*
 - b. Contains exactly one [1..1] *Fasting Status* (templateId: 2.16.840.1.113883.10.20.23.39)
 - Used to indicate the fasting status - time since consumption of food - for the study subject.
- 22. **MAY** contain zero or one [0..1] **entryRelationship**
 - 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)
 - Carries information about the severity or intensity associated with the finding.
- 23. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains @typeCode="COMP" *COMP*
 - b. Contains exactly one [1..1] *Death Relationship* (templateId: 2.16.840.1.113883.10.20.23.29)
 - Records the relationship of the finding to the death of the subject.
- 24. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains @typeCode="COMP" *COMP*
 - b. Contains exactly one [1..1] *Assay Quantitation* (templateId: 2.16.840.1.113883.10.20.23.16)
 - Records the lower limit of quantitation for an assay.
- 25. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains @typeCode="COMP" *COMP*
 - b. Contains exactly one [1..1] *Category* (templateId: 2.16.840.1.113883.10.20.23.20)
 - The record of a category to be used in organizing information items.
- 26. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains @typeCode="COMP" *COMP*
 - b. Contains exactly one [1..1] *Sub- Category* (templateId: 2.16.840.1.113883.10.20.23.91)
 - The record of a sub-category to be used in organizing information items.
- 27. **MAY** contain zero or more [0..*] **entryRelationship**
 - a. Contains @typeCode="REFR" *REFR*
 - b. Contains exactly one [1..1] *Related Record* (templateId: 2.16.840.1.113883.10.20.23.75)
 - Establishes a relationship between this record and another record.
- 28. **MAY** contain zero or more [0..*] **entryRelationship**
 - a. Contains @typeCode="COMP" *COMP*

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

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

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

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

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

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

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

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

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

- Allows recording of additional findings related to the finding.

Study Subject Finding example

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<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="2.16.840.1.113883.10.20.23.86"/>
  <id root="1490674225" extension="MDHT"/>
  <code code="688661998"/>
  <text>Text Value</text>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <interpretationCode code="1891654073"/>
  <methodCode codeSystemName="NCI Thesaurus"/>
  <targetSiteCode codeSystem="2.16.840.1.113883.3.26.1.1"/>
  <participant>
    <participantRole classCode="ASSIGNED">
      <templateId root="null"/>
    </participantRole>
  </participant>
  <participant>
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      <templateId root="null"/>
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Thesaurus"/>
    </participantRole>
  </participant>
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      <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>
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        <high value="2012"/>
      </effectiveTime>
      <value xsi:type="CD" code="2029511583"/>
      <interpretationCode code="493900009"/>
      <methodCode code="1005458572"/>
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  </entryRelationship>
```

```

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codeSystemName="NCI Thesaurus"/>
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    <text>Text Value</text>
    <statusCode code="completed"/>
    <effectiveTime>
      <low value="2012"/>
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    </effectiveTime>
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    <targetSiteCode code="1065515298"/>
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      <templateId root="null"/>
    </specimen>
    <entryRelationship typeCode="COMP"/>
    <entryRelationship typeCode="COMP"/>
    <entryRelationship typeCode="COMP"/>
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  </entryRelationship>
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  </act>
</entryRelationship>
</procedure>
</entryRelationship>
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codeSystemName="NCI Thesaurus"/>
    <text>Text Value</text>
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    <effectiveTime>
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    </effectiveTime>
    <value xsi:type="ED">Text Value</value>
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    <methodCode code="1096335050"/>
    <targetSiteCode code="1290284532"/>
    <participant/>
  </entryRelationship>
</observation>
</entryRelationship>
</entryRelationship>

```

```

    <observation>
      <templateId root="2.16.840.1.113883.10.20.23.30"/>
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codeSystemName="NCI Thesaurus"/>
      <text>Text Value</text>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <value xsi:type="CD" code="406442751"/>
      <interpretationCode code="281804153"/>
      <methodCode code="2044771909"/>
      <targetSiteCode code="922121827"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <act classCode="ACT">
      <templateId root="2.16.840.1.113883.10.20.23.75"/>
      <id root="331680623" 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"/>
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    </act>
  </entryRelationship>
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    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.23.96"/>
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Type"/>
      <text>Text Value</text>
      <statusCode code="completed"/>
      <effectiveTime>
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      </effectiveTime>
      <interpretationCode code="757235468"/>
      <methodCode code="548914881"/>
      <targetSiteCode code="960775388"/>
      <participant/>
      <entryRelationship typeCode="COMP"/>
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codeSystemName="NCI Thesaurus"/>
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      <interpretationCode code="80173387"/>

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        <methodCode code="350853596"/>
        <targetSiteCode code="737230489"/>
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        <targetSiteCode code="1599961329"/>
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codeSystemName="NCI Thesaurus"/>
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        </effectiveTime>
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        <interpretationCode code="754522578"/>
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        <targetSiteCode code="174507172"/>
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codeSystemName="NCI Thesaurus"/>
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        <value xsi:type="CD" code="1747312731"/>
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        <methodCode code="1145511772"/>
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        <statusCode code="completed"/>
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            <high value="2012"/>
        </effectiveTime>
        <value xsi:type="IVL_PQ"/>
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        <methodCode code="2059527328"/>
        <targetSiteCode code="2025767234"/>
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        <targetSiteCode code="202925859"/>
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        <entryRelationship typeCode="REFR"/>
        <entryRelationship>
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                <code code="C83204" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
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        </entryRelationship>
    </entryRelationship>
    <observation classCode="OBS">
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</entryRelationship>
<entryRelationship>
    <act/>
</entryRelationship>
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    <observation/>
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```

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      <observation>
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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)
2. **SHALL** contain exactly one [1..1] **@moodCode**= "EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain [1..2] **id**
 - A sponsor supplied reference number for the treatment. A sequence number is required.
4. **MAY** contain zero or one [0..1] **text**
 - A text description of the intervention or dosing. [Study Data Tabulation Model: -DOSTXT]
5. **MAY** contain zero or one [0..1] **statusCode**
 - Used to indicate whether the activity - use of a particular medication or treatment - did occur. Use statusCode "Completed" if the use occurred. [Study Data Tabulation Model: -OCCUR]
6. **MAY** contain zero or one [0..1] **effectiveTime**
 - Information on when and how often 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 frequency. 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 effective time attribute is used to capture information regarding the start, stop, duration and frequency of use for the concomitant medication. There shall be Two SXPR components created. The first will be an interval of time stamps (IVL_TS) to address 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 Tabulation Model: -DOSFRQ,]
7. **MAY** contain zero or one [0..1] **routeCode**, where the @code **SHALL** be selected from ValueSet [Route of Administration](#) C66729 **STATIC**
 - The route by which the treatment is administered. [Study Data Tabulation Model: -ROUTE]
8. **MAY** contain zero or one [0..1] **approachSiteCode** with data type CE, where the @code **SHALL** be selected from ValueSet [Anatomical Location](#) C74456 **STATIC**

- An indication of the location, e.g. left arm, where the substance was administered. [Study Data Tabulation Model: -LOC]
- 9. SHOULD** contain zero or one [0..1] **doseQuantity**
- The amount of a treatment taken at a single administration. The physical quantity data type is used. Dose units go into the units property of the datatype. [Study Data Tabulation Model: -DOSE, DOSU]
- 10. MAY** contain zero or one [0..1] **maxDoseQuantity**
- Information on the total daily dose of the medication or treatment. The structure also accommodates periods other than a day. Therefore 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 Tabulation Model: -DOSTOT]
- 11.** Contains exactly one [1..1] **consumable**, where its type is *Consumable*
- 12. SHALL** contain exactly one [1..1] **entryRelationship**
- a. Contains **@typeCode="REFR"** *REFR*
 - b. Contains exactly one [1..1] *Domain Assignment* (templateId: 2.16.840.1.113883.10.20.23.30)
 - Identifies the SDTM or SEND domain the record is assigned to.
- 13. MAY** contain zero or one [0..1] **entryRelationship**
- a. Contains **@typeCode="REFR"** *REFR*
 - b. Contains exactly one [1..1] *Study Epoch* (templateId: 2.16.840.1.113883.10.20.23.83)
- 14. MAY** contain zero or one [0..1] **entryRelationship**
- a. This entryRelationship **SHALL** contain exactly one [1..1] **@typeCode="COMP"**
 - b. This entryRelationship **SHALL** contain exactly one [1..1] **observation**
 - a. This observation **SHALL** contain exactly one [1..1] **@classCode="OBS"** *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass)
 - b. This observation **SHALL** contain exactly one [1..1] **@moodCode="EVN"** *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
 - c. This observation **SHALL** contain exactly one [1..1] **code/@code="ELOtbd"** (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)
 - The code value indicates the observation captures an element's order within a trial arm.*
 - d. This observation **SHALL** contain zero or more [0..*] **value** with data type INT
 - A value that gives the order of an element within the trial arm. [SDTM: TAETORD]*
- 15. MAY** contain zero or one [0..1] **entryRelationship**
- a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Group Identifier* (templateId: 2.16.840.1.113883.10.20.23.42)
 - Indicates an identifier that is used to group associated interventions.
- 16. MAY** contain zero or one [0..1] **entryRelationship**
- a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Data Collection* (templateId: 2.16.840.1.113883.10.20.23.27)
 - Information on whether a predefined data item was collected, and the timing of collection.
- 17. MAY** contain zero or one [0..1] **entryRelationship**
- a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Non Performance Reason* (templateId: 2.16.840.1.113883.10.20.23.56)
 - Information on the reason a scheduled activity was not carried out.
- 18. MAY** contain zero or one [0..1] **entryRelationship**
- a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Pre-Specified Event* (templateId: 2.16.840.1.113883.10.20.23.70)

- Indicates whether or not the event was prespecified on the CRF.
- 19. SHOULD** contain zero or one [0..1] **consumable**
- Identifies and carries information for the consumable item that is being referred to.
- 20. MAY** contain zero or one [0..1] **entryRelationship**
- 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**
- 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**
- 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**
- a. Contains **@typeCode="REFR"** *REFR*
 - b. Contains exactly one [1..1] *Timing Reference* (templateId: 2.16.840.1.113883.10.20.23.97)
- Creates an association between the timing of an activity and a defined reference time point.
- 24. MAY** contain zero or one [0..1] **entryRelationship**
- a. Contains **@typeCode="REFR"** *REFR*
 - b. Contains exactly one [1..1] *Study Day Period* (templateId: 2.16.840.1.113883.10.20.23.82)
- A reference to the study days corresponding to the time period of the observation.
- 25. MAY** contain zero or one [0..1] **entryRelationship**
- a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Category* (templateId: 2.16.840.1.113883.10.20.23.20)
- The record of a category to be used in organizing information items.
- 26. MAY** contain zero or one [0..1] **entryRelationship**
- a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Sub- Category* (templateId: 2.16.840.1.113883.10.20.23.91)
- The record of a sub-category to be used in organizing information items.
- 27. MAY** contain zero or more [0..*] **entryRelationship**
- a. Contains **@typeCode="REFR"** *REFR*
 - b. Contains exactly one [1..1] *Related Record* (templateId: 2.16.840.1.113883.10.20.23.75)
- Establishes a relationship between this record and another record.
- 28. MAY** contain zero or more [0..*] **entryRelationship**
- a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Supplemental Value* (templateId: 2.16.840.1.113883.10.20.23.96)
- Allows the association of a supplemental value - outside of the content specified for the domain - to the record.
- 29. MAY** contain zero or more [0..*] **entryRelationship**
- a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Comment* (templateId: 2.16.840.1.113883.10.20.23.23)
- A place to insert comments related to a particular finding.
- 30. MAY** contain zero or more [0..*] **entryRelationship**
- a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Finding About* (templateId: 2.16.840.1.113883.10.20.23.40)

- Allows recording of additional findings related to the intervention.

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

- Contains **@typeCode="COMP"** *COMP*
 - Contains exactly one [1..1] *Event Duration* (templateId: 2.16.840.1.113883.10.20.23.102)
- Records the duration of an intervention in cases in which this cannot be derived from existing start and stop information.

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="1649391315" extension="MDHT"/>
  <text>Text Value</text>
  <statusCode code="completed"/>
  <effectiveTime value="20120907"/>
  <routeCode code="970867267"/>
  <approachSiteCode xsi:type="CE" code="777739112"/>
  <doseQuantity/>
  <maxDoseQuantity/>
  <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">
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      <id root="35868679" 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="1933493095" extension="MDHT"/>
      <code codeSystem="locally defined" codeSystemName="Study Epoch Type"/>
      <text>Text Value</text>
      <statusCode code="completed"/>
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    <act>
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      <code codeSystem="2.16.840.1.113883.3.26.1.1"/>
      <text>Text Value</text>
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```

        <statusCode code="completed"/>
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        </effectiveTime>
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    <observation/>
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        </entryRelationship>
    </act>
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        <templateId root="2.16.840.1.113883.10.20.23.56"/>
        <id root="1012159274" 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>
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        </effectiveTime>
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    <observation classCode="OBS" moodCode="EVN">
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codeSystemName="NCI Thesaurus"/>
        <text>Text Value</text>
        <statusCode code="completed"/>
        <effectiveTime>
            <low value="2012"/>
            <high value="2012"/>
        </effectiveTime>
    </observation>
</entryRelationship>

```

```

    <participant/>
    <entryRelationship/>
  </observation>
</entryRelationship>
<entryRelationship>
  <observation>
    <templateId root="2.16.840.1.113883.10.20.23.30"/>
    <id root="186571563" extension="MDHT"/>
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codeSystemName="NCI Thesaurus"/>
    <text>Text Value</text>
    <statusCode code="completed"/>
    <effectiveTime>
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      <high value="2012"/>
    </effectiveTime>
  </observation>
</entryRelationship>
<entryRelationship>
  <act classCode="ACT">
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    <id root="1397550450" 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="1989093407" extension="MDHT"/>
    <code codeSystem="locally defined" codeSystemName="Supplemental Value
Type"/>
    <text>Text Value</text>
    <statusCode code="completed"/>
    <effectiveTime>
      <low value="2012"/>
      <high value="2012"/>
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    <participant/>
    <entryRelationship typeCode="COMP"/>
  </observation>
</entryRelationship>
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  <observation classCode="OBS" moodCode="EVN">
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    <id root="669027257" 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>
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      <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus"/>
      <text>Text Value</text>
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    </observation>
  </entryRelationship>
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      <code code="412982733"/>
      <text>Text Value</text>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
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  </entryRelationship>
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    <observation classCode="OBS" moodCode="EVN">
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      <id root="805999773" extension="MDHT"/>
      <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus"/>
      <text>Text Value</text>
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  </entryRelationship>
  <entryRelationship>
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      <code code="1684271324"/>
      <text>Text Value</text>
      <statusCode code="completed"/>
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        <low value="2012"/>
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    </observation>
  </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="125860860" 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)
2. **SHALL** contain exactly one [1..1] **@moodCode="EVN"** *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **code/@code="C66767"** (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)
 - 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, where the **@code** **SHALL** be selected from ValueSet *Action Taken with Study Treatment* C66767 **STATIC**

- 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="204578668" 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="870136055"/>
</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.

- SHALL** contain exactly one [1..1] **@classCode="OBS"** *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass)
- SHALL** contain exactly one [1..1] **@moodCode="EVN"** *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
- SHALL** contain exactly one [1..1] **code/@code="STCtbd"** (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)
 - A value to indicate that the observation provides the investigator's opinion regarding the causality of the event to the treatment.
- SHALL** contain exactly one [1..1] **value** with data type CD, where the **@code** **SHALL** be selected from ValueSet *Study Treatment Causality* CXXXXX **STATIC**
 - 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="1485092930" 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="2039018672"/>
</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**
2. **SHALL** contain exactly one [1..1] **@moodCode**
3. **SHALL** contain exactly one [1..1] **code**, where the **@code** **SHALL** be selected from ValueSet [Subject Data Domain SubCategory Type](#) CXXXXX **STATIC**
 - 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
 - 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="373903422" 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="1816421971"/>
</observation>
```

Subject Characteristic

[Observation: templateId 2.16.840.1.113883.10.20.23.92]

The template is used 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)
2. **SHALL** contain exactly one [1..1] **@moodCode="EVN"** *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain [1..2] **id**
 - 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**, where the **@code** **SHALL** be selected from ValueSet [Subject Characteristic Type](#) C74559 **STATIC**
 - A coded value that identifies the subject characteristic. 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**

- Used to indicate whether or not the specified study characteristic response was elicited. [SDTM: SCSTAT]

6. SHOULD contain zero or one [0..1] **value**

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

7. SHALL contain exactly one [1..1] **entryRelationship**

- Contains **@typeCode="REFR"** *REFR*
 - Contains exactly one [1..1] *Domain Assignment* (templateId: 2.16.840.1.113883.10.20.23.30)
- Identifies the SDTM or SEND domain the record is assigned to.

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

- Contains **@typeCode="COMP"** *COMP*
 - Contains exactly one [1..1] *Group Identifier* (templateId: 2.16.840.1.113883.10.20.23.42)
- Allows capture of a group identifier for the subject characteristics.

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

- Contains **@typeCode="REFR"** *REFR*
 - Contains exactly one [1..1] *Data Collection* (templateId: 2.16.840.1.113883.10.20.23.27)
- 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.

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

- Contains **@typeCode="COMP"** *COMP*
 - Contains exactly one [1..1] *Non Performance Reason* (templateId: 2.16.840.1.113883.10.20.23.56)
- Provides a reason for not capturing information for the subject characteristic.

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

- Contains **@typeCode="COMP"** *COMP*
 - Contains exactly one [1..1] *Category* (templateId: 2.16.840.1.113883.10.20.23.20)
- The record of a category to be used in organizing information items.

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

- Contains **@typeCode="COMP"** *COMP*
 - Contains exactly one [1..1] *Sub- Category* (templateId: 2.16.840.1.113883.10.20.23.91)
- The record of a sub-category to be used in organizing information items.

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

- Contains **@typeCode="REFR"** *REFR*
 - Contains exactly one [1..1] *Related Record* (templateId: 2.16.840.1.113883.10.20.23.75)
- Establishes a relationship between this record and another record.

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

- Contains **@typeCode="REFR"** *REFR*
 - Contains exactly one [1..1] *Supplemental Value* (templateId: 2.16.840.1.113883.10.20.23.96)
- Allows the association of a supplemental value - outside of the content specified for the domain - to the record.

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

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

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

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

- Contains **@typeCode="COMP"** *COMP*
 - Contains exactly one [1..1] *Finding About* (templateId: 2.16.840.1.113883.10.20.23.40)
- Allows recording of additional findings related to the subject characteristic.

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="1480602253" 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="583590505" extension="MDHT"/>
      <code code="829097025"/>
      <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="117461222" 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="699919817"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <act classCode="ACT">
      <templateId root="2.16.840.1.113883.10.20.23.42"/>
      <id root="1039125892" 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="1838692174" 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="1370506160" 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="1507164087"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <act classCode="ACT">
    <templateId root="2.16.840.1.113883.10.20.23.75"/>
    <id root="64632986" 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="828544624" 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="1113225120" 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="772276755"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <observation/>
</entryRelationship>
<entryRelationship>
  <observation>
    <id root="963835719" extension="MDHT"/>
    <code code="238240259"/>
    <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)
2. **SHALL** contain exactly one [1..1] **@moodCode="EVN"** *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **id**
 - The identifier is assigned to ensure uniqueness of the subject records within the domain. [SDTM: SESEQ]
4. **SHALL** contain exactly one [1..1] **code**, where the **@code** **SHALL** be selected from (CodeSystem: locally defined Subject Element Type)
 - The code value indicates the nature of the element. If the element is unplanned, the code value should indicate this. Use original text to provide the verbatim content of the element - whether planned or unplanned. [SDTM: ETCDD, ELEMENT, SEUPDES], [SEND: ETCDD, ELEMENT, SEUPDES]
5. **SHALL** contain exactly one [1..1] **effectiveTime**
 - Information that records the start and stop dates of the element. A value for the start date - interval lower bound is required. [SDTM: SESDTC, SEENDTC], [SEND: SESDTC, SEENDTC]
6. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode="REFR"** *REFR*
 - b. Contains exactly one [1..1] *Study Epoch* (templateId: 2.16.840.1.113883.10.20.23.83)
 - Records the study epoch during which the information was collected.
7. **MAY** contain zero or one [0..1] **entryRelationship**

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

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

A value that gives the order of an element within the trial arm. Since this order could be hierarchically 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**
 - a. Contains **@typeCode="REFR"** *REFR*
 - b. Contains exactly one [1..1] *Domain Assignment* (templateId: 2.16.840.1.113883.10.20.23.30)
 - Identifies the SDTM or SEND domain the record is assigned to.
9. **MAY** contain zero or more [0..*] **entryRelationship**
 - a. Contains **@typeCode="REFR"** *REFR*

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

- Establishes a relationship between this record and another record.

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

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

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

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

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

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

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

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

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

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

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

- Allows recording of additional findings related to the element.

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="1202760205" 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="1298111729" 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="236023898" 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>
</act>
```

```

</entryRelationship>
<entryRelationship>
  <observation>
    <templateId root="2.16.840.1.113883.10.20.23.30"/>
    <id root="1660091660" 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="926095507" 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="749919324" 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="1641276517" extension="MDHT"/>
    <code code="1978831402"/>
    <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>

```

Subject Pool

[Act: templateId 2.16.840.1.113883.10.20.23.94]

The template supports the definition of a pool (group) that is created in order to allow findings that refer to a group of subjects rather than to a single one. When a pool is defined, it may be the subject of the report.

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)
3. **SHALL** contain exactly one [1..1] **id**
 - The identifier for the pool. It is the linking value that is used as a common identifier for all members of the pool. [SEND: POOLID]
4. **SHALL** contain exactly one [1..1] **code/@code="SPTbd"** (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)
 - A code to indicate the act of joining a group of subjects into a pool for the purpose of structuring reporting from the trial.
5. **SHALL** contain zero or more [0..*] **participant**

The association establishes the link between the pool and its members.

- a. Such participants **SHALL** contain exactly one [1..1] **@typeCode="RCT"**
- b. Such participants **SHALL** contain exactly one [1..1] **participantRole**

The association provides identifying information for the individual pool member.

- a. This participantRole **SHALL** contain exactly one [1..1] **@classCode="IDENT"**
- b. This participantRole **SHALL** contain exactly one [1..1] **id**

An identifier assigned to a pool member. The identifier value must be usable within the context of the study so that data collected for the pool can be merged with that collected for the study subject. [SEND: USUBJID]

The association provides identifying information for the individual pool member.

Subject Pool 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="2.16.840.1.113883.10.20.23.94"/>
  <id root="265415181" extension="MDHT"/>
  <code code="SPTbd" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <participant typeCode="RCT">
    <participantRole classCode="IDENT"/>
  </participant>
</act>

```

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 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)
2. **SHALL** contain exactly one [1..1] **@moodCode="EVN"** *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **code**, where the **@code** **SHALL** be selected from (CodeSystem: locally defined Supplemental Value Type)
 - A code that indicates the type of information being provided. [SDTM: QNAM, QLABEL], [SEND: QNAM, QLABEL]
4. **SHALL** contain exactly one [1..1] **value**
 - 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**

Information on the source of the supplemental information.

 - a. This entryRelationship **SHALL** contain exactly one [1..1] **@typeCode="COMP"**
 - b. This entryRelationship **SHALL** contain zero or one [0..1] **observation**
 - a. This observation **SHALL** contain exactly one [1..1] **@classCode="OBS"** *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass)
 - b. This observation **SHALL** contain exactly one [1..1] **@moodCode="EVN"** *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
 - c. This observation **SHALL** contain exactly one [1..1] **code/@code="DOTbd"** (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)

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, where the **@code** **SHALL** be selected from ValueSet *Data Origin Type* CXXXXXX **STATIC**

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**

- a. Contains exactly one [1..1] *Study Finding Evaluator* (templateId: 2.16.840.1.113883.10.20.23.84)
 - Identification of the party responsible for (author of) the supplemental information.

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="542801336" 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)
2. **SHALL** contain exactly one [1..1] **@moodCode="EVN"** *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **MAY** contain zero or one [0..1] **id**
 - 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/@code="TRtbd"** (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)
 - A fixed code value to indicate the observation contains timing reference information.
5. **MAY** contain zero or one [0..1] **text**
 - 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: EXPTPT, LBTPT, PCTPT, VSTPT, EGTPT], [Study Data Tabulation Model: -TPT]
6. **MAY** contain zero or one [0..1] **effectiveTime**

- The planned elapsed time - a duration - at which the event or measurement is to take place with reference to the anchoring time point. The width property of the IVL_TS data type is used. [SDTM: LBELTM, VSELTM], [SEND: EXELTM, BGELM, CLELTM, VSELTM, EGELTM]

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

Indicates the reference point associated with a timing offset.

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

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

- This act **SHALL** contain exactly one [1..1] **@classCode= "ACT"** *Act* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass)
- This act **SHALL** contain exactly one [1..1] **@moodCode**
- This act **SHALL** contain exactly one [1..1] **code/@code= "ATPtbd"** (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)

A code that indicates the nature of the fixed reference point that is referred to by the timing reference. If a suitable value set has not been defined, the original text property of the coded type is used. [SDTM: LBPTREF, VSTPTREF]. [SEND: EXPTREF, BGPTREF, CLPTREF, LBPTREF, VSTPTREF, EGPTREF]

- This act **MAY** contain zero or one [0..1] **effectiveTime**

The date time of the anchor time point. [SDTM: LBRFTDTC, VSRFTDTC], [SEND: EXRFTDTC, 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 timing is indicated as an offset from the time point reference.

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="1799425635" 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.

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

2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **code/@code**="TOTbd" (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)
 - The code value indicates that toxicity information is being provided.
4. **SHALL** contain exactly one [1..1] **value** with data type CD, where the **@code** **SHALL** be selected from ValueSet *Toxicity Measure Type* CXXXXX **STATIC**
 - 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="927721815" 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="50157404"/>
</observation>
```

Tumor Finding

[Observation: templateId 2.16.840.1.113883.10.20.23.99]

The template is used to represent findings for tumors related to the study subject.

1. Contains exactly one [1..1] **@classCode**="OBS" *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass)
2. Contains exactly one [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **id**
 - A value that is provided to ensure the uniqueness of the subject characteristic item. [SEND: TFSEQ]
4. **SHALL** contain exactly one [1..1] **code**, where the **@code** **SHALL** be selected from (CodeSystem: locally defined Tumor Examination Type)
 - A value to indicate the particular tumor finding observation. [SEND: TFTESTCD, TFTEST]
5. **MAY** contain zero or one [0..1] **statusCode**
 - Used to indicate whether or not a measurement has been performed. [SEND: TFSTAT]
6. **SHOULD** contain zero or one [0..1] **value** with data type CD
 - The recorded organ measurement finding. [SEND: TFORRES, TFSTRESC]
7. **MAY** contain zero or one [0..1] **methodCode**, where the **@code** **SHALL** be selected from ValueSet *Method* C85492 **STATIC**
 - Indicates the method of the test or examination. [SEND: TFMETHOD]
8. **SHALL** contain zero or one [0..1] **entryRelationship**
 - a. Contains **@typeCode**="REFR" *REFR*
 - b. Contains exactly one [1..1] *Domain Assignment* (templateId: 2.16.840.1.113883.10.20.23.30)

- Identifies the SEND domain the record is assigned to.
- 9. MAY** contain zero or one [0..1] **entryRelationship**
- a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Group Identifier* (templateId: 2.16.840.1.113883.10.20.23.42)
- Indicates an identifier that is used to group associated findings.
- 10. MAY** contain zero or one [0..1] **entryRelationship**
- a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Non Performance Reason* (templateId: 2.16.840.1.113883.10.20.23.56)
- Information on the reason a scheduled activity was not carried out.
- 11. MAY** contain zero or one [0..1] **entryRelationship**
- a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Specimen Information* (templateId: 2.16.840.1.113883.10.20.23.78)
- 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.
- 12. SHOULD** contain zero or one [0..1] **participant**
- a. Contains exactly one [1..1] *Mass Identification* (templateId: 2.16.840.1.113883.10.20.23.51)
- Records the identifier of a body mass associated with the observation.
- 13. MAY** contain zero or one [0..1] **participant**
- a. Contains exactly one [1..1] *Study Test Organization* (templateId: 2.16.840.1.113883.10.20.23.88)
- Used to identify the organization that performed the test.
- 14. SHALL** contain exactly one [1..1] **entryRelationship**
- A record of the number of days from the start of dosing until the detection of the tumor.*
- a. This entryRelationship **SHALL** contain exactly one [1..1] **@typeCode="COMP"**
 - b. This entryRelationship Contains zero or one [0..1] **observation** with data type *detection Delay*
- 15. SHALL** contain zero or one [0..1] **entryRelationship**
- a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Death Relationship* (templateId: 2.16.840.1.113883.10.20.23.29)
- Records the relationship of the finding to the death of the subject.
- 16. SHALL** contain zero or one [0..1] **entryRelationship**
- a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Result Category* (templateId: 2.16.840.1.113883.10.20.23.76)
- For Tumor Findings, the result category is used to record the malignancy status of the tumor.
- 17. MAY** contain zero or one [0..1] **entryRelationship**
- a. Contains **@typeCode="REFR"** *REFR*
 - b. Contains exactly one [1..1] *Related Record* (templateId: 2.16.840.1.113883.10.20.23.75)
- Establishes a relationship between this record and another record.
- 18. MAY** contain zero or one [0..1] **entryRelationship**
- a. Contains **@typeCode="COMP"** *COMP*
 - b. Contains exactly one [1..1] *Supplemental Value* (templateId: 2.16.840.1.113883.10.20.23.96)
- Allows the association of a supplemental value - outside of the content specified for the domain - to the record.
- 19. MAY** contain zero or one [0..1] **entryRelationship**
- a. Contains **@typeCode="COMP"** *COMP*

- b. Contains exactly one [1..1] *Comment* (templateId: 2.16.840.1.113883.10.20.23.23)
- A place to insert comments related to a particular finding.

Tumor 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="2.16.840.1.113883.10.20.23.99"/>
  <id root="455838869" extension="MDHT"/>
  <code codeSystem="locally defined"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <value xsi:type="CD" code="514819609"/>
  <methodCode codeSystemName="NCI Thesaurus"/>
  <participant>
    <participantRole classCode="ROL"/>
  </participant>
  <participant>
    <participantRole classCode="ASSIGNED">
      <templateId root="null"/>
    </participantRole>
  </participant>
  <entryRelationship typeCode="COMP"/>
  <entryRelationship>
    <act classCode="ACT">
      <templateId root="2.16.840.1.113883.10.20.23.42"/>
      <id root="1493558073" 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="1290402701" extension="MDHT"/>
      <code code="1272802087"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <methodCode code="1207658685"/>
      <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>
</observation>
```

```

    </act>
  </entryRelationship>
</procedure>
</entryRelationship>
<entryRelationship>
  <observation classCode="OBS">
    <templateId root="2.16.840.1.113883.10.20.23.56"/>
    <id root="1912702710" 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="502237713"/>
    <methodCode code="2087644536"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <observation classCode="OBS" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.23.23"/>
    <id root="100577680" 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="1874659670"/>
    <participant/>
    <entryRelationship/>
  </observation>
</entryRelationship>
<entryRelationship>
  <observation>
    <templateId root="2.16.840.1.113883.10.20.23.30"/>
    <id root="1621899742" 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="710383408"/>
    <methodCode code="1610851910"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <act classCode="ACT">
    <templateId root="2.16.840.1.113883.10.20.23.75"/>
    <id root="992345274" 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="1005344589" extension="MDHT"/>
    <code codeSystem="locally defined" codeSystemName="Supplemental Value
Type"/>
    <statusCode code="completed"/>
    <effectiveTime>
      <low value="2012"/>
      <high value="2012"/>
    </effectiveTime>
    <methodCode code="2127916844"/>
    <participant/>
    <entryRelationship typeCode="COMP"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <observation>
    <templateId root="2.16.840.1.113883.10.20.23.76"/>
    <id root="113469764" 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="522699612"/>
    <methodCode code="1288972999"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <observation classCode="OBS" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.23.29"/>
    <id root="896206606" extension="MDHT"/>
    <code code="C95087" 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="1490228563"/>
    <methodCode code="157401173"/>
  </observation>
</entryRelationship>
</observation>

```

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)
2. **SHALL** contain exactly one [1..1] **@moodCode="EVN"** *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **id**
 - 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 Type](#) C66741 **STATIC**
 - 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**
 - 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**
 - 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 zero or more [0..*] **value**
 - The result of the observation. Note, if the observation was not performed, the value will not be present. Observation values may be provided as text, as coded data, or as physical quantities. 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**, where the @code **SHALL** be selected from ValueSet [Subject Data Interpretation Type](#) CXXXXX **STATIC**
 - 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**, where the @code **SHALL** be selected from ValueSet [Anatomical Location](#) C74456 **STATIC**
 - The body location relevant to the vital sign measurement. [SDTM: VSLOC], [SEND: VSLOC]
10. **SHALL** contain exactly one [1..1] **entryRelationship**
 - a. Contains @typeCode="REFR" *REFR*
 - b. Contains exactly one [1..1] [Domain Assignment](#) (templateId: 2.16.840.1.113883.10.20.23.30)
 - Identifies the SDTM or SEND domain the record is assigned to.
11. **SHOULD** contain zero or one [0..1] **entryRelationship**
 - a. Contains @typeCode="COMP" *COMP*
 - b. Contains exactly one [1..1] [Group Identifier](#) (templateId: 2.16.840.1.113883.10.20.23.42)
 - Indicates an identifier that is used to group associated findings.
12. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains @typeCode="COMP" *COMP*
 - b. Contains exactly one [1..1] [Non Performance Reason](#) (templateId: 2.16.840.1.113883.10.20.23.56)
 - Provides a reason for not capturing information for the vital sign.
13. **MAY** contain zero or one [0..1] **entryRelationship**
 - a. Contains @typeCode="COMP" *COMP*
 - b. Contains exactly one [1..1] [Exclusion Reason](#) (templateId: 2.16.840.1.113883.10.20.23.38)
 - Information on the reason that a data item is to be excluded from tabulation.
14. **MAY** contain zero or one [0..1] **entryRelationship**
 - 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**

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**
- b. This entryRelationship **SHALL** contain exactly one [1..1] **@moodCode**
- c. This entryRelationship **SHALL** contain exactly one [1..1] **code/@code="CStbd"** (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)

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, where the **@code** **SHALL** be selected from ValueSet *Consciousness State* CXXXXX **STATIC**

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**

- a. Contains **@typeCode="REFR"** *REFR*
- b. Contains exactly one [1..1] *Event Study Day* (templateId: 2.16.840.1.113883.10.20.23.37)
 - Used to record the study day associated with an activity taking place during a single day.

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

- a. Contains **@typeCode="REFR"** *REFR*
- b. Contains exactly one [1..1] *Timing Reference* (templateId: 2.16.840.1.113883.10.20.23.97)
 - Orients the collection of the vital sign information with respect to a study defined timepoint.

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

- a. Contains **@typeCode="REFR"** *REFR*
- b. Contains exactly one [1..1] *Planned Study Day* (templateId: 2.16.840.1.113883.10.20.23.68)
 - A record of the study day on which the vital statistics observation was planned for.

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

- a. Contains **@typeCode="REFR"** *REFR*
- b. Contains exactly one [1..1] *Study Day Period* (templateId: 2.16.840.1.113883.10.20.23.82)
 - A record of the study date/time on which an activity took place. If relevant, both starting and stopping time points can be recorded.

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

- a. Contains **@typeCode="COMP"** *COMP*
- b. Contains exactly one [1..1] *Category* (templateId: 2.16.840.1.113883.10.20.23.20)
 - The record of a category to be used in organizing information items.

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

- a. Contains **@typeCode="COMP"** *COMP*
- b. Contains exactly one [1..1] *Sub- Category* (templateId: 2.16.840.1.113883.10.20.23.91)
 - The record of a sub-category to be used in organizing information items.

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

- a. Contains **@typeCode="REFR"** *REFR*
- b. Contains exactly one [1..1] *Related Record* (templateId: 2.16.840.1.113883.10.20.23.75)
 - Establishes a relationship between this record and another record.

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

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

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

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

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

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

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

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

- Allows recording of additional findings related to the finding.

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="1104374360" extension="MDHT"/>
  <code codeSystem="2.16.840.1.113883.3.26.1.1"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2012"/>
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  </effectiveTime>
  <interpretationCode codeSystemName="NCI Thesaurus"/>
  <targetSiteCode code="1831526604"/>
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    <observation>
      <id root="970806999" extension="MDHT"/>
      <code code="2029122212"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <value xsi:type="INT" value="1"/>
      <interpretationCode code="365031355"/>
      <targetSiteCode code="2146427576"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <act>
      <templateId root="2.16.840.1.113883.10.20.23.97"/>
      <id root="1567072483" extension="MDHT"/>
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      <statusCode code="completed"/>
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      </effectiveTime>
      <entryRelationship typeCode="COMP"/>
    </act>
  </entryRelationship>
  <entryRelationship>
    <observation classCode="OBS">
      <templateId root="2.16.840.1.113883.10.20.23.56"/>
      <id root="1585158624" extension="MDHT"/>
      <code codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus" displayName="Reason for non completion"/>
      <statusCode code="completed"/>
    </observation>
  </entryRelationship>
</observation>
```

```

    <effectiveTime>
      <low value="2012"/>
      <high value="2012"/>
    </effectiveTime>
    <value xsi:type="CD" code="1530661"/>
    <interpretationCode code="1690615443"/>
    <targetSiteCode code="769282979"/>
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<entryRelationship>
  <observation/>
</entryRelationship>
<entryRelationship>
  <observation>
    <id root="701478451" extension="MDHT"/>
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    <statusCode code="completed"/>
    <effectiveTime>
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      <high value="2012"/>
    </effectiveTime>
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    <interpretationCode code="300575701"/>
    <targetSiteCode code="1971891978"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <observation>
    <id root="607642945" extension="MDHT"/>
    <code code="1677824148"/>
    <statusCode code="completed"/>
    <effectiveTime>
      <low value="2012"/>
      <high value="2012"/>
    </effectiveTime>
    <value xsi:type="IVL_INT" value="1"/>
    <interpretationCode code="1007643015"/>
    <targetSiteCode code="1512157947"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <observation classCode="OBS">
    <templateId root="2.16.840.1.113883.10.20.23.38"/>
    <id root="786906814" 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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      <high value="2012"/>
    </effectiveTime>
    <value xsi:type="CD" code="1912322908"/>
    <interpretationCode code="338586053"/>
    <targetSiteCode code="1997004606"/>
  </observation>
</entryRelationship>
<entryRelationship>
  <act classCode="ACT">
    <templateId root="2.16.840.1.113883.10.20.23.42"/>
    <id root="501558266" 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>
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  <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
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      <id root="1819596155" extension="MDHT"/>
      <code code="C49569" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
      <statusCode code="completed"/>
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        <high value="2012"/>
      </effectiveTime>
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      <targetSiteCode code="277095829"/>
      <participant/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation>
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codeSystemName="NCI Thesaurus"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <value xsi:type="CD" code="2023872226"/>
      <interpretationCode code="828685992"/>
      <targetSiteCode code="1126293446"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <act classCode="ACT">
      <templateId root="2.16.840.1.113883.10.20.23.75"/>
      <id root="1210184931" 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="343897937" extension="MDHT"/>
      <code codeSystem="locally defined" codeSystemName="Supplemental Value
Type"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <interpretationCode code="606182180"/>

```

```

        <targetSiteCode code="1455319374"/>
        <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="223101894" 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="594266988"/>
        <interpretationCode code="272628932"/>
        <targetSiteCode code="2073307056"/>
    </observation>
</entryRelationship>
<entryRelationship>
    <observation/>
</entryRelationship>
<entryRelationship>
    <observation/>
</entryRelationship>
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    <observation>
        <id root="238040069" extension="MDHT"/>
        <code code="239128787"/>
        <statusCode code="completed"/>
        <effectiveTime>
            <low value="2012"/>
            <high value="2012"/>
        </effectiveTime>
        <interpretationCode code="2031283702"/>
        <targetSiteCode code="245399647"/>
        <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:

- [*Consumable Material*](#)
- [*Reference Range*](#)
- [*Study Finding Evaluator*](#)
- [*Study Test Organization*](#)
- [*Consumable Material*](#)
- [*Mass Identification*](#)
- [*Reference Range*](#)
- [*Study Finding Evaluator*](#)
- [*Study Test Organization*](#)

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, concomitant 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"**
2. **SHALL** contain zero or one [0..1] **manufacturedProduct**

Information for the substance that is playing the role of medication.

- a. This manufacturedProduct **SHALL** contain exactly one [1..1] **@classCode= "MANU"**
- 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"**
- b. This manufacturedMaterial Contains exactly one [1..1] **@determinerCode= "KIND"**
- c. This manufacturedMaterial **SHALL** contain exactly one [1..1] **code**, where the **@code** **SHALL** be selected from (CodeSystem: locally defined Medication Item Type)

The code attribute captures information about the nature of the drug, medication or therapy. Within SDTM, medication information can appear as a concomitant 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 Tabulation Model: -TRT, MODIFY, DECOD]

- d. This manufacturedMaterial **SHOULD** contain zero or one [0..1] **formCode** with data type CD, where the **@code** **SHALL** be selected from ValueSet [Pharmaceutical Dose Form](#) C66726 **STATIC**

Captures the dose form of the medication. Note, while expected for an exposure drug, it is permitted for a concomitant medication. [SDTM: EXDOSFRM, SUDOSFRM, CMDOSFRM], [SEND: EXDOSFRM], [SDM: -DOSFRM]

- e. This manufacturedMaterial **MAY** contain zero or one [0..1] **lotNumberText**

The lot number is relevant when information regarding the study treatment is provided. [SDTM: EXLOT], [SEND: EXLOT], [Study Data Tabulation Model: -LOT]

- f. This manufacturedMaterial **MAY** contain zero or one [0..1] **asSpecializedKind**

Used to capture information about the drug class into which the medication falls.

- a. This asSpecializedKind **SHALL** contain exactly one [1..1] **@classCode= "ASSIGNED"**

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**, where the **@code** **SHALL** be selected from (CodeSystem: unknown Medication Class)

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**

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"**

The proper class code is "MAT", material.

- b. This representedOrganization **SHALL** contain exactly one [1..1] **@determinerCode= "KIND"**
- 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**

Used to provide information about active ingredients and/or treatment vehicles.

- a. Such ingredientRoles **SHALL** contain exactly one [1..1] **@classCode= "ASSIGNED"**

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 information 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**

INLINE

- a. This assignedPerson **SHALL** contain exactly one [1..1] **@classCode= "MMAT"**
- b. This assignedPerson **SHALL** contain exactly one [1..1] **@determinerCode= "INSTANCE"**
- c. This assignedPerson **SHALL** contain exactly one [1..1] **code**, where the **@code** **SHALL** be selected from (CodeSystem: unknown Substance Ingredient Type)

Identifies an ingredient within the formulation provided to the patient as a study treatment. The substance identified 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

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 verbatim medication name is captured as the original text property within the material.code attribute.
- 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.
- 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.

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)
2. **SHALL** contain exactly one [1..1] **@moodCode="EVN.CRT"** (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **code/@code="C78736"** (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)
 - 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**
 - 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 reference range values go into the base value and unit, while the original 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](#)
 - 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 reusable structure to capture information on the role of a person who evaluates a study finding.

1. **SHALL** contain exactly one [1..1] **@typeCode="PRF"**
2. **SHALL** contain exactly one [1..1] **participantRole**
 - a. This participantRole **SHALL** contain zero or one [0..1] **@classCode="ASSIGNED"**
 - b. This participantRole **SHALL** contain zero or one [0..1] **code** with data type CD, where the **@code** **SHALL** be selected from ValueSet [Evaluator Role Type](#) C76735 **STATIC**

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

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>

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, concomitant 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"**
2. **SHALL** contain zero or one [0..1] **manufacturedProduct**

Information for the substance that is playing the role of medication.

- a. This manufacturedProduct **SHALL** contain exactly one [1..1] **@classCode="MANU"**
- 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"**
- b. This manufacturedMaterial Contains exactly one [1..1] **@determinerCode="KIND"**
- c. This manufacturedMaterial **SHALL** contain exactly one [1..1] **code**, where the @code **SHALL** be selected from (CodeSystem: locally defined Medication Item Type)

The code attribute captures information about the nature of the drug, medication or therapy. Within SDTM, medication information can appear as a concomitant 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 Tabulation Model: -TRT, MODIFY, DECOD]

- d. This manufacturedMaterial **SHOULD** contain zero or one [0..1] **formCode** with data type CD, where the @code **SHALL** be selected from ValueSet [Pharmaceutical Dose Form C66726 STATIC](#)

Captures the dose form of the medication. Note, while expected for an exposure drug, it is permitted for a concomitant medication. [SDTM: EXDOSFRM, SUDOSFRM, CMDOSFRM], [SEND: EXDOSFRM], [SDM: -DOSFRM]

- e. This manufacturedMaterial **MAY** contain zero or one [0..1] **lotNumberText**

The lot number is relevant when information regarding the study treatment is provided. [SDTM: EXLOT], [SEND: EXLOT], [Study Data Tabulation Model: -LOT]

- f. This manufacturedMaterial **MAY** contain zero or one [0..1] **asSpecializedKind**

Used to capture information about the drug class into which the medication falls.

- a. This asSpecializedKind **SHALL** contain exactly one [1..1] **@classCode="ASSIGNED"**

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**, where the @code **SHALL** be selected from (CodeSystem: unknown Medication Class)

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**

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"**

The proper class code is "MAT", material.

- b. This representedOrganization **SHALL** contain exactly one [1..1] **@determinerCode= "KIND"**
- 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**

Used to provide information about active ingredients and/or treatment vehicles.

- a. Such ingredientRoles **SHALL** contain exactly one [1..1] **@classCode= "ASSIGNED"**

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 information 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**

INLINE

- a. This assignedPerson **SHALL** contain exactly one [1..1] **@classCode= "MMAT"**
- b. This assignedPerson **SHALL** contain exactly one [1..1] **@determinerCode= "INSTANCE"**
- c. This assignedPerson **SHALL** contain exactly one [1..1] **code**, where the **@code** **SHALL** be selected from (CodeSystem: unknown Substance Ingredient Type)

Identifies an ingredient within the formulation provided to the patient as a study treatment. The substance identified 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

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 verbatim medication name is captured as the original text property within the material.code attribute.
- 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.
- 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.

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>

```

Mass Identification

[Participant2: templateId 2.16.840.1.113883.10.20.23.51]

The template is used to record a mass identifier such as MASS 1 or MASS A. It is used when the mass was discovered during the in-life phase or during pathology and assigned a mass identifier. The mass identification should be unique within the subject, regardless of mass location.

1. **SHALL** contain exactly one [1..1] **@typeCode="SBJ"**
2. **SHALL** contain exactly one [1..1] **participantRole**
 - a. This participantRole **SHALL** contain exactly one [1..1] **@classCode="ROL"**
 - b. This participantRole **SHALL** contain exactly one [1..1] **id**

An identifier for the mass. The identifier shall be unique within the subject. [SEND: CLSPID, MASPID, MISPID, PMSPID, TFSPID]

Mass Identification 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="SBJ">
  <templateId root="2.16.840.1.113883.10.20.23.51"/>
  <time>
    <low value="2012"/>
    <high value="2012"/>
  </time>
  <participantRole classCode="ROL">
    <id root="2128353300" extension="MDHT"/>
  </participantRole>
</participant2>

```

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)
2. **SHALL** contain exactly one [1..1] **@moodCode="EVN.CRT"** (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **code/@code="C78736"** (CodeSystem: 2.16.840.1.113883.3.26.1.1 NCI Thesaurus)
 - 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**
 - 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 reference range values go into the base value and unit, while the original values use the translation property of the PQR type. [SDTM: LBORNRL0, LBORNRLHI, LBSTRRL0, LBSTNRHI, LBSTNRCL], [SEND: LBORNRL0, LBORNRLHI,

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**

- 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 reusable structure to capture information on the role of a person who evaluates a study finding.

1. **SHALL** contain exactly one [1..1] @typeCode="PRF"
2. **SHALL** contain exactly one [1..1] **participantRole**
 - a. This participantRole **SHALL** contain zero or one [0..1] @classCode="ASSIGNED"
 - b. This participantRole **SHALL** contain zero or one [0..1] **code** with data type CD, where the @code **SHALL** be selected from ValueSet [Evaluator Role Type](#) C76735 **STATIC**

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

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

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.

REFERENCES

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- CDISC Standard for Exchange of Nonclinical Data 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.

