Integrating the Healthcare Enterprise

IHE Quality, Research and Public Health Technical Framework Supplement

Clinical Research Process Content (CRPC)

Revision 2.1 – Trial Implementation

Date: September 7, 2018

Author: IHE QRPH Technical Committee

Email: qrph@ihe.net

Please verify you have the most recent version of this document. See here for Trial Implementation and Final Text versions and here for Public Comment versions.

Foreword

This is a supplement to the IHE Quality, Research and Public Health (QRPH) Technical Framework. Each supplement undergoes a process of public comment and trial implementation before being incorporated into the volumes of the Technical Frameworks.

This supplement is published on September 7, 2018 for trial implementation and may be available for testing at subsequent IHE Connectathons. The supplement may be amended based on the results of testing. Following successful testing it will be incorporated into the QRPH Technical Framework. Comments are invited and may be submitted at http://www.ihe.net/QRPH_Public_Comments.

This supplement describes changes to the existing technical framework documents.

"Boxed" instructions like the sample below indicate to the Volume Editor how to integrate the relevant section(s) into the relevant Technical Framework volume.

Amend Section X.X by the following:

Where the amendment adds text, make the added text **bold underline**. Where the amendment removes text, make the removed text ~~**bold strikethrough**~~. When entire new sections are added, introduce with editor's instructions to "add new text" or similar, which for readability are not bolded or underlined.

General information about IHE can be found at www.ihe.net.

Information about the IHE Quality, Research and Public Health domain can be found at ihe.net/IHE_Domains.

Information about the organization of IHE Technical Frameworks and Supplements and the process used to create them can be found at http://ihe.net/IHE_Process and http://ihe.net/Profiles.

The current version of the IHE Quality, Research and Public Health Technical Framework can be found at http://ihe.net/Technical_Frameworks.

CONTENTS

Introduction to this Supplement

This proposal is to specify content, which is appropriate to help automate the sharing of information among systems during the clinical research process. Using the transactions from the Retrieve Process for Execution (RPE) Profile, the proposed content profiles will improve the recruitment for, setup, and performance of clinical trials.

Open Issues and Questions

None

Closed Issues

1. Currently we assume that the CTMS will implement both the Process Definition Manager and Process State Manager Actors from RPE (see Figure X-1.1). Is this a realistic assumption? Do we need to consider cases where there are more than the CTMS (Research Protocol Source) and EMR (Research Protocol Consumer) systems involved?
    a. Content Creator and Content Consumer are sufficiently specific actors to be extended to additional use cases as they arise. No additional systems have been identified as needing additional handling.
2. Use case 2 (patient recruitment at the point of care) assumes that the matching of patient to study includes any screening performed as per the study definition, and the Initiate Process transaction occurs after the information is collected and will contain the corresponding patient data as necessary. Is that a valid assumption?
    a. There is patient pre-enrollment screening that may be done in the Recruitment at Point of Care use case. This is to be distinguished from a separate use case, where enrollment is done on the healthcare side, and so there is no need to send any additional information besides the information that the patient has been enrolled.
3. It is not clear where the boundaries for de-identification of patient data and for patient confidentiality lie. The questions that come up are: is it appropriate to include the study subject ID as part of the patient's list of identifiers? Where is de-identified data expected?
    a. This is outside the scope of the CRPC Profile. For specific use cases, refer to the IHE ITI De-Identification handbook.
4. In the Initiate Process transaction we need to specify which study is associated with the patient. What information is needed to identify the study?
    a. The transactions have been restructured to allow proper identification within CP IHE-QRPH-0063.

General Introduction and Shared Appendices

The IHE Technical Framework General Introduction and Shared Appendices are components shared by all of the IHE domain technical frameworks. Each technical framework volume contains links to these documents where appropriate.

Appendix A – Actor Summary Definitions

No new actors.

Appendix B – Transaction Summary Definitions

No new transactions.

Appendix D – Glossary

No new Glossary terms.

Volume 1 – Profiles

Copyright Licenses

Not applicable.

Domain-specific additions

Not applicable.

X Clinical Research Process Content (CRPC) Profile

Research protocols are complex documents that guide the conduct of trials. A healthcare provider site that participates in a trial may perform subsets of:

- The protocol / process
- The trial design model and schedule of activities
- The planned sequence of events and interventions pertaining to a study
- Activities described within the protocol / process

The existing IHE Retrieve Process for Execution (RPE) Profile acts as a framework providing messaging interactions used to convey the necessary information. The CRPC Profile utilizes the RPE framework to solve the issues of exchanging detailed content specific to the research domain.

X.1 CRPC Actors, Transactions, and Content Modules

This section defines the actors, transactions, and/or content modules in this profile. General definitions of actors are given in the Technical Frameworks General Introduction Appendix A. IHE Transactions can be found in the Technical Frameworks General Introduction Appendix B. Both appendices are located at http://ihe.net/Technical_Frameworks/#GenIntro

Figure X.1-1 shows the actors directly involved in the CRPC Profile and the direction that the content is exchanged.

A product implementation using this profile may group actors from this profile with actors from a workflow or transport profile to be functional. The grouping of the content module described in this profile to specific actors is described in more detail in Required Actor Groupings QRPH TF-1: X.3 or in Cross Profile Considerations QRPH TF-1: X.6.

Figure X.1-1: CRPC Actor Diagram

Table X.1-1 lists the content module(s) defined in the CRPC Profile. To claim support with this profile, an actor shall support all required content modules (labeled "R") and may support optional content modules (labeled "O").

Table X.1-1: CRPC: Actors and Content Modules

Actors	Content Modules	Optionality	Reference
Content Creator	Study Definition Content Module	R	QRPH TF-3: 8.3.1.D.1
Content Consumer	Study Definition Content Module	R	QRPH TF-3: 8.3.1.D.1

X.1.1 Actor Descriptions and Actor Profile Requirements

Most requirements are documented in QRPH TF-3 Content Modules. This section documents any additional requirements on profile's actors.

X.1.1.1 Content Creator

A CRPC Content Creator SHALL support groupings defined within Section X.3.

X.1.1.2 Content Consumer

A CRPC Content Consumer SHALL support groupings defined within Section X.3.

X.2 CRPC Actor Options

Options that may be selected for each actor in this profile, if any, are listed in the Table X.2-1. Dependencies between options, when applicable, are specified in notes.

Table X.2-1: CRPC – Actors and Options

Actor	Option Name	Reference
Content Creator	No options defined	--
Content Consumer	No options defined	--

X.3 CRPC Required Actor Groupings

An actor from this profile (Column 1) shall implement all of the required transactions and/or content modules in this profile ***in addition to all*** of the requirements for the grouped actor (Column 2).

If this is a content profile, and actors from this profile are grouped with actors from a workflow or transport profile, the Reference column references any specifications for mapping data from the content module into data elements from the workflow or transport transactions.

Section X.5 describes some optional groupings that may be of interest for security considerations and Section X.6 describes some optional groupings in other related profiles.

Table X.3-1: CRPC Profile – Required Actor Groupings

CRPC Actor	Actor(s) to be grouped with	Reference	Content Bindings Reference
Content Creator	Process Activity Executor	QRPH RPE X.1.1.3	See Section X.3.1
	Process Definition Manager	QRPH RPE X.1.1.1	See Section X.3.2
	Process State Manager	QRPH RPE X.1.1.2	See Section X.3.3
Content Consumer	Process Activity Executor	QRPH RPE X.1.1.3	See Section X.3.1
	Process State Manager	QRPH RPE X.1.1.2	See Section X.3.3

X.3.1 Process Activity Executor Groupings

The Process Activity Executor as defined in the Retrieve Process for Execution Profile (RPE) Profile SHALL be grouped with both the Content Creator and Content Consumer from the CRPC Profile. The content for those transactions SHALL be the Study Definition Content Module.

The following interactions are expected. The RPE Profile details transaction level requirements.

- Receipt of Publish Process Definitions [QRPH-22] including serving as Content Consumer for the Study Definition Content Module.
- Receipt of Retrieve Process Definitions Response [QRPH-20] including serving as Content Consumer for the Study Definition Content Module.
- Receipt of Retrieve Activities Response [QRPH-26] including serving as Content Consumer for the Study Definition Content Module.
- Transmission of Update Activities Request [QRPH-27] including serving as Content Creator for the Study Definition Content Module.

X.3.2 Process Definition Manager Groupings

The Process Definition Manager as defined in the Retrieve Process for Execution Profile (RPE) Profile SHALL be grouped with the Content Creator from the CRPC Profile. The content for those transactions SHALL be the Study Definition Content Module.

The following interactions are expected. The RPE Profile details transaction level requirements.

- Transmission of Publish Process Definitions [QRPH-22] including serving as Content Creator for the Study Definition Content Module.
- Transmission of Retrieve Process Definitions Response [QRPH-20] including serving as Content Creator for the Study Definition Content Module.

X.3.3 Process State Manager Groupings

The Process State Manager as defined in the Retrieve Process for Execution (RPE) Profile SHALL be grouped with the Content Creator and Content Consumer from the CRPC Profile. The content for those transactions SHALL be the Study Definition Content Module.

The following interactions are expected. The RPE Profile details transaction level requirements.

- Receipt of Publish Process Definitions [QRPH-22] including serving as Content Consumer for the Study Definition Content Module.
- Receipt of Retrieve Process Definitions Response [QRPH-20] including serving as Content Consumer for the Study Definition Content Module.
- Transmission of Retrieve Activities Response [QRPH-26] including serving as Content Creator for the Study Definition Content Module.
- Receipt of Update Activities Request [QRPH-27] including serving as Content Consumer for the Study Definition Content Module.

X.4 CRPC Overview

X.4.1 Concepts

Not applicable.

X.4.2 Use Cases

X.4.2.1 Use Case #1: Recruitment at the Point of Care

This use case provides an example of creating a new study within a CTMS and publishing the definition to an EMR. The EMR then uses that information to send interest and pre-enrollment information back to the CTMS.

X.4.2.1.1 Recruitment at the Point of Care Use Case Description

A researcher at a health system is planning to conduct a clinical research study. A number of pre-approval steps are tracked in the Clinical Trial Management System (CTMS). A member of the study support staff creates a study in the clinical trials management system in order to start tracking these preparatory activities for the potential study. One of the typical steps will be to specify the definition of the study schedule of events, a labor intensive step.

Once the study has received all necessary approvals, study information must also be made available to the EMR to support activities that are inherently tied the provisioning of services to patients being treated within their organization (e.g., research-appropriate scheduling, ordering, billing).

As part of this normal operation, the healthcare organization uses a decision support engine in the EMR to identify patients at the point of care that may be eligible for the study. Information in

the patient's medical record triggers a notification in the PCP's workflow she may be a candidate for the study.

The PCP can indicate without leaving the clinical workflow if the patient is willing to be contacted to learn more and the EMR can automatically notify the study. Pre-enrollment actions such as screening tests and consent forms are completed in the EMR. Knowledge of this pre-enrollment association between the patient and the study may also be desired in the research system.

X.4.2.1.2 Recruitment at the Point of Care Process Flow

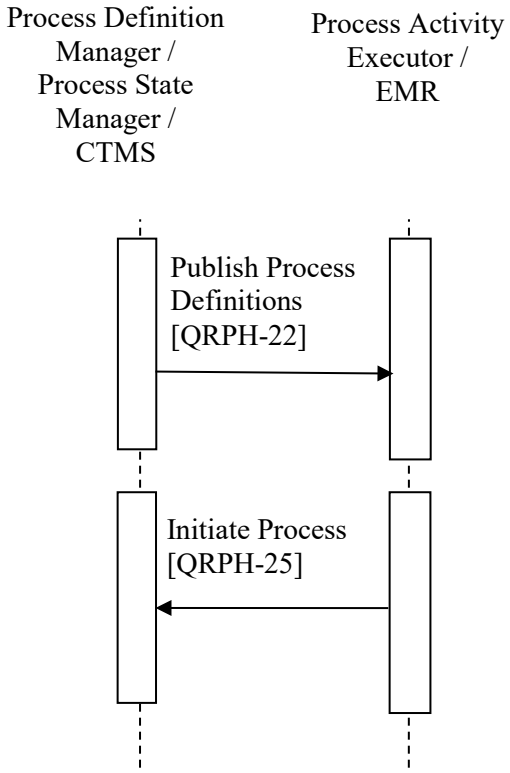


Figure X.4.2.1.2-1: Recruitment at the Point of Care in CRPC Profile

Pre-conditions:

- The study receives pre-approval within the CTMS.
- A member of the study support staff creates the study in the CTMS.

Main Flow:

- The study receives final approval within the CTMS.
- The CTMS publishes the process definitions to the EMR.

- The CTMS serves as a CRPC Content Creator and an RPE Process Definition Manager.
- The CTMS sends a Publish Process Definitions [QRPH-22] transaction to the EMR. This notifies the EMR that a new study is available for patients.
- The EMR serves as a CRPC Content Consumer and an RPE Process Activity Executor.

- An end user in the EMR identifies a patient as being potentially interested in the research study.
  - The EMR serves as a CRPC Content Creator and an RPE Process Activity Executor.
  - The EMR sends an Initiate Process [QRPH-25] transaction to the CTMS. This notifies the CTMS of pre-enrollment activities and interest in the study.
  - The CTMS serves as a CRPC Content Creator and an RPE Process State Manager.

Post-conditions:

The study definitions now exist in the EMR and can be used to support activities in that system. As individuals are identified as interested within the EMR, their interest and pre-enrollment activities are communicated back to the CTMS.

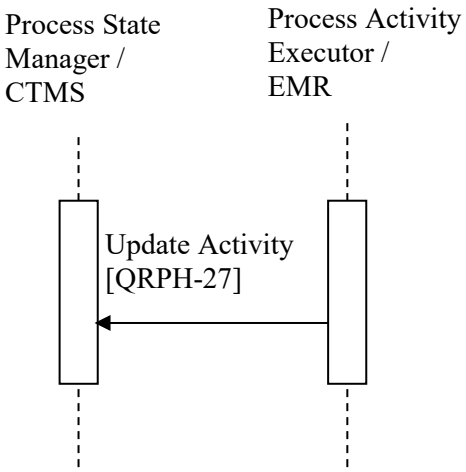
X.4.2.2 Use Case #2: Update of Patient-specific Study Events

X.4.2.2.1 Update Patient-specific Study Events Use Case Description

A study coordinator captures documentation while working with the patient. When that information is entered into the EMR as part of service delivery, it may have an impact on the schedule of events as documented in the CTMS.

Information that impacts the study will be transmitted from the EMR to the CTMS as part of the study. This includes documentation of the start date of the patient within the study. This information assists with managing the study and the requisite billing requirements in the CTMS.

X.4.2.2.2 Update of Patient-specific Study Events Process Flow



320 **Figure X.4.2.2.2-1: Basic Process Flow in CRPC Profile**

Pre-conditions:

- The patient is enrolled within the study.
- The patient enrollment status has already been shared between the CTMS and the EMR.

Main Flow:

325
- The patient start date within the study is documented in the EMR.
  - The EMR serves as a CRPC Content Creator and an RPE Process Activity Executor.
  - The EMR sends an Update Activity [QRPH-27] transaction to the CTMS. This notifies the CTMS of the newly documented start date of the patient within the study.
  - The CTMS serves as a CRPC Content Consumer and an RPE Process State Manager.

330 **Post-conditions:**

The relevant study information is now shared between both the CTMS and the EMR as part of the process of documenting clinically relevant study information in the EMR.

X.5 CRPC Security Considerations

X.5.1 Consistent Time (CT)

In order to address identified security risks, all actors in CRPC SHOULD be grouped with the Consistent Time (CT) Profile - Time Client Actor. This grouping will assure that all systems have a consistent time clock to assure a consistent timestamp for audit logging and form accuracy.

X.5.2 Audit Trail and Node Authentication (ATNA)

Transactions that include CRPC content may include clinical documentation related to the information subject. In those cases, it is anticipated that transfers of Personal Health Information (PHI) will be protected. The IHE ITI Audit Trail and Node Authentication (ATNA) Profile SHOULD be implemented to protect node-to-node communication and to produce an audit trail of the PHI related actions when they exchange messages.

X.5.3 Consent

In some jurisdictions, consent may be needed to provide this information to public health. For these cases, the IHE ITI BPPC or the IHE ITI APPC Integration Profile SHOULD be used to enable this consent management.

X.5.4 Subject Identification

For particular use cases, it may be desirable to de-identify subject information of a study. For guidance on de-identification, refer to the IHE ITI De-Identification handbook.

X.6 CRPC Cross Profile Considerations

Not applicable

Appendices

Not applicable.

Volume 2 – Transactions

Not applicable.

Appendices

Not applicable.

Volume 2 Namespace Additions

Not applicable.

Volume 3 – Content Modules

5 IHE Namespaces, Concept Domains and Vocabularies

Not applicable.

8 Content Modules

8.3.1 HL7®[1] V3 Content Modules

8.3.1.D Study Definition Content Module

375 The Study Definition Content Module describes a clinical research study in a machine-readable format.

8.3.1.D.1 Format Code

The processDefinitionLanguage for the Study Definition Content Module is:

- http://www.omg.org/spec/BPMN/2.0/

380 #### 8.3.1.D.2 Parent Template

Not applicable.

8.3.1.D.3 Referenced Standards

All standards which are referenced in this document are listed below with their common abbreviation, full title, and link to the standard.

385 **Table 8.3.1.D.3-1: Study Definition Content Module – Referenced Standards**

Abbreviation	Title	URL
BIOMEDRR	HL7 Biomedical Research and Regulation	http://www.hl7.org/Special/committees/rcrim/listserv.cfm
SDM	CDISC Study Design Model	http://www.hl7.org/Special/committees/rcrim/listserv.cfm
RPE	Retrieve Process for Execution	https://wiki.ihe.net/index.php/Retrieve_Process_for_Execution
CRD	Clinical Research Document	http://wiki.ihe.net/index.php/Clinical_Research_Document

8.3.1.D.4 Data Element Requirement Mappings to CDA®[2]

Not applicable.

[1] HL7 is the registered trademark of Health Level Seven International.

[2] CDA is the registered trademark of Health Level Seven International.

8.3.1.D.5 Study Definition Content Module Document Content Module Specification

This entry content module describes the general structure of a research study description. At its most general applicability, the model can describe an action plan for a formal investigation to assess the utility, impact, pharmacological, physiological, and psychological effects of a particular treatment, procedure, drug, device, biologic, food product, cosmetic, care plan, or subject characteristic. The definitions presented here are constrained for the most common clinical research studies.

Table 8.3.1.D.5-1: Study Definition Content Module Specification

General Description	The Study Definition Content Module describes a clinical research study in a machine-readable format.			
Document Code	http://www.omg.org/spec/BPMN/2.0/			
Opt and Card	**Attribute or Element Name**	**Description**	**Specification Document**	**Vocabulary Constraint**
clinicalStudyDefinition				
R [1..1]	@classCode	HL7 classCode		“CLNTRL”
R [1..1]	@moodCode	HL7 moodCode		“DEF”
O [0..*]	templateId	HL7 templateId		
O [0..*]	id	HL7 Identifier for the study		
R2 [0..1]	title	HL7 Alphanumeric description for the study		
R2 [0..1]	text	HL7 Alphanumeric study detail information		
Elements				
R2 [0..*]	precondition	Eligibility Criteria	See Section 8.3.1.D.5.1	
R2 [0..*]	component1	Epoch Definition	See Section 8.3.1.D.5.2	
R2 [0..*]	component2	Arm Definition	See Section 8.3.1.D.5.3	
O [0..1]	component3	Reason for Revision	See Section 8.3.1.D.5.4	
R2 [0..*]	component4	Timing Events	See Section 8.3.1.D.5.5	
R [1..*]	subjectOf	Study Characteristics	See Section 8.3.1.D.5.6	

8.3.1.D.5.1 Eligibility Criteria

Eligibility criteria are a set of conditions that a subject must meet in order to participate in a study. Because eligibility criteria affect recruitment into a study, they are often the subject of protocol amendments.

One eligibility criterion may supersede another. The most commonly occurring types of criteria involve age, sex, the type and stage of a disease, treatment history, and other medical conditions.

Eligibility Criteria are a list of pre-conditions, combined with a conjunction code. Complex criteria are expressed using the recursive structure of pre-conditions.

When eligibility criteria are on the same level, they are evaluated in sequence. The nesting of eligibility criteria is used to group conditional expressions, e.g., A AND (B OR C)

Table 8.3.1.D.5.1-1: Eligibility Criteria - precondition

Attribute or Element Name	Opt and Card	Description
precondition		
@typeCode	R [1..1]	HL7 typeCode
Elements		
conjunctionCode	R [1..1]	HL7 Code
@code	R [1..1]	One of "AND", "OR", or "XOR"
eligibilityCriterion	R [1..*]	See Table 8.3.1.D.5.1-2

Table 8.3.1.D.5.1-2: Eligibility Criteria - eligibilityCriterion

Attribute or Element Name	Opt and Card	Description
eligibilityCriterion		
@classCode	R [1..1]	HL7 classCode
@moodCode	R [1..1]	HL7 moodCode
id	O [0..*]	HL7 Identifier for the eligibility criterion
code	R2 [0..1]	HL7 Code
negationInd	O [0..1]	HL7 Boolean
text	R2 [0..1]	HL7 Alphanumeric eligibility criteria detail information
value	R2 [0..1]	HL7 Code
Elements		
precondition	O [0..*]	See Table 8.3.1.D.5.1-1 When eligibility criteria are on the same level, they are evaluated in sequence. The nesting of eligibility criteria is used to group conditional expressions, e.g., A AND (B OR C)

8.3.1.D.5.2 Epoch Definition

A subject moves from one Epoch to another and can only be in one epoch at a time. The subject can only move to an Epoch with a greater sequenceNumber. The main purpose of the Epoch is to organize the Arms for comparison purposes. Activities in the same Epoch but a different Arm need not be similar in time and pattern.

Table 8.3.1.D.5.2-1: Epoch Definition – component1

Attribute or Element Name	Opt and Card	Description
component1		
@typeCode	R [1..1]	HL7 typeCode
sequenceNumber	R [1..1]	HL7 Numerical
pauseQuantity	O [0..1]	HL7 Numerical
Elements		
epoch	R [1..1]	See Table 8.3.1.D.5.2-2

Table 8.3.1.D.5.2-2: Epoch Definition – epoch

Attribute or Element Name	Opt and Card	Description
epoch		
@classCode	R [1..1]	"CLNTRL"
@moodCode	R [1..1]	"DEF"
id	O [0..*]	HL7 Identifier for the epoch
code	R2 [0..1]	HL7 Code
title	R2 [0..1]	HL7 Alphanumeric epoch detail information
Elements		

8.3.1.D.5.3 Arm Definition

An Arm is a path through a study. It describes what activities the subject will be involved in as they pass through the study and is typically equivalent to a treatment group in a parallel design trial. Generally, each subject is assigned to an Arm, and the design of the study is reflected in the number and composition of the individual arms. This intended path the subject progresses in a trial is composed of a study cell (Timing Event) for each Epoch of the study. Each timing event, in turn, has a pattern of child time points through which the subject would pass. This planned path thus describes how to treat subjects in the Arm.

Table 8.3.1.D.5.3-1: Arm Definition – component2

Attribute or Element Name	Opt and Card	Description
component2		
@typeCode	R [1..1]	"COMP"
Elements		
arm	R [1..1]	See Table 8.3.1.D.5.3-2

Table 8.3.1.D.5.3-2: Arm Definition – arm

Attribute or Element Name	Opt and Card	Description
arm		
@classCode	R [1..1]	"CLNTRL"
@moodCode	R [1..1]	"DEF"
id	O [0..*]	HL7 Identifier for the study arm
title	R2 [0..1]	HL7 Alphanumeric arm detail information
Elements		

8.3.1.D.5.4 Reason for Revision

The Reason for Revision is the codified reason why the study protocol was revised.

Table 8.3.1.D.5.4-1: Reason for Revision – component3

Attribute or Element Name	Opt and Card	Description
component3		
@typeCode	R [1..1]	"COMP"
Elements		
controlActEvent	R [1..1]	See Table 8.3.1.D.5.4-2

Table 8.3.1.D.5.4-2: Reason for Revision – controlActEvent

Attribute or Element Name	Opt and Card	Description
controlActEvent		
@classCode	R [1..1]	"ACTN"

Attribute or Element Name	Opt and Card	Description
@moodCode	R [1..1]	"EVN"
text	R2 [0..1]	HL7 Alphanumeric control act event detail information
Elements		
reasonCode	R [1..1]	See Table 8.3.1.D.5.4-3

Table 8.3.1.D.5.4-3: Reason for Revision – reasonCode

Attribute or Element Name	Opt and Card	Description
reasonCode		
@validTimeHigh	R [1..1]	HL7 Date/Time
item	R [1..1]	HL7 Code
Elements		

8.3.1.D.5.5 Timing Events

Timing Events describe the definitions of Study Cells, Study Segments and Study Activities. Each Timing Event may have various characteristics, entry and exit conditions, and links to other activities.

Study Cells are recognized by the links to the Epoch and Arm(s) they belong to. This uses the componentOf1 and componentOf2 structures to inherit links from their Epoch and Arm(s).

Study Segments are time definitions contained within Study Cells. This uses the component1 structure. They contain a list of links to Study Activities, which are part of the segment.

Study Activities refer to points in time with various characteristics and may refer to clinical acts or contain references to other study activities or events. They are represented by the subjectOf structure.

Table 8.3.1.D.5.5-1: Timing Events – component4

Attribute or Element Name	Opt and Card	Description
component4		
@typeCode	R [1..1]	"COMP"
Elements		
timePointEventDefinition	R [1..1]	See Table 8.3.1.D.5.5-2

Table 8.3.1.D.5.5-2: Timing Events – timePointEventDefinition

Attribute or Element Name	Opt and Card	Description
timePointEventDefinition		
@classCode	R [1..1]	"CTTEVENT"
@moodCode	R [1..1]	"DEF"
templateId	O [0..1]	HL7 templateId
id	O [0..*]	HL7 Identifier for the time point event
code	R2 [0..1]	HL7 Code
effectiveTime	R2 [0..1]	HL7 Date/Time
Elements		
subject	O [0..1]	See Table 8.3.1.D.5.5-3 Indicates that the patient is in this activity.
component1	O [0..*]	See Table 8.3.1.D.5.5-6 Time definitions for activities within this segment.
component2	O [0..*]	See Table 8.3.1.D.5.5-7 Content definitions for activities within this segment.
subjectOf	O [0..*]	See Table 8.3.1.D.5.5-10 Provides detail on Study Characteristics.
componentOf1	O [0..1]	See Table 8.3.1.D.5.5-12 Provides a link to an Epoch.
componentOf2	O [0..*]	See Table 8.3.1.D.5.5-13 Provides a link to one or more Arms.

Table 8.3.1.D.5.5-3: Timing Events – subject

Attribute or Element Name	Opt and Card	Description
subject		
@typeCode	R [1..1]	"SBJ"
Elements		
experimentalUnit	R [1..1]	See Table 8.3.1.D.5.5-4

450 **Table 8.3.1.D.5.5-4: Timing Events – experimentalUnit**

Attribute or Element Name	Opt and Card	Description
experimentalUnit		
@classCode	R [1..1]	"RESBJ"
Elements		
subjectPersonKind	R [1..1]	See Table 8.3.1.D.5.5-5

Table 8.3.1.D.5.5-5: Timing Events – subjectPersonKind

Attribute or Element Name	Opt and Card	Description
subjectPersonKind		
@classCode	R [1..1]	"PSN"
@determinerCode	R [1..1]	"KIND"
id	O [0..*]	HL7 Identifier for the subject person kind
Elements		

Table 8.3.1.D.5.5-6: Timing Events – component1

Attribute or Element Name	Opt and Card	Description
component1		
@typeCode	R [1..1]	"COMP"
splitCode	O [0..*]	HL7 Code
joinCode	O [0..*]	HL7 Code
sequenceNumber	O [0..1]	HL7 Numerical
Elements		
timePointEventDefinition	R [1..1]	See Table 8.3.1.D.5.5-2

Table 8.3.1.D.5.5-7: Timing Events – component2

Attribute or Element Name	Opt and Card	Description
component2		
@typeCode	R [1..1]	"COMP"
Elements		
encounter	O [0..1]	See Table 8.3.1.D.5.5-8

Attribute or Element Name	Opt and Card	Description
observation	O [0..1]	See Table 8.3.1.D.5.5-9
procedure	O [0..1]	See Table 8.3.1.D.5.5-10

Table 8.3.1.D.5.5-8: Timing Events – encounter

Attribute or Element Name	Opt and Card	Description
encounter		
@classCode	R [1..1]	"ENC"
@moodCode	R [1..1]	HL7 moodCode
code	O [0..1]	HL7 Code
effectiveTime	O [0..1]	The effectiveTime describes an interval around the activityTime during which the activity can still be performed while staying within the parameters of the study. The effectiveTime in an instantiated protocol for a specific patient directly corresponds to the uncertainty range in the protocol definition.
activityTime	O [0..1]	The activity time designates the point in time when the activity is supposed to occur (or has already occurred, if the moodCode is EVN).
Elements		

455 **Table 8.3.1.D.5.5-9: Timing Events – observation**

Attribute or Element Name	Opt and Card	Description
observation		
@classCode	R [1..1]	"CLNTRL"
@moodCode	R [1..1]	HL7 moodCode
code	O [0..1]	HL7 Code
effectiveTime	O [0..1]	The effectiveTime describes an interval around the activityTime during which the activity can still be performed while staying within the parameters of the study. The effectiveTime in an instantiated protocol for a specific patient directly corresponds to the uncertainty range in the protocol definition.
activityTime	O [0..1]	The activity time designates the point in time when the activity is supposed to occur (or has already occurred, if the moodCode is EVN).
Elements		

Table 8.3.1.D.5.5-10: Timing Events – procedure

Attribute or Element Name	Opt and Card	Description
procedure		
@classCode	R [1..1]	"PROC"
@moodCode	R [1..1]	HL7 moodCode
code	O [0..1]	HL7 Code
effectiveTime	O [0..1]	The effectiveTime describes an interval around the activityTime during which the activity can still be performed while staying within the parameters of the study. The effectiveTime in an instantiated protocol for a specific patient directly corresponds to the uncertainty range in the protocol definition.
activityTime	O [0..1]	The activity time designates the point in time when the activity is supposed to occur (or has already occurred, if the moodCode is EVN).
Elements		

Table 8.3.1.D.5.5-11: Timing Events – subjectOf

Attribute or Element Name	Opt and Card	Description
subjectOf		
@typeCode	R [1..1]	"SBJ"
Elements		
timePointEventCharacteristic	R [1..1]	See Table 8.3.1.D.5.5-12

Table 8.3.1.D.5.5-12: Timing Events – timePointEventCharacteristic

Attribute or Element Name	Opt and Card	Description
timePointEventCharacteristic		
@classCode	R [1..1]	"CLNTRL" or "VERIF" The code "VERIF" indicates there is an external form used to document this activity. The id represents a formID, and the value is the URL where the form can be accessed via Clinical Research Document (CRD).
@moodCode	R [1..1]	"EVN"
id	O [0..*]	HL7 Identifier for the time point event characteristic
code	O [0..1]	HL7 Code
value	O [0..1]	HL7 Code

Attribute or Element Name	Opt and Card	Description
Elements		

Table 8.3.1.D.5.5-13: Timing Events – componentOf1

Attribute or Element Name	Opt and Card	Description
componentOf1		
@typeCode	R [1..1]	"COMP"
Elements		
epochStub	R [1..1]	See Table 8.3.1.D.5.5-14

460 **Table 8.3.1.D.5.5-14: Timing Events – epochStub**

Attribute or Element Name	Opt and Card	Description
epochStub		
@classCode	R [1..1]	"CLNTRL"
@moodCode	R [1..1]	"DEF"
id	O [0..*]	HL7 Identifier for the epoch stub
Elements		

Table 8.3.1.D.5.5-15: Timing Events – componentOf2

Attribute or Element Name	Opt and Card	Description
componentOf2		
@typeCode	R [1..1]	"COMP"
Elements		
armStub	R [1..1]	See Table 8.3.1.D.5.5-16

Table 8.3.1.D.5.5-16: Timing Events – armStub

Attribute or Element Name	Opt and Card	Description
armStub		
@classCode	R [1..1]	"CLNTRL"

Attribute or Element Name	Opt and Card	Description
@moodCode	R [1..1]	"DEF"
id	O [0..*]	HL7 Identifier for the arm stub
Elements		

8.3.1.D.5.6 Study Characteristics

Study Characteristics are attributes of a study. One possible list of Study Characteristics can be found in the protocol registration data elements at ClinicalTrials.gov.

- https://prsinfo.clinicaltrials.gov/definitions.html

Table 8.3.1.D.5.6-1: Study Characteristics - subjectOf

Attribute or Element Name	Opt and Card	Description
subjectOf		
@typeCode	R [1..1]	"SUBJ"
Elements		
studyCharacteristic	R [1..1]	See Table 8.3.1.D.5.6-2

Table 8.3.1.D.5.6-2: Study Characteristics - studyCharacteristic

Attribute or Element Name	Opt and Card	Description
studyCharacteristic		
@classCode	R[1..1]	"CLNTRL"
@moodCode	R [1..1]	"EVN"
code	O [0..1]	HL7 Code
statusCode	O [0..1]	HL7 Code
value	O [0..1]	HL7 Code
Elements		

8.3.1.D.6 Study Definition Content Module Conformance and Example

Note that these examples are meant to be informative and not normative.


```
<clinicalStudyDefinition xmlns="urn:hl7-org:v3"
    xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" classCode="CLNTRL"
moodCode="DEF">
    <templateId root=""/>
    <id root="1.2.3.4" extension="ABCD"/>
    <title value="Study Title"/>
    <text value="Study Description"/>

    <!-- Eligibility Criteria Examples -->
    <precondition typeCode="PRCN">
        <!-- See Figure 8.3.1.D.6-2 for Examples -->
    </precondition>

    <!-- Epoch Definition Examples -->
    <component1 typeCode="COMP">
        <sequenceNumber value="1"/>
        <epoch classCode="CLNTRL" moodCode="DEF">
            <id extension="ABDC" root="1.2.3.4"/>
            <code code="Treatment" valueSet="2.3.4.5"/>
            <title value="First Treatment Epoch"/>
        </epoch>
    </component1>
    <component1 typeCode="COMP">
        <sequenceNumber value="2"/>
        <epoch classCode="CLNTRL" moodCode="DEF">
            <id root="2.3.4.5" extension="ABLMN"/>
            <code code="Treatment" valueSet="2.3.4.5"/>
            <title value="Second treatment epoch"/>
        </epoch>
    </component1>

    <!-- Arm Definition Examples -->
    <component2 typeCode="COMP">
        <arm classCode="CLNTRL" moodCode="DEF">
            <id root="2.3.4.6" extension="MLNOP"/>
            <title value="Arm 1"/>
        </arm>
    </component2>
    <component2 typeCode="COMP">
        <arm classCode="CLNTRL" moodCode="DEF">
            <id root="2.3.4.6" extension="MLNOQ"/>
            <title value="Arm 2"/>
        </arm>
    </component2>

    <!-- Reason for Revision Example -->
    <component3 typeCode="COMP">
        <controlActEvent classCode="ACTN" moodCode="EVN">
            <text value="Timing events in the protocol refined"/>
            <reasonCode validTimeHigh="20120411">
                <item code="eventsRefined" valueSet="3.2.5.6"/>
            </reasonCode>
        </controlActEvent>
```



```
    </component3>

    <!-- Timing Events Examples -->
    <component4 typeCode="COMP">
        <!-- See Figure 8.3.1.D.6-3 for Examples -->
    </component4>

    <!-- Study Characteristics -->
    <subjectOf typeCode="SUBJ">
        <!-- See Figure 8.3.1.D.6-4 for Examples -->
    </subjectOf>
</clinicalStudyDefinition>
```

Figure 8.3.1.D.6-1: Clinical Study Definition Example

```
<!-- Eligibility Criterion -->
<!-- Adults age 18-55-->
<precondition typeCode="PRCN">
    <conjunctionCode code="AND"/>
    <eligibilityCriterion classCode="CLNTRL" moodCode="CRT">
        <id root="6.2.3.4.5" extension="218"/>
        <code code="AGE" valueSet="3.3.4.5"/>
        <text value="Adults between 18 and 55"/>
        <value xsi:type="IVL_PQ">
            <low value="18" unit="year"/>
            <high value="55" unit="year"/>
        </value>
    </eligibilityCriterion>
</precondition>

<!-- Eligibility Criterion -->
<!-- Patients with Diabetes Mellitus, and not blind, coded in ICD-10 -->
<precondition typeCode="PRCN">
    <conjunctionCode code="AND"/>
    <eligibilityCriterion classCode="CLNTRL" moodCode="CRT">
        <id root="6.2.3.4.5" extension="234"/>
        <code code="DIAG" valueSet="3.3.4.5"/>
        <text value="Diagnosis of Diabetes"/>
        <value xsi:type="CD" code="E10-E14"
codeSystem="2.16.840.1.113883.6.90"/>
        <precondition typeCode="PRCN">
            <conjunctionCode code="AND"/>
            <eligibilityCriterion classCode="CLNTRL" moodCode="CRT">
                <code code="DIAG" codeSystem="3.3.4.5"/>
                <negationInd value="true"/>
                <text value="Not blind"/>
                <value xsi:type="CD" code="H54.0"
codeSystem="2.16.840.1.113883.6.90"/>
            </eligibilityCriterion>
        </precondition>
```



```
    </eligibilityCriterion>
</precondition>
```

Figure 8.3.1.D.6-2: Eligibility Criteria Examples

```
<!-- Study Cell -->
<component4 typeCode="COMP">
    <timePointEventDefinition classCode="CTTEVENT" moodCode="DEF">
        <templateId root=""/>
        <id root="3.2.4.4.5" extension="CELL.SCREEN"/>
        <code code="CELL.SCREEN" codeSystem="1.2.3.4.8.2"
displayName="Screening Cell"/>
        <effectiveTime xsi:type="IVL_TS">
            <low value="20120317"/>
            <high value="20120517"/>
        </effectiveTime>
        <!-- Time Definitions for activities in this segment -->
        <component1 typeCode="COMP">
            <splitCode code=""/>
            <joinCode code=""/>
            <timePointEventDefinition classCode="CTTEVENT" moodCode="DEF">
                <id root="1.2.3.4.8.2" extension="SCREENSEG"/>
                <code code="SCREENSEG" codeSystem="1.2.3.4.8.2"
displayName="Screening Segment"/>

                <!-- Time Definitions for activities in this segment -->
                <component1 typeCode="COMP">
                    <sequenceNumber value="1"/>
                    <timePointEventDefinition classCode="CTTEVENT"
moodCode="DEF">
                        <id root="1.2.3.4.8.2"
extension="ACT.INFORMEDCONSENT"/>
                    </timePointEventDefinition>
                </component1>
                <component1 typeCode="COMP">
                    <sequenceNumber value="2"/>
                    <timePointEventDefinition classCode="CTTEVENT"
moodCode="DEF">
                        <id root="1.2.3.4.8.2"
extension="ACT.PATIENTNUMBERASSIGNMENT"/>
                    </timePointEventDefinition>
                </component1>
                <component1 typeCode="COMP">
                    <sequenceNumber value="3"/>
                    <timePointEventDefinition classCode="CTTEVENT"
moodCode="DEF">
                        <id root="1.2.3.4.8.2"
extension="ACT.MEDICALHISTORY_01"/>
                    </timePointEventDefinition>
                </component1>
                <component1 typeCode="COMP">
                    <sequenceNumber value="4"/>
```



```
                    <timePointEventDefinition classCode="CTTEVENT"
moodCode="DEF">
                        <id root="1.2.3.4.8.2" extension="ACT.VITALSIGNS_01"/>
                    </timePointEventDefinition>
                </component1>
                <component1 typeCode="COMP">
                    <sequenceNumber value="5"/>
                    <timePointEventDefinition classCode="CTTEVENT"
moodCode="DEF">
                        <id root="1.2.3.4.8.2"
extension="ACT.AMB_ECG_PLACEMENT_01"/>
                    </timePointEventDefinition>
                </component1>
                <component1 typeCode="COMP">
                    <sequenceNumber value="6"/>
                    <timePointEventDefinition classCode="CTTEVENT"
moodCode="DEF">
                        <id root="1.2.3.4.8.2"
extension="ACT.AMB_ECG_REMOVAL_01"/>
                    </timePointEventDefinition>
                </component1>
                <component1 typeCode="COMP">
                    <sequenceNumber value="7"/>
                    <pauseQuantity value="7" unit="day">
                        <uncertainRange>
                            <low xsi:type="PQ" value="-24" unit="hours"/>
                            <high xsi:type="PQ" value="48" unit="hours"/>
                        </uncertainRange>
                    </pauseQuantity>
                    <timePointEventDefinition classCode="CTTEVENT"
moodCode="DEF">
                        <id root="1.2.3.4.8.2" extension="ACT.VITALSIGNS_02"/>
                    </timePointEventDefinition>
                </component1>
                <component1 typeCode="COMP">
                    <sequenceNumber value="8"/>
                    <timePointEventDefinition classCode="CTTEVENT"
moodCode="DEF">
                        <id root="1.2.3.4.8.2"
extension="ACT.PATIENTRANDOMIZATION"/>
                    </timePointEventDefinition>
                </component1>
                <component1 typeCode="COMP">
                    <sequenceNumber value="9"/>
                    <timePointEventDefinition classCode="CTTEVENT"
moodCode="DEF">
                        <id root="1.2.3.4.8.2" extension="ACT.HACHINSKI"/>
                    </timePointEventDefinition>
                </component1>
            </timePointEventDefinition>
        </component1>

        <!-- Study Characteristics -->
```



```
        <!-- The screening part of the study is not blinded with respect to the
arms -->
        <subjectOf typeCode="SUBJ">
            <timePointEventCharacteristic classCode="CLNTRL" moodCode="EVN">
                <code code="BLINDED" codeSystem="1.2.3.4.8.2"/>
                <value xsi:type="BL" value="false"/>
            </timePointEventCharacteristic>
        </subjectOf>

        <!-- Epoch Information -->
        <componentOf1 typeCode="COMP">
            <epochStub classCode="CLNTRL" moodCode="DEF">
                <id extension="EP.SCREPOCH" root="1.2.3.4"/>
            </epochStub>
        </componentOf1>

        <!-- Arm Information -->
        <componentOf2 typeCode="COMP">
            <armStub classCode="CLNTRL" moodCode="DEF">
                <id root="2.3.4.6" extension="ARM.PLACEBO"/>
            </armStub>
        </componentOf2>
        <componentOf2 typeCode="COMP">
            <armStub classCode="CLNTRL" moodCode="DEF">
                <id root="2.3.4.6" extension="ARM.LOWDOSE"/>
            </armStub>
        </componentOf2>
        <componentOf2 typeCode="COMP">
            <armStub classCode="CLNTRL" moodCode="DEF">
                <id root="2.3.4.6" extension="ARM.HIGHDOSE"/>
            </armStub>
        </componentOf2>
    </timePointEventDefinition>
</component4>

<!-- Study Cell -->
<!-- Treatment -->
<component4 typeCode="COMP">
    <timePointEventDefinition classCode="CTTEVENT" moodCode="DEF">
        <templateId root=""/>
        <id root="3.2.4.4.5" extension="CELL.TREATMENT"/>
        <code code="CELL.TREATMENT" codeSystem="1.2.3.4.8.2"
displayName="Treatment Cell"/>

        <!-- Study Characteristics -->
        <!-- The treatment part of the study is blinded with respect to the
arms -->
        <subjectOf typeCode="SUBJ">
            <timePointEventCharacteristic classCode="CLNTRL" moodCode="EVN">
                <code code="BLINDED" codeSystem="1.2.3.4.8.2"/>
                <value xsi:type="BL" value="true"/>
            </timePointEventCharacteristic>
        </subjectOf>
```



```
        <!-- Epoch Information -->
        <componentOf1 typeCode="COMP">
            <epochStub classCode="CLNTRL" moodCode="DEF">
                <id extension="EP.TREPOCH" root="1.2.3.4"/>
            </epochStub>
        </componentOf1>

        <!-- Arm Information -->
        <componentOf2 typeCode="COMP">
            <armStub classCode="CLNTRL" moodCode="DEF">
                <id root="2.3.4.6" extension="ARM.PLACEBO"/>
            </armStub>
        </componentOf2>
        <componentOf2 typeCode="COMP">
            <armStub classCode="CLNTRL" moodCode="DEF">
                <id root="2.3.4.6" extension="ARM.LOWDOSE"/>
            </armStub>
        </componentOf2>
        <componentOf2 typeCode="COMP">
            <armStub classCode="CLNTRL" moodCode="DEF">
                <id root="2.3.4.6" extension="ARM.HIGHDOSE"/>
            </armStub>
        </componentOf2>
    </timePointEventDefinition>
</component4>


<!-- Study Cell -->
<!-- Followup -->
<component4 typeCode="COMP">
    <timePointEventDefinition classCode="CTTEVENT" moodCode="DEF">
        <templateId root=""/>
        <id root="3.2.4.4.5" extension="CELL.FOLLOWUP"/>
        <code code="CELL.FOLLOWUP" codeSystem="1.2.3.4.8.2"
displayName="Follow-up Cell"/>

        <!-- Study Characteristics -->
        <!-- The followup part of the study is blinded with respect to the arms
-->
        <subjectOf typeCode="SUBJ">
            <timePointEventCharacteristic classCode="CLNTRL" moodCode="EVN">
                <code code="BLINDED" codeSystem="1.2.3.4.8.2"/>
                <value xsi:type="BL" value="true"/>
            </timePointEventCharacteristic>
        </subjectOf>

        <!-- Epoch Information -->
        <componentOf1 typeCode="COMP">
            <epochStub classCode="CLNTRL" moodCode="DEF">
                <id extension="EP.FUPEPOCH" root="1.2.3.4"/>
            </epochStub>
        </componentOf1>
```



```
        <!-- Arm Information -->
        <componentOf2 typeCode="COMP">
            <armStub classCode="CLNTRL" moodCode="DEF">
                <id root="2.3.4.6" extension="ARM.PLACEBO"/>
            </armStub>
        </componentOf2>
        <componentOf2 typeCode="COMP">
            <armStub classCode="CLNTRL" moodCode="DEF">
                <id root="2.3.4.6" extension="ARM.LOWDOSE"/>
            </armStub>
        </componentOf2>
        <componentOf2 typeCode="COMP">
            <armStub classCode="CLNTRL" moodCode="DEF">
                <id root="2.3.4.6" extension="ARM.HIGHDOSE"/>
            </armStub>
        </componentOf2>
    </timePointEventDefinition>
</component4>


<!-- Study Cell -->
<!-- Informed Consent -->
<component4 typeCode="COMP">
    <timePointEventDefinition classCode="CTTEVENT" moodCode="DEF">
        <id root="3.2.4.4.5" extension="ACT.INFORMEDCONSENT"/>
        <code code="ACT.INFORMEDCONSENT" codeSystem="1.2.3.4.8.2"
displayName="Informed Consent"/>

        <!-- Study Characteristics -->
        <!-- Clinical Research Document (CRD) Form -->
        <subjectOf typeCode="SUBJ">
            <timePointEventCharacteristic classCode="VERIF" moodCode="EVN">
                <id root="1.2.3.4.5" extension="form1ID"/>
                <code code="FO.INFORMEDCONSENT" codeSystem="1.2.3.4.8.2" />
                <value xsi:type="TEL"
value="https://some.formmanager.addr/forms/"/>
            </timePointEventCharacteristic>
        </subjectOf>
    </timePointEventDefinition>
</component4>


<!-- Study Cell -->
<!-- Visit Activity -->
<component4 typeCode="COMP">
    <timePointEventDefinition classCode="CTTEVENT" moodCode="DEF">
        <id root="3.2.4.4.5" extension="VisitDefinitionID"/>
        <code code="ACT.VISIT" codeSystem="1.2.3.4.8.2"/>

        <!-- Content Definitions - Encounter Detail -->
        <component2 typeCode="COMP">
            <encounter classCode="ENC" moodCode="DEF">
```



```
                <code code="Visit1" codeSystem="1.2.3.4.8.2"/>
                <effectiveTime xsi:type="IVL_TS">
                    <low value="201206110900"/>
                    <high value="201206140900"/>
                </effectiveTime>
                <activityTime xsi:type="TS" value="201206120900"/>
            </encounter>
        </component2>

        <!-- Study Characteristics -->
        <!-- Clinical Research Document (CRD) Form -->
        <subjectOf typeCode="SUBJ">
            <timePointEventCharacteristic classCode="VERIF" moodCode="EVN">
                <id root="1.2.3.4.5" extension="form2ID"/>
                <code code="FO.VISIT" codeSystem="1.2.3.4.8.2" />
                <value xsi:type="TEL"
value="https://some.formmanager.addr/forms/"/>
            </timePointEventCharacteristic>
        </subjectOf>
    </timePointEventDefinition>
</component4>

<!-- Study Cell -->
<!-- Vital Signs activity -->
<component4 typeCode="COMP">
    <timePointEventDefinition classCode="CTTEVENT" moodCode="DEF">
        <id root="1.2.3.4.8.2" extension="ACT.VITALSIGNS_01"/>
        <code code="ACT.VISIT" codeSystem="1.2.3.4.8.2"/>

        <!-- Content Definitions - Clinical Observation-->
        <component2 typeCode="COMP">
            <observation classCode="CLNTRL" moodCode="EVN">
                <code code="Observation1" codeSystem="3.4.2.3.5"/>
            </observation>
        </component2>

        <!-- Study Characteristics -->
        <!-- Clinical Research Document (CRD) Form -->
        <subjectOf typeCode="SUBJ">
            <timePointEventCharacteristic classCode="VERIF" moodCode="EVN">
                <id root="1.2.3.4.5" extension="form3ID"/>
                <code code="FO.VITALS" codeSystem="1.2.3.4.8.2" />
                <value xsi:type="TEL"
value="https://some.formmanager.addr/forms/"/>
            </timePointEventCharacteristic>
        </subjectOf>
        <!-- Billed to regular care, and not to Clinical Trial -->
        <subjectOf typeCode="SUBJ">
            <timePointEventCharacteristic classCode="VERIF" moodCode="EVN">
                <code code="BILL_TO_TRIAL" codeSystem="1.2.3.4.8.2" />
                <value xsi:type="BL" value="false"/>
            </timePointEventCharacteristic>
```



```
        </subjectOf>
    </timePointEventDefinition>
</component4>


<!-- Study Cell -->
<!-- ECG activity -->
<component4 typeCode="COMP">
    <timePointEventDefinition classCode="CTTEVENT" moodCode="DEF">
        <id root="1.2.3.4.8.2" extension="ACT.AMB_ECG_PLACEMENT_01"/>
        <code code="ACT.AMB_ECG_PLACEMENT_01" codeSystem="1.2.3.4.8.2"/>

        <!-- Patient is in this activity -->
        <subject typeCode="SBJ">
            <experimentalUnit classCode="RESBJ">
                <subjectPersonKind classCode="PSN" determinerCode="KIND">
                    <id extension="patID" root="2.1.3.4.5.9"/>
                </subjectPersonKind>
            </experimentalUnit>
        </subject>

        <!-- Content Definitions - Procedure-->
        <component2 typeCode="COMP">
            <procedure classCode="PROC" moodCode="EVN">
                <code code="Procedure1" codeSystem="3.4.2.3.5"/>
            </procedure>
        </component2>

        <!-- Study Characteristics -->
        <!-- Clinical Research Document (CRD) Form -->
        <subjectOf typeCode="SUBJ">
            <timePointEventCharacteristic classCode="VERIF" moodCode="EVN">
                <id root="1.2.3.4.5" extension="form3ID"/>
                <code code="FO.VITALS" codeSystem="1.2.3.4.8.2" />
                <value xsi:type="TEL"
value="https://some.formmanager.addr/forms/"/>
            </timePointEventCharacteristic>
        </subjectOf>
    </timePointEventDefinition>
</component4>
```

Figure 8.3.1.D.6-3: Timing Events Examples

```
<!-- Study Characteristic -->
<!-- Version of Study -->
<subjectOf typeCode="SUBJ">
    <studyCharacteristic classCode="CLNTRL" moodCode="EVN">
        <code code="VERSION" valueSet="7.6.5.4" displayName="Version of the
study"/>
        <statusCode code="active"/>
        <value xsi:type="ST" value="V1.3"/>
    </studyCharacteristic>
```



```
</subjectOf>

<!-- Study Characteristic -->
<!-- Duration of Study -->
<subjectOf typeCode="SUBJ">
    <studyCharacteristic classCode="CLNTRL" moodCode="EVN">
        <code code="Duration" valueSet="7.6.5.4"/>
        <statusCode code="active"/>
        <value xsi:type="IVL_TS">
            <low value="20120325"/>
            <high value="20120825"/>
        </value>
    </studyCharacteristic>
</subjectOf>

<!-- Study Characteristic -->
<!-- Active Phase of Study -->
<subjectOf typeCode="SUBJ">
    <studyCharacteristic classCode="CLNTRL" moodCode="EVN">
        <code code="Phase" valueSet="7.6.5.4"/>
        <statusCode code="active"/>
        <value xsi:type="INT" value="4"/>
    </studyCharacteristic>
</subjectOf>
```

Figure 8.3.1.D.6-4: Study Characteristics Examples

Appendices

Not applicable.

Volume 4 – National Extensions

Not applicable.

