

# HITSP Clinical Research Workflow Component

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HITSP/C156



Healthcare Information Technology Standards Panel

*Submitted to:*

**Healthcare Information Technology Standards Panel**

*Submitted by:*

**Care Management and Health Records Domain Technical Committee**



## DOCUMENT CHANGE HISTORY

Version Number	Description of Change	Name of Author	Date Published
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## 1.0 INTRODUCTION

### 1.1 OVERVIEW

The Healthcare Information Technology Standards Panel (HITSP) Clinical Research Workflow Component describes the Clinical Data Acquisition Standards Harmonization (CDASH) data elements and common identifier variables that pertain to the research-specific workflow. HITSP/C151 Clinical Research Document (CRD) defines the clinical research data to populate a clinical research form using Retrieve Form Data Capture (RFD). Clinical Research Workflow describes the data elements that allow the RFD system roles Form Filler and Form Manager to identify what needs to be done. Clinical Research Workflow defines the content and format of the workflow data to be used within the Retrieve Form transaction described within the RFD Integration Profile. The purpose of Clinical Research Workflow is to support a standard set of data specific to research usage, as found in CDISC CDASH standard.

### 1.2 COPYRIGHT PERMISSIONS

#### COPYRIGHT NOTICE

© 2010 ANSI. This material may be copied without permission from ANSI only if and to the extent that the text is not altered in any fashion and ANSI's copyright is clearly noted.

### 1.3 REFERENCE DOCUMENTS

A list of key reference documents and background material is provided in the table below. HITSP-maintained reference documents can be retrieved from the [HITSP Web Site](#).

**Table 1-1 Reference Documents**

Reference Document	Document Description
<a href="#">HITSP Acronyms List</a>	Lists and defines the acronyms used in this document
<a href="#">HITSP Glossary</a>	Provides definitions for relevant terms used by HITSP documents
<a href="#">TN900 - Security and Privacy</a>	TN900 is a reference document that provides the overall context for use of the HITSP Security and Privacy constructs
<a href="#">TN903 - Data Architecture</a>	TN903 is a reference document that provides the overall context for use of the HITSP Data Architecture constructs
<a href="#">TN904 - Harmonization Framework and Exchange Architecture</a>	TN904 is a reference document that provides the overall context for use of the HITSP Harmonization Framework and Exchange Architecture

### 1.4 CONFORMANCE

This section describes the conformance criteria, which are objective statements of requirements that can be used to determine if a specific behavior, function, interface, or code set has been implemented correctly.

#### 1.4.1 CONFORMANCE CRITERIA

In order to claim conformance to this construct specification, an implementation must satisfy all the requirements and mandatory statements listed in this specification, the associated HITSP Interoperability Specification or Capability, its associated construct specifications, as well as conformance criteria from the selected base and composite standards. A conformant system must also implement all of the required



interfaces within the scope, subset or implementation option that is selected from the associated Interoperability Specification.

Claims of conformance may only be made for the overall HITSP Interoperability Specification or Capability with which this construct is associated.

#### 1.4.2 CONFORMANCE SCOPING, SUBSETTING AND OPTIONS

A HITSP Interoperability Specification or Capability must be implemented in its entirety for an implementation to claim conformance to the specification. HITSP may define the permissibility for interface scoping, subsetting or implementation options by which the specification may be implemented in a limited manner. Such scoping, subsetting and options may extend to associated constructs, such as this construct. This construct must implement all requirements within the selected scope, subset or options as defined in the associated Interoperability Specification or Capability to claim conformance.



## 2.0 COMPONENT DEFINITION

### 2.1 CONTEXT OVERVIEW

The Clinical Research Workflow Component describes the CDASH data elements and common identifier variables that pertain to the research-specific workflow. It prescribes the content and format to be used within the Retrieve Form Request transaction within RFD, which uses Web-Services as transport described within the IHE ITI 34 Integration Profile.

#### 2.1.1 COMPONENT DEPENDENCIES

Table 2-1 Component Dependencies

Standard/HITSP Component	Depends On (Name of standard/HITSP Component that it depends on)	Dependency Type (Pre-condition, Post-condition, General)	Purpose (Reason for this dependency)
HITSP/C156– Clinical Research Workflow	HITSP/TP50 – Retrieve Form for Data Capture	Integration Profile	This is a content profile that is used in the context of the RFD Integration profile
HITSP/C156 – Clinical Research Workflow	HITSP/C154 – Data Dictionary	General	Identifies the data in the workflow elements used by this Component

### 2.2 RULES FOR IMPLEMENTING

#### 2.2.1 DATA MAPPING

The following sections describe the content modules for the Clinical Research Document.

##### 2.2.1.1 CLINICAL RESEARCH DOCUMENT

C156-[CT1-01] Implementations of this Component SHALL support IHE CRD with the specific HITSP constraint on the workflow data specified in Table 2-2.

Table 2-2 Data Mapping – Clinical Research Workflow

CDASH Data Elements	HITSP Data Elements	HITSP Optional Entry	HITSP Repeatable Entry	Specification Reference
workflowData/context/SplID (Sponsor Identifier)	23.01 Sponsor ID	R	N	
workflowData/context/StudyID (Protocol/Study Identifier)	23.02 Protocol Study ID	R	N	
workflowData/context/SiteID (Study Site Identifier)	23.03 Study Site ID	R	N	
workflowData/context/SubjID (Subject Identifier)	1.02 Person ID	R	N	
workflowData/context/InvID (Investigator Identifier)	23.04 Investigator ID	O	N	
workflowData/context/Visit (Study Visit)	16.01 Encounter ID, 16.02 Encounter Type, 16.03 Encounter Free Text Type	R	N	C154-[DE-16.02-1] Encounter Type <b>SHOULD</b> be coded as specified in HITSP/C80 Section 2.2.3.9.3 Encounter Type
workflowData/context/VisDatTim (Date of Visit)	16.04 Encounter Date/Time	R	N	

Optionality Legend: “R” for Required, “R2” for Required if Known or “O” for Optional, or “C” for Conditional. Repeatable = “Y” for Yes, “N” for No



## GUIDELINES AND EXAMPLES

```
<context>
  <StudyID> a String identifying the Protocol/Study Identifier </ StudyID >
  <SiteID> a String identifying the Site Identifier </ SiteID >
  <SubjID> a String identifying the Subject Identifier </ SubjID >
  <InvID> a String identifying the Investigator Identifier </ InvID >
  <Visit> a String identifying the Visit Name </ Visit >
  <VisitNum> a String identifying the Visit Number </ VisitNum >
  <VisDatTim>
    <effectiveTime xsi:type='TS'>
      <low value=' '/>
      <high value=' '/>
    </effectiveTime>
  </ VisDatTim >
  <PrePopArchiveID> a String identifying the Prepopulation Archive XDSDocumentEntry.uniqueld
</PrePopArchiveID>
</context>
```

## 2.3 STANDARDS

### 2.3.1 REGULATORY GUIDANCE

Table 2-3 Regulatory Guidance

Regulation	Description
No applicable regulatory guidance	

### 2.3.2 SELECTED STANDARDS

Table 2-4 Selected Standards

Standard	Description
IHE Integrating the Healthcare Enterprise (IHE) Quality, Research and Public Health (QRPH) Technical Framework Supplement Clinical Research Document (CRD) Trial Implementation Supplement, August 20, 2009	The Clinical Research Document Profile (CRD) describes the content and format to be used within the Retrieve Form Request described within the RFD Integration Profile and an additional Archive CRD Data transaction that reuses the Provide and Register Set transaction with Web-Services as transport described within the IHE ITI XDS Integration Profile (for cross-enterprise 85 document sharing). The purpose of this profile is to support a standard set of pre-population and workflow data in which the Form Filler provides for use in Clinical Research. This profile also extends the Form Filler's capability and provides for an additional Archive CRD Data transaction for the pre-population and workflow data. For more information visit <a href="http://www.ihe.net">www.ihe.net</a>

### 2.3.3 INFORMATIVE REFERENCE STANDARDS

Table 2-5 Informative Reference Standards

Standard	Reason for Use
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) 2007 – 2008 Supplement, Retrieve Form for Data Capture (RFD) Integration Profile	The Retrieve Form for Data Capture Profile (RFD) provides a method for gathering data within a user's current application to meet the requirements of an external system. RFD supports the retrieval of forms from a form source, display and completion of a form, and return of instance data from the display application to the source application. The profile relies upon XForms technology to support negotiation between the form display and form provider systems, so that iterative exchanges can deal with issues like form selection, completion of a series of forms, partial completion of forms, returning to forms partially filled out in earlier sessions. RFD also supports archiving a copy of the completed form. For more information visit <a href="http://www.ihe.net">www.ihe.net</a>





Standard	Reason for Use
Clinical Data Interchange Standards Consortium (CDISC) CDASH STD-1.0 2008-10-0	CDASH describes recommended (minimal) data collection sets case report forms, for 16 domains, including demographic, adverse events, and other safety domains that are common to all therapeutic areas and types of clinical research. The document also includes implementation recommendations and best practice guidelines, regulatory references and other information on the CDASH project. <a href="#">CDASH STD-1.0 2008-10-0</a> For more information visit <a href="http://www.cdisc.org">www.cdisc.org</a>



## 3.0 APPENDIX

The following sections include relevant materials referenced throughout this document.

### Template Identifiers

See the relevant HL7 Implementation Guides and IHE Profiles for a complete listing of all other template identifiers that are required for declaring conformance to HITSP defined templates.

- [2.16.840.1.113883.3.88.11.48.1 HITSP/C151 Clinical](#) Research Document



## 4.0 DOCUMENT UPDATES

This section provides the history of changes made to this document.

### 4.1 NOVEMBER 9, 2009

No changes. This is the first published version of the document.

### 4.2 JANUARY 18, 2010

- Updated to conform to new HITSP template
- Corrected misspellings and grammatical errors

### 4.3 JANUARY 25, 2010

Upon approval by the HITSP Panel on January 25, 2010, this document is now Released for Implementation.

