

# HITSP Clinical Research Document Component

---

HITSP/C151



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
Template V2.4	Template Update	Project Team	July 31, 2008
0.0.1	Review Copy	Care Management and Health Records Domain Technical Committee	November 9, 2009
0.0.2	Review Copy	Care Management and Health Records Domain Technical Committee	January 18, 2010
1.0	Released for Implementation	Care Management and Health Records Domain Technical Committee	January 25, 2010



## TABLE OF CONTENTS

<b>1.0</b>	<b>INTRODUCTION.....</b>	<b>5</b>
1.1	Overview.....	5
1.2	Copyright Permissions.....	5
1.3	Reference Documents.....	5
1.4	Conformance .....	5
1.4.1	Conformance Criteria .....	5
1.4.2	Conformance Scoping, Subsetting and Options .....	6
<b>2.0</b>	<b>COMPONENT DEFINITION.....</b>	<b>7</b>
2.1	Context Overview .....	7
2.1.1	Component Dependencies .....	7
2.2	Rules for Implementing.....	7
2.2.1	Data Mapping .....	7
2.2.1.1	Clinical Research Document.....	7
2.3	Standards .....	8
2.3.1	Regulatory Guidance .....	8
2.3.2	Selected Standards .....	8
2.3.3	Informative Reference Standards.....	9
<b>3.0</b>	<b>APPENDIX .....</b>	<b>10</b>
<b>4.0</b>	<b>DOCUMENT UPDATES .....</b>	<b>11</b>
4.1	November 9, 2009 .....	11
4.2	January 18, 2010 .....	11
4.3	January 25, 2010 .....	11



## FIGURES AND TABLES

Table 1-1 Reference Documents .....	5
Table 2-1 Component Dependencies .....	7
Table 2-2 Data Mapping - Clinical Research Document.....	8
Table 2-3 Regulatory Guidance .....	8
Table 2-4 Selected Standards .....	8
Table 2-5 Informative Reference Standards .....	9



## 1.0 INTRODUCTION

### 1.1 OVERVIEW

The Healthcare Information Technology Standards Panel (HITSP) Clinical Research Document (CRD) Component describes the content and format to be used for pre-population data within the Retrieve Form Transaction described within the IHE Retrieve Form for Data-Capture (RFD) Integration Profile. HITSP supports RFD through HITSP/TP50 Retrieve Form for Data Capture.

The purpose of the CRD Component is to support a standard set of data in the HL7 Continuity of Care Document (CCD) format which the Form Filler provides for use in Clinical Research. In addition this profile will reference the ability to convert this output into a standard case report form (Standard CRF) based on the Clinical Data Acquisition Standards Harmonization (CDASH) specification and the Operational Data Modal (ODN) of Clinical Data Interchange Standards Consortium (CDISC).

### 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

#### 2.1.1 COMPONENT DEPENDENCIES

Table 2-1 Component Dependencies

Standard/HITSP Component	Depends On (Name of HITSP Component that it depends on)	Dependency Type (Pre-condition, Post-condition, General)	Purpose (Reason for this dependency)
HITSP/C151 – Clinical Research Document	HITSP/C83 – CDA Content Modules	General	Identifies the data in the workflow elements used by this Component
HITSP/C151 – Clinical Research Document	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

### 2.2 RULES FOR IMPLEMENTING

#### 2.2.1 DATA MAPPING

For all constraints applied to the data the reader must refer to:

- HITSP/C83 CDA Content Modules
- IHE Clinical Research Document Trial Implementation Supplement CRD composite standard, which describes the content and format used by the Retrieve Form Request [ITI-34] and an additional Archive CRD Data transaction which reuses the Provide and Register Set transaction [ITI-15] with Web-Services as transport described within the IHE ITI XDS Integration Profile

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

##### 2.2.1.1 CLINICAL RESEARCH DOCUMENT

C151-[CT3-1] Implementations of this Component **SHALL** support Integrating the Healthcare Enterprise (IHE) Quality, Research and Public Health (QRPH) Technical Framework Supplement Clinical Research Document (CRD) Trial Implementation Supplement, August 20, 2009 Additional HITSP constraints are specified in Table 2-2

The template identifier for this 2.16.840.1.113883.3.88.11.151.1

C151-[CT3-2] Implementations of this Component **SHALL** declare conformance to this specification by including a **<templateId>** element with the root attribute set to the value 2.16.840.1.113883.3.88.11.151.1

HITSP has requested LOINC to add the code “Clinical Document” to the document type value set. Implementations should use this code once created by LOINC. Feature versions of this Component may require the use of the pending LOINC code.



**Table 2-2 Data Mapping - Clinical Research Document**

Constraint ID	Content Module	HITSP Optional Entry <sup>1</sup>	HITSP Repeatable Entry	Specification Reference
C151-[CT2-1]	Active Problems	R	N	See HITSP/C83 Section 2.2.2.7 Active Problems
C151-[CT2-2]	Allergies and Other Adverse Reactions	R	N	See HITSP/C83 Section 2.2.2.6 Allergy/Drug Sensitivity
C151-[CT2-3]	Current Medications	R	N	See HITSP/C83 Section 2.2.2.8 Medications
C151-[CT2-4]	Physical Exam	R2	N	See HITSP/C83 Section 2.2.2.7 Condition
C151-[CT2-5]	Social History	R2	N	See HITSP/C83 Section 2.2.2.19 Social History
C151-[CT2-6]	Vital Signs	R2	N	See HITSP/C83 Section 2.2.2.14 Vital Signs
C151-[CT2-7]	Coded Results	R2	N	See HITSP/C83 Section 2.2.2.15 Result
C151-[CT2-8]	Past Medical History	R2	N	See HITSP/C83 Section 2.2.2.7 Condition
C151-[CT2-9]	Procedures and Interventions	R2	N	See HITSP/C83 Section 2.2.2.17 Procedures

**GUIDELINES AND EXAMPLES**

The link below to the IHE Quality, Research and Public Health (QRPH) Technical Framework Supplement Clinical Research Document (CRD) Trial Implementation Supplement provides guidelines and examples for implementation.

[ftp://ftp.ihe.net/Quality/2009\\_2010\\_YR\\_3/Technical/TrialImplementation/PublishedVersions/IHE\\_QRPH\\_TF\\_Supplement\\_CRD\\_TI\\_2009-08-11.pdf](ftp://ftp.ihe.net/Quality/2009_2010_YR_3/Technical/TrialImplementation/PublishedVersions/IHE_QRPH_TF_Supplement_CRD_TI_2009-08-11.pdf)

**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>

<sup>1</sup> Optionality = "R" for Required, "R2" for Required if Known or "O" for Optional, or "C" for Conditional. Repeatable = "Y" for yes, "N" for No



### 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>
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="http://www.cdisc.org">CDASH STD-1.0 2008-10-0</a> For more information visit <a href="http://www.cdisc.org">www.cdisc.org</a>
Operational Data Model (ODM) of Clinical Data Interchange Standards Consortium (CDISC)	The Clinical Data Interchange Standards Consortium (CDISC) describes the release of a final version 1.1 Specification for the Operational Data Model (ODM). The XML-based Operational Data Model provides a format for representing the study metadata, study data, and administrative data associated with a clinical trial. It represents only the data that would be transferred among different software systems during a trial, or archived after a trial. 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.

- A listing of all HITSP Template identifiers defined within 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.

- 2.16.840.1.113883.3.88.11.151.1 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

Changes based upon Public Comments:

- 8619, 8620

The full text of the comments along with the Technical Committee's disposition can be reviewed on the [HITSP Public Web Site](#).

- Updated to conform to new HITSP template
- Corrected Table 2-1 rows 2 and 3, column 1
- Corrected Table 2-4 to reflect appropriate content modules of HITSP/C83
- Corrected misspellings and grammatical errors
- Removed reference to HITSP/C154-Data Dictionary as specific data elements are not constraint via this construct. They are constrained by supporting the HITSP/C83 CDA Content Modules sections
- Turned constraint C151-[CT3-2] into text as the document type of Clinical Document has not yet been placed into LOINC
- Corrected the constraint for the HITSP template
- Deleted Appendix Section 3.1 HITSP Constraints in this Document as it is duplicate information already defined

### 4.3 JANUARY 25, 2010

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

