

HITSP Retrieve and Populate Form Capability

HITSP/CAP135



Healthcare Information Technology Standards Panel

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1.0 INTRODUCTION

This Healthcare Information Technology Standards Panel (HITSP) document is divided into Requirements Analysis, External Capability Options, Design Specifications and Standards sections which may be used by analysts, architects and implementers. Analysts refer to this document to determine if the Capability satisfies their requirements. Architects and system implementers refer to this document as the architectural specifications for a system design, while software developers will use a Capability as the source of the design for interoperable information exchange. The Appendix lists requirements satisfied by this Capability.

All sections may be useful to analysts and architects. However as shown in Table 1-1, different readers may find specific sections of greater interest and utility. This table is provided as an aid to readers to assist them in identifying sections to focus on. Readers are encouraged to review all sections of this document to further their understanding of HITSP's work.

Table 1-1 Reader's Guide for Capability

Document Section	Section Number	Intended Audience	Information Contained
Section 2.0 Requirements Analysis	2.1 Introduction	Policy Managers Policy Analysts Executive Leadership	Provides an overview of the requirements which this Capability addresses, and identifies the system roles supported by the Capability
	2.2 Requirements	Program Managers Policy Analysts Executive Leadership Architects Business Analysts	Defines the actual information exchanges supported by the Capability in terms of exchange actions and exchange content. It shows how these roles can be assigned at a higher level to real world systems, such as an Electronic Health Record
Section 3.0 External Capability Options	3.1 Security and Privacy	Policy Analysts Architects Business Analysts Developers	Describes the integrated and optional Security and Privacy functions supported by the Capability
Section 4.0 Design Specification	4.1 Requirements Mapped to Constructs	Program Managers Architects Business Analysts Developers	Maps the information exchanges developed in requirements to the actual HITSP construct used by the Capability to support the exchange
	4.2 Constraints and Assumptions	Business Analysts Developers	Lists the context that is necessary to use the Capability, including constraints, assumptions, pre-conditions, post-conditions and triggers
	4.3 Specified Interfaces by System Role	Business Analysts Developers	Identifies the constructs and their interfaces assigned to each system role. It also lists the implementation conditions for use
Section 5.0 Standards	5.1 Standards Used	Program Managers Policy Analysts Architects Business Analysts Developers	Lists regulatory guidance, selected standards and informative references used by the Capability and all its supporting constructs
	5.2 Standards Gaps and Overlaps	Program Managers Policy Analysts Architects Business Analysts Developers	Identifies gaps or overlaps in standards to implement the Capability including a plan to resolve issues

1.1 CAPABILITY OVERVIEW

This Capability addresses interoperability requirements to support the upload of specific captured data (e.g., public health surveillance reportable conditions, healthcare associated infection reporting, clinical



research case report forms) to Public Health Monitoring Systems, Quality Organizations Systems, and clinical research sponsored systems such as Electronic Data Capture (EDC) and Electronic Source Document Archiving systems. The forms presented may be pre-populated by information provided by the clinical or laboratory information systems to avoid manual re-entry. A number of supplemental information variables may be captured from within the user's clinical information system to improve the workflow and timeliness of required reporting. One or more types of form content may be supported:

- Pre-population for Public Health Case Reports from Structured Documents using CDA
- Pre-population for Quality Data from Structured Documents using CDA
- Pre-population for clinical research using HITSP/C151 Clinical Research Document
- No pre-population content

The request for clarification function found in HITSP/TP50 and Integrating the Healthcare Enterprise (IHE) Retrieve Form for Data Capture is not included in this Capability.

1.2 SCOPE

A Capability enables business and policy requirements for a business need to be implemented through information exchanges specified in HITSP constructs. The objective of a Capability is to provide the bridge between the business, policy and implementation disciplines by defining a set of information exchanges at a level relevant to policy and business decisions and specifying the use of HITSP constructs sufficiently for implementation. A Capability supports stakeholder requirements and business processes and includes information content, infrastructure, security and privacy. The design of Capabilities leverages existing HITSP constructs and communication methodologies. As new constructs become available, the scope of this Capability may be extended.

1.3 COPYRIGHT PERMISSIONS

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1.4 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 1-2 Reference Documents

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



1.5 GUIDANCE FOR USE OF A CAPABILITY

NOTE: For questions related to details on HITSP Capabilities and HITSP System Roles, please refer to HITSP/TN904 Harmonization Framework and Exchange Architecture Technical Note.

To use a HITSP Capability, a HITSP Interoperability Specification or an implementation conformance statement must assign specific systems to one or more HITSP Capability System Roles and identify how the HITSP Capability Options are to be addressed. In order to assign systems to HITSP System Roles, the reader uses Table 2-3 Supported Information Exchanges to determine what systems can support the specific information exchanges required. For an example of how HITSP System Roles and systems are mapped, readers can consult a HITSP Interoperability Specification Table 3-3 Orchestration of Capabilities by System. In the case of an Implementation Guide, systems can be assigned to HITSP System Roles using a similar methodology.

The use of a HITSP Capability implies that these specific rules will be followed:

For each HITSP Capability System Role listed in Table 2-2 Capability System Roles, the defined responsibilities of that HITSP Capability System Role are supported. Responsibilities for the HITSP Capability System Role are defined as support for the HITSP Construct interfaces listed in Section 4.3 Specified Interfaces by System Role. Support implies that the system assigned to the HITSP Capability System Role makes the associated HITSP construct interfaces available for use by other systems. For those HITSP construct interfaces in Section 4.3 that have associated content optionality, the HITSP Capability System Role must comply with the optionality condition listed in Table 4-8 Implementation Conditions.

Responsibilities also include the constraints and assumptions associated with use of a Capability, as outlined in Table 4-3 Context. For those Capabilities with Section 3.2 options, the following additional rules apply:

1. Each topology option listed in Table 3-2 Topology Related Options should be supported by the implementation
2. Each content import option listed in Table 3-3 Content Import Options should be supported by the implementation
3. Each document content option listed in Table 3-4 Document Content Options should be supported by the implementation



2.0 REQUIREMENTS ANALYSIS

The following table is provided as an aid to readers to assist them in identifying the parts of this section to focus on. Readers are encouraged to review all sections of this document to further their understanding of HITSP's work.

Table 2-1 Reader's Guide for Section 2.0

Document Section	Section Number	Intended Audience	Information Contained
Section 2.0 Requirements Analysis	2.1 Introduction	Policy Managers Policy Analysts Executive Leadership	Provides an overview of the requirements which this Capability addresses, and identifies the system roles supported by the Capability
	2.2 Requirements	Program Managers Policy Analysts Executive Leadership Architects Business Analysts	Defines the actual information exchanges supported by the Capability in terms of exchange actions and exchange content. It shows how these roles can be assigned at a higher level to real world systems, such as an Electronic Health Record

2.1 INTRODUCTION

Table 2-2 summarizes the system roles of the Capability. Section 2.2 identifies how these system roles participate in the set of information exchanges.

Table 2-2 Capability System Roles

System Role	System Role Definition
Form Filler	Retrieves form from Form Manager; Provides pre-population data to Form Manager; Returns data instance to Form Receiver; Archive data instance in Forms Archiver
Form Manager	Binds pre-population data to form; Returns pre-populated form to Form Filler
Form Receiver	Receives data instance, i.e. completed form, from Form Filler
Form Archiver	Receives data instance, i.e. completed form, from Form Filler as an archive

2.2 REQUIREMENTS

2.2.1 INFORMATION EXCHANGES

Table 2-3 defines each of the Information Exchanges supported by this Capability in terms of the Exchange Action (EA) or Exchange Content (EC) used.

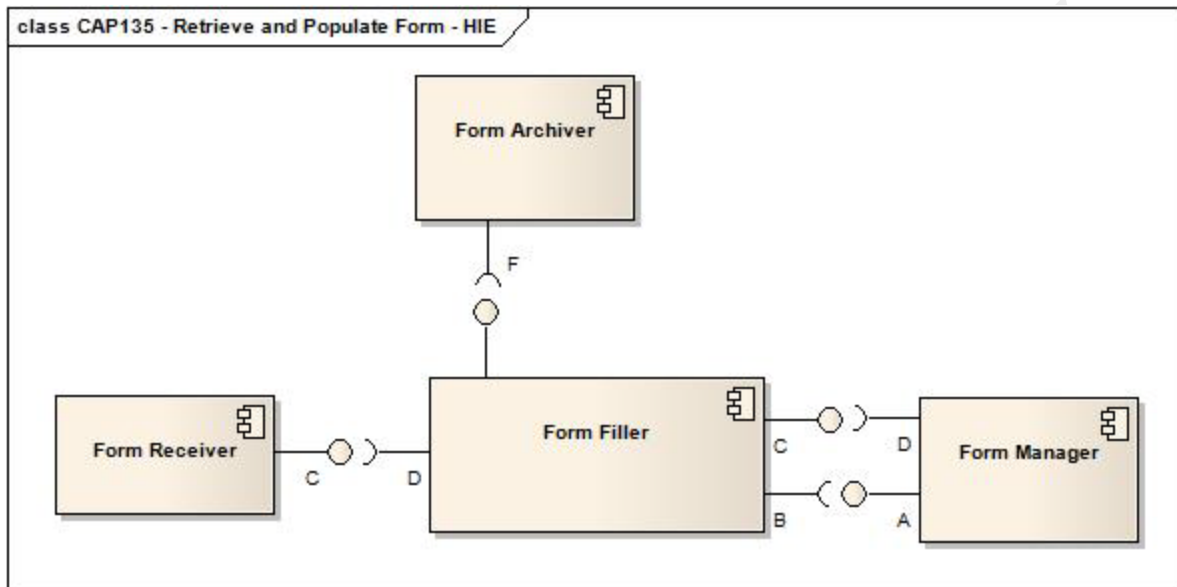
Table 2-3 Supported Information Exchanges

Information Exchange Identifier	Exchange Action	Exchange Content
A	Send	Pre-population data
B	Receive	Pre-population data
C	Send	Pre-populated form
D	Receive	Pre-populated form
E	Send	Data instance
F	Receive	Data instance



Figure 2-1 identifies how this Capability supports various system roles within multiple system architectures. For example, either an Electronic Health Record (EHR) system or a Health Information Exchange (HIE) might fill a document repository system role in an information exchange. In an implementation architecture, system roles may be combined locally (e.g., Hospital EHR System) and in others, the system roles may be provided by multiple-distributed trusted third parties (e.g., pharmacies within an HIE).

Figure 2-1 Information Exchanges Between System Roles



3.0 EXTERNAL CAPABILITY OPTIONS

The following table is provided as an aid to readers to assist them in identifying the parts of this section to focus on. Readers are encouraged to review all sections of this document to further their understanding of HITSP's work.

Table 3-1 Reader's Guide for Section 3.0

Document Section	Section Number	Intended Audience	Information Contained
Section 3.0 External Capability Options	3.1 Security and Privacy	Policy Analysts Architects Business Analysts Developers	Describes the integrated and optional Security and Privacy functions supported by the Capability

This section is primarily for architects, engineers and analysts. It allows those who consider using this Capability to evaluate and/or constrain the options that are externally made available for the Capability implementers.

Interoperability among system roles defined by this Capability often requires the selection of consistent options.

3.1 SECURITY AND PRIVACY

The application of Security and Privacy is highly influenced by the security and privacy policies. The HITSP Security and Privacy Technical Note (HITSP/TN900) provides a detailed discussion of the Security and Privacy constructs, including consideration and appropriate context for needed security and privacy related policy decisions. Security and Privacy constructs are integrated comprehensively into the Service Collaborations. The actual constructs used and the way in which the constructs are used is dependent on the policies and physical setting. Conformance claims are against the Security and Privacy constructs that are chosen to enforce the policies.



4.0 DESIGN SPECIFICATION

The following table is provided as an aid to readers to assist them in identifying the parts of this section to focus on. Readers are encouraged to review all sections of this document to further their understanding of HITSP's work.

Table 4-1 Reader's Guide for Section 4.0

Document Section	Section Number	Intended Audience	Information Contained
Section 4.0 Design Specification	4.1 Requirements Mapped to Constructs	Program Managers Architects Business Analysts Developers	Maps the information exchanges developed in requirements to the actual HITSP construct used by the Capability to support the exchange
	4.2 Constraints and Assumptions	Business Analysts Developers	Lists the context that is necessary to use the Capability including constraints, assumptions, pre-conditions, post-conditions, and triggers
	4.3 Specified Interfaces by System Role	Business Analysts Developers	Identifies the constructs and their interfaces assigned to each system role. It also lists the implementation conditions for use

4.1 REQUIREMENTS MAPPED TO CONSTRUCTS

4.1.1 CONSTRUCTS

Table 4-2 defines the mapping of the Information Exchanges supported by this Capability in terms of the Exchange Action (EA), Exchange Content (EC) and any Constraints applied to the Information Exchange with specific initiating and/or responding system interfaces. This provides the traceability of constructs to the information exchanges identified in Section 2.0 above. Content modules and terminology Components are not listed here because they are referenced by other constructs, but do not provide an interface. HITSP/TN903 discusses how content modules and terminology Components are referenced by other constructs.

Table 4-2 Information Exchanges Mapped to Constructs

Information Exchange Identifier	Exchange Type	Construct Identifier	Description
A,B,C,D,E,F	Action	HITSP/TP50- Retrieve Form for Data Capture HITSP/T17 – Secured Communication Channel HITSP/SC108 – Access Control HITSP/SC109 – Security Audit	Provides for the capture and submission of filled or pre-populated specific data to Public Health Monitoring Systems, Quality Organizations Systems, and Clinical Research Systems
A,B,C,D,E,F	Action	HITSP/T17 – Secured Communication Channel HITSP/SC108 – Access Control HITSP/SC109 – Security Audit	Provides the electronic communication (transport mechanism) for conducting secure communication between Form Filler and Form Receiver/Manager/Archiver



Information Exchange Identifier	Exchange Type	Construct Identifier	Description
A,B,C,D,E,F	Content	HITSP/C75 - Healthcare Associated Infection Report or HITSP/C76 - Case Report Pre-populate or HITSP/C105 - Patient Level Quality Data or HITSP/C151 – Clinical Research Document or HITSP/C152- Labor and Delivery Record Or HITSP/C156 – Clinical Research Workflow or HITSP/C161- Antepartum Record or HITSP/C170 – Vital Records Pre-populate	Provides for the capture of electronic case report form data for clinical research studies as specified by the research protocol including nonrepudiation of origin or Provides for the capture and submission of filled or pre-populated specific data to Public Health Monitoring Systems and Quality Organizations Systems

4.2 CONSTRAINTS AND ASSUMPTIONS

Table 4-3 specifies the context that must be provided in order to use the Capability, identifying any assumptions, pre-conditions, post-conditions, and triggers relevant for use of the Capability.

Table 4-3 Context

Assumptions, Pre-Conditions, Post-Conditions, and Triggers	Type of Context
Capability supports various users e.g. investigators, clinicians, public health officials, etc	Assumption
Authorizations for capture of supplemental data are defined by jurisdiction	Assumption
The entity that needs to receive/file the report is determined by jurisdiction or domain policy agreements	Assumption
Trans-border communication expectations/specifications and mutual reporting are specified by policy	Assumption
Security/communications policies between institutions are established using established standards for trust management, risk assessment and cross-jurisdiction information exchange	Assumption
Secure communications are in place, and all policy, compliance, and authorization issues are addressed through automated or manual means	Pre-conditions
The receiving Information System has received the submitted data	Post-conditions
Terminology mapping is required Assume that there may be a statistician encoding the rules Transformation mapping Assume that the implementation of the mathematical formula is not specified in the Interoperability Specification and is left to product innovation	Assumption
The EHR is a resource for structured data	Assumption
Manual entry of data may be required where pre-population does not complete required fields	Assumption
Data are ready for submission to recipient	Pre-condition



4.3 SPECIFIED INTERFACES BY SYSTEM ROLE

This section specifies the HITSP Capability interfaces in terms of the System Roles identified in Table 2-2 Capability's System Roles.

Table 4-4 specifies interfaces for initiating system roles as defined in Table 2-2.

Table 4-4 Form Filler System Role Mapped to HITSP Construct Interfaces

Construct Interface	Interface Type	T/TP/SC or Content	T/SC/Content Optionality
Retrieve Form	Initiating	Retrieve Form for Data Capture (HITSP/TP50)	R
Submit Form	Initiating	Retrieve Form for Data Capture (HITSP/TP50)	R
Archive Form	Initiating	Retrieve Form for Data Capture (HITSP/TP50)	R
N/A	Initiating	Healthcare Associated Inspection (HAI) Report (HITSP/C75)	C135 [101]
N/A	Initiating	Case Report Pre-populate (HITSP/C76)	C135 [101]
N/A	Initiating	Patient Level Quality Data Document using HL7Quality Reporting Document (QRDA) (HITSP/C105)	C135 [101]
N/A	Initiating	Clinical Research Document (HITSP/C151)	C135 [101]
N/A	Initiating	Labor and Delivery Report (HITSP/C152)	C135 [101]
N/A	Initiating	Antepartum Record (HITSP/C161)	C135 [101]
N/A	Initiating	Vital Records Pre-populate (HITSP/C170)	C135 [101]

Optionality Legend: "R" for Required, "O" for Optional, or "C" for Conditional

Table 4-5 specifies interfaces for Form Manager system roles as defined in Table 2-2.

Table 4-5 Form Manager System Role Mapped to HITSP Construct Interfaces

Construct Interface	Interface Type	T/TP/SC or Content	T/SC/Content Optionality
Retrieve Form	Responding	Retrieve Form for Data Capture (HITSP/TP50)	R
N/A	Responding	Healthcare Associated Inspection (HAI) Report (HITSP/C75)	C135 [101]
N/A	Responding	Case Report Pre-populate (HITSP/C76)	C135 [101]
N/A	Responding	Patient Level Quality Data Document using HL7Quality Reporting Document (QRDA) (HITSP/C105)	C135 [101]
N/A	Responding	Clinical Research Document (HITSP/C151)	C135 [101]
N/A	Responding	Labor and Delivery Report (HITSP/C152)	C135 [101]
N/A	Responding	Antepartum Record (HITSP/C161)	C135 [101]
N/A	Responding	Vital Records Pre-populate (HITSP/C170)	C135 [101]

Optionality Legend: "R" for Required, "O" for Optional, or "C" for Conditional

Table 4-6 specifies interfaces for the Form Receiver system role as defined in Table 2-2.



Table 4-6 Form Receiver System Role Mapped to HITSP Construct Interfaces

Construct Interface	Interface Type	T/TP/SC or Content	T/SC/Content Optionality
Submit Form	Responding	Retrieve Form for Data Capture (HITSP/TP50)	R
N/A	Responding	Healthcare Associated Inspection (HAI) Report (HITSP/C75)	C135 [101]
N/A	Responding	Case Report Pre-populate (HITSP/C76)	C135 [101]
N/A	Responding	Patient Level Quality Data Document using HL7Quality Reporting Document (QRDA) (HITSP/C105)	C135 [101]
N/A	Responding	Clinical Research Document (HITSP/C151)	C135 [101]
N/A	Responding	Labor and Delivery Report (HITSP/C152)	C135 [101]
N/A	Responding	Antepartum Record (HITSP/C161)	C135 [101]
N/A	Responding	Vital Records Pre-populate (HITSP/C170)	C135 [101]

Optionality Legend: “R” for Required, “O” for Optional, or “C” for Conditional

Table 4-7 specifies interfaces for the Form Archiver system role as defined in Table 2-2.

Table 4-7 Form Archiver System Role Mapped to HITSP Construct Interfaces

Construct Interface	Interface Type	T/TP/SC or Content	T/SC/Content Optionality
Archive Form	Responding	Retrieve Form for Data Capture (HITSP/TP50)	R
N/A	Responding	Healthcare Associated Inspection (HAI) Report (HITSP/C75)	C135 [101]
N/A	Responding	Case Report Pre-populate (HITSP/C76)	C135 [101]
N/A	Responding	Patient Level Quality Data Document using HL7Quality Reporting Document (QRDA) (HITSP/C105)	C135 [101]
N/A	Responding	Clinical Research Document (HITSP/C151)	C135 [101]
N/A	Responding	Labor and Delivery Report (HITSP/C152)	C135 [101]
N/A	Responding	Antepartum Record (HITSP/C161)	C135 [101]
N/A	Responding	Vital Records Pre-populate (HITSP/C170)	C135 [101]

Optionality Legend: “R” for Required, “O” for Optional, or “C” for Conditional

Table 4-8 specifies optionality conditions referenced in Table 4-4 through Table 4-7 above.

Table 4-8 Implementation Conditions

Condition Code	Condition Description
C135 [101]	SHALL be supported if content is required by the implementation



5.0 STANDARDS

The following table is provided as an aid to readers to assist them in identifying the parts of this section to focus on. Readers are encouraged to review all sections of this document to further their understanding of HITSP's work.

Table 5-1 Reader's Guide for Section 5.0

Document Section	Section Number	Intended Audience	Contained Information
Section 5.0 Standards	5.1 Standards Used	Program Managers Policy Analysts Architects Business Analysts Developers	List regulatory guidance, selected standards and informative references used by the Capability and all its supporting constructs
	5.2 Standards Gaps and Overlaps	Program Managers Policy Analysts Architects Business Analysts Developers	Identifies gaps or overlaps in standards to implement the Capability including a plan to resolve issues

5.1 STANDARDS USED

5.1.1 REGULATORY GUIDANCE

Table 5-2 lists any regulatory guidance that determines or constrains use of standards.

Table 5-2 Regulatory Guidance

Regulation	Description
No applicable regulatory guidance	

5.1.2 SELECTED STANDARDS

Table 5-3 lists the standards selected as relevant to this Capability.

Table 5-3 Selected Standards Used in this Capability

Standard	Description
American Medical Association (AMA) Current Procedural Terminology (CPT®) Fourth Edition (CPT-4); CPT Evaluation and Management Codes	A uniform coding system used primarily to identify medical services and procedures furnished by physicians and other healthcare professionals. For more information visit www.ama-assn.org
Centers for Medicare and Medicaid Services (CMS) National Provider Identifier (NPI)	NPI is a unique 10-digit identification number issued to healthcare providers in the United States by the Centers for Medicare and Medicaid Services (CMS). All individual HIPAA covered healthcare providers (physicians, nurses, dentists, chiropractors, physical therapists, etc.) or organizations (hospitals, home healthcare agencies, nursing homes, residential treatment centers, group practices, laboratories, pharmacies, medical equipment companies, etc.) must obtain an NPI for use in all HIPAA standard transactions, even if a billing agency prepares the transaction. Once assigned, a provider's NPI is permanent and remains with the provider regardless of job or location changes. For more information visit www.cms.gov
Federal Information Processing Standards (FIPS) Codes for the Identification of the States, the District of Columbia and the Outlying Areas of the United States, and Associated Areas Publication # 5-2, May, 1987	A set of two-digit numeric codes and a set of two-letter alphabetic codes for representing the 50 states, the District of Columbia and the outlying areas of the United States, and associated areas. The standard covers all land areas under the sovereignty of the United States, the freely associated states of Federated States of Micronesia and Marshall Islands, and the trust territory of Palau. For more information visit www.itl.nist.gov NOTE: ASC X12 transactions and ASC X12N Implementation Guides do not allow use of this standard; instead they require use of the U.S. Postal Service's National Zip Code and Post Office Directory -- which provides similar alphabetic code values



Standard	Description
Federal Medication Terminologies	<p>A set of controlled terminologies and code sets developed and maintained as part of a collaboration between the Food and Drug Administration, National Library of Medicine, Veterans Health Administration, National Cancer Institute and Agency for Healthcare Research and Quality related to medications, including medication proprietary and nonproprietary names, clinical drug code (RxNorm); ingredient names and Unique Ingredient Identifiers (UNII); routes of administration, dosage forms, and units of presentation from the NCI Thesaurus (NCIt); and certain pharmacological drug classes from the National Drug File Reference Terminology (NDF-RT)</p> <p>The Federal Medication Terminology leverages medication models maintained by the Food and Drug Administration (ex. UNII, NDC Codes), National Library of Medicine (RxNorm), the Veterans Health Administration (NDF-RT), and the National Cancer Institute (NCIt)</p> <p>Information on the Federal Medication Terminologies may be found and downloaded from the NCI Web portal terminology resources page at www.cancer.gov/cancertopics</p>
Health Level Seven (HL7) HL7 Version 3 Standard: Clinical Document Architecture (CDA), Release 2	<p>The HL7 Clinical Document Architecture is an XML-based document markup standard that specifies the structure and semantics of clinical documents for the purpose of exchange. CDA is one instantiation of HL7's Version 3.0 Reference Information Model (RIM) into a specific message format. Of particular focus for HITSP Interoperability Specifications are message formats for Laboratory Results and Continuity of Care (CCD) documents. Release 2 of the HL7 Clinical Document Architecture (CDA) is an extension to the original CDA document markup standard that specifies the structure and semantics of clinical documents for the purpose of exchange. CDA R2 includes a prose document in HTML, XML schemas, data dictionary, and sample CDA documents. CDA R2 further builds upon other HL7 standards beyond just the Version 3.0 Reference Information Model (RIM) and incorporates Version 3.0 Data Structures, Vocabulary, and the XML Implementation Technology Specifications for Data Types and Structures. For more information visit www.hl7.org</p>
Health Level Seven (HL7) Implementation Guide for CDA Release 2.0: NHSN Healthcare Associated Infection (HAI) Reports, Release1	<p>The Healthcare Associated Infection Report Implementation Guide describes a standard for electronic submission of Healthcare Associated Infection (HAI) Reports to the National Healthcare Safety Network (NHSN) of the Centers for Disease Control and Prevention (CDC). It defines the overall approach and method of electronic submission and prescribes constraints defining specific HAI report types. Further information can be retrieved from www.hl7.org</p>
Health Level Seven (HL7) Version 2.5	<p>The HL7 Version 2.5 Messaging Standard is an application protocol for electronic data exchange in healthcare. It and prior versions have widespread use in the U.S. and internationally. Both message formats and value sets/code tables (e.g., diagnosis type, gender, patient class, result status, specimen collection method, abnormal flags, observation result status codes interpretation, timestamp format) are contained in the standard. Of particular focus for HITSP Interoperability Specifications are message formats described in Chapters 2, 3, 5, and 7 including patient demographic (ADT) and lab result reporting. These are also used within composite standards from IHE for Patient Identity Cross-Referencing and Feed (PIX), Patient Demographics Query (PDQ), and Acknowledgements. For more information visit www.hl7.org</p>
Health Level Seven (HL7) Version 2.5.1	<p>The HL7 Version 2.5.1 Messaging Standard is an application protocol for electronic data exchange in healthcare. It and prior versions have widespread use in the U.S. and internationally. Message formats and value sets/code tables (e.g., diagnosis type, gender, patient class, result status, specimen collection method, abnormal flags, observation result status codes interpretation, timestamp format) are contained in the standard. Of particular focus for HITSP Interoperability Specifications are message formats described in Chapters 2, 3, 4, 5, and 7 including patient demographic (ADT), and lab result reporting. These are also used within composite standards from IHE for Patient Identity Cross-Referencing and Feed (PIX), Patient Demographics Query (PDQ) and Acknowledgements. They are also used in HL7 order messages. For more information visit www.hl7.org</p>
Health Level Seven (HL7) Version 3.0	<p>The HL7 Version 3.0 Messaging Standard is an application protocol for electronic data exchange in healthcare. Version 3.0 is based on a Reference Information Model (RIM); which is used to instantiate various message formats. Value sets/code tables are contained in the standard. For more information visit www.hl7.org</p>



Standard	Description
Health Level Seven (HL7) eMeasure: Representation of Quality Measures in the Health Quality Measures Format (HQMF) Release 1 (Draft Standard for Trial Use)	The HL7 HQNF Standard is a formalism for encoding quality measures (aka creating eMeasures). The HL7 HQNF Standard is part of the HL7 Version 3.0 family of standards, based on a Reference Information Model (RIM). Visit http://www.hl7.org for more information
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 www.ihe.net
Implementation Guide for CDA Release 2 Quality Reporting Document Architecture (QRDA) Based on HL7 CDA Release 2.0 CDAR2_QRDA_R1D1_2009MAR	This Implementation Guide describes constraints on CDA Release 2 Header and Body elements for Quality Reporting Documents. Quality Reporting Document Architecture (QRDA) is a document format that provides a standard structure with which to report quality measure data to organizations that will analyze and interpret the data that is received. The balloted portion of this guide which covers Category 1
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (TF) Supplement, Retrieve Form for Data Capture (RFD), Draft for Trial Implementation, August 10, 2009	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 latest version of the IHE Technical Framework is available at www.ihe.net
Integrating the Healthcare Enterprise (IHE) Patient Care Coordination (PCC), Technical Framework Supplement, Labor and Deliver Record Trial Implementation Supplement, August 10, 2009	The IHE Patient Care Coordination Technical Framework (PCC TF) defines specific implementations (called Integration Profiles) of established standards to deal with integration issues that cross providers, patient problems or time. The Labor and Delivery Record (LDR) Supplement provides comprehensive information regarding the course of labor and delivery to healthcare providers caring for both the mother and the newborn in the postpartum period. For more information visit http://www.ihe.net/
Integrating the Healthcare Enterprise (IHE) Patient Care Coordination (PCC), Technical Framework Supplement, Antepartum Record, Draft for Trial Implementation, August 22, 2008	The IHE Patient Care Coordination Technical Framework (PCC TF) defines specific implementations (called Integration Profiles) of established standards to deal with integration issues that cross providers, patient problems or time. The Antepartum Record Profile (APR) is collection of folders of documents based on data elements from prenatal records currently in common use. APR groups summary documents for key relevant areas of interest and concern in monitoring and evaluating prenatal care. For more information visit http://www.ihe.net/
Integrating the Healthcare Enterprise (IHE) Quality, Research and Public Health (QRPH) Technical Framework Supplement 2008 – 2009, Drug Safety Content (DSC) Profile, Public Comment, Version 10	Describes the content and format to be used within the Pre-population Data transaction described within the RFD Integration Profile. The purpose of this profile is to support a standard set of data in CCD format which the Form Filler provides for use in reporting adverse events as it relates to Drug Safety. In addition this profile will reference the ability to convert this output into the ICH E2B (R3) standard. For more information visit www.ihe.net
International Classification of Diseases, 10 th Revision, Procedure Coding System (ICD-10-PCS, ICD-10-CM)	The International Classification of Diseases, 10th Revision, Procedure Coding System (ICD-10-PCS), describes the classification of inpatient procedures for statistical purposes and for the indexing of healthcare records by procedures. ICD-10-PCS is a procedural coding system managed by the Centers for Medicare and Medicaid Services (CMS). For more information visit www.cms.hhs.gov Note: ICD-10 is scheduled for deployment in the U.S. October 1, 2013
International Classification of Diseases, 9 th Revision, Clinical Modifications (ICD-9-CM)	The International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM), Volumes I, II (diagnoses) and III (procedures) describes the classification of morbidity information for statistical purposes and for the indexing of healthcare records by diseases and procedures. For more information visit www.cdc.gov/nchs Note: ICD-10-CM will replace ICD-9-CM with an implementation date of Oct 1 2013



Standard	Description
International Health Terminology Standards Development Organization (IHTSDO) Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®)	SNOMED CT consists of a technical design, core content architecture, and Core content. SNOMED CT Core content includes the technical specification of SNOMED CT and fully integrated multi-specialty clinical content. The Core content also includes a concepts table, description table, relationships table, history table, ICD-9-CM mapping, and Technical Reference Guide. Additionally, SNOMED CT provides a framework to manage language dialects, clinically relevant subsets, qualifiers and extensions, as well as concepts and terms unique to particular organizations or localities. For more information visit www.ihtsdo.com
Logical Observation Identifiers Names and Codes (LOINC®)	A database of universal identifiers for laboratory and other clinical observations. The laboratory portion of the LOINC database contains the usual categories of chemistry, hematology, serology, microbiology (including parasitology and virology), and toxicology; as well as categories for drugs and the cell counts typically reported on a complete blood count or a cerebrospinal fluid cell count. Antibiotic susceptibilities are a separate category. The clinical portion of the LOINC database includes entries for vital signs, hemodynamics, intake/output, EKG, obstetric ultrasound, cardiac echo, urologic imaging, gastroendoscopic procedures, pulmonary ventilator management, selected survey instruments, and other clinical observations. For more information visit www.loinc.org
National Library of Medicine (NLM) Unified Modeling Language System (UMLS) RxNorm	Provides standard names for (1) clinical drugs and (2) drug dose forms as administered to a patient. Also provides links from clinical drugs, both branded and generic, to their active ingredients, drug components (active ingredient + strength), and related brand names. Food and Drug Administration (FDA) National Drug Codes (NDCs) for specific drug products and many of the drug vocabularies commonly used in pharmacy management and drug interaction software are additionally linked to RxNorm. RxNorm is a part of the Federal Medication Terminologies. For more information visit www.nlm.nih.gov
National Uniform Billing Committee (NUBC) Uniform Bill Version 2007 (UB-04) Current UB Data Specification Manual Field 22, Patient Discharge Status, Codes	A code set identifying status of patient discharge on an institutional claim (e.g., inpatient, outpatient, hospice, home care). For more information visit www.nubc.org
Unified Code for Units of Measure (UCUM)	A code system intended to include all units of measures being contemporarily used in international science, engineering, and business. The purpose is to facilitate unambiguous electronic communication of quantities together with their units. The focus is on electronic communication, as opposed to communication between humans. For more information visit aurora.regenstrief.org
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. CDASH.STD-1.0.2008-10-0 For more information visit www.cdisc.org
2003 Revisions of the U.S. Standard Certificates of Live Birth and Death and the Fetal Death Report	The National Vital Statistics System is the basis for the nation's official statistics on births, deaths, and fetal deaths. These data are provided through vital registration systems which are maintained and operated by the states and territories where the original certificates are filed. While the legal authority for vital registration rests with the states and territories, the Secretary, through the Centers for Disease Control and Prevention (CDC) National Center for Health Statistics (NCHS), is required to produce national vital statistics by compiling data from the central vital records offices in all of the 57 registration areas, including all territories. Therefore, CDC closely collaborates with the states to develop standard certificates and reports for data collection and administrative purposes, as well as standardized procedures for data preparation and processing to promote a uniform national database. These certificates and reports provide guidance to the individual states responsible for collecting vital statistics data. The standards are universally accepted as the primary mechanism for promoting uniformity in information upon which national vital statistics are based. The U.S. standard certificates and report are issued as models for the states to use in developing mechanisms for collecting vital statistics data

5.1.3 INFORMATIVE REFERENCE STANDARDS

Table 5-4 includes reference standards that inform the overall semantic interoperability.



Table 5-4 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 www.ihe.net
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0	The IHE IT Infrastructure Technical Framework defines specific implementations of established standards to achieve integration goals that promote appropriate sharing of health information to support optimal patient care. IHE Integration Profiles offer a common language that healthcare professionals and vendors may use in communicating requirements for the integration of products. The current version of the ITI-TF, rev. 4.0 for Final Text, specifies the IHE transactions defined and implemented as of August 22, 2007. For more information visit www.ihe.net
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 www.cdisc.org

5.2 STANDARDS GAPS AND OVERLAPS

Table 5-5 identifies the information exchange requirements and known standards gaps, along with the recommended resolutions to the gaps.

Table 5-5 Information Exchange Requirements and Associated Standards Gaps

IER Gap Description	Responsible HITSP TC	Design Approach	Required Standards Now Unavailable for Constructs	SDO Working on Unavailable Standards	Expected Availability
None					

Table 5-6 lists any standards overlaps and describes plans to resolve each of the overlaps.

Table 5-6 Information Exchange Requirements and Associated Standards Overlaps

IER Number	Summary Description	Standard Overlap	Recommended Resolution
None			



6.0 APPENDIX

This section may include additional materials referenced throughout this document, such as requirements analysis tables and figures. If the Capability is yet to be implemented, it may contain the candidate standards, for Tier 2 evaluations.

- HITSP/IS02 Biosurveillance
- HITSP/IS11 Public Health Case Reporting
- HITSP/IS158 Clinical Research
- HITSP/IS06 Quality
- HITSP/IS92 Newborn Screening

Table 6-1 Interoperability Specification Requirements Analysis Used to Derive Information Exchanges

Functional Requirement	Information Exchange	Data Requirements	Analysis
3. A. The ability to review a listing of available general laboratory orders	A	None	
3. A.i. When selecting orders, the clinician may need the ability to review a listing of the available general laboratory orders. These listings may be acquired through libraries of commonly used general laboratory orders			



7.0 DOCUMENT UPDATES

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

7.1 NOVEMBER 9, 2009

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

7.2 JANUARY 18, 2010

- Updated to new HITSP Capabilities template
- Removed duplicate tables
- Corrected Table 5-3 Selected Standards Used in this Capability
- Updated document to HITSP Capability Template Version 2.3

The associated comment numbers for these updates are as follows:

- 8646

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

7.3 JANUARY 25, 2010

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

7.4 JANUARY 31, 2010

- Updated Table 4-4 though Table 4-7 to add HITSP/C170 – Vital Records Pre-populate
- Added 2003 Revisions of the U.S. Standard Certificates of Live Birth and Death and the Fetal Death Report to Table 5-3, Selected Standards

