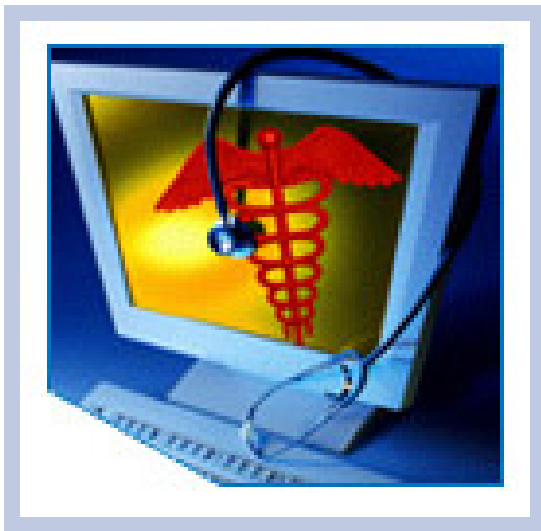


# HITSP Public Health Case Reporting Interoperability Specification

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HITSP/IS11



*Submitted to:*

**Healthcare Information Technology Standards Panel**

*Submitted by:*

**Population Perspective Technical Committee  
(Formerly Population Health Technical Committee)**



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RELEASED FOR IMPLEMENTATION



## 1.0 INTRODUCTION

As an introduction to the Healthcare Information Technology Standards Panel (HITSP) Public Health Case Reporting Interoperability Specification, this section provides a high level overview of the information sharing scenario enabled by following this specification, provides a document map of the construct relationships for the Interoperability Specification, acknowledges the copyright protections that pertain, and provides a list of key reference documents and background material.

### 1.1 INTEROPERABILITY SPECIFICATION OVERVIEW

This section provides a high level definition of this Interoperability Specification and background information about the underlying Use Case that it is based upon.

The HITSP Public Health Case Reporting Interoperability Specification supports the bi-directional information exchanges of the Public Health Case Reporting process. The Public Health Case Reporting Use Case addresses numerous domains which have similar content and processes at a high level, but which also are dissimilar in report content details and case management processes when considering any specific report.

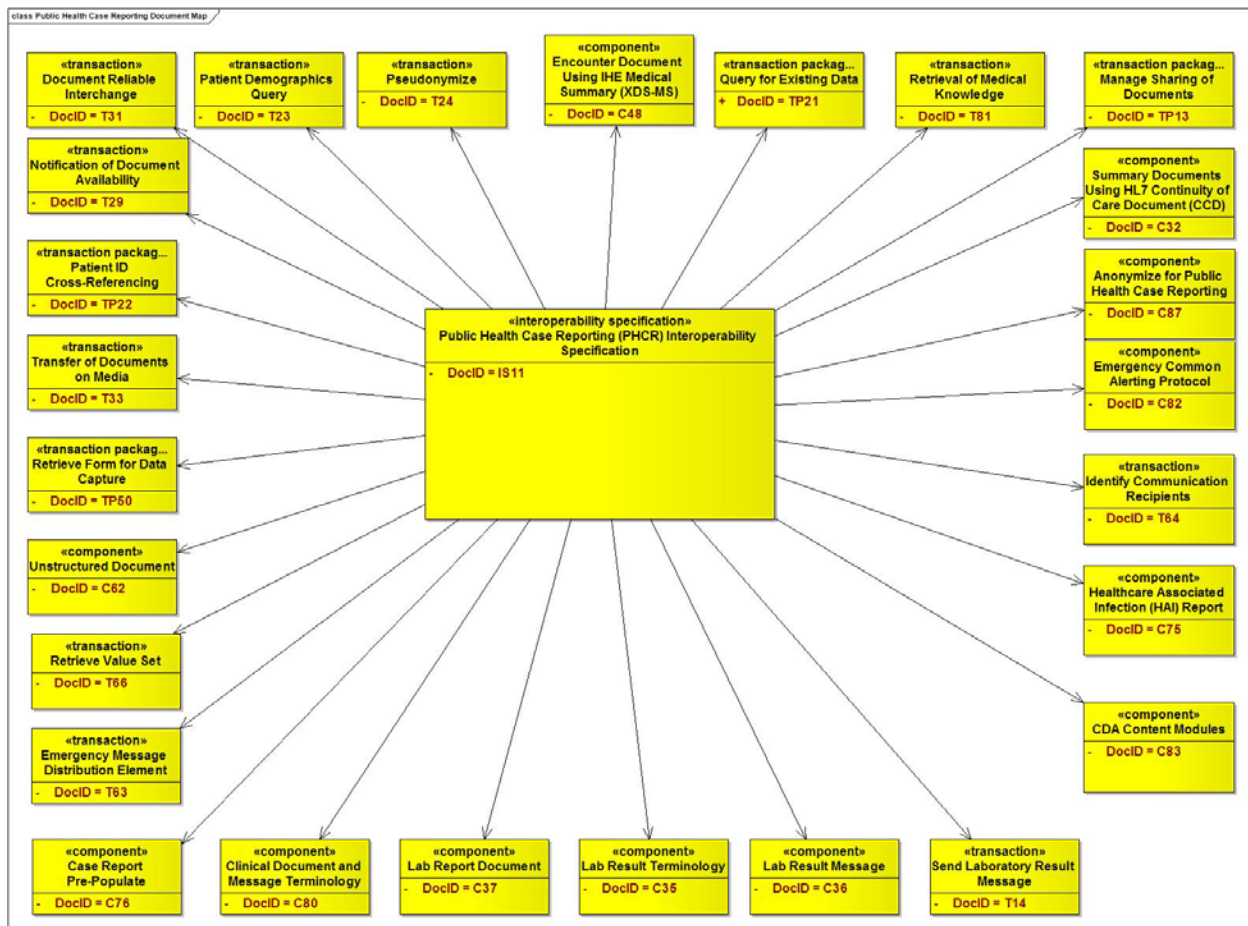
This Interoperability Specification focuses on enabling more efficient data capture at the point of care while allowing for optimal information delivery format and content while waiting for current standard development organization (SDO) efforts to be finalized. In the absence of standards in structured content and associated clinical decision support (CDS) for alerts and information reporting criteria, this Interoperability Specification provides options for the secure communication of basic presentation preserving content to better automate the current paper-based information flows.

### 1.2 INTEROPERABILITY SPECIFICATION DOCUMENT MAP

Each HITSP Interoperability Specification (IS) is comprised of a suite of constructs that, taken as a whole, define how to integrate and constrain existing standards and specifications to satisfy the requirements imposed by a given Use Case. The IS groups specific actions and actors to describe the relevant context(s) for the use of HITSP constructs that further identify and constrain standards where necessary. In addition to ISs, there are three other types of HITSP constructs called Transaction Packages (TP), Transactions (T), and Components (C). The document map in Figure 1.2-1 depicts how this IS integrates and constrains HITSP constructs to support the information exchange, within the defined context of the Use Case. Implementers should read the documents that describe the constructs depicted in the diagram for their details and specific uses. Note that the baseline Security and Privacy constructs are not shown in the diagram, however, they are described in Table 1.2.1-1.



Figure 1.2-1 Interoperability Specification Document Map



### 1.2.1 LIST OF CONSTRUCTS

The following table lists and describes the HITSP constructs that are used by the Interoperability Specification. All references to HITSP specifications are to the current, and Panel approved 'Released for Implementation' versions of the specifications retrieved from [www.hitsp.org](http://www.hitsp.org).

Where HITSP has adopted HL7 V3.0 CDA/CCD for conveying information between Electronic Health Record (EHR) and Personal Health Record (PHR) applications and in other healthcare scenarios, it has consolidated common constraints applied against the Content Modules in HITSP/C83 CDA Content Modules. Likewise, HITSP/C80 Clinical Document and Message Terminology maintains commonly applied terminology constraints. Readers should refer to HITSP/TN901 Technical Note for Clinical Documents to better understand how HITSP/C83 and HITSP/C80 are used by other constructs that are based upon HL7 V3.0 CDA/CCD (e.g., HITSP/C32 Summary Documents Using HL7 Continuity of Care Document (CCD), HITSP/C48 Encounter Document Using IHE Medical Summary (XDS-MS) and HITSP/C84 Consult and History & Physical Note Document).





**Table 1.2.1-1 List of Constructs**

Construct	Description
HITSP/C19 - Entity Identity Assertion	The Entity Identity Assertion Component provides the mechanisms to ensure that an entity is the person or application that claims the identity provided. An example of this Component is the validation and assertion of a consumer logging on to a Personal Health Record (PHR) system
HITSP/C26 - Nonrepudiation of Origin	The Nonrepudiation of Origin Component provides the mechanisms to support Nonrepudiation of Origin, which refers to both the proof of the integrity and origin of documents in a high-assurance manner, which can be verified by any party. This Component does not provide Nonrepudiation of Receipt
HITSP/C32 - Summary Documents Using HL7 Continuity of Care Document (CCD)	The Summary Documents Using HL7 Continuity of Care Document (CCD) Component describes the document content summarizing a consumer's medical status for the purpose of information exchange. The content may include administrative (e.g., registration, demographics, insurance, etc.) and clinical (problem list, medication list, allergies, test results, etc) information. This Component defines content in order to promote interoperability between participating systems such as Personal Health Record Systems (PHRs), Electronic Health Record Systems (EHRs), Practice Management Applications and others.
HITSP/C35 - Lab Result Terminology	The Lab Result Terminology Component defines the vocabulary for either message-based or document-based laboratory results reporting
HITSP/C36 - Lab Result Message	The Lab Result Message Component describes the use of a constrained Health Level Seven (HL7) Version 2.5.1 ORU – Unsolicited Observation Message for electronic laboratory results reporting
HITSP/C37 - Lab Report Document	The Lab Report Document Component prescribes the use of the standard Clinical Document Architecture Release 2 (CDA R2), as in the HL7 V3 2006 normative edition profiled by IHE LAB TF-3 for: transmission of complete, preliminary, final and updated laboratory results to the EHR system (local or remote) of the ordering clinician; transmission of complete, preliminary, final and updated (or notification) to the EHR system (local or remote) or other clinical data system of designated providers of care (with respect to a specific patient); transmission of laboratory result data from electronically enabled healthcare delivery and public health systems in standardized and anonymized format to authorized Public Health Agencies with less than one day lag time
HITSP/C48 - Encounter Document Using IHE Medical Summary (XDS-MS)	The Encounter Document Using IHE Medical Summary (XDS-MS) Component supports the process of sending patient encounter data (excluding laboratory and radiology) in a document sharing functional flow scenario. Patient encounter data are captured as part of the normal process of care performed by healthcare providers, such as hospitals, emergency departments and outpatient clinics
HITSP/C62 - Unstructured Document	The Unstructured Document Component is provided for the capture and storage of patient identifiable, unstructured document content, such as text, PDF, and images rendered in PDF. It is based on the Cross-Enterprise Sharing of Scanned Documents (XDS-SD) profile from the Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF)
HITSP/C75 - Healthcare Associated Infection (HAI) Report	The Healthcare Associated Infection (HAI) Report Component specifies 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). HITSP has adopted the HL7 Implementation Guide for CDA Release 2: NHSN Healthcare Associated Infection (HAI) Reports, Release 1 for this construct



Construct	Description
HITSP/C76 - Case Report Pre-Populate	The Case Report Pre-Populate Component supports the Data Mapping needed for Public Health Case Reports. Initially the Component supports only those data attributes that are universal or pertain to Drug Safety reporting. For those attributes that are universal in case reporting, this component may be used in support of pre-populating the remaining report types. However, other public health specific attributes will be addressed in subsequent releases
HITSP/C80 - Clinical Document and Message Terminology	The Clinical Document and Message Terminology Component defines the vocabularies and terminologies utilized by HITSP specifications for Clinical Documents and Messages used to support the interoperable transmission of information
HITSP/C82 - Emergency Common Alerting Protocol	The Emergency Common Alerting Protocol Component selects the OASIS Common Alerting Protocol (CAP) v1.1 standard, and is used as a multicast notification message sent to an identified channel. The intended recipients are populations such as "all emergency departments in XXX county", "within a geographic area", etc
HITSP/C83 - CDA Content Modules	The CDA Content Modules Component defines the content modules for document based HITSP constructs utilizing clinical information. These Content modules are based on IHE PCC Technical Framework Volume II, Release 4. That technical framework contains specifications for document sections that are consistent with all Implementation Guides for clinical documents currently selected for HITSP constructs
HITSP/C87 - Anonymize Public Health Case Reporting Data	The Anonymize Public Health Case Reporting Data Component provides specific instructions for anonymizing data that was created as part of routine clinical care data delivery in preparation for repurposing data for public health case reporting. This construct defines the Component specification that provides the ability to anonymize patient identifiable information. Anonymization, according to the International Organization for Standardization (ISO), is the process that removes the association between the identifying data set and the data subject
HITSP/T14 - Send Laboratory Result Message	The Send Laboratory Result Message Transaction supports: transmission of complete, preliminary, final and updated laboratory results to the EHR system (local or remote) of the ordering clinician; and transmission of complete, preliminary, final and updated laboratory results (or notification of the availability of laboratory results) to the EHR system (local or remote) or other clinical data system of designated providers of care (with respect to a specific patient)
HITSP/T15 - Collect and Communicate Security Audit Trail	The Collect and Communicate Security Audit Trail Transaction is a means to provide assurance that security policies are being followed or enforced and that risks are being mitigated. This document describes the mechanisms to define and identify security relevant events and the data to be collected and communicated as determined by policy, regulation or risk analysis. It also provides the mechanism to determine the record format to support analytical reports that are needed
HITSP/T16 - Consistent Time	The Consistent Time Transaction provides a mechanism to ensure that all of the entities that are communicating within the network have synchronized system clocks
HITSP/T17 - Secured Communication Channel	The Secured Communication Channel Transaction provides the mechanisms to ensure the authenticity, integrity, and confidentiality of transmissions, and the mutual trust between communicating parties. Its objectives include providing: mutual node authentication to assure each node of the others' identity; transmission integrity to guard against improper information modification or destruction while in transit; and transmission confidentiality to ensure that information in transit is not disclosed to unauthorized individuals, entities, or processes



Construct	Description
HITSP/T23 - Patient Demographics Query	The Patient Demographics Query Transaction is intended to provide a 'list patients and their demographics' query/patient(s) and their demographics identified' response message pair (QBP^K22, RSP^K22) for use wherever such needs exist. This Transaction document extracts the Health Level Seven (HL7) version 2.5 Query and Response data mapping. The underlying basis for this extraction can be found in the Integrating the Healthcare Enterprise IT Infrastructure Technical Framework, Patient Demographics Query integration profile
HITSP/T24 - Pseudonymize	The Pseudonymize Transaction describes a framework for including Pseudonymization Services where the use of "dummy" or pseudo references to specific patients or providers is required. Pseudo-identifiers are intended to allow accessibility to clinical information, while safeguarding any information that may compromise the privacy of the individual patient or provider. Using pseudo-identifiers can assist in compliance with HIPAA regulations regarding suppression of patient identification information
HITSP/T29 - Notification of Document Availability	The Notification of Document Availability Transaction is based on the Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (TF) Supplement - Notification of Document Availability (NAV). The Notification of Document Availability Transaction defines a mechanism for a healthcare stakeholder (e.g. provider, public health, etc) to notify providers or the patient about information that is available for retrieval pertaining to an identified patient. This Transaction defines the format, content, encoding and transmission of notification messages and acknowledgements between IHE NAV Actors and a known recipient (either a person or system) that participate in the same XDS Affinity Domain
HITSP/T31 - Document Reliable Interchange	The Document Reliable Interchange Transaction provides a standards-based mechanism for conveying a set of medical documents in a point-to-point network-based communication. This Transaction uses the IHE Cross-Enterprise Document Reliable Interchange (XDR) Integration Profile, a companion to the IHE Cross-Enterprise Document Sharing (XDS) Integration Profile. Cross-Enterprise Document Reliable Interchange (XDR) uses the XDS defined metadata formats in a simpler environment in which the communicating parties have agreed to a point-to-point interchange rather than communicating via document sharing
HITSP/T33 - Transfer of Documents on Media	The Transfer of Documents on Media Transaction describes both the type of media (CD-ROM, USB Memory, and e-Mail) that may be used to write the documents and provides a directory structure that must be followed in order for the contents to be successfully accessed and processed by systems. An example might be to transport data from one healthcare provider to another healthcare provider, or a healthcare consumer may wish to move the contents of a Personal Health Record (PHR) using physical media or e-Mail. This Transaction uses the IHE Cross-Enterprise Document Media Interchange Integration Profile developed by Integrating the Healthcare Enterprise (IHE), a companion to the IHE Cross-Enterprise Document Sharing (XDS) Integration Profile
HITSP/T63 - Emergency Message Distribution Element	The Emergency Message Distribution Element Transaction selects the Emergency Data Exchange Language (EDXL) Distribution Element (DE) v1.0 standard, and is a multicast notification message sent to an identified population (assume this is not to the general public, but to specifically identified populations, such as emergency departments)



Construct	Description
HITSP/T64 - Identify Communication Recipients	The Identify Communication Recipients Transaction is intended to serve the purpose of identification of communication recipients and the subsequent purpose of delivery of alerts and bi-directional communications (e.g., public health agencies notifying a specific group of service providers about an event.) The method and criteria by which individuals are added to a directory is a policy decision, which is out of scope for this construct. It uses the Integrating the Healthcare Enterprise (IHE) Personnel White Pages profile which provides access to basic directory information for identifying one or more recipients
HITSP/T66 - Retrieve Value Set	The Retrieve Value Set Transaction is used to transform human or computer vocabularies. For example, it can be used to convert the initial capture of a human-readable concept into a computer vocabulary captured in a document or message that will be communicated. It may also be used in the reverse, to take computer vocabulary and convert to human-readable form
HITSP/T81 - Retrieval of Medical Knowledge	The Retrieval of Medical Knowledge Transaction enables the request and receipt of additional knowledge about a medical concept based on specific context parameters. This transaction does not prescribe the knowledge content of the message returned but provides the specifications for the query for and receipt of additional knowledge. It uses the Health Level 7 (HL7) Context-Aware Information Retrieval (Infobutton) Specification: URL Implementation Guide as the base standard for implementation
HITSP/TP13 - Manage Sharing of Documents	The Manage Sharing of Documents Transaction Package supports the sharing of patient records in the form of source attested objects called documents. A healthcare document is a composite of structured and coded health information, both narrative and tabular, that describes acts, observations and services for the purpose of exchange. No assumption is made by this construct in terms of the format and structure of the content of documents shared
HITSP/TP20 - Access Control	The Access Control Transaction Package provides the mechanism for security authorizations which control the enforcement of security policies including: role-based access control; entity based access control; context based access control; and the execution of consent directives. An example of this is a functional role that has the permission to perform an act (e.g., consumer updating a Personal Health Record (PHR). In an emergency, this construct must support the capability to alter access privileges to the appropriate level (failsafe/emergency access), which may include override of non-emergency consents
HITSP/TP21 - Query for Existing Data	The Query for Existing Data Transaction Package is based on the IHE Query for Existing Data Integration Profile (QED) which supports dynamic queries for clinical data, including vital signs, problems, medications, immunizations, diagnostic results, procedures and visit history. A wide variety of systems often needs access to dynamic clinical information stored and maintained in an EMR system or other clinical data repository. The construct makes the information widely available to other systems within and across enterprises to support provision of better clinical care
HITSP/TP22 - Patient ID Cross-Referencing	The Patient ID Cross-Referencing Transaction Package is used for identifying and cross-referencing different attributes for the same patient. It contains a query for cross-reference and patient identity feed transactions. These transactions are used to identify patients from a list of potentials, and/or to communicate patient demographic data



Construct	Description
HITSP/TP30 - Manage Consent Directives	The Manage Consent Directives Transaction Package describes the messages needed to capture, manage, and communicate rights granted or withheld by a consumer to one or more identified entities in a defined role to access, collect, use or disclose individually identifiable health information (IIHI), and also supports the delegation of the patient's right to consent. The transactions described in this construct are intended to be carried out by HITSP/TP13 - Manage Sharing of Documents
HITSP/TP50 - Retrieve Form for Data Capture	The Retrieve Form for Data Capture Transaction Package enables capture of supplemental data variables not typically maintained in an electronic health record or laboratory information system through a more seamless integration with the local information system. This allows for the local system to retrieve a form specific to the identified potential public health threat. In the context of quality, it allows for the local system to capture supplemental data elements required for quality reporting that may not be available to the electronic health record

### 1.3 COPYRIGHT PERMISSIONS

#### COPYRIGHT NOTICE

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### 1.4 REFERENCE DOCUMENTS

This section provides a list of key reference documents and background material. If you are already familiar with this information, proceed to Section 2.

A list of key reference documents and background material is provided in the table below. These documents can be retrieved from [www.hitsp.org](http://www.hitsp.org).

**Table 1.4-1 Reference Documents**

Reference Document	Document Description
HITSP Interoperability Specification Overview	Provides background information about the HITSP and its role in the overall U.S. efforts to realize large scale interoperability of health information. The document also provides a description of the HITSP process for healthcare standards harmonization and explains how to use the Interoperability Specifications and other related documents to inform your health IT system development or refinement
HITSP Conventions List	Describes the conventions that are used to convey the full descriptions and usage of standards in the HITSP specifications
HITSP Acronyms List	Lists and defines the acronyms used in this document
HITSP Glossary	Provides definitions for relevant terms used by HITSP documents
HITSP Harmonization Framework	Describes the current framework within which the Interoperability Specifications are built



Public Health Case Reporting Detailed Use Case, March 21, 2008	AHIC Use Case that is the basis of this Interoperability Specification
TN900 - Security and Privacy Technical Note	<p>Developed as a reference document to provide the overall context for use of the HITSP Security and Privacy constructs. It includes the following:</p> <ul style="list-style-type: none"> <li>• The scope, reference policy background, and Security and Privacy principles used in the development of the constructs</li> <li>• A detailed description and schematics of the conceptual relationship between the Security and Privacy constructs</li> <li>• A mapping of existing standards and constructs to be used in meeting the stated requirements of the AHIC Use Cases</li> <li>• A list of identified gaps and the recommended approaches to resolving those gaps</li> <li>• A roadmap for how the Security and Privacy constructs will evolve and eventually align with other HITSP Interoperability Specifications</li> <li>• A conceptual framework for Security and Privacy management, including reference information on privacy policies, risk assessment, and risk management</li> <li>• A description of the application of the Security and Privacy constructs to the HITSP Interoperability Specifications for the three initial AHIC Use Cases – Biosurveillance, Electronic Health Records - Laboratory Results Reporting, and Consumer Empowerment</li> </ul> <p>HITSP will periodically update this Technical Note as required by the introduction of new contexts for use.</p>
TN901 - Technical Note for Clinical Documents	<p>Developed as a reference document to provide the overall context for use of the HITSP Care Management and Health Records constructs. It includes the following:</p> <ul style="list-style-type: none"> <li>• The scope, background, and principles for use in the development of the CMHR constructs</li> <li>• A detailed description and schematics of the relationship between CMHR constructs</li> <li>• A conceptual framework for the construction of clinical documents</li> <li>• An overview of Clinical Document concepts</li> <li>• An overview of Vocabulary concepts</li> </ul>





## 2.0 REQUIREMENTS

This section provides a high level description of the Public Health Case Reporting Use Case, as well as the specific information exchange and data requirements that are extracted from the Use Case. It includes the following information:

- Mapping from the Use Case actions and events, to the derived information exchange and data requirements – this table lists the requirements grouped by actor for each event and related action
- Data requirements – this table further describes the data requirements for each specified information exchange requirement
- Information exchange requirements – this table further describes the information exchange requirements for each applicable Use Case action
- Business Actors – this table defines the business actors that are included for the Interoperability Specification, and maps them to the applicable scenario, information exchange, and data requirements
- High level Diagrams – these diagrams are used to describe the interaction between the business actors, and the data involved in each scenario that is documented

### 2.1 USE CASE SYNOPSIS

This section provides a synopsis of the Public Health Case Reporting Use Case, including any applicable scenarios that are part of the Use Case.

In January 2007, AHIC approved a recommendation to develop a Use Case addressing population health relating to aspects of Public Health Case (PH Case) reporting and Adverse Event (AE) reporting. For the purposes of this Use Case, PH Case reporting may include the reporting of communicable/infectious and non-infectious diseases/conditions. AE reporting may include the reporting of AEs associated with post-market vaccines and medications. For both PH Case reporting and AE reporting, this Use Case focuses on using data in EHRs and augmenting EHR data in order to assist those individuals or entities performing provider roles in reporting to public health, manufacturers, etc.

This Use Case also discusses the incorporation of reporting criteria into EHRs which may assist in the possible identification and reporting of PH Cases and AEs. Reporting criteria which are incorporated and utilized by EHRs may include: general and specific reporting considerations, as well as the identification of data and events that may trigger a report, additional questions that may need to be asked of reporters, and the identification of specific data that may need to be reported. There are various stakeholders and methods used in determining reporting criteria. Specifics regarding PH Case reporting criteria are discussed further in 7.1.1.2., 7.2.1.1, and 7.2.1.2. Specifics regarding AE reporting criteria are discussed further in 7.1.1.3 and 7.2.1.3. Reporting criteria may differ for different types of PH Cases and AEs, but there are common technologies and information exchanges as well as data which will be helpful in supporting the wide range of activities.



Following the reporting of possible PH Cases, investigation and information sharing may occur by public health personnel in clinical care settings or public health agencies. There may be similar processes which support AE investigation and follow-up, but due to the presence of different information flows and stakeholders, AE investigations and recalls are not addressed in the scope of this Use Case.

Leveraging electronic clinical information to address population health data needs can also support providers in their decision making. Specifically, providers may benefit from having access to population health data (sometimes called bi-directional communication in reference to data flowing back from public health to clinical care personnel) to support decision support. As expressed in Section 10.0, Data Set Considerations and Appendix B, capabilities for data flowing back to clinical care personnel from public health may include communications which are: Case-specific or patient-specific, generalized to clinically relevant public health functions, or broad enough to be publicly available.

Providers and Public Health will benefit from having the ability to electronically exchange PH Case and AE information among various systems:

- Providers and Public Health will benefit from having the ability to electronically integrate reporting criteria into EHRs and/or other systems;
- Providers and Public Health will benefit from having the ability to use trigger data and events and reporting specifications to help identify possible PH Cases or AEs. In different circumstances trigger events or data may be based on the presence of clinical data in the EHR, Laboratory Information System (LIS), or potentially other sources of information. The utilization of trigger data and events and standardized electronic questions and forms will assist in pre-populating reporting data where possible and making multi-organizational data more comparable;
- Providers will still need to exercise clinical judgment, however; there may be instances where the capabilities described above may support the automated reporting of specific information or reports from providers to those performing public health functions; and
- Providers will benefit from population-level information being integrated with decision support in EHRs

One of the goals of AHIC is to establish a pathway, based on common data and technical standards that facilitates and incorporates interoperable reporting criteria including trigger data and events and reporting specifications into EHRs and/or other tools. This approach can support the reporting of AEs, as well as support the reporting, investigation, and information sharing associated with PH Cases. This Use Case was developed to support the various stakeholders who are active in the development and implementation of EHRs and those facilitating health information exchange activities, including those engaged in activities related to standards, interoperability, harmonization, architecture, policy development, and certification.





## 2.2 USE CASE REQUIREMENTS

This section describes the Use Case requirements and outlines all the given scenarios at a high level.

This Public Health Case Reporting Use Case focuses on the exchange of information between providers' EHRs, public health organizations, manufacturers, laboratories, and describes the following scenarios:

### **Reporting from EHRs**

Reporting criteria such as case criteria, including trigger data and events are identified and incorporated into providers' EHRs for the reporting of possible PH Cases or, where available, AEs. Information within EHRs and the ability to augment EHR information may assist providers in reporting possible PH Cases and AEs. The queuing of standardized report forms for completion by clinical support personnel and the pre-population of available EHR data will help to minimize provider burden. Specifics regarding criteria and reporting specifications are further addressed in the events and actions in sections 7.0 and 8.0.

### **Public Health Case Investigation and Information Sharing**

In evaluating the need for further actions, those performing public health functions may request and receive various types of appropriate authorized information when performing their investigations. The information exchanges and analysis conducted during investigations will assist public health in case status, refining reporting criteria, performing contact tracing to determine who else may have been exposed, assessing impact, determining management and response plans, and communicating appropriate public health information.

There are specific associations between the scenarios in this Use Case and the scenarios in the 2008 Immunizations and Response Management Detailed Use Case.

This Use Case assumes the developing presence of electronic systems such as EHRs, LISs and other local or web-based solutions supporting providers, laboratories, and public health. This Use Case also notes the variations in requirements for reporting across local, state, tribal, and territorial boundaries as well as voluntary versus mandatory requirements. Whereas mandated requirements for PH Case reporting at the federal level do not exist for most notifiable conditions, the federal government accepts and currently receives information which has been voluntarily reported. In some cases, disease prevention and control programs may provide funding that requires compliance with reporting requirements and in some cases, public health emergencies require more intense management of cases.

For reporting of AEs, both mandatory, as designated by the statutes and regulations of the Food and Drug Administration (FDA), and voluntary reporting exists. While acknowledging the issues and obstacles associated with this environment, this Use Case recognizes current efforts to standardize reporting requirements as well as reporting criteria, including those being focused on by Council of State and



Territorial Epidemiologists (CSTE), Centers for Disease Control and Prevention (CDC), FDA, and others to advance these and other initiatives, which promote improved population health.

## 2.2.1 MAPPING OF USE CASE ACTIONS TO INFORMATION EXCHANGE REQUIREMENTS

Section 6.3 contains the perspectives, scenarios, and events from the Use Case. This section maps these events and actions to extracted Information Exchange Requirements (IER), and Data Requirements (DR) that are described in Section 2.2.2. An Information Exchange Requirements (IER) describes a requirement for information exchange between HITSP Business Actors. Data Requirements (DR) define requirements for part, or all, of the data exchanged by one or more IERs. The DR's are defined as a set of information attributes with specific details for each attribute. IER's and DR's form the basis for the construct requirements of the Interoperability Specification that are described in Section 3.

## 2.2.2 DATA AND INFORMATION EXCHANGE REQUIREMENTS

This section contains an extraction of data and information requirements (Table 2.2.2-1) and information exchange requirements (Table 2.2.2-2).

Table 2.2.2-1 provides the data requirement numbers, requirement descriptions, and a listing of the actual data elements and information that meet the data requirements. These requirements are referenced from the Data Requirements column of the Use Case Mapping Table 6.3-1 provided in Section 6.3.

**Table 2.2.2-1 Data Element and Information Requirements (DR)**

Data Requirement Number (DR)	Description		
DR08	<p>Unstructured Data: Document that contains simple text such as a note to the patient, about a patient, or a note from the patient (e.g. camp form immunization summary, patient-specific immunization alert, patient listing alert to providers of patients needing vaccination). This document could include an unstructured, presentation preserved format, such as PDF . In the context of this Use Case, an example would be: For TB: need to represent cases identified by a clinician to researchers looking to investigate a particular strain)</p> <p>Metadata may include but is not limited to:</p> <table> <tr> <td> <ul style="list-style-type: none"> <li>Title</li> <li>clinic ID</li> </ul> </td><td> <ul style="list-style-type: none"> <li>date</li> </ul> </td></tr> </table>	<ul style="list-style-type: none"> <li>Title</li> <li>clinic ID</li> </ul>	<ul style="list-style-type: none"> <li>date</li> </ul>
<ul style="list-style-type: none"> <li>Title</li> <li>clinic ID</li> </ul>	<ul style="list-style-type: none"> <li>date</li> </ul>		
DR17	<p>Decision support data: Employed to evaluate a given clinical situation to suggest a course of action, or to set up criteria to trigger one or more actions when a clinical event meets those criteria.</p> <p>NOTE: Component Specification Deferred due to standards gaps (see scope and gaps)</p> <p>In general, the data may include, but is not limited to:</p>		



Data Requirement Number (DR)	Description	
	<ul style="list-style-type: none"> <li>• Medication reconciliation</li> <li>• Clinical protocols</li> <li>• Administrative protocols (E.g., Insurance)</li> <li>• Diagnosis</li> <li>• Laboratory results</li> </ul>	<p>Within the Public Health (PH) context, data may include, but is not limited to:</p> <ul style="list-style-type: none"> <li>• Decision support data input</li> <li>• Age range</li> <li>• Sex</li> <li>• Race</li> <li>• Risk Location of the exposure</li> <li>• Date/time of exposure</li> <li>• Type of exposure,</li> <li>• Occupation (e.g. first responders)</li> <li>• Clinical history</li> <li>• Patient Birth Date</li> <li>• Decision support feedback (pending further analysis)</li> <li>• Logic</li> <li>• Contraindications</li> <li>• Policy</li> <li>• Trigger Criteria</li> </ul>
DR21	<p>Terminology Data: Used to transform human or computer vocabularies. Data attributes may be specified based upon implementation. Within the context of this Use Case, translate from local vocabulary to standard vocabulary (e.g. Drug Reporting may be using MEDRA though LOINC has been specified by CHI; NOTE: SNOMED meaning may be different from CDC/CSTE meanings;) For example, the Clinician wants to use the vocabulary that supports their workflow. A Terminology service may be needed to provide the mapping from local vocabulary to the standard vocabulary; challenge in harmonizing the vocabulary to service the multiple stakeholders and multi-purpose the data elements</p>	
DR24	<p>Case Report Pre-populate Data: Supports a standard set of data, terminology constraints, and associated mapping to EHR elements for pre-population within a Form Filler to optimize data capture from EHR for use in Public Health Case Reporting</p>	



Data Requirement Number (DR)	Description	
	<ul style="list-style-type: none"> <li>• Facility/ Importer Name</li> <li>• Facility Identifier</li> <li>• Address</li> <li>• Telephone</li> <li>• Contact Person</li> <li>• Contact Phone Number</li> <li>• Responsible Physician/ Healthcare provider name</li> <li>• User Facility/ Importer Report Number</li> <li>• Type of Report</li> <li>• Report Date</li> <li>• Reported Previously</li> <li>• Report sent to</li> <li>• Report sent to FDA</li> <li>• Date User Facility/ Importer Became Aware of Event</li> <li>• Date report sent</li> <li>• Date sent to FDA</li> <li>• Report Source</li> <li>• Reporter Name</li> <li>• Occupation of Reporter</li> <li>• Telephone</li> <li>• Reporter Email</li> <li>• Type of Reporter</li> <li>• Reporter Address (street name, city, state, zip)</li> <li>• Patient Identifier</li> <li>• Patient Name (First, MI, Last)</li> <li>• Patient Alias Name: First, Middle, Last</li> <li>• Date of Birth</li> <li>• Age</li> <li>• Gender</li> <li>• Pregnancy Status</li> <li>• Estimated Deliver Date</li> <li>• Weight</li> <li>• Birth Weight</li> <li>• Number of Siblings</li> <li>• Name of Treatment</li> <li>• Admission Date</li> <li>• Discharge Date</li> <li>• Hospital Name</li> <li>• Death</li> <li>• Patient Address (street name, city, state, zip)</li> <li>• Patient Telephone</li> </ul>	<ul style="list-style-type: none"> <li>• Patient County</li> <li>• Patient Country</li> <li>• Race</li> <li>• Ethnicity</li> <li>• Date of Death</li> <li>• Date of Event</li> <li>• Description of Event</li> <li>• Name of Condition</li> <li>• Event Patient Problem Code</li> <li>• Type of Event and/or Issue</li> <li>• Concomitant Medical Product Name</li> <li>• Therapy Dates</li> <li>• Pre-existing clinician diagnosed allergies, birth defects</li> <li>• Current Medications (concomitant meds)</li> <li>• Previous Vaccine Type</li> <li>• Previous Vaccine Manufacturer</li> <li>• Previous Vaccine Lot #</li> <li>• Previous Vaccine Route/Site</li> <li>• Previous Vaccine Date Given</li> <li>• Suspect Product Name</li> <li>• Product Dose</li> <li>• Product Frequency</li> <li>• Product Route Used</li> <li>• Product Therapy Dates</li> <li>• NDC# or Unique ID</li> <li>• Suspect Medical Device Brand Name</li> <li>• Common Device Name</li> <li>• Signs and Symptoms</li> <li>• Symptom/ Illness Onset Date/Time</li> <li>• Patient Class</li> <li>• Report Date/Time</li> <li>• Results Status</li> <li>• Resulted Test</li> <li>• Result Unit</li> <li>• Test Interpretation</li> <li>• Test Status</li> <li>• Test Method</li> <li>• Test Result</li> <li>• Diagnosis/ Injury Code</li> <li>• Diagnosis Type</li> <li>• Administration of Treatment</li> <li>• Date of Administration of Treatment</li> </ul>



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Data Requirement Number (DR)	Description
DR25	<p>Case Report Content: Case data of the report to be submitted. For this Use Case, there are multiple reporting types:</p> <ul style="list-style-type: none"> <li>• Biovigilance (blood, organ, and tissue) reporting to include post-marketing surveillance</li> <li>• Drug Safety (AE related to drug) (see tier 2)</li> <li>• Device Safety Report</li> <li>• Drug administration management</li> <li>• Vaccine AE report</li> <li>• Food safety</li> <li>• Reportable disease reports</li> <li>• HAI</li> <li>• Other HC safety reports other than Infection (e.g. falls) (including Sentinel events; all never-events, anything that may become a never-event; AHRQ)</li> </ul> <p>Many of the attributes are common across these report types. The data requirements below are listed as 3 subsets: Case data captured universally, data requirements that are specific to public health reporting, and those that are specific to adverse event reports. Report-specific attributes are not identified here, though an example of these can be found in section 6.2. The complete list of attributes and associated detail is summarized in Section 6.2</p> <p>Universal data requirements supporting all case report types</p>



Data Requirement Number (DR)	Description	
	<ul style="list-style-type: none"> <li>• Facility/ Importer Name</li> <li>• Facility Identifier</li> <li>• Address</li> <li>• Telephone</li> <li>• Contact</li> <li>• Contact Person</li> <li>• Contact Phone Number</li> <li>• Responsible Clinician/ Healthcare provider name</li> <li>• User Facility/Importer Report Number</li> <li>• Type of Report</li> <li>• Report Date</li> <li>• Reported Previously</li> <li>• Report Sent To</li> <li>• Date User Facility/Importer Became Aware of Event</li> <li>• Date Report Sent</li> <li>• Date Sent to Manufacturer</li> <li>• Report Source</li> <li>• Reporter Name</li> <li>• Occupation of Reporter</li> <li>• Telephone</li> <li>• Reporter Email</li> <li>• Report Date/Time</li> <li>• Type of Reporter</li> <li>• Reporter Address (street name, city, state, zip)</li> <li>• Patient Identifier</li> <li>• Patient Name (First, MI, Last)</li> <li>• Patient Alias Name: First, Middle, Last</li> <li>• Date of Birth</li> <li>• Age</li> <li>• Physiological Sex</li> <li>• Pregnancy Status</li> <li>• Birth Weight</li> <li>• Patient Address (street name, city, state, zip)</li> </ul>	<ul style="list-style-type: none"> <li>• Patient Telephone</li> <li>• Patient County</li> <li>• Patient Country</li> <li>• Race</li> <li>• Ethnicity</li> <li>• Date of Death</li> <li>• Date of Event</li> <li>• Description of Event</li> <li>• Name of Condition</li> <li>• Signs and Symptoms</li> <li>• Symptom/ Illness Onset Date/Time</li> <li>• Reporting Laboratory Identifier</li> <li>• Performing Laboratory</li> <li>• Results Status</li> <li>• Ordered Test Code</li> <li>• Resulted Test</li> <li>• Result Unit</li> <li>• Test Interpretation</li> <li>• Test Status</li> <li>• Date of Test</li> <li>• Test Method</li> <li>• Test Result</li> <li>• Specimen Collection Date</li> <li>• Source of Specimen</li> <li>• Name of Organization Collecting Specimen</li> <li>• Diagnosis Date/Time</li> <li>• Administration of Treatment</li> <li>• Date of Admin of Treatment</li> <li>• Name of Treatment</li> <li>• Hospitalization</li> <li>• Admission Date</li> <li>• Discharge Date</li> <li>• Recovered</li> </ul>
	Data requirements for Public Health reporting	
	<ul style="list-style-type: none"> <li>• Estimated Deliver Date</li> <li>• Number of Siblings</li> <li>• Occupation</li> <li>• Patient Country of Birth</li> </ul>	<ul style="list-style-type: none"> <li>• Patient Country of Origin</li> <li>• Time arrived in the US</li> <li>• Hospital Name</li> <li>• Death</li> </ul>
	Data requirements for Adverse Event Reports	



Data Requirement Number (DR)	Description	
	<ul style="list-style-type: none"> <li>Report Sent to FDA</li> <li>Date sent to FDA</li> <li>Weight</li> <li>Event Patient Problem Code</li> <li>Event Device Problem Code</li> <li>Type of Reportable Event</li> <li>Type of Event and/or Issue</li> <li>Approximate Age of Device</li> <li>Outcome Attributed to AE</li> <li>Patient Recovered</li> <li>Diagnosis</li> <li>Location where Event Occurred</li> <li>Adverse Event Terms</li> <li>Event Abated after use stopped or dose reduced?</li> <li>Event Reappeared after reintroduction</li> <li>Concomitant Medical Product Name</li> <li>Therapy Dates</li> <li>Pre-existing clinician diagnosed allergies, birth defects. Medical conditions</li> <li>Current Medications (concomitant meds)</li> <li>Previous Vaccine Type</li> <li>Previous Vaccine Manufacturer</li> <li>Previous Vaccine Lot #</li> <li>Previous Vaccine Route/Site</li> <li>Vaccine # Previous Doses</li> <li>Previous Vaccine Date Given</li> <li>AE Following Prior Vaccination</li> <li>Immunization Services Funding Eligibility</li> <li>Suspect Product Name</li> <li>Product Dose</li> </ul>	<ul style="list-style-type: none"> <li>Product Frequency</li> <li>Product Route Used</li> <li>Product Therapy Dates</li> <li>Product Diagnosis for Use</li> <li>Product Lot #</li> <li>Expiration Date</li> <li>NDC# or Unique ID</li> <li>Common Device Name</li> <li>Manuf. Name, City and State</li> <li>Medical Device Model #</li> <li>Medical Device Catalog #</li> <li>Medical Device Serial #</li> <li>Medical Device Lot #</li> <li>Medical Device Other #</li> <li>Operator of Device</li> <li>If implanted give date</li> <li>If explanted give date</li> <li>Is this a single use device that was reprocessed and reused on patient?</li> <li>Name and Address of Reprocessor</li> <li>Product available for evaluation?</li> <li>Date product returned to manuf.</li> <li>Concomitant Medical Products &amp; Therapy Dates</li> <li>Patient Class</li> <li>Diagnosis/Injury Code</li> <li>Diagnosis Type</li> <li>Previous Event Report Details</li> <li>Reason for Non-Evaluation</li> <li>Type of Follow-Up</li> <li>Type of Remedial Action</li> </ul>
DR26	Reporting Criteria Content - Structured content – machine processable. Data requirements pending further analysis and SDO development. (see gaps)	
DR59	<p>Generic Alert Data – Public Health: A non-patient identifiable alert (message or presentation preserving document) sent to an identified set of recipients. This may be used to communicate unstructured reporting requirements, and alerts.</p> <p>Data requirements include but are not limited to:</p>	
	<ul style="list-style-type: none"> <li>Target population</li> <li>A descriptive directive</li> </ul>	<ul style="list-style-type: none"> <li>Severity</li> <li>Source/Author</li> </ul>

Table 2.2.2-2 below contains an extraction of the Information Exchange Requirements from the Use Case. Information Exchange Requirements map to the Information Exchange Requirements column in the Use Case Mapping Table 6.3-1 provided in Section 6.3.



**Table 2.2.2-2 Information Exchange Requirements (IER)**

Information Exchange Requirement Number (IER)	Description
IER 01	Provide authorization and consent: System authenticates user and verifies authorization.: IS11: NOTE: May have new actors in an emergency situation (e.g. labs or employers, healthcare provider not traditionally involved in immunization administration, mobile service) In the context of this Use Case, specific consideration must be given to IRB/research authorization, emergency events, and exposure notifications
IER02	Send data over secured communication channel: A session oriented, synchronous, point-to-point communication channel establishing a secure path through which data can be transmitted
IER03	Create audit log entry: Provides assurance that security policies are being followed or enforced and that risks are being mitigated
IER04	Synchronize system time: Ensures that all of the entities that are communicating within the network have synchronized system clocks
IER05	Verify entity identity: Secure message system authenticates user. Entities are asserted to assure that the entity is the person or application that claims the identity
IER06	Provide proof of document integrity and origin: Support Nonrepudiation of Origin, which refers to both the proof of the integrity and origin of documents in a high-assurance manner which can be verified by any party. In the context of this Use Case, this may be used to verify clinician review and authorization to send a report or to verify the validity of the source of a request for information
IER10	Identify patient: Support for identifying, cross referencing, and query of patients. NOTE: Method for identifying where the patient's records across multiple domains use HITSP/TP13- XCA – need another method for identifying patient records in a non-document-centric environment
IER 13	Send/receive notification of document availability: Mechanism to notify providers or the patient that there is patient-related information available for retrieval supporting the pro-active sending of notifications from public health
IER18	Send/receive clinical document: Supports the sharing of patient records in the form of source attested objects called documents, using physical media and email to transport clinical document information from a source to a destination, or communicate a clinical document to a recipient through direct communication conveying a set of medical documents in a point-to-point network-based communication
IER26	Identify communication recipients: For the identification of communication recipients for the delivery of alerts, and bi-directional communications from public health services (e.g. identify communication details for those who may have received a bad lot of vaccine, based upon clinical decision support output, providers in a particular geographic area at risk) NOTE: Organization Role or POC/authorized recipient needs to be identified: Internal/external reporting practices may have a primary source reporter (e.g. nurse/individual). Some organizations may have a Risk Manager to handle communications. When a PH agency does an investigation, the information flow is back to reporting facility; Typically, communications are to the Risk Manager, contact office, or to the primary source reporter. The contact office may be specific to the report type e.g. FDA, PH, etc. If the communication is to the patient where the patient is under 18 it is the guardian/parent. For AE, it is an agency-specific POC. For a device, it may be the device administrator by product type; For PH it may be an infection control practitioner
IER27	Send non-patient notification message or alert: Supports the communication of text-based, non-patient specific notifications supporting pro-active notifications from public health (e.g. notification of a population at risk in need of intervention)
IER29	Send/receive electronic form for data capture: Enables capture of supplemental data variables not typically maintained in an electronic health record or laboratory information system through a more seamless integration with the local information system. For Public Health Case Reporting, this includes support for human review of submissions, multiple persons or time-points of entry, and augmentation mechanisms
IER40	Query for existing data: Supports dynamic queries for clinical data, including vital signs, problems, medications, immunizations, diagnostic results, procedures and visit history





Information Exchange Requirement Number (IER)	Description
IER42	Request/receive medical concept knowledge: Supports the query and receipt of ancillary medical knowledge
IER49	Report confirmation: Confirmation of receipt of a report. In the context of this Use Case, this may be accomplished through a form confirmation button or through nonrepudiation
IER55	Anonymize patient identifiable data: Supports the process that removes the association between the identifying data set and the data subject. For this specification, this specifically supports data provisioning for clinical decision support. In the context of this Use Case, specific consideration must be given to small cell sizes, data provisioning for clinical decision support
IER56	Pseudonymize patient identifying information: Supports pseudonymization - is a particular type of anonymization that both removes the association with a data subject and adds an association between a particular set of characteristics relating to the data subject and one or more pseudonyms. For this specification, this specifically supports data provisioning for clinical decision support. In the context of this Use Case, considerations must be given to protection of discoverable information, clinician and organization protections, and re-identification. Primary consideration for this requirement is to support adverse event reporting

### 2.2.3 IDENTIFICATION OF BUSINESS ACTORS, MAPPED TO REQUIREMENTS

This section describes the Business Actors that impact information exchange requirements for each scenario. A Business Actor is an abstraction that is instantiated as an IT system application that a Stakeholder uses in the exchange of data needed to complete Use Case action(s); a Business Actor is not a Stakeholder. A HITSP Stakeholder is a person, organization or "personified system" that performs actions in a Use Case. Only Business Actors as an IT system are directly engaged and benefit from the real world information exchange defined within a business Use Case action. Only Business Actors are associated with Technical Actors, which support the data exchanges of the Business Actors (see Section 3.2 for Technical Actors). The table below identifies the significant Use Case Business Actors, their descriptions, the Stakeholders they support, the Use Case scenarios, and the information exchange or data requirements for which they are used. Refer to the Use Case for a more detailed description of the listed stakeholders.



**Table 2.2.3-1 Business Actors**

Business Actor	Description	Supported Stakeholders	Use Case Scenario	Information Exchange Requirement Numbers (IER)	Data Requirement Numbers (DR)
Electronic Health Record (EHR) System	The Electronic Health Record (EHR) System is a secure, real-time, point-of-care, patient-centric information resource for clinicians	HIS, EHR Healthcare Delivery Organizations, Ancillary Entities, Clinicians Care Delivery Actor	1, 2	<p>IER26 Identify communication recipients</p> <p>IER27 Send non-patient notification message or alert</p> <p>IER42 Request/receive medical concept knowledge</p> <p>IER29 Send/receive electronic form for data capture</p> <p>IER55 Anonymize patient identifiable data</p> <p>IER56 Pseudonymize patient identifying information</p> <p>IER18 Send/receive clinical document</p> <p>IER40 Query for existing data</p> <p>IER18 Send/receive clinical document</p> <p>IER10 Identify patient</p> <p>IER5 Verify entity identity</p> <p>IER01 Provide authorization and consent</p> <p>IER02 Send data over secured communication channel</p> <p>IER49 Report confirmation</p> <p>IER06 Provide proof of document integrity and origin</p> <p>IER03 Create audit log entry</p> <p>IER04 Synchronize system time</p> <p>IER13 Send/receive notification of document availability</p>	<p>DR17 Decision Support Data Content</p> <p>DR21 Terminology Data</p> <p>DR24 Case Report Pre-populate Data</p> <p>DR25 Case Report Content</p> <p>DR8 Unstructured Data</p> <p>DR59 Generic Alert Data – Public Health</p>



Business Actor	Description	Supported Stakeholders	Use Case Scenario	Information Exchange Requirement Numbers (IER)	Data Requirement Numbers (DR)
Health Information Exchange (HIE)	A Health Information Exchange (HIE) is a multi-stakeholder system that enables the exchange and use of health information, in a secure manner, for the purpose of promoting the improvement of health quality, safety and efficiency	RHIO	1,2	IER26 Identify communication recipients IER55 Anonymize patient identifiable data IER56 Pseudonymize patient identifying information IER49 Report confirmation IER03 Create audit log entry IER04 Synchronize system time	DR21 Terminology Data DR24 Case Report Pre-populate Data DR8 Unstructured Data DR59 Generic Alert Data – Public Health
Laboratory Information Systems	Information system supporting the testing, analysis, and information management for laboratory organizations. Medical laboratories, in either in a hospital or ambulatory environment, which analyze specimens as ordered by clinicians to assess the health status of patients. Laboratories, depending on how they are affiliated with hospitals, can be part of either Individual Healthcare Facilities or Integrated Healthcare Data Suppliers. These business actors are responsible for updating interface engine rules and triggers in response to Use Case modifications of requested data feeds.	Laboratories	1,2	IER13 Send/receive notification of document availability IER03 Create audit log entry IER04 Synchronize system time IER18 Send/receive clinical document IER27 Send non-patient notification message or alert	DR17 Decision Support Data Content DR25 Case Report Content DR8 Unstructured Data DR59 Generic Alert Data – Public Health



Business Actor	Description	Supported Stakeholders	Use Case Scenario	Information Exchange Requirement Numbers (IER)	Data Requirement Numbers (DR)
Public Health Information System	An automated and integrated system used to document and address information of interest to public health. Local, state, and federal government organizations and personnel use these systems to help protect and improve the health of their respective constituents. A critical effort under this charge is collecting health information to monitor for the existence of emerging health threats appearing in the population and manage these threats once manifested. Staff of these agencies interacts with the public health information system to verify and validate system indications of public health threats, and to assert acknowledgements that may be required by system processes.	Local/state/federal public health agencies including FDA, CDC	1,2	<p>IER26 Identify communication recipients</p> <p>IER27 Send non-patient notification message or alert</p> <p>IER42 Request/receive medical concept knowledge</p> <p>IER29 Send/receive electronic form for data capture</p> <p>IER55 Anonymize patient identifiable data</p> <p>IER56 Pseudonymize patient identifying information</p> <p>IER18 Send/receive clinical document</p> <p>IER40 Query for existing data</p> <p>IER10 Identify patient</p> <p>IER01 Provide authorization and consent</p> <p>IER05 Verify entity identity</p> <p>IER1 Provide authorization and consent</p> <p>IER02 Send data over secured communication channel</p> <p>IER03 Create audit log entry</p> <p>IER04 Synchronize system time</p> <p>IER49 Report confirmation</p> <p>IER06 Provide proof of document integrity and origin</p> <p>IER13 Send/receive notification of document availability</p>	<p>DR17 Decision Support Data Content</p> <p>DR21 Terminology Data</p> <p>DR24 Case Report Pre-populate Data</p> <p>DR25 Case Report Content</p> <p>DR8 Unstructured Data</p> <p>DR59 Generic Alert Data – Public Health</p> <p>DR26 Reporting Criteria Content</p>



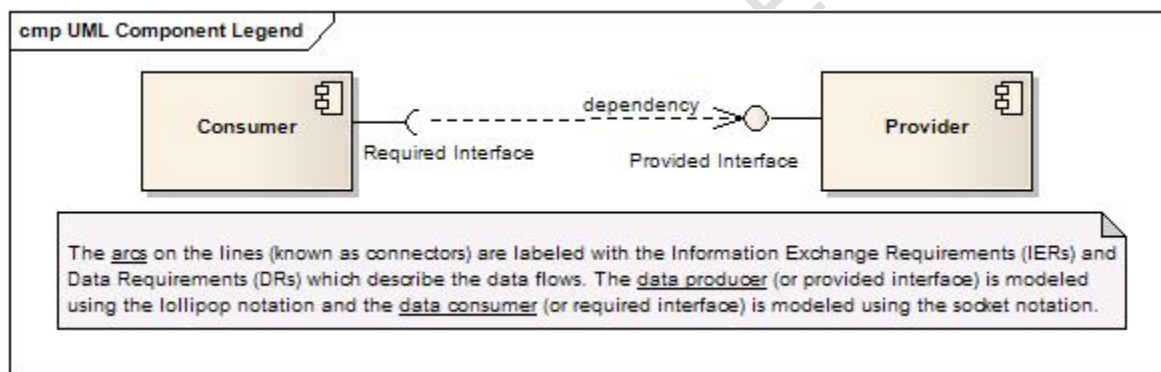
## 2.2.4 HIGH-LEVEL DIAGRAMS

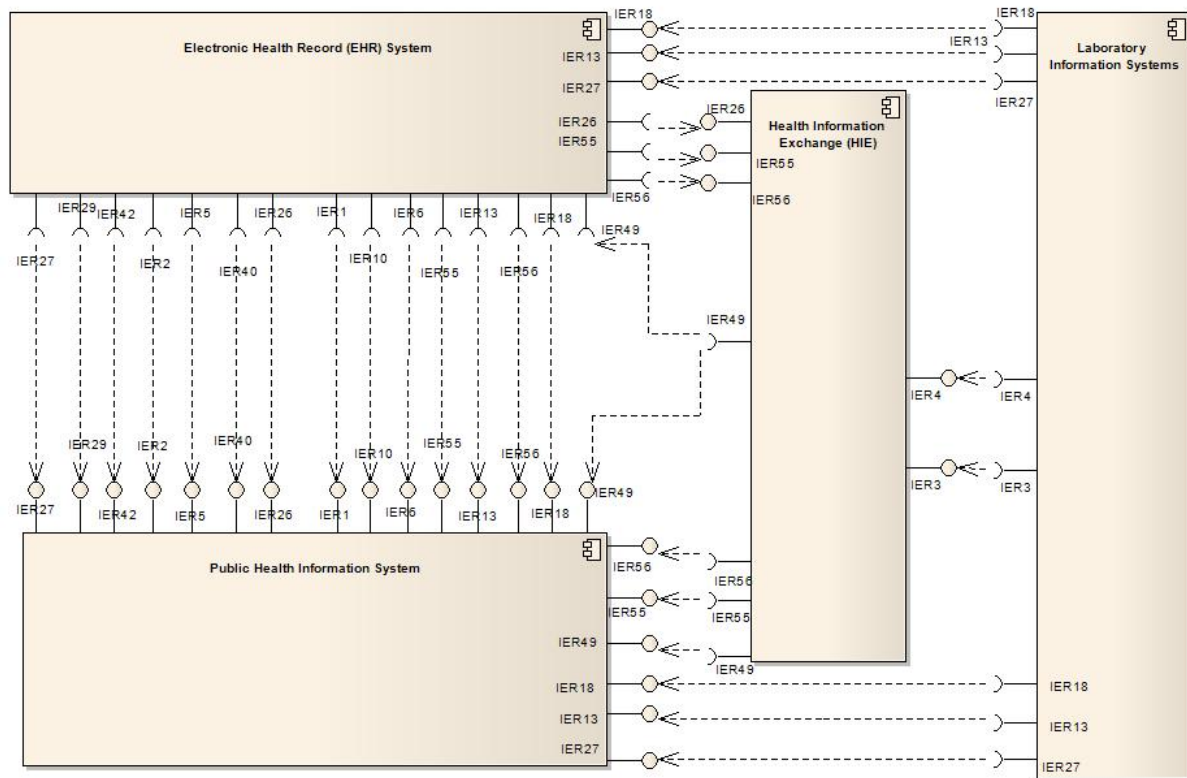
This section contains diagrams that describe the relationships and data interactions between the primary and alternative business actors and stakeholders for each Use Case scenario.

High level Sequence diagrams are provided in Section 6.4 that illustrate each Use Case scenario with a representation of a normal sequence of exchange between the primary actors. The interactions are supported by the various constructs which will be introduced in Section 3 of this Interoperability Specification.

Figure 2.2.4-1 is a Component Data Flow diagram that illustrates the data flow and information exchanges between the primary actors. The information exchange and data requirement numbers from tables in Section 2.2.2 are annotated on the diagrams to show how the requirements relate to the primary actors. The in-scope requirements are supported by constructs which will be introduced in Section 3 of this Interoperability Specification.

**Figure 2.2.4-1 Public Health Case Reporting Component Data Flow Diagram**





## 3.0 DESIGN

The design for the Interoperability Specification is the result of the requirements analysis and iterative standards selection process. This section describes the design based on the specified Business Actors and their Information Exchange and Data Requirements. It provides a detailed mapping of the specified requirements to HITSP constructs and their Technical Actors, groupings of specific Technical Actors which support Business Actors are specified to further describe the relevant interactions from existing or new HITSP constructs required for interoperability.

### 3.1 SCOPE OF DESIGN

This section describes the scope of the design as it relates to the requirements for this Use Case that were identified in Section 2.2 above. The scope identifies the assumptions that provide the boundaries for the specification and the constraints that limit the use of the specification. In addition, any pre-conditions, post-conditions and triggers that underlie the interactions between the various actors, data and transactions are provided.

The focus of the initial design is to optimize electronic data capture of Public Health Case Reporting and adverse event data from electronic health records. This will be accomplished through the mapping of data elements that are cross-cutting among the multiple reporting purposes to electronic health record data elements. This mapping will enable pre-population of data within the context of HITSP/TP50 Retrieve Form for Data Capture which can then be leveraged for the capture of supplemental reporting criteria not typically maintained as part of the electronic health record.

The design leverages existing HITSP constructs and communication methodologies. Additional communication support methodologies are specified to support identification of communication recipients for alerts and notifications not containing PHI.

Use Case actions requiring clinical decision support capabilities are deferred pending the development of HITSP constructs supporting the expression and communication of associated logic. This includes support for reporting, and triggering criteria for both public health adverse event cases. It also includes support for prioritization of responses.

The following schedule indicates the proposed multi-release implementation plan for the Population Perspective Committee to complete the analysis and Interoperability Specification development for the final Public Health Case Reporting Use Case.

The Population Perspective Technical Committee plans a multi-release approach, with each release adding to the value and capabilities of the proposed constructs.



Release 1:

- Establish Transaction Packages, Transactions, and components to complete the Use Case requirements related to the electronic data capture of report content from the electronic health record
- Communication of structured content for Healthcare Associated Infections (HAI) to public health authorities
- Leverage existing HITSP constructs to enable EHR compilation of augmented data surrounding case reporting for a given patient leveraging common data elements identified across the multiple case reporting domains, those common within the domains, and detailed case reporting examples. Detailed case reporting examples in public health will be limited to Tuberculosis, Hepatitis B, Tularemia, and Anthrax
- Establish one component (Case Reporting Terminology) to enable mapping of common case reporting data elements from EHR to enable pre-population of forms from the HITSP/TP50 Retrieve Form for Data Capture form manager

While there are workflow commonalities between public health case reporting and adverse event reporting, there are differences in workflow policy and data elements routinely captured today. As harmonization is under way through cross-agency initiatives to align data and terminology requirements for case reporting to support both public health and varying adverse event reporting needs, the HITSP Population Perspective TC will identify, observe, and contribute to harmonization efforts and defer content specification for non-HAI communications until the standardization/harmonization is completed. This decision is supported by Tier 2 Readiness Criteria Assessment efforts.

For the purpose of submitting a case report, we will develop the HITSP Case Report Pre-populate Component based upon our common data requirements that will work in conjunction with HITSP/TP50 to enable pre-population, but which WILL NOT be specified as a component for the communication of the populated payload to the end agency recipient. This very important consensus construct (component) is deferred until such time as we have a consensus-based content /transport that can be specified and generated from a variety of architectures for submission to the agency. The report construct specified for communication of the case report to the report recipient will vary by report type. For HAI reports, this Interoperability Specification specifies an HL7 structured document specifically established for this purpose (HITSP/C75). For Drug Safety reporting, this Interoperability Specification will provisionally select ICSR V3, which is pending ballot in both HL7 and ISO TC215 as an international harmonized effort addressing drug safety reporting. Development of the associated HITSP construct will be deferred in order to adopt this work. Constructs for other case report types are similarly pending SDO and domain harmonization efforts.

Mapping of common data elements specified in this Interoperability Specification to CDA documents already specified by HITSP (HITSP/C32, HITSP/C48) is specified by HITSP/C76 enabling the EHR to send data for pre-population of the HITSP/TP50 Form and minimize data entry. The resulting construct to





be sent from the form manager (or directly from a conformant EHR) to the end agency is a deferred construct and we will remain silent on specifying this in the Interoperability Specification until we have the consensus document. The one exception to the format that was identified was the HL7 HAI which is specified as a provisional construct pending the consensus document. The approach in this Interoperability Specification should be considered 'for implementation testing' only until we have the remaining case report constructs defined, given that the final constructs could impact the data capture and transport options.

#### Release 2:

This second release will address the following gaps identified by the HITSP Population Perspective Technical Committee:

- No consolidation of overlapping methods for case reporting and adverse event reporting. The second release will leverage harmonization efforts currently underway to specify common structured content for communication of public health and adverse event reporting data.
- Availability of constructs supporting clinical decision support

The following table identifies constructs that the Population Perspective Technical Committee plans to specify for Releases 1 and 2:

**Table 3.1-1 Scope for Releases 1 and 2**

Activity	Topic	Scoped to:	Reason for Deferral	Requirement
Case Reports	Drug Safety	Release 2	Immature, standards in progress. Pending harmonization of case reporting content	
	Device Safety	Release 2	Immature, standards in progress. Pending harmonization of case reporting content	
	Drug admin management	Release 2	Immature, standards in progress. Pending harmonization of case reporting content	
	Vaccine AE report	Release 2	Immature, standards in progress. Pending harmonization of case reporting content	Case Report (VAERS)
	Food safety	Release 2	Immature, standards in progress. Pending harmonization of case reporting content	
	Reportable disease reports	Release 2	Immature, standards in progress. Pending harmonization of case reporting content	Case Report (Public Health Case Report)
	HAI	Release 1 (HITSP/C75)	NA	Case Report (HAI)



	Other HC safety reports other than Infection (e.g. falls) (including Sentinel events; all never-events, anything that may become a never-event; AHRQ)	Release 2	Immature, standards in progress. Pending harmonization of case reporting content	Case Report (Patient Safety, AE)
	Standard Case Report Construct	Release 2	NOTE: There are currently multiple studies underway to propagate the information about an adverse event from source to the recipient. Specification will be deferred to leverage the outcome of these efforts	Case Report (all)
Case Report Pre-populate	Mapping of common data elements to EHR data	Release 1 (HITSP/C76)		Case Report Pre-populate
Reporting Criteria Content	Common/basic	Release 1 (HITSP/C82, HITSP/T63)	NA	
	Case-specific	Release 2	Immature, standards in progress	Reporting Criteria
Clinical Decision Support Content	Trigger Events Clinical Decision Support Content (Report triggers, prioritization)	Release 2	(Domain TC to flesh out)	CDS: Reporting Criteria Triggers Prioritization
Generic Alert to Identified Clinicians	Clinical Report	Release 2+	Immature Standards	
	Basic Clinical (scanned) Report	Release 1 (HITSP/C82, HITSP/T63)		
	Public Report	Release 2+	Immature Standards	
	Basic Public (scanned) Report	Release 1 (HITSP/C82, HITSP/T63)		
Patient-specific Report Document	Basic (scanned) Content, Transport	Release 1 (see Alert and Reporting Criteria discussion below) (HITSP/C62)		
	Structured Content, Transport	Release 2 pending CDS	Pending CDS support	
Identify Communication Recipients	Support communication of non-PHI alerts and notifications	Release 1 (HITSP/T64)		
Terminology Service	Support value set communication to support translation from local vocabulary to standard vocabulary	Release 1 (HITSP/T66)		



**Alerts and Reporting Criteria:**

Release 1 scope is limited to the use of the HITSP Unstructured Document Component for patient identifiable communications and to the use of Generic Alerts to Identified Clinicians with HITSP/T64 Identify Communication Recipients for non-patient identifiable communications. Details regarding this approach are provided in Section 3.2 in the Safety and Health Alert Functionality section. Further refinement of structured content may be provided in subsequent releases of the Interoperability Specification pending SDO development of supporting content constructs and HITSP development of Clinical Decision Support constructs.

**Patient Safety Roadmap:**

The AHIC Quality Workgroup established a sub-group to define a data set for use by HITSP for the Public Health Case Reporting Use Case. That data set is provided in this Interoperability Specification and HITSP/C76 Case Report Pre-populate. Although this effort is valuable for identifying EHR-generated data elements for use with reporting, harmonization with other government and industry efforts is important. The Agency for Healthcare Research and Quality (AHRQ) initiated a similar effort represented by the AHRQ Common Formats. The AHRQ effort results from the Patient Safety and Quality Improvement Act of 2005 which establishes a framework by which doctors, hospitals, and other healthcare providers may voluntarily report information on a privileged and confidential basis regarding patient safety events and quality of care.

The Statute authorizes the collection of this information in a standardized manner. The AHRQ has coordinated the development of a set of common definitions and reporting formats (AHRQ Common Formats) that facilitate the voluntary collection of patient safety event information and the reporting of this information to Patient Safety Organizations. The AHRQ Common Formats effort provides an ongoing methodology to establish a standardized data set for patient safety reporting. AHRQ released a Beta version in August, 2008. The National Quality Forum is currently receiving feedback on the Beta version. AHRQ will use this feedback to enhance the Beta version, and AHRQ anticipates completion AHRQ Common Formats Version 1.0 in approximately June 2009, with annual version updates thereafter.

The AHRQ Common Formats delineate definitions, data elements, and reporting formats that allow healthcare providers to collect and submit standardized information regarding patient safety events. They are event focused in contradistinction to EHR records, which are patient focused. Patient safety reporting is also a function of a reporting system and not an EHR document. However, to the extent that EHR captured data can feed the reporting system, significant value will be generated. This HITSP Interoperability Specification identifies a mechanism for filling required information in a form automatically from EHR data and enabling clinicians to add additional information, then return the form to the reporting system using HITSP/TP50 Retrieve Form for Data Capture. A human Risk Manager will almost always be required to validate the information before actual reporting to any agency or Patient Safety Organization.



To the extent possible, EHRs may be able to trigger the need for reporting based on a standard data set of triggers. Such a standard data set has not been established to date.

In establishing interoperability with the HITSP Interoperability Specification, there are three main categorizations of the AHRQ Common Formats elements to consider:

1. AHRQ Common Formats data elements which may correspond directly to EHR elements.
  - a. Patient's Name
  - b. Patient's Date of Birth
  - c. Patient's Gender
2. AHRQ Common Formats data elements which may appear to correspond directly to EHR elements, but have different usage in the Patient Safety arena.
  - a. Location
    - i. This is the location where the unsafe event or condition occurred. This does not necessarily correspond to the patient's location as customarily documented in an EHR.
  - b. Date
    - i. This is the date the event occurred, and can be documented validly as "unknown." This does not correspond to the date the patient first noted symptoms (or was admitted to a facility), as customarily documented in an EHR.
  - c. Device Type
    - i. The type of device involved in an event may be documented as: Implantable device, non-implantable device, or any other type of medical equipment, or medical/surgical supply. These categorizations are less concrete than device information customarily documented in an EHR. An EHR usually contains details of the procedure during which the device was used/implanted, etc.
3. AHRQ Common Formats data elements which are assumed not to exist in an EHR. Most of the AHRQ Common Formats data elements fall under this category.
  - a. Number of Patients (How many patients the incident reached).
  - b. Rescue Attempted (Whether or not "rescue" was attempted following the discovery of an incident).
  - c. Level of Preventability (How preventable the event or unsafe condition was).

It is expected that the AHRQ Common Formats Version 1.0 will be mapped, to the extent possible given limitations as outlined above, to EHR data elements for September/October 2009 release from HITSP. This effort will harmonize with the existing AHIC data set information provided in HITSP/C76.

Notifiable disease information is captured in a common format defined in concert by the Council of State and Territorial Epidemiologists (CSTE) and the Centers for Disease Control and Prevention (CDC). The Association of Public Health Laboratories (APHL) also evaluates codes used for laboratory reporting of these reportable conditions. The output of the CSTE effort, Reporting Criteria for Nationally Notifiable Conditions, is expected to be completed in June 2009. The effort is also expected to list triggers that can



enable EHRs to generate information for national notifiable conditions. The results of this effort will also be harmonized with data available within EHRs in the 2009 HITSP effort.

### 3.1.1 ASSUMPTIONS

This section provides an overview of the assumptions, including the circumstances, actors, policies and/or technologies that need to be in place for the design to be completed as specified. Assumptions are different from constraints which are specifically used to narrow the definition, or indicate limitations of the specified interactions.

**Table 3.1.1-1 Assumptions**

Assumption	Use Case Scenario
7.1.1.1 This event for AE invokes an investigation by regulation	1: AE
7.1.1.1 For PH the decision to investigate may be more subjective	1: PH
7.1.1.1 Assume that AE is limited to post-marketing not to clinical trials (note Drug Safety report from IHE is ICHE E2b – is pre/post market)	1: AE
7.1.1.1 Data may not apply to AE Requires a HC provider or someone in the care process to make judgment that an AE occurred	1:AE
7.1.1.1 For AE if it meets regulatory definition for AE, then there must an investigation. For PH the decision to investigate may be more subjective	1:all
7.1.1.1 Medical judgment may need attestation from the clinician; post-marketing situations may have certain tracking/PH response or severity-based decisions (e.g. syphilis – VDRL – lab generates a report to PH – in a 72yr old man – clinician may look at this and determine other potential reasons for a false positive – and rules out a case). May need clinician validation/human judgment to kick off a next step. There may be a cascade of trigger events – there may be limited knowledge as to how to respond to a trigger event. Same would apply well to patient safety	1:all
7.1.1.2, 7.1.1.3 Forms is a very ambiguous word – we may have assumptions surrounding the interpretations. The common aspect is XML	1: All
7.1.1.2, 7.1.1.3 Requires Communicate trigger events from 7.1.1.1	1:All
7.1.1.3 This IS needs to refer to this in an architecturally neutral way. In some states, it may be varied or perhaps regulated (funding, distribution, schedule) differs. (expression of schedule is in 7.4.1)	1:All
7.1.2.1, 7.1.2.2 Handling between PH/AE may be different	1:All
7.1.2.2 Need to consider reporting workflow: ID, review, report	1:All
7.1.3.2, 7.1.5.1 Auto-report option needed	1:All
7.1.3.2, 7.1.5.1 Need to consider workflow management: optionality for human review; review /comment/ modification option before sending	1:All
7.1.3.2 Need to support various reporting users: User may be clinician or office staff/hospital staff (e.g. stand-alone infection control applications, clinical registries, etc.)	1:All
7.1.4.1 Behavior and Policy of PSO is defined by jurisdiction	1: AE
7.1.4.1 Need to consider Case Report workflow: preliminary report with detailed follow-up	1: All



Assumption	Use Case Scenario
7.1.4.2 Human review: Communication to report outside institution – clinician input as to whether or not to report	1: All
7.1.5.3 The Use Case description does not necessarily represent the workflow of what actually happens	1: All
7.1.6.1 Linked/case-associated records (e.g. mom/baby supplement data, food borne outbreak, vaccine failure)	1: All
7.1.6.1 Case finding vs. case investigation are not well distinguished from this step/Use Case – data requirements consideration	1: All
7.1.6.2 Authorizations for capture of supplemental data are defined by jurisdiction	1: All
7.1.6.2, 7.1.6.3 Augmentation mechanisms require appropriate authorizations: Not just PH agencies, but clinicians that may be reaching out in various ways to capture data that may not have been available in original data source	1: All
7.1.7.1 Lab reporting to PH is included despite the lack of specified actor in scenario 1: State reporting requirements for condition reporting when a lab value results in a required report	1: PH
7.1.7.1 Assume that confirm means that clinician confirms transmission in that point in time. Clinician may be able to gather info from a PHR	1: All
7.2.1.1 This perspective also represents that of other agencies and professional societies receiving PH information; and agencies AE/patient safety reports (e.g. CDC, CSTE, FDA, AHRQ)	1: All
7.2.1.4 Human readable and machine readable – problematic to choose which is wanted – for certain classes should have commonality – e.g. define ph case – a standard way to represent that definition e.g. text sections, list of standards/data elements	1: All
7.2.2.1 if it is a required report, the report is filed; if not required (e.g. AE is not required), does not exist until it is reported	1: All
7.2.2.1 Until the case is reported, the AE or event is not known	1: AE
7.2.2.1 An unreported event may fall under Quality Use Case	1: All
7.2.2.1 The entity that needs to receive/file the report is determined by jurisdiction or domain policy agreements	1: All
7.2.2.1 Trans-border communication expectations/specifications and mutual reporting are specified by policy	1: PH
7.2.2.1 Need to distinguish preliminary notification from confirmed case	1: All
7.2.2.1 PH does not receive initial notification – all notifications are to be considered	1: PH
7.2.3.1 PH (FDA and AHRQ are also PH agencies in this case along with state/local/tribal PH)	1,2: All
7.2.3.1 State-level responses are in place for many state preparedness planning	1,2: PH
7.2.3.1 Criticality may require no response other than tallying – no investigation typically conducted (e.g. Chlamydia)	1,2: PH
7.2.3.2 Workflow considerations: Feedback loop to go back and clarify with clinician	1,2: All
8.1.1 Assumption is made that this is operating in an acceptably secure environment	2: All
8.1.1.1 There is a triage system; (e.g. there are some conditions that do not trigger a case investigation such as chlamydia)	2: PH
8.1.1.1 Workflow considerations	2: All



Assumption	Use Case Scenario
8.1.1.1 HepB – example – need trans-aminase to verify – can leverage HIE rather than going back to the clinician for this detail	2: PH
8.1.1.2 Implies inter-jurisdiction exchanges	2: All
8.1.1.2 Same type of information is appropriate to AEs. This is how AEs often work; Odds of information coming in an electronically standardized fashion is not good (follow-up may be an autopsy report – e.g. validating cause of death – not necessarily mortality report – autopsy report may be used for contributing factors or organ systems/biological changes, discharge summary); no need to have a standardized autopsy report for a data requirement; notification of death is of interest	2: All
8.1.1.3 Implication is that the prior information collection events include collection of data that can represent: PH Cases onset, symptoms, risk factors, laboratory results, procedures, diagnosis, health status, counts, trends, patterns, etc	2: PH
8.1.2.1 Case definition can be defined and can be provided in an unambiguous format	2: All
8.2.1.1 Workflow issue – human interaction	2: All
8.1.2.2 PH event may impact a community; from EHR point of view, may not be enough cases to trigger the PH event – at community level can detect the event	2: PH
8.1.2.2 Implication that there is an oversight mechanism for refining the definitions; if want a national definition, this needs to be handles with professional society oversight	2: All
8.1.2.2 For AE, process is not as formal	2:AE
8.1.3.1 PH investigation purpose is to identify populations at risk and to contact patients to see if they need to be investigated. Also to do queries on population characteristics	2: All
8.1.3.1 Drug manufacturer may need to ID patients that are similar for Medical devices/drugs; need to add language to extend the definition of 'contact tracing' to apply to population characteristic for drug/med devices etc (e.g. teens/antidepressants; implant in a population at risk)	2: AE
8.1.3.1 Contact Tracing – applies to both cases, may be the same in some instances and different in others: AE, Devices, Notification via clinician, Manufacturer	2: All
8.1.3.2 Case count is not the priority/purpose here – goal is to manage/contain event not to produce a case count	2: All
8.1.3.2 PH case workers may act in notification process from 7.1; these exposures may not be identified by a clinician – may be identified by PH and referred to clinician for treatment	2: PH
8.1.4.1 Assume that the perspective addresses both National and local jurisdiction; Local PH jurisdiction perspective may differ from CDC perspective: Local PH jurisdiction – will have internal tools based on standardization of input data (using CHI vocabularies); Passes through local PH jurisdiction to CDC – data are using CHI standards; Many of these cases are cross-jurisdiction; e.g. in CA: if LA county PH in a train derailment chlorine gas issue, may cross multiple counties/jurisdictions – need to transfer case reports	2: PH
8.1.4.1 Possibly (for AE is likely locally defined process/edge system issue). Need standard way to transfer the case reports – standards for inter-jurisdiction case report/transfer message; from management perspective, issues of If a protocol is needed the protocol may need interoperability (e.g. CAP protocol between networks between HANs)	2:AE





Assumption	Use Case Scenario
8.1.4.2 Management plan is not an interoperability requirement; AE will not be the same as PH; depending on the nature of event, the management plan will be different depending upon event; This step is not necessarily an automated process and it depends on the issue/agency involved (e.g. FBI) Multiple agencies may be involved, may be an inter-agency management plan involved; This is outside scope of HITSP effort	2: All
8.1.4.2 Assumption: Needs human intervention for a management plan	2: All
8.1.4.2 Assumption: Agency-specific, situation-specific determination and is not yet a candidate for automation	2: All
8.1.5.1 The initial communication may differ in the level of detail (depending on PH and AE) confirmation of the 'disease'; for PH it may already be well defined during report event; for AE it may still be undefined that there is an event and this may be a simple confirmation	2: All
8.1.5.2 An example would be TB: Need to represent cases identified by a clinician to researchers looking to investigate a particular strain	2: PH
8.1.5.2 Policy considerations apply to exposure notifications and IRB/research authorization	2: All
8.2.1.1 Jurisdiction or HIE Policy may impose information exchange restrictions for some of these communications if electronic	2: All
8.3.1.2 Lab report content constraints are defined by policy	2: All
8.3.1.2 The feed for the results reporting is not necessarily the same as the report to PH – be sure this note is included in the IS	2: All
8.3.2.1 Currently private sector labs are excluded from this information	2: All
Assumption – for different types of reports, assume report creators will create a sufficiently unique code – assumption that assigning authority would want something unique	2: All
This Use Case assumes the developing presence of electronic systems such as Electronic Health Records (EHRs), Personal Health Records (PHRs), and other local or Web-based solutions supporting consumers and clinicians, while recognizing the issues and obstacles associated with these assumptions. This approach helps promote the development of longer-term efforts. Reference: HITSP Immunizations and Response Management Use Case Requirements, Design and Standards Selection, pg 10, Section 2.2	1, 2: All

### 3.1.2 CONSTRAINTS

This section describes the constraints that limit the context in which the Interoperability Specification may be used. A constraint describes a rule that limits the use of the actors, actions or data within the given context, or to which the interactions must conform to be used within the described context. It is a description of the limits and scope of the interactions and can describe actions or events that are not part of the initial definition for the context.

**Table 3.1.2-1 Constraints**

Constraint	Use Case Scenario
HITSP/T16 - Consistent Time SHALL be implemented for each system grouping of actors	1 and 2
HITSP/T17 - Secured Communication Channel SHALL be implemented for each system grouping of actors	1 and 2





Constraint	Use Case Scenario
The policy of the implementation environment MAY require HITSP/C26 - Nonrepudiation of Origin for one or more information sources initiating a HITSP Transaction with a payload of Case Report Reporting Criteria Unstructured Document (HITSP/C62)	1 and 2
HITSP/T15 - Collect and Communicate Audit Trail SHALL be implemented for each information source initiating a HITSP Transaction with a payload of Case Report Reporting Criteria Unstructured Document (HITSP/C62)	1 and 2
The policy of the implementation environment MAY require HITSP/C19 - Entity Identity Assertion	1 and 2
The policy of the implementation environment MAY require HITSP/C87 - Anonymize for analytical data uses	1 and 2
The policy of the implementation environment MAY require HITSP/T24 - Pseudonymize for analytical data uses	1 and 2
The policy of the implementation environment MAY require the HITSP/TP20 - Access Control	1 and 2
The policy of the implementation environment WILL require the HITSP/TP30 - Manage Consent Directives wherever access to IIHI is required	1 and 2

### 3.1.3 PRE-CONDITIONS

This section describes the necessary conditions that must be in place prior to the start of each scenario. The pre-conditions are used to convey any conditions that must be true at the outset of a scenario. It describes the context that must be established before the scenario is executed. They are not however the triggers that initiate a Use Case. Where one or more pre-conditions are not met, the behavior of the Use Case should be considered uncertain.

**Table 3.1.3-1 Pre-conditions**

Pre-condition	Use Case Scenario
Support the technical measures to ensure Security and Privacy of consumer/patient health information	All
Authentication service to authenticate requestors and/or data submissions from various locations	All
Security and Privacy policies, procedures and practices are commonly implemented to support acceptable levels of consumer/patient security and privacy	All
Legal and governance issues regarding data access authorizations, data ownership, and data use are in effect	All



Pre-condition	Use Case Scenario
Support the following HITSP Security and Privacy constructs: HITSP/C19 – Entity Identity Assertion HITSP/T16 - Consistent Time – Maintain time HITSP/T17 - Secured Communication Channel – Authenticate node HITSP/T15 - Collect and Communicate Security Audit Trail – Record audit event in repository HITSP/TP30 - Manage Consent Directives – Capture/Request consent directive HITSP/TP20 - Access Control – Access control request	All
All pre-conditions from the lower level constructs are incorporated	All
When needed, the patient is uniquely registered with the Patient Identity Cross-Referencing service	All
Patient Identities (name, demographics etc.) are known and are consistent with policies	All
There is an existing electronic record from which reports can be generated	All
8.1.1.1 Pre-condition – (for this scenario, there are rules in place that guide the prioritization and workflow considerations) NOTE: Challenging pre-condition as these do not exist in any electronic processable format; cases subject to investigation are designated notifiable would be the pre-condition – may be some cases (AE included) where it is always subject to a case investigation	2
Scenario 1 – Cases for investigation have been communicated	2
Immunizations and Response Management Use Case reporting of an adverse event	2

### 3.1.4 POST-CONDITIONS

This section provides an overview of the conditions or results that must occur at the end of each scenario in order for the scenario to be deemed successfully completed. This includes any required outputs from the scenario, or specific actor states.

**Table 3.1.4-1 Post-conditions**

Post-condition	Use Case Scenario
Appropriate case report information has been communicated and acted upon by Public Health	1
The case investigation has been concluded	2
Informing the PH decision making process	2

### 3.1.5 PROCESS TRIGGERS

This section describes the triggers, including actors and/or processes, which are necessary to start any scenarios, actions or events. It can be an automatic or manual process or result that in turn starts off another scenario, action or event. A trigger is not the same as a pre-condition that describes a context that needs to be in place at the start of the event.



**Table 3.1.5-1 Process Triggers**

Process Trigger	Use Case Scenario
<p>Various sources may communicate information which assists public health in determining criteria including: trigger data and reporting specifications:</p> <p>An update to the decision process rules. These may be event-driven or routine updates</p>	1
<p>Clinicians may initially notify Public Health of possible PH Cases or Adverse Events through information exchange activities or in an ad-hoc manner. Clinicians may also notify Manufacturers of possible AEs through information exchange activities or in an ad-hoc manner</p> <p>A possible reportable event is detected or suspected. Human review is performed on possible events to make the final decision on reporting</p> <p>Lab:</p> <p>Requirement for reporting to public health met – typically either a positive result or a required measured result (e.g. blood lead)</p>	1
<p>Possible AEs may be communicated to clinicians which may be internal or external to a public health setting. Specifics are addressed in the 2008 Immunizations and Response Management Detailed Use Case</p> <p>An external report was received by Public Health that indicates a detected or suspected adverse event. Human review is performed by public health on possible events to make the final decision on reporting</p>	1
<p>Possible PH Cases or AE reports may be communicated via information exchange activities to public health</p> <p>A possible reportable event is detected or suspected. Human review is performed on possible events to make the final decision on reporting</p> <p>NOTE: Triggers for AE, may have a broad category and add human intervention; sensitivity is high, and specificity is low - err on the side of false positives; Re-training the workforce will enable more specificity</p>	1
<p>Public Health accesses additional information to assist in their investigations. Therefore, additional information is requested by PH, the request is received by clinicians, and additional information is provided to Public Health via health information exchange activities</p> <p>Information reported to Public Health is sufficient to begin a case investigation. Public Health investigates the report and finds that it needs additional information to develop the case investigation</p>	2
<p>Public Health communicates case and/or patient specific information to clinicians and laboratories via health information exchange activities</p> <p>Public Health decides it needs to communicate information to the clinician community and chooses the appropriate means to do community</p>	2
<p>Public Health communicates specific information supporting clinical care to other public health agencies/ organizations via information exchange activities</p> <p>Public Health decides it needs to communicate information to the public health community and chooses the appropriate means to do community</p> <p>NOTE: Intra-government issues – trigger events may cause the need to involve another federal agency – same issue for state/local government</p>	2
<p>Public Health communicates publicly available information to other entities via information exchange activities</p> <p>Public Health decides it needs to communicate information to the general public and chooses the appropriate means to do community</p>	2



Process Trigger	Use Case Scenario
Based on Public Health information received via health information exchanges, clinicians may manage and treat PH Cases. Specifics are addressed in the 2008 Immunizations and Response Management Detailed Use Case  The clinician has patients or patients with contacts that are subject to a Public Health notification	2

## 3.2 DETAILED DESIGN

This section provides a detailed description of the technical design, along with an analysis of the main interactions and decisions between all actors, actions and data in support of the specific requirements for each scenario of the Use Case. In addition, this section provides the data element details and an overview of the HITSP constructs used to meet the business and technical requirements for this Use Case. Any variances in the Security and Privacy implementation are also described here.

Note that with respect to Security and Privacy, local implementation policy as determined by risk assessment, including assessment of jurisdictional and regulatory requirements, will determine which assurance level of nonrepudiation of origin is needed. For instance, in document-based transmissions, a low level is offered by the use of HITSP/TP13 Manage Sharing of Documents Construct. A medium level of assurance is offered by the use of the HITSP/TP13 Construct option called "Document Integrity." A high level of assurance is offered by the use of the HITSP/C26 Nonrepudiation of Origin Construct which requires the existence of a Public Key Infrastructure (PKI) (See TN900 for a discussion on the challenges with PKI's).

The ability to convey the patient's authorization for sharing information is managed differently by individual states and needs to be addressed as a policy issue. The IS allows for this process to be asserted by policy leveraging HITSP/TP30 Manage Consent Directives for primary information use and for information repurposing.

### **Examples:**

- "Opt out" functionality can be supported by HITSP/TP30
- A policy to prevent redistribution of data can be enforced by HITSP/TP20 and HITSP/TP30, by utilizing BPPC
- Facilities will need to determine, through policy, if a consumer choice or regulatory requirement would prohibit or restrict distribution of EHR data

For analytical information repurposing, policy which could be asserted by HITSP/TP30 may also call for anonymization (HITSP/C88 Anonymize for Immunization and Response Management Data) or pseudonymization (HITSP/T24 Pseudonymize).

HITSP/TP30 could be used to communicate obligations to be performed by applications. Pseudonymization and Anonymization are not performed in the underlying security infrastructure.



Access to patient information should be in the context of appropriate use as directed by policy (policy managed by HITSP/TP30, and access managed by HITSP/TP20). Refer to HITSP/TN900 for a discussion on separation of functionality and policy.

1. Step 1: Gathering the case report data from existing health information systems

The clinician system may, in order to acquire data available electronically for reporting, retrieve patient data from other clinical systems using HITSP/TP21 or HITSP/TP13

2. Step 2: Pre-population of the data

The clinician system sends common case reporting data elements to the form manager to allow for pre-population of the electronic data capture form from existing clinical data known to the clinician EHR (either directly or through the query mechanisms listed in Step 1)

3. Step 3: Completing the form and sending the data

The clinician or support staff fill in the remaining data elements in the case reporting data collection form supplied by the Form Manager. The Form Manager requests confirmation that the data submitted is accurate (human review), and upon confirmation, formats the data as required to send the resulting electronic report to the receiving agency or entity. At this time, the only case report component that is specified is for Healthcare Associated Infection reports. Other case report constructs will remain unspecified and implementations unconstrained until the deferred harmonized 'Standard Case Report Component' construct is available or other domain-specific component is specified.

#### Safety and Health Alert Functionality

For notification of reporting requirements, safety warnings, public health alerts, and patient-specific case investigation communications, there are two types of communications:

- Option 1: Non-patient-specific push – Where the alert is generic and not specific to a particular patient (e.g. an increase in incidence of a communicable disease has been noticed by public health which needs to notify local providers) and the communication requires presentation preserving properties. The communication recipients are identified using the Identify Communication Recipients (HITSP/T64) construct, and the generic alert is sent to those providers leveraging the Emergency Message Distribution Element (HITSP/T63) with the Emergency Common Alerting Protocol (HITSP/C82). The communication itself may be conducted using email, Health Alert Network (HAN), or FAX as specified by the implementation. Communication recipients may be identified using the HITSP/T64 Communication Recipients Construct
- Option 2 - Where the alert is generic and not specific to a particular patient (e.g an increase in incidence of a communicable disease has been noticed by public health which needs to notify local providers) and the communication is text-based, the communication recipients are identified using the HITSP/T64 Communication Recipients Construct, and the generic alert is sent to those providers using HITSP/T63
- Option 3 – Where the alert is patient-specific in nature, the notification of document availability (HITSP/T29) is sent to the alert recipient (may be patient or provider). The person receiving the alert may then retrieve the patient-specific alert as an Unstructured Document (HITSP/C62) which will contain the immunization notification alert and instructions for the clinician or patient



- Option 4 – Context specific information may be requested by the EHR or PHR using Retrieval of Medical Knowledge (HITSP/T81) as part of the user interface or pre-fetching options. This approach may be used to address the request of alerts and reporting requirements. This option leverages a retrieval model and can not be leveraged for a distribution only approach

### 3.2.1 TECHNICAL ACTOR ROLE DESCRIPTIONS

This section identifies the Technical Actors used within the Interoperability Specification. Note that a Technical Actor represents an internal software component or IT system, which supports a specific aspect of a real world business information interchange (e.g., set of message exchanges). Technical Actors implement system data exchange transactions, which support real world Business Actor information interchanges (see Section 2.2.3 for Business Actor definitions). The table below identifies the Technical Actors and provides a description of the Technical Actor roles involved in the Interoperability Specification.

**Table 3.2.1-1 Technical Actor Role Descriptions**

Technical Actor(s)	Actor Role	Construct
Access Control Service (ACS)	The enterprise security service that supports and implements user-side and/or service side access control capabilities. This service would be utilized by the Service User, and/or Service Provider	HITSP/TP20
Alert Message Receiver	This actor receives notifications and emergency data from the Message Transmitter	HITSP/T63
Alert Message Transmitter	The holder of emergency data that is communicating that data to the message receiver	HITSP/T63
Audit Record Repository	This actor provides a repository for audit events	HITSP/T15
Audit Record Source	The actor that, on behalf of another actor that performs an action requiring logging, creates and communicates an Audit Record to the Audit Record Repository	HITSP/T15
Clinical Data Consumer	A clinical data consumer makes use of clinical patient data	HITSP/TP21
Clinical Data Source	Maintains patient information about vital signs, problem and allergies, results from diagnostic tests (e.g., Lab, Imaging, or other test results), medications, immunizations or historical or planned visits and procedures	HITSP/TP21
Consent Directive Requestor	Accesses consent directive located through a Consent Registry from Consent Repositories, (lack of definition in current public comment version)	HITSP/TP30
Consent Originator	Captures consent directives and may publish the consent directive as a document. It is responsible for sending Manage Consent Directive Requests to a Consent Repository. It also supplies Metadata to the Consent Repository for subsequent registration of the Consent within a Consent Registry	HITSP/TP30
Consent Registry	Responsible for providing location information and sender notification regarding consent directives. The Consent Registry receives a Manage Consent Directive Metadata Request	HITSP/TP30



Technical Actor(s)	Actor Role	Construct
Consent Repository	Responsible for both the persistent storage of consent directives as well as for their registration with the appropriate Consent Registry. It assigns a Uniform Resource Identifier (URI) and Metadata such as confidentiality codes to the Consent Directive for subsequent retrieval by an authorized consumer, e.g., for association with published personal health information or for evaluation at a policy decision point	HITSP/TP30
Content Consumer	Responsible for viewing, import, or other processing of content created by a Content Creator Actor	HITSP/C32 HITSP/C48 HITSP/C35 HITSP/C36 HITSP/C37 HITSP/C62 HITSP/C75 HITSP/C76 HITSP/C80 HITSP/C83 HITSP/C87 HITSP/C26 HITSP/C82 HITSP/TP30
Content Creator	Responsible for the creation of content and transmission to a Content Consumer	HITSP/C32 HITSP/C48 HITSP/C35 HITSP/C36 HITSP/C37 HITSP/C62 HITSP/C75 HITSP/C76 HITSP/C80 HITSP/C83 HITSP/C87 HITSP/C26 HITSP/C82 HITSP/TP30
Diagnostic Data Repository	A Diagnostic Data Repository maintains results from diagnostic tests (e.g., Lab, Imaging, or other test results)	HITSP/TP21
DNS Server	This actor has authoritative location information	HITSP/T64
Document Consumer	The Document Consumer queries a Document Registry for documents meeting certain criteria, and retrieves selected documents from one or more Document Repository actors	HITSP/TP13
Document Recipient	This actor receives a set of documents sent by another actor. Typically this document set will be made available to the intended recipient who will choose to either view it or integrate it into a Health Record	HITSP/TP31





Technical Actor(s)	Actor Role	Construct
Document Registry	The Document Registry maintains metadata about each registered document in a document entry. This includes a link to the Document in the Repository where it is stored. The Document Registry responds to queries from Document Consumer actors about documents meeting specific criteria. It also enforces some healthcare specific technical policies at the time of document registration	HITSP/TP13
Document Repository	Responsible for both the persistent storage of these documents as well as for their registration with the appropriate Document Registry. It assigns a Uniform Resource Identifier (URI) to documents for subsequent retrieval by a Document Consumer	HITSP/TP13
Document Source	Producer and publisher of documents. It is responsible for sending documents to a Document Repository Actor. It also supplies metadata to the Document Repository Actor for subsequent registration of the documents with the Document Registry Actor	HITSP/TP13 HITSP/T31
Form Archiver	The actor responsible for receiving form instance data for archival purposes. For Quality, supports the option to enable manual or cut/paste information capture of patient level quality data content	HITSP/TP50
Form Filler	The actor responsible for retrieving a form from a Form Manager and for submitting form instance data to a Form Receiver. The mechanism by which a unique identification of a form is obtained is outside the scope of the Retrieve Form for Data Capture profile. For Quality, used as an option to enable manual or cut/paste information capture of patient level quality data content. For Quality, Option for CIS to enable manual or cut/paste information capture	HITSP/TP50
Form Manager	The actor that supplies a form based upon a request that supplies unique form identification. For Quality, used as an option to enable manual or cut/paste information capture of patient level quality data content	HITSP/TP50
Form Receiver	The actor that receives form instance data. For Quality, supports the option to enable manual or cut/paste information capture of patient level quality data content	HITSP/TP50
Identity Provider	Receives the credentials and identifier from the Entity (principal). It may perform authentication at that point or may require additional authentication from another source (the Service Provider)	HITSP/C19
Immunizations Data Repository	Maintains patient immunization data	HITSP/TP21
Knowledge Requestor	System that formulates and sends a contextual request for ancillary information about a medical concept. Takes the parameters and sends to the resource available	HITSP/T81
Knowledge Resource	The system that holds the information requested and responds to the request from the Knowledge Requestor	HITSP/T81
Laboratory Result Message Receiver	An authorized entity that is receiving a laboratory result message	HITSP/T14
Laboratory Result Message Sender	The holder of a laboratory result who is communicating a laboratory result message to another actor	HITSP/T14
Medications Data Repository	A Medications Data Repository maintains patient medication data	HITSP/TP21
Node	The originating or terminating point of information or signal flow in a telecommunications network. This actor is equivalent to the Secure Node in the IHE-ITI-TF ATNA Transaction	HITSP/T17



Technical Actor(s)	Actor Role	Construct
Notification Receiver	Receives notifications of availability for documents in an XDS registry, and may optionally send acknowledgments of them	HITSP/T29
Notification Sender	Sends notifications of availability for documents in an XDS registry, and receives acknowledgments of these notifications	HITSP/T29
Patient Demographics Consumer	Queries the Patient Demographics Supplier for a list of patient demographic information, if any, and receives a list of corresponding patient demographic information from the Patient Demographics Supplier	HITSP/T23
Patient Demographics Supplier	Receives the query for a list of corresponding patient demographics from the Patient Demographics Consumer, sends a list of corresponding patient demographic information to the Patient Demographics Consumer, maintains one or more Patient Information Sources of patient demographics data	HITSP/T23
Patient Identifier Cross-Reference Consumer	Queries the Patient Identifier Cross-Reference Manager for a list of corresponding patient identifiers, if any and receives a list of corresponding patient identifiers from the Patient Identifier Cross-Reference Manager	HITSP/TP22
Patient Identifier Cross-Reference Manager	Receives the query for a list of corresponding patient identifiers from the Patient Identifier Cross-Reference Consumer. Sends a list of corresponding patient identifiers to the Patient Identifier Cross-Reference Consumer. Receives patient demographic information from the Patient Identity Source	HITSP/TP22
Patient Identity Source	Sends patient demographic information when requested, assigns a unique identifier to each instance of a patient, and maintains a collection of identity traits	HITSP/TP22 HITSP/T24
Person Identification Service	System that maintains a cross-domain person and/or patient index including all known identifiers (real and pseudo) for each person and/or patient, within all domains with which it communicates	HITSP/T24
Personnel White Pages Consumer	This actor has a use for information that can be found in the Personnel White Pages Directory	HITSP/T64
Personnel White Pages Directory	This actor has authoritative Personnel White Pages information on the human workforce members of the enterprise	HITSP/T64
Portable Media Creator	The Portable Media Creator writes the selected information to media (CD-ROM, USB-Memory, e-Mail) following the directory structure outlined by XDMThe Portable Media Creator writes the selected information from a consumer's PHR to media following the directory structure outlined by XDM	HITSP/T33
Portable Media Importer	The Portable Media Importer reads the selected information from media (CD-ROM, USB-Memory, e-Mail) following the directory structure outlined by XDMThe Portable Media Importer processes all the contents written by a Portable Media Creator on the physical media. The Portable Media Importer must successfully process all documents	HITSP/T33
Problems and Allergies Data Repository	Maintains patient problems and allergy data	HITSP/TP21
Professional Services Data Repository	A Professional Services Data Repository maintains data about historical or planned visits and procedures	HITSP/TP21
Pseudonymization Service	Supplier of alternative identification information that permits a patient to be referred to by a key that suppresses his/her actual identification information	HITSP/T24
Service Provider (SP)	The Service Provider represents the system providing a protected resource and relies on the provided security service	HITSP/TP20 HITSP/C19



Technical Actor(s)	Actor Role	Construct
Service User	The entity represents any individual entity (such as a clinician or an EHR/PHR system) that needs to make a service request of a Service Provider. The Entity may also be known as a principal and/or entity, which represents an end user, an application, a machine, or any other type of entity that may act as a requester in a transaction. A principal is typically represented in a transaction with a digital identity and the principal may have multiple valid digital identities to use with different transaction	HITSP/TP20, HITSP/C19
Time Client	Establishes time synchronization with one or more Time Servers using the NTP protocol and either the NTP or SNTP algorithms. Maintains the local computer system clock synchronization with UTC based on synchronization with the Time Servers	HITSP/T16
Time Server	Provides NTP time services to Time Clients. It is either directly synchronized to a UTC master clock (e.g. satellite time signal) or is synchronized by being grouped with a Time Client to other Time Server(s)	HITSP/T16
Value Set Consumer	An actor that receives a specific, new, or updated terminology based on its OID, and possibly its version if the latter is available	HITSP/T66
Value Set Repository	A Vital Signs Data Repository maintains patient vital signs data	HITSP/T66

### 3.2.2 CONSTRUCT REQUIREMENTS

This section incorporates the comprehensive business and technical requirements and a detailed specification of the transactions and information content specified to complete the information exchange actions identified in each Use Case scenario.

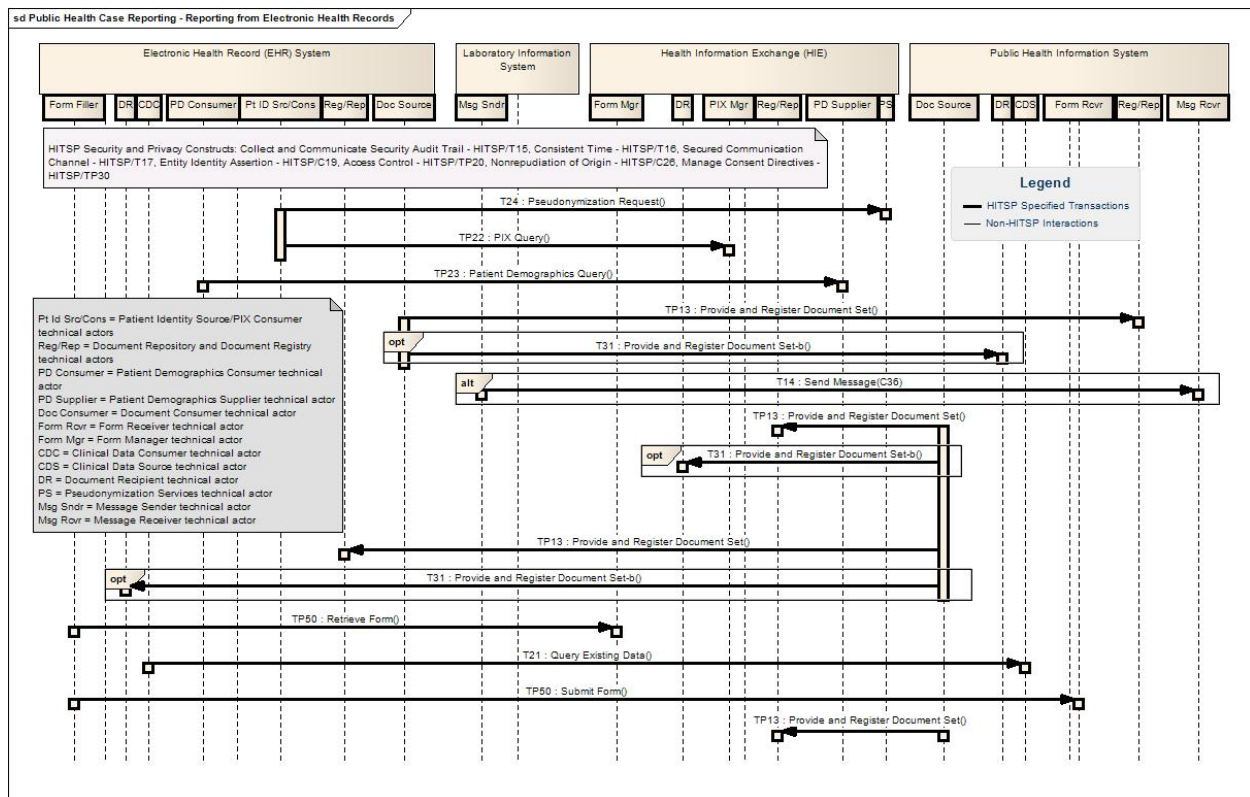
Table 6.5-1 (see Section 6.0) provides a mapping of the HITSP constructs that will be used in the design of the Interoperability Specification, and the data and information exchange requirements that are being satisfied by the construct. The requirements are limited to those that are deemed within scope for this Interoperability Specification, which are described in Section 3.1. Further details about the required technical actors, transactions, and content are also provided in the sections below.

The Unified Modeling Language (UML) sequence diagrams used in this section incorporate the detailed data requirements for the selected standards (defined in Section 2.2.2), with the Technical Actors, and their specific and detailed Transactions and content (encapsulated in the HITSP constructs listed above). The detailed actor Transactions described in these diagrams show all common or independent technical actors, data, and the specific transactions from the HITSP constructs that are used for the Interoperability Specification.

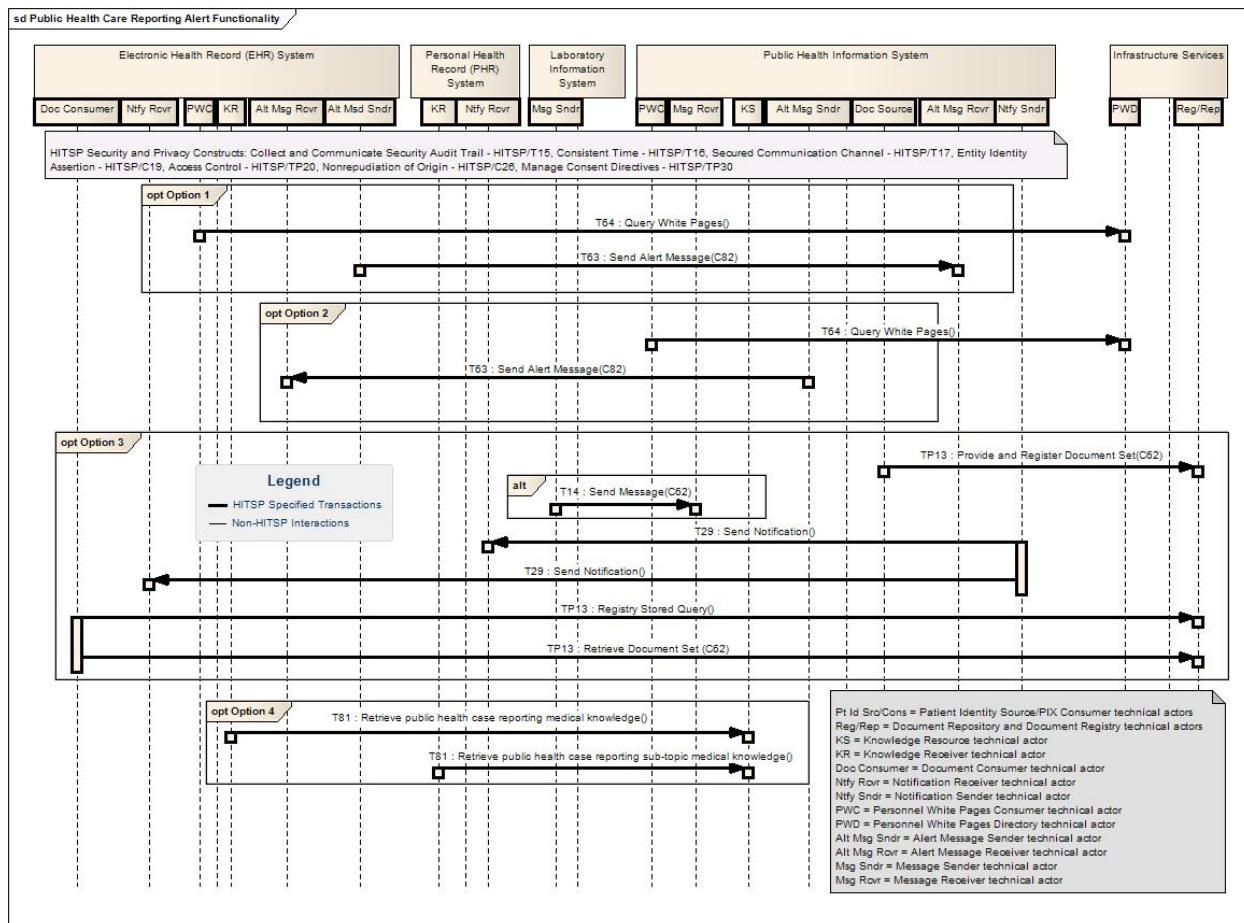
Transactions that make use of existing HITSP constructs are shown explicitly, indicating opportunities for reuse.



**Figure 3.2.2-1 Detailed Sequence Diagram for Scenario 1 – Reporting from Electronic Health Records**



**Figure 3.2.2-2 Detailed Sequence Diagram for Scenario 2 – Alert Functionality**



### 3.2.3 MAPPING OF BUSINESS ACTORS TO TECHNICAL ACTORS AND CONSTRUCTS WITH OPTIONALITY

The table below maps the individual business actors to the technical actors defined in the Interoperability Specification and depicted in the above detailed UML sequence diagram. Table 3.2.3-1 below specifies the requirements associated with each business actor in the Interoperability Specification. For each implemented business actor, the table specifies the following:

1. All Required or Conditionally Required technical actors listed for the business actor shall be supported as specified in the associated construct
2. Optional technical actors listed for the business actor may be supported as specified in the associated construct
3. All Required or Conditionally Required transactions and content subsets listed for each implemented technical actor assigned to the business actor shall be supported as specified in the associated construct



4. Optional transactions and content subsets listed for each implemented technical actor assigned to the business actor may be supported as specified in the associated construct

This table also includes the corresponding technical actors associated with the relevant Security and Privacy constructs that are used for this Interoperability Specification. Section 1.2 provides a summary description of all the referenced HITSP constructs. Note that this table only shows the business and technical actors that are implemented by the specification. Business actors that are out of scope, or gaps are not included in this section, however, they are discussed in Section 3.1 if they are out of scope, or in Section 4.2 if they are found to be gaps where there are no standards.

**Table 3.2.3-1 Business-Technical Actor Mapping to Transaction and/or Content**

Business Actor	Technical Actor(s)	Actor Optionality*	Construct	Transaction/Content (T/C)	T/C Optionality <sup>1</sup>
Laboratory Information Systems (Message Sender/Bio Data Sender, Document Source)	Content Creator	R	HITSP/C35	Lab Result Terminology	R
		C <a href="#">[105]</a>	HITSP/C36	Lab Result Message	R
		C <a href="#">[105]</a>	HITSP/C37	Lab Report Document Component	R
		C <a href="#">[107]</a>	HITSP/T24	Pseudonymization Request	R
		C <a href="#">[108]</a>	HITSP/C87	Anonymize	R
	Patient Demographic Consumer	C <a href="#">[101]</a>	HITSP/T23	Patient Demographics Query	R
	Patient Identity Source	C <a href="#">[101]</a>	HITSP/TP22	PIX Identity Feed	R
	PIX Consumer	C <a href="#">[101]</a>	HITSP/TP22	PIX Query	R
				PIX Update Notification	O
	Document Source	C <a href="#">[102]</a> C <a href="#">[105]</a>	HITSP/TP13	Provide & Register Document Set-b	C <a href="#">[202]</a>
				Provide & Register Document Set	C <a href="#">[202]</a>
			HITSP/C19	Convey Assertion	O
	Document Consumer	O	HITSP/TP13	Registry Stored Query	C <a href="#">[203]</a>
				Retrieve Document Set	C <a href="#">[203]</a>
				Stored Query	C <a href="#">[203]</a>
				Retrieve Document	C <a href="#">[203]</a>
			HITSP/C19	Convey Assertion	O
	Document Repository	O	HITSP/TP13	Provide and Register Document Set-b	C <a href="#">[204]</a>
				Register Document Set-b	C <a href="#">[204]</a>
				Retrieve Document Set	C <a href="#">[204]</a>

op





Business Actor	Technical Actor(s)	Actor Optionality*	Construct	Transaction/Content (T/C)	T/C Optionality <sup>1</sup>
				Register Document Set	C <a href="#">[204]</a>
				Provide & Register Document Set	C <a href="#">[204]</a>
				Retrieve Document	C <a href="#">[204]</a>
	Document Registry	O	HITSP/C19	Convey Assertion	O
			HITSP/TP13	Patient Identity Feed	R
				Registry Stored Query	C <a href="#">[205]</a>
				Provide & Register Document Set- b	C <a href="#">[205]</a>
				Stored Query	C <a href="#">[205]</a>
				Provide & Register Document Set	C <a href="#">[205]</a>
				Provide & Register Document Set (offline mode)	C <a href="#">[205]</a>
			HITSP/C19	Convey Assertion	O
	Laboratory Result Message Sender	C <a href="#">[104]</a> C <a href="#">[105]</a>	HITSP/T14	Send Lab Result Message	R
			HITSP/C35	Lab Result Terminology	R
			HITSP/C36	Lab Result Message	R
	Laboratory Result Message Receiver	C <a href="#">[104]</a> C <a href="#">[106]</a>	HITSP/T14	Send Lab Result Message	R
			HITSP/C35	Lab Result Terminology	R
			HITSP/C36	Lab Result Message	R
	Audit Record Source	R	HITSP/T15	Record Audit Event in Repository	R
	Audit Record Repository	O	HITSP/T15	Record Audit Event in Repository	R
	Time Client	R	HITSP/T16	Maintain Time	R
	Time Server	O	HITSP/T16	Maintain Time	R
	Node	R	HITSP/T17	Secured Communication Channel	R
	Identity provider	C <a href="#">[113]</a>	HITSP/C19	Provide Assertion	R
				Verify Assertion	O
	Consent Originator	O	HITSP/TP30	Provide and Register Document Set	R
	Consent Registry	O	HITSP/TP30	Register Document Set	R
				Stored Query	R
	Consent Repository	O	HITSP/TP30	Provide and Register Document Set	R
				Register Document Set	R
	Consent Directive Requestor	R	HITSP/TP30	Stored Query	R
				Retrieve Document Set	R
	Service User	R	HITSP/TP20	Access Control Request	O





Business Actor	Technical Actor(s)	Actor Optionality*	Construct	Transaction/Content (T/C)	T/C Optionality <sup>1</sup>
	Access Control Service	R	HITSP/TP20	Access Control Request	O
	Service Provider	C <a href="#">[102]</a>	HITSP/TP20	Access Control Request	O
Electronic Health Record (EHR) System	Patient Identity Source	C <a href="#">[101]</a>	HITSP/T23	Patient Demographics Query	R
	PIX Consumer	C <a href="#">[101]</a>	HITSP/TP22	PIX Identity Feed	R
				PIX Query	R
	Patient Demographics Consumer	C <a href="#">[101]</a>	HITSP/T23	Patient Demographics Query	R
	Laboratory Result Message Sender	C <a href="#">[104]</a> C <a href="#">[105]</a>	HITSP/T14	Send Lab Result Message	R
			HITSP/C35	Lab Result Terminology	R
			HITSP/C36	Lab Result Message	R
	Laboratory Result Message Receiver	C <a href="#">[104]</a> C <a href="#">[106]</a>	HITSP/T14	Send Lab Result Message	R
			HITSP/C35	Lab Result Terminology	R
			HITSP/C36	Lab Result Message	R
	Document Source	C <a href="#">[102]</a> C <a href="#">[105]</a>	HITSP/TP13	Provide & Register Document Set-b	C <a href="#">[202]</a>
				Provide & Register Document Set	C <a href="#">[202]</a>
			HITSP/C19	Convey Assertion	O
	Document Consumer	C <a href="#">[102]</a> C <a href="#">[106]</a>	HITSP/TP13	Registry Stored Query	C <a href="#">[203]</a>
				Retrieve Document Set	C <a href="#">[203]</a>
				Stored Query	C <a href="#">[203]</a>
				Retrieve Document	C <a href="#">[203]</a>
	Document Repository	O	HITSP/TP13	Convey Assertion	O
				Provide and Register Document Set-b	C <a href="#">[204]</a>
				Register Document Set-b	C <a href="#">[204]</a>
				Retrieve Document Set	C <a href="#">[204]</a>
				Register Document Set	C <a href="#">[204]</a>
				Provide & Register Document Set	C <a href="#">[204]</a>
				Retrieve Document	C <a href="#">[204]</a>
	Document Registry	O	HITSP/TP13	Convey Assertion	O
				Patient Identity Feed	R
				Registry Stored Query	C <a href="#">[205]</a>
				Provide & Register Document Set-b	C <a href="#">[205]</a>
				Stored Query	C <a href="#">[205]</a>



Business Actor	Technical Actor(s)	Actor Optionality*	Construct	Transaction/Content (T/C)	T/C Optionality <sup>1</sup>
				Provide & Register Document Set	C [205]
			HITSP/C19	Convey Assertion	O
	Portable Media Creator	C [105] C [109]	HITSP/T33	Distribute Document Set on Media	R
	Portable Media Importer	C [106] C [109]	HITSP/T33	Distribute Document Set on Media	R
	Document Source	C [103] C [105] C [110]	HITSP/T31	Provide & Register Document Set.b (online mode)	R
			HITSP/C19	Convey Assertion	O
	Document Recipient	C [106] C [110]	HITSP/T31	Provide & Register Document Set.b (online mode)	R
			HITSP/C19	Convey Assertion	O
	Clinical Data Consumer	O	HITSP/TP21	Query Existing Data	C [202]
			HITSP/C19	Convey Assertion	O
	Clinical Data Source	O	HITSP/TP21	Query Existing Data	R
			HITSP/C19	Convey Assertion	O
	Knowledge Requestor	O	HITSP/T81	Retrieve Topic Medical Knowledge	R
	Value Set Consumer	O	HITSP/T66	Retrieve Value Set	R
	Form Filler	R	HITSP/TP50	Retrieve Form	R
			HITSP/TP50	Submit Form	R
			HITSP/TP50	Archive Form	O
			HITSP/TP50	Retrieve Clarifications	O
	Form Manager	O	HITSP/TP50	Retrieve Form	R
				Retrieve Clarifications	R
	Form Receiver	O	HITSP/TP50	Submit Form	R
	Form Archiver	O	HITSP/TP50	Archive Form	R
	Content Creator	O	HITSP/C75	Adverse Event Reports: CDC – Healthcare Associated Infection Reporting	C [201]
		R	HITSP/TP30	Consent Document	R
		O	HITSP/C32	Summary Documents Using HL7 Continuity of Care Document (CCD)	R
		O	HITSP/C48	Encounter Document Using IHE Medical Summary (XDS-MS)	R
		O	HITSP/C76	Case Report Pre-Populate	R
		C [111]	HITSP/C35	Lab Result Terminology	R



Business Actor	Technical Actor(s)	Actor Optionality*	Construct	Transaction/Content (T/C)	T/C Optionality <sup>1</sup>
		O	HITSP/C36	Lab Result Message	R
		O	HITSP/C37	Lab Report Document Component	R
		C <a href="#">[107]</a>	HITSP/T24	Pseudonymization Request	R
		C <a href="#">[108]</a>	HITSP/C87	Anonymize	R
		O	HITSP/C26	Nonrepudiation	R
		O	HITSP/C82	Emergency Common Alerting Protocol	R
	Content Consumer	R	HITSP/C62	Unstructured Document	O
		R	HITSP/TP30	Consent Document	R
		O	HITSP/C26	Nonrepudiation	R
		O	HITSP/C82	Emergency Common Alerting Protocol	R
		O	HITSP/C32	Summary Documents Using HL7 Continuity of Care Document (CCD)	R
		O	HITSP/C48	Encounter Document Using IHE Medical Summary (XDS-MS)	R
	Audit Record Source	R	HITSP/T15	Record Audit Event in Repository	R
	Audit Record Repository	O	HITSP/T15	Record Audit Event in Repository	R
	Time Client	R	HITSP/T16	Maintain Time	R
	Time Server	O	HITSP/T16	Maintain Time	R
	Node	R	HITSP/T17	Secured Communication Channel	R
	Identity Provider	C <a href="#">[113]</a>	HITSP/C19	Provide Assertion	R
				Verify Assertion	O
	Consent Originator	O	HITSP/TP30	Provide and Register Document Set	R
	Consent Registry	O	HITSP/TP30	Register Document Set	R
				Stored Query	R
	Consent Repository	O	HITSP/TP30	Provide and Register Document Set	R
				Register Document Set	R
	Consent Directive Requestor	R	HITSP/TP30	Stored Query	R
				Retrieve Document Set	R
	Service User	R	HITSP/TP20	Access Control Request	O
	Access Control Service	R	HITSP/TP20	Access Control Request	O
	Service Provider	C <a href="#">[102]</a>	HITSP/TP20	Access Control Request	O



Business Actor	Technical Actor(s)	Actor Optionality*	Construct	Transaction/Content (T/C)	T/C Optionality <sup>1</sup>
Health Information Exchange (HIE)	Patient Demographic Supplier	C <a href="#">[101]</a>	HITSP/T23	Patient Demographics Query	R
	PIX Manager	C <a href="#">[101]</a>	HITSP/TP22	PIX Identity Feed	R
				PIX Query	R
	Laboratory Result Message Sender	C <a href="#">[104]</a> C <a href="#">[105]</a>	HITSP/T14	Send Lab Result Message	R
			HITSP/C35	Lab Result Terminology	R
			HITSP/C36	Lab Result Message	R
	Laboratory Result Message Receiver	C <a href="#">[104]</a> C <a href="#">[106]</a>	HITSP/T14	Send Lab Result Message	R
			HITSP/C35	Lab Result Terminology	R
			HITSP/C36	Lab Result Message	R
	Person Identification Service	C <a href="#">[107]</a>	HITSP/T24	Person Identity Feed	R
				Person Identity Cross-Reference Query	R
				PIX Update Notification	R
				Pseudonymization Request	R
	Document Source	R	HITSP/TP13	Provide & Register Document Set	R
			HITSP/C19	Convey Assertion	O
	Document Consumer	R	HITSP/TP13	Query Registry	R
				Retrieve Documents	R
			HITSP/C19	Convey Assertion	O
	Form Manager	O	HITSP/TP50	Retrieve Form	R
				Retrieve Clarifications	R
	Form Receiver	O	HITSP/TP50	Submit Form	R
	Form Archiver	O	HITSP/TP50	Archive Form	R
	Content Creator	O	HITSP/C75	Adverse Event Reports: CDC – Healthcare Associated Infection Reporting	C <a href="#">[201]</a>
		R	HITSP/TP30	Consent Document	R
		O	HITSP/C76	Case Report Pre-Populate	R
		C <a href="#">[111]</a>	HITSP/C35	Lab Terminology	R
		O	HITSP/C36	Lab Message	R
		O	HITSP/C37	Lab Report Document Component	R
		C <a href="#">[107]</a>	HITSP/T24	Pseudonymization Request	R
		C <a href="#">[108]</a>	HITSP/C87	Anonymize	R
		O	HITSP/C62	Unstructured Document	R
		O	HITSP/C26	Nonrepudiation	R



Business Actor	Technical Actor(s)	Actor Optionality*	Construct	Transaction/Content (T/C)	T/C Optionality <sup>1</sup>
		O	HITSP/C82	Emergency Common Alerting Protocol	R
		O	HITSP/C32	Summary Documents Using HL7 Continuity of Care Document (CCD)	R
		O	HITSP/C48	Encounter Document Using IHE Medical Summary (XDS-MS)	R
	Alert Message Transmitter	O	HITSP/T63	Send Alert Message	R
			HITSP/C82	Non Patient Notification Message	C <sup>[201]</sup>
			HITSP/C19	Convey Assertion	O
	Pseudonymization Service	O	HITSP/T24	Pseudonymize	R
	Personnel White Pages Directory	O	HITSP/T64	Query Personnel White Pages	R
	Knowledge Source	O	HITSP/T81	Retrieve Topic Medical Knowledge	R
	Value Set Repository	O	HITSP/T66	Retrieve Value Set	R
	Content Consumer	R	HITSP/C62	Unstructured Document	O
		R	HITSP/TP30	Consent Document	R
		O	HITSP/C76	Case Report Pre-Populate	R
		O	HITSP/C75	Adverse Event Reports: CDC – Healthcare Associated Infection Reporting	C <sup>[201]</sup>
		O	HITSP/C62	Unstructured Document	R
		O	HITSP/C26	Nonrepudiation	R
		O	HITSP/C82	Emergency Common Alerting Protocol	R
		O	HITSP/C32	Summary Documents Using HL7 Continuity of Care Document (CCD)	R
		O	HITSP/C48	Encounter Document Using IHE Medical Summary (XDS-MS)	R
	Audit Record Source	R	HITSP/T15	Record Audit Event in Repository	R
	Audit Record Repository	O	HITSP/T15	Record Audit Event in Repository	R
	Time Client	R	HITSP/T16	Maintain Time	R
	Time Server	O	HITSP/T16	Maintain Time	R
	Node	R	HITSP/T17	Secured Communication Channel	R
	Identity Provider	C <sup>[113]</sup>	HITSP/C19	Provide Assertion	R
				Verify Assertion	O
	Consent Originator	O	HITSP/TP30	Provide and Register Document Set	R



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Business Actor	Technical Actor(s)	Actor Optionality*	Construct	Transaction/Content (T/C)	T/C Optionality <sup>1</sup>
	Consent Registry	O	HITSP/TP30	Register Document Set	R
				Stored Query	R
	Consent Repository	O	HITSP/TP30	Provide and Register Document Set	R
				Register Document Set	R
	Consent Directive Requestor	R	HITSP/TP30	Stored Query	R
				Retrieve Document Set	R
	Service User	R	HITSP/TP20	Access Control Request	O
	Access Control Service	R	HITSP/TP20	Access Control Request	O
	Service Provider	C <a href="#">102</a>	HITSP/TP20	Access Control Request	O
Public Health Information System	Patient Demographic Consumer	O	HITSP/T23	Patient Demographics Query	R
	Patient Identity Source	O	HITSP/TP22	PIX Identity Feed	R
	PIX Consumer	O	HITSP/TP22	PIX Query	R
	Personnel White Pages Directory	O	HITSP/T64	Query Personnel White Pages	R
	Personnel White Pages Consumer	O	HITSP/T64	Find Personnel White Pages	O
				Query Personnel White Pages	R
	Notification Sender	O	HITSP/T29	Send Notification	R
	Notification Receiver	O	HITSP/T29	Send Notification	R
	Document Recipient	O	HITSP/T31	Receive Document	R
			HITSP/C19	Convey Assertion	O
	Alert Message Transmitter	O	HITSP/T63	Send Alert Message	R
			HITSP/C82	Non Patient Notification Message	C <a href="#">201</a>
			HITSP/C19	Convey Assertion	O
	Value Set Repository	O	HITSP/T66	Retrieve Value Set (response)	R
	Pseudonymization Service	O	HITSP/T24	Pseudonymize	R
	Knowledge Resource	O	HITSP/T81	Retrieve Topic Medical Knowledge	R
	Alert Message Receiver	O	HITSP/T63	Send Alert Message	C <a href="#">201</a>
			HITSP/C82	Emergency Common Alerting Protocol	C <a href="#">201</a>
			HITSP/C19	Convey Assertion	O
	Laboratory Message Receiver	C <a href="#">104</a> C <a href="#">106</a>	HITSP/IS06	Receive Message	R
				Send Ack	R



Business Actor	Technical Actor(s)	Actor Optionality*	Construct	Transaction/Content (T/C)	T/C Optionality <sup>1</sup>
	Document Source	C <a href="#">[103]</a>	HITSP/TP13	Provide & Register Document Set	R
		C <a href="#">[105]</a>	HITSP/C19	Convey Assertion	O
	Document Consumer	C <a href="#">[103]</a> C <a href="#">[106]</a>	HITSP/TP13	Query Registry	R
				Retrieve Documents	R
			HITSP/C19	Convey Assertion	O
	Portable Media Creator	C <a href="#">[105]</a> C <a href="#">[109]</a>	HITSP/T33	Distribute Document Set on Media	R
	Portable Media Importer	C <a href="#">[106]</a> C <a href="#">[109]</a>	HITSP/T33	Distribute Document Set on Media	R
	Document Source	C <a href="#">[105]</a> C <a href="#">[110]</a>	HITSP/T31	Provide & Register Document Set.b (online mode)	R
			HITSP/C19	Convey Assertion	O
	Document Recipient	C <a href="#">[103]</a> C <a href="#">[106]</a> C <a href="#">[110]</a>	HITSP/T31	Provide & Register Document Set.b (online mode)	R
			HITSP/C19	Convey Assertion	O
	Form Manager	O	HITSP/TP50	Retrieve Form	R
				Retrieve Clarifications	R
	Form Receiver	O	HITSP/TP50	Submit Form	R
	Form Archiver	O	HITSP/TP50	Archive Form	R
	Content Creator	R	HITSP/C62	Unstructured Document	O
		C <a href="#">[107]</a>	HITSP/T24	Pseudonymization Request	R
		C <a href="#">[108]</a>	HITSP/C87	Anonymize	R
		R	HITSP/C62	Unstructured Document	R
		R	HITSP/TP30	Consent Document	R
		O	HITSP/C26	Nonrepudiation	R
		O	HITSP/C32	Summary Documents Using HL7 Continuity of Care Document (CCD)	R
		O	HITSP/C48	Encounter Document Using IHE Medical Summary (XDS-MS)	R
	Content Consumer	R	HITSP/C82	Emergency Common Alerting Protocol	R
		R	HITSP/TP30	Consent Document	R
		O	HITSP/C76	Case Report Pre-Populate	R
		O	HITSP/C75	Adverse Event Reports: CDC – Healthcare Associated Infection Reporting	C <a href="#">[201]</a>
		R	HITSP/C35	Lab Result Terminology	R
		C <a href="#">[105]</a>	HITSP/C36	Lab Result Message	R



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Business Actor	Technical Actor(s)	Actor Optionality*	Construct	Transaction/Content (T/C)	T/C Optionality <sup>1</sup>
		C <sup>[105]</sup>	HITSP/C37	Lab Report Document	R
		R	HITSP/C62	Unstructured Document	O
		O	HITSP/C26	Nonrepudiation	R
		O	HITSP/C82	Emergency Common Alerting Protocol	R
		O	HITSP/C32	Summary Documents Using HL7 Continuity of Care Document (CCD)	R
		O	HITSP/C48	Encounter Document Using IHE Medical Summary (XDS-MS)	R
	Audit Record Source	R	HITSP/T15	Record Audit Event in Repository	R
	Audit Record Repository	O	HITSP/T15	Record Audit Event in Repository	R
	Time Client	R	HITSP/T16	Maintain Time	R
	Time Server	O	HITSP/T16	Maintain Time	R
	Node	R	HITSP/T17	Secured Communication Channel	R
	Identity Provider	C <sup>[113]</sup>	HITSP/C19	Provide Assertion	R
				Verify Assertion	O
	Consent Originator	O	HITSP/TP30	Provide and Register Document Set	R
	Consent Registry	O	HITSP/TP30	Register Document Set	R
				Stored Query	R
	Consent Repository	O	HITSP/TP30	Provide and Register Document Set	R
				Register Document Set	R
	Consent Directive Requestor	R	HITSP/TP30	Stored Query	R
				Retrieve Document Set	R
	Service User	R	HITSP/TP20	Access Control Request	O
	Access Control Service	R	HITSP/TP20	Access Control Request	O
	Service Provider	C <sup>[102]</sup>	HITSP/TP20	Access Control Request	O

**\*NOTE:** Optionality = “R” for Required, “R2” for Required if known, “O” for Optional, or “C” for Conditional.

### Implementation Conditions/Constraints

The following table describes the implementation conditions or constraints placed on the technical actors, transactions, or content. The constraint codes listed below correspond to the codes placed in the Actor and Transaction/Content optionality column in Table 3.2.3-1 above. For example, the Patient



Demographics Consumer Technical Actor has an optionality code of C<sup>[105]</sup> <sup>[106]</sup> which represents a conditionally required Actor with the constraint codes of 105 and 106 described in the table below.

**Table 3.2.3-2 Implementation Conditions/Constraints**

Constraint Code	Constraint Description
101	Shall support (Patient Identity Source plus PIX Consumer) and/or Patient Demographics Consumer where shared patient identity management interoperability is to be supported
102	Required if Access Control Request Transaction is not supported
103	Required when a Document Repository and/or a Document Registry is supported
104	Required for message-based functional flow
105	Business Actor shall support at least one of these technical actors to communicate outbound content
106	Business Actor shall support at least one of these technical actors to receive or retrieve inbound content
107	Required where pseudonymization is required by the jurisdiction or information sharing agreements or selected by PHR
108	Required where anonymization is required by the jurisdiction or information sharing agreements or selected by PH
109	Required for Portable Media support
110	Required for Document Reliable Interchange support
111	Required where C36 or C37 is supported
112	Required where C32, C48, or C75 is supported
113	There must be at least one in a group of business actors
201	Shall support either form filler or case report construct
202	The Actor shall support at least one of these transactions
203	The Document Consumer shall support either XDS.a transactions, XDS.b transactions, or both. Where Identity Assertion is required, the Document Consumer shall support XDS.b (Registry Stored Query, Retrieve Document Set)
204	The Document Repository shall support either XDS.a transactions, XDS.b transactions, or both. Where Identity Assertion is required, the Document Repository shall support XDS.b (Provide & Register Document Set-b, Register Document Set-b, Retrieve Document Set)
205	The Document Registry shall support either XDS.a transactions, XDS.b transactions, or both. Where Identity Assertion is required, the Document Repository shall support XDS.b to query the registry (Registry Stored Query)

The following sections describe the implementation subset options by which the specification may be implemented in a limited manner. These implementation subsets are focused on delivering specific content. Any dependencies between subsets, and business actors are also described. Conformance considerations for implementing this Interoperability Specification and any of its subsets are described in detail in Section 5.0.



### 3.2.4 CONSTRUCT DEPENDENCIES

The following table shows a list of constructs with their existing dependencies. Dependencies usually exist when there are some additional pre-requisites for a specific construct. To support a dependent construct, a technical actor must implement all the required actions in the pre-requisite construct, or be grouped together with another construct as specified in the table below:

**Table 3.2.4-1 Construct Dependencies**

Construct	Depends On (Name of construct that it depends on)	Dependency Type (Pre-condition, Post-condition, General)	Purpose (Reason for this dependency)
HITSP/T63 - Emergency Message Distribution Element	HITSP/T64 Identify Communication Recipients	Pre-condition	Retrieve communication parameters
HITSP/C62 Unstructured Document	HITSP/T64 Identify Communication Recipients	Pre-condition	Retrieve communication parameters
HITSP/C62 Unstructured Document	HITSP/T29 - Notification of Document Availability	Pre-condition	Communicate notification of document availability and location
HITSP/C62 Unstructured Document	HITSP/TP13 or HITSP/T31 or HITSP/T33	Pre-condition	Transport mechanism for notification
HITSP/C76 Case Report Pre-Populate	HITSP/TP50 Retrieve Form for Data Capture	Pre-condition	RFD form pre-population is supported by C76

### 3.2.5 ADDITIONAL CONSTRAINTS ON REQUIRED CONSTRUCTS

This section describes the constraints that further limit the constructs that are used by this Interoperability Specification.

Vocabulary constraints for Case Report attributes that can be pre-populated from a CDA document are specified within the HITSP/C76 Case Report Pre-Populate. Since the constructs supporting the delivery of the case report to the receiving agency are deferred for this release of the Public Health Case Reporting Interoperability Specification due to standards gaps, vocabulary constraints for attributes not available from a CDA document are identified as part of the data element constraints listed below. Section 6.3 provides a detailed list of Case Reporting attributes along with associated vocabulary constraints for the convenience of the reader.

**Table 3.2.5-1 Additional Constraints on Required Constructs**

Data Element	Construct	Constraint	Constraint Type (Pre-condition, Post-condition, General)	Purpose (Reason for this constraint)
Contact Person: The name of the person to be contacted for further information	HITSP/TP50	HL7 Name	General	Coded interoperable content



Data Element	Construct	Constraint	Constraint Type (Pre-condition, Post-condition, General)	Purpose (Reason for this constraint)
Contact Phone Number: The telephone number for the contact person	HITSP/TP50	HL7 Phone	General	Coded interoperable content
Report Date: The date that the Case Report is being sent	HITSP/TP50	HL7 Timestamp	General	Coded interoperable content
Reported Previously: Indication if the information is supplemental to update in event already reported	HITSP/TP50	Boolean datatype Y/N/U	General	Coded interoperable content
Report sent to FDA: Indication if the report is submitted to the Food and Drug Administration (FDA)	HITSP/TP50	Boolean datatype Y/N/U	General	Coded interoperable content
Date User Facility/ Importer Became Aware of Event: The date the event was first recognized by an observer	HITSP/TP50	HL7 Timestamp	General	Coded interoperable content
Date report sent: The date the report is submitted	HITSP/TP50	HL7 Timestamp	General	Coded interoperable content
Date sent to FDA: The date the report was submitted to the FDA – U.S.	HITSP/TP50	HL7 Timestamp	General	Coded interoperable content
Report Source: The originator of the report	HITSP/TP50	Where possible, use HL7 Table 0235 – Report source Value C Clinical trial L Literature H Health professional  R Regulatory agency D Database/registry/poison control center N Non-healthcare professional P Patient M Manufacturer/marketing authority holder E Distributor O Other -	General	Coded interoperable content (may be updated in future IS11 Releases pending additional C80 review)
Reporter Name: The name of the person or facility sending the Case Report	HITSP/TP50	HL7 Name	General	Coded interoperable content
Occupation of Reporter: The role of the reporter (e.g., physician, nurse, administrator, etc.)	HITSP/TP50	North American Industry Classification System	General	Coded interoperable content



Data Element	Construct	Constraint	Constraint Type (Pre-condition, Post-condition, General)	Purpose (Reason for this constraint)
Telephone: The phone number of the person or facility sending the Case Report	HITSP/TP50	HL7 Phone	General	Coded interoperable content
Reporter Email: The email contact information for the reporter	HITSP/TP50	HL7 email	General	Coded interoperable content
Patient Country: The country of the address of the subject of the case report	HITSP/TP50	ISO 3166-1	General	Coded interoperable content
Occupation: The occupation of subject of the case report	HITSP/TP50	North American Industry Classification System	General	Coded interoperable content
Location where Event Occurred: The location of the event – e.g., home, hospital, other facility, etc	HITSP/TP50	HAI Service Delivery Location – HL7, Home, Work	General	Coded interoperable content
Event Abated after use stopped or dose reduced: Indication that the event resolved/ abated after usage stopped or dose reduced	HITSP/TP50	Boolean datatype Y/N/U	General	Coded interoperable content
Event Reappeared after reintroduction: Indication if the reaction reoccurred after rechallenging the patient to the suspected substance	HITSP/TP50	Boolean datatype Y/N/U	General	Coded interoperable content
Immunization Services Funding Eligibility: Indication of vaccination source (e.g., special program such as Vaccine for Children, state or provincial programs, etc)	HITSP/TP50	C80 data element for financial class – 2.2.3.5.5“Immunization Services Funding Eligibility”	General	Coded interoperable content
Product Diagnosis for Use: The reason the product was initially used	HITSP/TP50	Shall be coded as specified in HITSP/C80 Section 2.2. 3.1.3 Diagnosis	General	Coded interoperable content
Expiration Date: The expiration date of the product	HITSP/TP50	HL7 Timestamp	General	Coded interoperable content
Manufacturer name, City and State: Manufacturer of the device	HITSP/TP50	The State component shall be coded as specified in HITSP/C80 Section 2.2.1.1.1 State	General	Coded interoperable content
Operator of Device: The individual managing the device – (e.g. Health professional, lay user, patient, other)	HITSP/TP50	North American Industry Classification System	General	Coded interoperable content
If implanted give date: Date of implantation of the device (if implanted)	HITSP/TP50	HL7 Timestamp	General	Coded interoperable content



Data Element	Construct	Constraint	Constraint Type (Pre-condition, Post-condition, General)	Purpose (Reason for this constraint)
If explanted give date: Date device was removed (if removed)	HITSP/TP50	HL7 Timestamp	General	Coded interoperable content
Is this a single use device that was reprocessed and reused on patient?: Indication if the device is a single-use device that was cleaned/reprocessed and is reused on the affected patient	HITSP/TP50	Boolean datatype Y/N/U	General	Coded interoperable content
Administration of Treatment: Was treatment administered?	HITSP/TP50	Boolean datatype Y/N/U	General	Coded interoperable content
Name and Address of Reprocessor: Name and address of the individual/organization reprocessing the single use device	HITSP/TP50	The State component shall be coded as specified in HITSP/C80 Section 2.2.1.1.1 State	General	Coded interoperable content
Product available for evaluation: Indication if the product is still available to be evaluated	HITSP/TP50	Boolean datatype Y/N/U	General	Coded interoperable content
Date product returned to manuf.: If returned to the manufacturer, date of return	HITSP/TP50	HL7 Timestamp	General	Coded interoperable content
Concomitant Medical Products & Therapy Dates: Other medical products and treatment used proximal to the event	HITSP/TP50	Medications should reference NDC and RxNorm as identified in HITSP/C80. Vaccines are represented by CVX codes (also identified in HITSP/C80). Non-medication product terms are to be represented with ICSR 3 and therefore, these are a GAP for this release. In the user interface, the user will need to select one or more (n) of a list.	General	Coded interoperable content
AE Following Prior Vaccination: Description of the adverse event	HITSP/TP50	In HITSP/C80, the VA/KP SNOMED Subset identifies adverse events (e.g., hives, difficulty breathing) and is selected for reporting adverse events (from the Allergy/Adverse Event section of a document).	General	Coded interoperable content



Data Element	Construct	Constraint	Constraint Type (Pre-condition, Post-condition, General)	Purpose (Reason for this constraint)
Suspect Product Name: Product name	HITSP/TP50	Medications should reference NDC and RxNorm as identified in HITSP/C80. Vaccines are represented by CVX codes (also identified in HITSP/C80). Non-medication product terms are to be represented with ICSR 3 and therefore, these are a GAP for this release. In the user interface, the user will need to select one or more (n) of a list.	General	Coded interoperable content
Reporting Laboratory Identifier: Identifier for laboratory that is sending the result. This laboratory may be sending results received back from reference laboratories	HITSP/TP50	See HITSP/C35	General	Coded interoperable content
Performing Laboratory: Laboratory that produced the test result. This may be a reference laboratory identifier	HITSP/TP50	See HITSP/C35	General	Coded interoperable content
Ordered Test Code: The identifier code for the requested observation/test/battery	HITSP/TP50	See HITSP/C35	General	Coded interoperable content
Date of Test: The date that the laboratory test was performed for the subject of the Case Report	HITSP/TP50	See HITSP/C35	General	Coded interoperable content
Specimen Collection Date: The date that the specimen for the laboratory test was taken from the subject of the Case Report	HITSP/TP50	See HITSP/C35	General	Coded interoperable content
Source of Specimen: The physical body location from where the specimen for the lab report was taken from the subject	HITSP/TP50	See HITSP/C35	General	Coded interoperable content
Name of Organization Collecting Specimen: Name of organization collecting specimen which may be different from the organization performing the laboratory analysis	HITSP/TP50	See HITSP/C35	General	Coded interoperable content
Diagnosis Date/Time: The date that the subject of the Case Report was diagnosed with Condition above	HITSP/TP50	HL7 Timestamp	General	Coded interoperable content





Data Element	Construct	Constraint	Constraint Type (Pre-condition, Post-condition, General)	Purpose (Reason for this constraint)
Previous Event Report Details	HITSP/TP50	Shall be coded as specified in HITSP/C80 Section 2.2. 3.1.1 Problem	General	Coded interoperable content
Hospitalization: If the subject of the case report was hospitalized	HITSP/TP50	Boolean datatype Y/N/U	General	Coded interoperable content
Recovered: Did the subject recover from the disease?	HITSP/TP50	Boolean datatype Y/N/U	General	Coded interoperable content
All	HITSP/C35, HITSP/C36, HITSP/C37	Constraints as per CDC/CSTE sponsored calls for electronic lab reporting (ELR) – are expected to be in the optionality rather than in the vocabulary. No new data elements expected	Pre-condition	Allow for communications with destination of Public Health rather than clinicians
NA	Require Acknowledgement	HITSP/T31, HITSP/TP30 : Need to be sure business actor binding messenger with sender – needs to bind with an Xform response back to the human	General	Enable Acknowledgement receipt for submission of case report
NA	Generic Alert to identified providers	This construct cannot be a targeted communication as this would entail risks of disclosure of PHI	General	Support PHI Protection
N/A	HITSP/TP13 – Manage Sharing of Documents (Provide and Register)	Data sent to the shared document repository and recorded in the shared registry used for analytical purposes must be Anonymized and Pseudonymized unless otherwise permitted through legal and out-of-band arrangements	Pre-condition	Required to protect the confidentiality of the patients whose personal health information is sent to the Public Health Information System such that the patients can be re-identified as needed to manage public health threats
NA	HITSP/TP13 – Manage Sharing of Documents (Shared Document Resource)/ Query Registry Transaction Stored Query Transaction Retrieve Document Transaction	Support queries and stored queries for documents which do not require a patient id as a query parameter	General	Asserted to enable public health information retrieval support to enable pull of repository data to the Public Health Information System or to ask public health questions of the data



Data Element	Construct	Constraint	Constraint Type (Pre-condition, Post-condition, General)	Purpose (Reason for this constraint)
NA	HITSP/TP13 – Manage Sharing of Documents (Query Registry)	HITSP/TP30 should be referenced to record the OID of the authorization policy under which the patient data are disclosed to the authorized public health authority	Post-condition	Asserted to record authorized disclosure in compliance with HIPAA
NA	HITSP/TP13 – Manage Sharing of Documents (Provide and Register)	HITSP/TP30 should be referenced to record the OID of the authorization policy under which the patient data are disclosed to the authorized public health authority	Pre-condition	Asserted to record authorized disclosure to public health authority in audit logs
NA	HITSP/T15 Collect and Communicate Security Audit Trail	HITSP/T15 should be constrained to record the OID of the authorization policy under which the patient data are disclosed to the authorized public health authority	Post-condition	Asserted to record authorized disclosure to public health authority in audit logs
NA	HITSP/TP22 Patient Identity Cross- Referencing (Uniquely identify a Patient across enterprises)	Constrain to return single value for pseudonymization steps	General	In order to link pseudo identifiers across entities
XSDDocumentEntry.eventCodeList	HITSP/TP13 – Manage Sharing of Documents (Provide and Register)	The metadata element should be required when there is a known condition as required by or of interest to public health authorities, and must contain a value from a controlled vocabulary describing the reportable condition.	Pre-condition	The list of codes aims to represent the main clinical acts documented



Data Element	Construct	Constraint	Constraint Type (Pre-condition, Post-condition, General)	Purpose (Reason for this constraint)
XSDocumentEntry 'confidentialityCode'	HITSP/TP13 – Manage Sharing of Documents (Provide and Register)	Extend the usage to signify when patient information in the document and corresponding metadata has been pseudonymized Attribute: confidentialityCode Optionality: R2 Vocabulary: Need to assign a unique OID and code values to indicate pseudonymization	Pre-condition	This code indicates the level of confidentiality for the corresponding document

In support of public health investigation, Table 3.2.5 -2 describes the constraints placed on several of the elements of the XSDocumentEntry object type from HITSP/TP13 – Manage Sharing of Documents where the document sharing resource is leveraged for analytical purposes:

**Table 3.2.5-2 XSDocumentEntry Element Constraints**

XDS Metadata Attribute	Optionality*	Extended Discussion	Source Type
XSDocumentEntry.eventCodeList	R <sup>2</sup>	See 3.2.5.1	Coded in Affinity Domain with Transform (CADT)
XSDocumentEntry.confidentialityCode	R	See 3.2.5.2	Fixed by Affinity Domain (FAD)
XSDocumentEntry.patientID and XDSSubmissionSet.patientID	R	See 3.2.5.3	Source document Attribute with Transformation (SAT)
XSDocumentEntry.sourcePatientID and XDSSubmissionSet.sourcePatientID	R	See 3.2.5.4	Source document Attribute with Transformation (SAT)

**\* NOTE:** Optionality = “R” for Required, “R2” for Required if Known or “O” for Optional, or “C” for Conditional.

#### 3.2.5.1 XSDocumentEntry.eventCodeList

An XSDocumentEntry.eventCodeList metadata element that contains a value from a controlled vocabulary describing reportable conditions should be required when there is a known condition as required by, or of interest to, public health authorities. Other XSDocumentEntry.eventCodeList metadata

op

<sup>2</sup> This metadata element is optional in the XDS Provide and Register Transaction, but required for use with the Biosurveillance specifications.



elements may also be present using local codes or other controlled terminology, however, these are outside of the scope of this specification. The eventCodeList could contain, for instance, a value from the Nationally Notifiable Diseases and Other Conditions of Public Health Importance Event Code List published by the Centers for Disease Control and Prevention. See [www.cdc.gov](http://www.cdc.gov) for more details.

The vocabulary shall be identified by the OID representing the coding system from which these events are pulled present in the codingScheme data element.

```
<rim:Classification
  classificationScheme="urn:uuid:2c6b8cb7-8b2a-4051-b291-b1ae6a575ef4"
  classifiedObject="theDocument" nodeRepresentation="eventCode">
  <rim:Name>
    <rim:LocalizedString value="eventCodeDisplayName" />
  </rim:Name>
  <rim:Slot name="codingScheme">
    <rim:ValueList>
      <rim:Value>2.16.840.1.114222.4.5.255</rim:Value>
    </rim:ValueList>
  </rim:Slot>
</rim:Classification>
```

The population of this code is not in any way circumventing, defining, or changing state/federal requirements reporting. Vocabulary and reporting compliance need to be validated and audited independent of this specification.

#### 3.2.5.2 XDSDocumentEntry.confidentialityCode

The confidentialityCode attribute shall contain the following OID when the submitted document has been pseudonymized according to HITSP/T24 Pseudonymize: 2.16.840.1.113883.3.88.5.2.1

#### 3.2.5.3 XDSDocumentEntry.patientID and XDSSubmissionSet.patientID

The XDSDocumentEntry.patientID and XDSSubmissionSet.patientID attributes shall contain either the actual patient identifier used by the XDS registry, or shall contain a pseudonymized identifier generated during the HITSP/T24 Pseudonymize.

#### 3.2.5.4 XDSDocumentEntry.sourcePatientID and XDSSubmissionSet.sourcePatientID

The XDSDocumentEntry.sourcePatientID and XDSSubmissionSet.sourcePatientID attributes shall contain either the actual patient identifier used by the document source, or shall contain a pseudonymized identifier generated during the HITSP/T24 Pseudonymize.



## 4.0 STANDARDS SELECTION

This section presents the standards required to support each major Use Case event. Standards selection is based on the following process:

- **Evaluation:** The Technical Committee evaluates the standards using the Tier 2 Readiness Criteria.
- **Selection:** Based on the Tier 2 evaluations, named standards are selected and listed in the table of selected standards below. It is important to understand that the standards selected here are within the context of the specific Use Case requirements and do not necessarily reflect selection in other contexts
- **Gap and Overlap Analysis and Recommendations:** The Technical Committee also identifies and analyzes gaps and overlaps within the standards industry as they relate to the specific Use Case. The Technical Committee provides a description of the gaps, including missing or incomplete standards, a description of all overlaps, or competition among standards for the relevant Use Cases, and recommendations for resolving these gaps and overlaps

It is HITSP's policy to incorporate only standards that have been approved according to the formal policy of the standards organization, as defined by HITSP, which publishes the standard. HITSP interprets approval to include Draft Standards for Trial Use. The objective is to incorporate only standards that are managed within a formal life cycle process as defined by the standards organization. In some cases, where we believe a standard that is not yet approved may best meet the requirements of an Interoperability Specification, HITSP may provide a roadmap of its future intent conditional on future actions by either or both the standards organization and the HITSP Technical Committee. Thus there are four classes of HITSP-committed standards.

- **Approved for Use** – standards included for unconditional use within a HITSP construct
- **Interim** – standards included for use now within a HITSP construct but for a defined time period or conditional on future actions, e.g., “Intended for Use” standard is available
- **Provisional** – standards that are not yet but are expected to be approved by the standards organization at the time the Interoperability Specification is released by HITSP. A “Provisional” standard becomes an “Approved for Use” standard only if:
  - It is approved by the Standards Organization by the time that the Interoperability Specification is released by HITSP and
  - It is substantially the same as it was when it was provisionally used and
  - It requires no further action by the Technical Committee
- **Intended for Use** – proposed standards that are roadmapped for future use pending actions by the Technical Committee and/or the standards organization. Therefore a standard is defined as “Intended for Use” if it will not be approved by the standard organization at the time that the HITSP construct is released, but is sufficiently defined to enable detailed evaluation of how well it will meet technical and information exchange requirements.



HITSP may continue to use “Provisional” or “Interim” standards as they existed when incorporated into the HITSP construct if the expected conditions are not satisfied until such time as HITSP can replace it with a more suitable standard. In this circumstance, the standards organization would have no responsibility to maintain or correct this artifact. If a standard “Intended for Use” is not developed and approved in terms of time frame or content as expected by the Technical Committee at the time of its initial selection, it may be replaced. All standards used by HITSP must meet the HITSP selection criteria. The use of “Interim” and “Intended for Use” standards will be weighed against the alternative of simply declaring a gap for HITSP and the standards organizations to resolve.

## 4.1 STANDARDS

It is important to understand that the standards selected here are within the context of the specific Use Case requirements and do not necessarily reflect selection in other contexts. In addition, adherence to the selected standards alone is not sufficient to ensure interoperability. In order to ensure interoperability for the Use Case, and to claim conformance to the specification, an implementation must satisfy all the requirements and mandatory statements listed in the HITSP Interoperability Specification, its associated construct specifications, as well as conformance criteria from the selected base and composite standards. A conformant system must also be constrained as specified in Table 3.1.2-1, and implement all of the required technical actors from Table 3.2.3-1, within the scope and implementation subset that is selected.

The standards used by this Interoperability Specification fall into the following categories:

- Regulatory guidance is a legal or other authoritative declaration that HITSP must abide by in standards selection (see Section 4.1.1)
- Selected standards are necessary for interoperability. These are standards that are used to meet information exchange requirements of associated constructs. For example, they are used to realize direct information exchange, to provide the transport mechanism, to specify the content, or to address security (see Section 4.1.2)
- Informative reference standards provide additional background information or guidance, and are not required for interoperability. These standards are not required to implement the Interoperability Specification (see Section 4.1.3)

### 4.1.1 REGULATORY GUIDANCE

The following table provides a list of legal or other authoritative guidelines that HITSP must abide by, or has agreed to use as guidance in the selection of standards. Note that only the referenced sections of the regulations are relevant to this Interoperability Specification.



**Table 4.1.1-1 Regulatory Guidance**

Regulation	Description
Clinical Laboratory Improvement Amendments (CLIA) of 1988	Establishes quality standards for all laboratory testing to ensure the accuracy, reliability, and timeliness of patient test results regardless of where the test is performed. The Centers for Medicare and Medicaid Services (CMS) regulates all laboratory testing (except research) performed on humans in the U.S. based on CLIA. For more information visit <a href="http://www.fda.gov">http://www.fda.gov</a> and <a href="http://www.cms.hhs.gov">http://www.cms.hhs.gov</a>
Health Insurance Portability and Accountability Act (HIPAA) – Administrative Simplification	A listing of national standards plus rules adopted by federal regulation for electronically communicating specified administrative and financial healthcare transactions, and protecting the security and privacy of healthcare information, as applied to the three types of defined covered entities: health plans, healthcare clearinghouses, and healthcare providers who conduct any of the specified healthcare transactions. See the Code of Federal Regulations, Title 45, Parts 160, et. Seq. for more information

#### 4.1.2 SELECTED STANDARDS

The following table provides a list of standards that are used to meet information exchange requirements of the Interoperability Specification, and the HITSP constructs that use each standard. A detailed description of each standard is also provided in the Appendix.

Note that the standards selected for this Interoperability Specification are approved for use except as cited in the Scope of Design section of this document as defined in Section 4.0 above.

**Table 4.1.2-1 Selected Standards Linked to HITSP Constructs**

Standard	HITSP Construct	Remarks/ Minor Gaps
Accredited Standards Committee (ASC) X12 Standards Release 004010	HITSP/C80 – Clinical Document and Message Terminology	Vocabularies are enabled via HITSP/C32
American Medical Association (AMA) Current Procedural Terminology (CPT®) Fourth Edition (CPT-4); CPT Evaluation and Management Codes	HITSP/C80 – Clinical Document and Message Terminology	Vocabularies are enabled via HITSP/C32, HITSP/C48
ASTM International Standard Guide for Electronic Authentication of Health Care Information: # E1762-95(2003)	HITSP/C26 – Nonrepudiation of Origin	
CDC Race and Ethnicity Code Sets	HITSP/C80 – Clinical Document and Message Terminology	Vocabularies are enabled via HITSP/C32, HITSP/C48, and HITSP/C76
Centers for Disease Control and Prevention Implementation Guide for Immunizations Data Transaction using Version 2.3.1 of the Health Level Seven (HL7) Standard Protocol. Implementation Guide Version 2.2 June 2006	HITSP/C80 – Clinical Document and Message Terminology	
Digital Imaging and Communications in Medicine (DICOM) Part 3.12: Media Formats and Physical Media for Media Interchange	HITSP/T33 – Transfer of Documents on Media	





Standard	HITSP Construct	Remarks/ Minor Gaps
European Telecommunications Standards Institute (ETSI) Technical Specification TS 101 903: XML Advanced Electronic Signatures (XadES)	HITSP/C26 – Nonrepudiation of Origin	
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	HITSP/C80 – Clinical Document and Message Terminology	Vocabularies are enabled via HITSP/C32, HITSP/C48, and HITSP/C76
Federal Medication Terminologies	HITSP/C80 – Clinical Document and Message Terminology	Vocabularies are enabled via HITSP/C32, HITSP/C48, and HITSP/C76
Food and Drug Administration (FDA) - Unique Ingredient Identifier (UNII)	HITSP/C80 – Clinical Document and Message Terminology	Vocabularies are enabled via HITSP/C32, HITSP/C48, and HITSP/C76
Food and Drug Administration (FDA) - National Drug Code (NDC)	HITSP/C80 – Clinical Document and Message Terminology	Vocabularies are enabled via HITSP/C32, HITSP/C48, and HITSP/C76
Health Level Seven (HL7) Common Terminology Services (CTS) Release 1	HITSP/ T66 – Retrieve Value Set	
Health Level Seven (HL7) HL7 Version 3 Standard: Clinical Document Architecture (CDA), Release 2	HITSP/C48 – Encounter Document Using IHE Medical Summary (XDS-MS) HITSP/C75 – Healthcare Associated Infection (HAI) Report HITSP/C37 – Lab Report Document HITSP/C83 – CDA Content Modules	
Health Level Seven (HL7) Implementation Guide for CDA Release 2: NHSN Healthcare Associated Infection (HAI) Reports, Release 1	HITSP/C75 – Healthcare Associated Infection (HAI) Report	
Health Level Seven (HL7) Implementation Guide for CDA Release 2: History and Physical (H&P) Notes	HITSP/C83 – CDA Content Modules	
Health Level Seven (HL7) Implementation Guide for CDA Release 2: Consultation Note	HITSP/C83 – CDA Content Modules	
Health Level Seven (HL7) Implementation Guide: CDA Release 2 – Continuity of Care Document (CCD), April 01, 2007	HITSP/C32 – Summary Documents Using HL7 Continuity of Care Document (CCD) HITSP/C83 – CDA Content Modules	
Health Level Seven (HL7) Standard Code Set CVX - Vaccines Administered	HITSP/C80 - Clinical Document and Message Terminology	Vocabularies are enabled via HITSP/C32 and HITSP/C76
Health Level Seven (HL7) Standard Code Set MVX - Manufacturers of Vaccines	HITSP/C80 - Clinical Document and Message Terminology	Vocabularies are enabled via HITSP/C32 and HITSP/C76
Health Level Seven (HL7) U.S. Realm – Interoperability Specification: Lab Result Message to EHR (ORU^R01) (HL7 Version 2.5.1) September, 2007	HITSP/C36 – Lab Result Message	



Standard	HITSP Construct	Remarks/ Minor Gaps
Health Level Seven (HL7) V3 RBAC, R1-2008, HL7 Version 3 Standard: Role Based Access Control (RBAC) Healthcare Permissions Catalog, Release 1, February 2008	HITSP/ TP20 – Access Control	
Health Level Seven (HL7) Version 2.3.1 Chapter 2 – Control, Chapter 3 – Patient Administration	HITSP/TP22 – Patient ID Cross-Referencing	
Health Level Seven (HL7) Version 2.5, Chapter 2 – Control, Chapter 3 – Patient Administration, Chapter 5 – Query	HITSP/T23 – Patient Demographics Query HITSP/TP22 – Patient ID Cross-Referencing	
Health Level Seven (HL7) Version 2.5.1	HITSP/C35 – Lab Result Terminology HITSP/C36 – Lab Result Message HITSP/C76 – Case Report Pre-Populate – HITSP/ T14 – Send Laboratory Result Message	
Health Level Seven (HL7) Version 2.5.1 – Vocabularies and Value Sets	HITSP/C80 – Clinical Document and Message Terminology	
Health Level Seven (HL7) Version 3.0	HITSP/C76 – Case Report Pre-Populate	
Health Level Seven (HL7) Version 3.0 – Vocabularies and Value Sets	HITSP/C80 – Clinical Document and Message Terminology	Vocabularies are enabled via HITSP/C32, HITSP/C48, and HITSP/C76
Health Level Seven (HL7) Version 3.0 Context-Aware Information Retrieval Specification: URL Implementation Guide	HITSP/ T81 – Retrieval of Medical Knowledge	
Health Level Seven (HL7) Version 3.0 Infrastructure Management – Query Infrastructure, Release 2 DSTU Ballot 1 – September 2008	HITSP/TP21 – Query for Existing Data	
Health Level Seven (HL7) Version 3.0 Privacy Consent related specifications RCMR_RM010001 – Data Consent	HITSP/ TP30 – Manage Consent Directives	
Health Level Seven (HL7) Version 3.0 Standard: Transport Specification – Web Services Profile, Release 2 Committee Ballot 1 – May 2008	HITSP/TP21 – Query for Existing Data	
HUGO Gene Nomenclature Committee at the European Bioinformatics Institute – Gene Names	HITSP/C80 – Clinical Document and Message Terminology	
Human Genome Variation Society (HGVS) – Description of Sequence Variants – February, 20, 2008	HITSP/C80 – Clinical Document and Message Terminology	
Integrating the Healthcare Enterprise (IHE) Exchange of Personal Health Record Content (XPHR)	HITSP/C32 – Summary Documents Using HL7 Continuity of Care Document (CCD)	



Standard	HITSP Construct	Remarks/ Minor Gaps
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Volume 2 Supplement 2007 – 2008 Cross-Enterprise User Assertion (XUA)	HITSP/C19 – Entity Identity Assertion	
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Supplement Volume 3 – Document Digital Signature (DSG) Content Profile	HITSP/C26 – Nonrepudiation of Origin	
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) –Revision 5.0 or later, Cross Enterprise Sharing of Scanned Documents (XDS-SD) Integration Profile–	HITSP/C62 – Unstructured Document	
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0 or later, Audit Trail and Node Authentication Profile (ATNA)	HITSP/T15 – Collect and Communicate Security Audit Trail	
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0 or later, Audit Trail and Node Authentication (ATNA) Integration Profile, Section 9.1 Authentication	HITSP/T17 – Secured Communication Channel	
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0 or later, Consistent Time (CT) Integration Profile	HITSP/ T16 – Consistent Time	
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 5.0 or later, Patient Demographics Query (PDQ) Integration Profile	HITSP/T23 – Patient Demographics Query	
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Supplement 2008 – 2009, Pediatric Demographics, Draft for Trial Implementation (August 22, 2008)–	HITSP/T23 – Patient Demographics Query HITSP/TP22 – Patient ID Cross-Referencing	
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (TF) Supplement 2007 – 2008, Notification of Document Availability Integration Profile, Draft for Trial Implementation, October 10, 2008–	HITSP/ T29 – Notification of Document Availability	
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) 2007-2008 Trial Implementation Supplement Cross-enterprise Document Reliable Interchange (XDR) Release 3	HITSP/ T31 – Document Reliable Interchange	
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework, Revision 4.0 or later, Personnel White Pages profile	HITSP/ T64 – Identify Communication Recipients	



Standard	HITSP Construct	Remarks/ Minor Gaps
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Supplement 2008-2009 Sharing Value Sets (SVS)	HITSP/ T66 – Retrieve Value Set	
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0, Section 10 Cross-Enterprise Document Sharing (XDS.a)	HITSP/TP13 – Manage Sharing of Documents HITSP/TP30 – Manage Consent Directives	
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0 – Registry Stored Query Transaction for XDS Profile Supplement [ITI-18]–	HITSP/TP13 – Manage Sharing of Documents HITSP/TP30 – Manage Consent Directives	
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0 XCA Supplement	–HITSP/TP30 – Manage Consent Directives	
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Supplement 2008-2009, Cross-Community Access (XCA), Trial Implementation, October 10, 2008	HITSP/TP13 – Manage Sharing of Documents	
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Volume 2 Supplement 2007 – 2008 Cross-Enterprise Document Sharing-B (XDS.b)	HITSP/TP13 – Manage Sharing of Documents HITSP/TP30 – Manage Consent Directives	
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0 or later, Patient Identifier Cross-Referencing Integration Profile (PIX)	HITSP/TP22 – Patient ID Cross-Referencing	
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Supplement 2007 – 2008 Basic Patient Privacy Consents (BPPC) – Trial Implementation–	HITSP/TP30 – Manage Consent Directives	
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (TF) Supplement, Retrieve Form for Data Capture (RFD), Draft for Trial Implementation, October 10 2008	HITSP/TP50 – Retrieve Form for Data Capture	
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 5.0 or later, Cross-Enterprise Document Media Interchange (XDM) Integration Profile	HITSP/T33 – Transfer of Documents on Media	
Integrating the Healthcare Enterprise (IHE) Laboratory Technical Framework Volume 3 (LAB TF-3) Document-based Transactions, Revision 2.0 – For Trial Implementation, August 16, 2007–	HITSP/C37 – Lab Report Document	



Standard	HITSP Construct	Remarks/ Minor Gaps
Integrating the Healthcare Enterprise (IHE) Patient Care Coordination (PCC), Revision 4.0	HITSP/C83 – CDA Content Modules	
Integrating the Healthcare Enterprise (IHE) Patient Care Coordination (PCC), Revision 4.0, 2008 – 2009, Cross-Enterprise Sharing of Medical Summaries (XDS-MS) Integration Profile–	HITSP/C48 – Encounter Document Using IHE Medical Summary (XDS-MS)	
Integrating the Healthcare Enterprise (IHE) Patient Care Coordination (PCC) Technical Framework Supplement 2008 – 2009, Draft for Trial Implementation, August 22, 2008	HITSP/TP21 – Query for Existing Data	
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	HITSP/C76 – Case Report Pre-Populate	
International Classification of Functioning, Disability and Health (ICF)	HITSP/C80 – Clinical Document and Message Terminology	Vocabularies are enabled via HITSP/C48
International Health Terminology Standards Development Organisation (IHTSDO) Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®)	HITSP/C35 – Lab Result Terminology HITSP/C36 – Lab Result Message HITSP/C80 – Clinical Document and Message Terminology	Vocabularies are enabled via HITSP/C32, HITSP/C48, and HITSP/C76
International Organization for Standardization (ISO) Health Informatics – Pseudonymisation, Unpublished Technical Specification # 25237–	HITSP/C87 – Anonymize Public Health Case Reporting Data HITSP/T24 – Pseudonymize	
International Organization for Standardization (ISO) Health Informatics – 9660 Level 1–	HITSP/T33 – Transfer of Documents on Media	
International Organization for Standardization (ISO) ISO 3166-1	HITSP/C80 – Clinical Document and Message Terminology	Vocabularies are enabled via HITSP/C32, HITSP/C48, and HITSP/C76
International Organization for Standardization (ISO) PDF/A ISO 19005-1b. Document management – Electronic document file format for long-term preservation – Part 1: Use of PDF (PDF/A)–	HITSP/C62 – Unstructured Document	
Internet Engineering Task Force (IETF) Network Time Protocol (Version 3) Specification, Implementation and Analysis, "Request for Comment" (RFC) #1305, March, 1992"	HITSP/T16 – Consistent Time	
Internet Engineering Task Force (IETF) Simple Network Time Protocol (SNTP) Version 4, "Request for Comment" (RFC) #2030, October, 1996"	HITSP/T16 – Consistent Time	
Internet Engineering Task Force (IETF) Tags for Identifying Languages, "Request for Comment" (RFC) # 4646, September, 2006	HITSP/C80 - Clinical Document and Message Terminology	Vocabularies are enabled via HITSP/C32, HITSP/C48, and HITSP/C76



## HITSP Public Health Case Reporting Interoperability Specification

Released for Implementation  
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Standard	HITSP Construct	Remarks/ Minor Gaps
Logical Observation Identifiers Names and Codes (LOINC®)	HITSP/C35 – Lab Result Terminology HITSP/C80 – Clinical Document and Message Terminology	Vocabularies are enabled via HITSP/C32, HITSP/C48, and HITSP/C76
National Cancer Institute (NCI) Thesaurus	HITSP/C80 – Clinical Document and Message Terminology	
National Cancer Institute (NCI) Thesaurus: Route of Administration	HITSP/C80 – Clinical Document and Message Terminology	Vocabularies are enabled via HITSP/C32, HITSP/C48, and HITSP/C76
National Center for Biotechnology Information (NCBI) – Genetic Reference Sequences –	HITSP/C80 – Clinical Document and Message Terminology	
National Center for Biotechnology Information (NCBI) – Single Nucleotide Polymorphisms	HITSP/C80 – Clinical Document and Message Terminology	
National Library of Medicine (NLM) Unified Medical Language System (UMLS) RxNorm	HITSP/C80 – Clinical Document and Message Terminology	Vocabularies are enabled via HITSP/C32, HITSP/C48, and HITSP/C76
National Uniform Billing Committee (NUBC) Uniform Bill Version 2007 (UB-04) Current UB Data Specification Manual Field 22, Patient Discharge Status, Codes	HITSP/C80 – Clinical Document and Message Terminology	Vocabularies are enabled via HITSP/C32, HITSP/C48, and HITSP/C76
Organization for the Advancement of Structured Information Standards (OASIS) Common Alerting Protocol (CAP) V1.1, October 2005	HITSP/C82 – Emergency Common Alerting Protocol	
Organization for the Advancement of Structured Information Standards (OASIS) Emergency Data Exchange Language (EDXL) Distribution Element (DE) Version 1.0	HITSP/T63 – Emergency Message Distribution Element	
Organization for the Advancement of Structured Information Standards (OASIS) Security Assertion Markup Language (SAML) Core v2.0 OASIS Standard; ITU-T X.1141	HITSP/TP20 – Access Control	
Organization for the Advancement of Structured Information Standards (OASIS) WS-Trust Version 1.3, March 2007	HITSP/TP20 – Access Control	
Organization for the Advancement of Structured Information Standards (OASIS) eXtensible Access Control Markup Language (XACML), ITU-T Recommendation X.1142, February 2005	HITSP/TP20 – Access Control	
Organization for the Advancement of Structured Information Standards (OASIS) Simple Object Access Protocol (SOAP) Version 1.1	HITSP/TP21 – Query for Existing Data	



Standard	HITSP Construct	Remarks/ Minor Gaps
Organization for the Advancement of Structured Information Standards (OASIS) Simple Object Access Protocol (SOAP) Version 1.2	HITSP/TP21 – Query for Existing Data	
U.S. National Uniform Claims Committee Health Care Provider Taxonomy Code Set	HITSP/C80 – Clinical Document and Message Terminology	
Unified Code for Units of Measure (UCUM)	HITSP/C35 – Lab Result Terminology HITSP/C80 – Clinical Document and Message Terminology	Vocabularies are enabled via HITSP/C32, HITSP/C48, and HITSP/C76
United States Postal Service (USPS) – Postal Codes	HITSP/C80 – Clinical Document and Message Terminology	
USB Removable Device Type 2.0 (USB Implementers Forum)	HITSP/T33 – Transfer of Documents on Media	
VHA National Drug File Reference Terminology (NDF-RT) Formulary	HITSP/C80 – Clinical Document and Message Terminology	Vocabularies are enabled via HITSP/C32, HITSP/C48, and HITSP/C76
VHA National Drug File Reference Terminology (NDF-RT) Formulary	HITSP/C80 – Clinical Document and Message Terminology	

#### 4.1.3 INFORMATIVE REFERENCE STANDARDS

The following table lists standards that provide additional background information or guidance; however, they are not required for the implementation of the Interoperability Specification.

**Table 4.1.3-1 Informative Reference Standards**

Standard	Description
American National Standards Institute (ANSI) International Committee for Information Technology Standards (INCITS), #359-2004	This standard describes RBAC features that have achieved acceptance in the commercial marketplace. It includes a reference model and functional specifications for the RBAC features defined in the reference model. It is intended for (1) software engineers and product development managers who design products incorporating access control features; and (2) managers and procurement officials who seek to acquire computer security products with features that provide access control capabilities in accordance with commonly known and understood terminology and functional. For more information visit <a href="http://www.ansi.org">http://www.ansi.org</a>





Standard	Description
ASTM International Standard Guide for Privilege Management Infrastructure (PMI) Guidelines: #E2595-07	<p>Defines interoperable mechanisms to manage privileges in a distributed environment. This standard is oriented towards support of a distributed or service-oriented architecture (SOA) where security services are themselves distributed and applications are consumers of distributed services. This standard incorporates privilege management mechanisms alluded to in a number of existing standards (e.g., E1986, E2084). The privilege mechanisms in this standard support policy-based access control (including role, entity and contextual-based access control) including the application of policy constraints, patient requested restrictions and delegation. Finally, the standard supports hierarchical, enterprise-wide privilege management.</p> <p>The mechanisms defined in this standard may be used to support a privilege management infrastructure (PMI) using existing public key infrastructure (PKI) technology. This standard does not specifically support mechanisms based on secret-key cryptography. Mechanisms involving privilege credentials are specified in International Organization for Standardization (ISO) 9594-8:2000 (attribute certificates), and Organization for the Advancement of Structured Information Standards (OASIS) Security Assertion Markup Language (SAML) (attribute assertions); however, this standard does not mandate or assume the use of such standards.</p> <p>Many current systems require only local privilege management functionality (on a single computer system). Such systems frequently use proprietary mechanisms. This standard does not address this type of functionality; rather, it addresses an environment where privileges and capabilities (authorizations) must be managed between computer systems across the enterprise, and with business partners. For more information visit <a href="http://www.astm.org">www.astm.org</a></p>
American Society for Testing and Materials (ASTM) Standard Specification for Audit and Disclosure Logs for Use in Health Information Systems: # E2147-01	E2147-01 "is for the development and implementation of security audit/disclosure logs for health information. It specifies how to design an access audit log to record all access to patient identifiable information maintained in computer systems and includes principles for developing policies, procedures, and functions of health information logs to document all disclosure of health information to external users for use in manual and computer systems. The process of information disclosure and auditing should conform, where relevant, with the Privacy Act of 1974 (1)." For more information visit <a href="http://www.astm.org">www.astm.org</a>
Assessing interoperability in emergency management standards Pack, D. Coleman, C., United States Navy, Charleston; This paper appears in: Southeastcon, 2008. IEEE Publication Date: 3-6 April 2008; On page(s): 334-339	Paper identifies the contributions that OASIS EDXL-DE standard will have on interoperability in emergency management, and provides a case study for evaluation purposes
Council for Affordable Quality Health Care (CAQH) Committee on Operating Rules for Information Exchange (CORE) Phase I Operating Rules	Provide agreed-upon business rules and guidelines for using and processing eligibility inquiry and response transactions between providers and health plans; in particular those that have been adopted under HIPAA. For more information visit <a href="http://www.cagh.org">www.cagh.org</a>
Digital Imaging and Communications in Medicine (DICOM) Attribute Level Confidentiality Supplement: # 55	Adds a mechanism for selective protection of individual attributes within arbitrary DICOM service-object pair (SOP) instances. It may be used to achieve protection of identifying information, e.g. a reversible anonymization or pseudonymization of DICOM SOP instances while continuing to use unmodified lower level message and protocol services for network transfer, storage, and media exchange of composite image information objects. For more information visit <a href="http://medical.nema.org">http://medical.nema.org</a>



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). For more information visit <a href="http://www.cancer.gov/cancertopics/terminologyresources/page4">www.cancer.gov/cancertopics/terminologyresources/page4</a>.</p>
Health Level Seven (HL7) Clinical Document Architecture Release 2 (CDA R2)	<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 <a href="http://www.hl7.org">www.hl7.org</a>.</p>
Health Level Seven (HL7) Consent related vocabulary including Confidentiality Codes	<p>HL7 concept domains, including ConfidentialityCodes, ActInformationCategoryCode, ActInformationAccessType, ActInformationAccessContextCode, AuthorizedParticipationFunctionCode, ActPolicyType, ActConsentType, and ActMaskableCode For more information visit <a href="http://www.hl7.org">www.hl7.org</a></p>
Health Level Seven (HL7) Minimal Lower Layer Protocol (MLLP) Release 2	<p>This document specifies Release 2 of the Minimal Lower Layer Message Transport protocol (MLLP, a.k.a. MLP). The goal of the MLLP Message Transport protocol is to provide an interface between HL7 Applications and the transport protocol that uses minimal overhead. MLLP is based on a minimalistic OSI-session layer framing protocol. It is assumed that MLLP will be used only in a network environment. For more information visit <a href="http://www.hl7.org">www.hl7.org</a></p>
Health Level Seven (HL7) V3 RBAC, R1-2008, HL7 Version 3 Standard: Role Based Access Control (RBAC) Healthcare Permissions Catalog, Release 1, February 2008	<p>The Healthcare Permission Catalog provides the necessary content for creating interoperable roles facilitating inter-organizational communications and information sharing among healthcare organizations and their business partners. For more information visit <a href="http://www.hl7.org">www.hl7.org</a></p>



Standard	Description
Health Level Seven (HL7) Version 2.5	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 <a href="http://www.hl7.org">www.hl7.org</a>
Health Level Seven (HL7) Version 3.0	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 <a href="http://www.hl7.org">www.hl7.org</a>
Health Level Seven (HL7) Version 3.0 Clinical Document Architecture (CDA/CDA R2)	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 <a href="http://www.hl7.org">www.hl7.org</a>
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0, Volume 2 Transactions, Appendix C	Section 2.1 of Appendix C in the framework provides network guidelines for the network communications protocol for the HL7 message. For more information visit <a href="http://www.ihe.net">www.ihe.net</a>
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0, Volume 2 Transactions, Appendix M Using Patient Demographics Query in a Multi-Domain Environment	Appendix M – Using Patient Data Query (PDQ) in a Multi-Domain Environment, provides an architectural discussion of how Query Parameter Definition, QPD-8 is processed For more information visit <a href="http://www.ihe.net">www.ihe.net</a>
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. The latest version of the IHE Technical Framework is available at <a href="http://www.ihe.net">www.ihe.net</a>



Standard	Description
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. The latest version of the IHE Technical Framework is available at <a href="http://www.ihe.net">www.ihe.net</a>
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0, Audit Trail and Node Authentication (ATNA) Integration Profile	Audit Trail and Node Authentication (ATNA) establishes the characteristics of a Basic Secure Node. It describes the security environment (user identification, authentication, authorization, access control, etc.) assumed for the node so that security reviewers may decide whether this matches their environments. It defines basic auditing requirements for the node. It defines basic security requirements for the communications of the node using TLS or equivalent functionality. It establishes the characteristics of the communication of audit messages between the Basic Secure Nodes and Audit Repository nodes that collect audit information. This integration profile has been designed so that specific domain frameworks may extend it through an option defined in the domain specific technical framework. Extensions are used to define additional audit event reporting requirements, especially actor specific requirements. The latest version of the IHE Technical Framework is available at <a href="http://www.ihe.net">www.ihe.net</a>
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. The latest version of the IHE Technical Framework is available at <a href="http://www.ihe.net">www.ihe.net</a>
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. The latest version of the IHE Technical Framework is available at <a href="http://www.ihe.net">www.ihe.net</a>
Integrating the Healthcare Enterprise (IHE) Patient Care Coordination (PCC) Technical Framework Revision 1.0	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 Cross-Enterprise Document Sharing of Medical Summaries (XDS-MS) Integration Profile enables sharing of health information between enterprises of a regional health network, and further describes how to map content in a CDA medical document into registry metadata. In the registry, healthcare providers publish pointers to documents stored in distributed repositories. Other healthcare providers may search and retrieve these and other documents. For more information visit <a href="http://www.ihe.net">www.ihe.net</a>



Standard	Description
Integrating the Healthcare Enterprise (IHE) Patient Care Coordination (PCC), Revision 3.0, 2007 – 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 Cross-Enterprise Document Sharing of Medical Summaries (XDS-MS) Integration Profile enables sharing of health information between enterprises of a regional health network, and further describes how to map content in a CDA medical document into registry metadata. In the registry, healthcare providers publish pointers to documents stored in distributed repositories. Other healthcare providers may search and retrieve these and other documents. For more information visit <a href="http://www.ihe.net">www.ihe.net</a>
International Organization for Standardization (ISO) Health informatics – Directory services for security, communications and identification of professionals and patients, Technical Specification #21091	Defines minimal specifications for directory services for health care using the X.500 framework. This Technical Specification provides the common directory information and services needed to support the secure exchange of health care information over public networks. It addresses the health directory from a community perspective in anticipation of supporting inter-enterprise, inter-jurisdiction and international health care communications. ISO/TS 21091:2005 also supports directory services aiming to support identification of health professionals and organizations and the patients/consumers. The latter services include aspects sometimes referred to as master patient indices. The health care directory will only support standard LDAP Client searches. Specific implementation guidance, search criteria and support are out of scope of this document. For more information, visit <a href="http://www.iso.org">www.iso.org</a>
International Organization for Standardization (ISO) Health informatics – Information technology – Open Systems Interconnection – Systems Management: Security alarm reporting function, Technical Specification #10164–Part 7: Security Alarm Reporting Function, 1992	Establishes user requirements for the service definition needed to support the security alarm reporting function, defines the service provided by the security alarm reporting function, specifies the protocol that is necessary in order to provide the service, defines the relationship between the service and management notifications, defines relationships with other systems management functions, specifies conformance requirements. The security alarm reporting function is a systems management function which may be used by an application process in a centralized or decentralized management environment to exchange information for the purpose of systems management. For more information visit <a href="http://www.iso.org">www.iso.org</a>
International Organization for Standardization (ISO) Health informatics – Information technology – Text and office systems – Office Document Architecture (ODA) and interchange format, Technical Report on ISO 8613 implementation testing, Technical Specification # ISO/IEC CD 10183 – Part 3: Testing procedure.	Specifies a general framework for the provision of access control. The purpose of access control is to counter the threat of unauthorized operations involving a computer or communication system. For more information visit <a href="http://www.iso.org">www.iso.org</a>
International Organization for Standardization (ISO) Health informatics – Privilege management and access control(PMAC), Technical Specification #22600 – Part 1: Overview and policy management, July 2006	Supports the needs of healthcare information sharing across unaffiliated providers of healthcare, healthcare organizations, health insurance companies, their patients, staff members and trading partners. It is also intended to support inquiries from both individuals and application systems. For more information visit <a href="http://www.iso.org">www.iso.org</a>



Standard	Description
International Organization for Standardization (ISO) Health informatics – Functional and Structural Roles (ISO SF Roles), Technical Specification #21298 , Draft May, 2007	<p>This document contains a specification for encoding information related to roles for health professionals and consumers. At least four areas have been identified where a model for encoding role information is needed.</p> <ol style="list-style-type: none"> <li>1. Privilege management and access control: role-based access control is not possible without an effective means of recording role information for healthcare actors.</li> <li>2. Directory services: structural roles are usefully recorded within directories of health care providers (see for example, ISO TS 21091 Health Informatics – Directory services for security, communications, and identification of professionals and patients).</li> <li>3. Audit trails: functional roles are usefully recorded within audit trails for health information applications.</li> <li>4. Public key infrastructure (PKI): The three part ISO standard 17090 Health Informatics – Public Key Infrastructure (PKI) allows for the encoding of healthcare roles in certificate extensions, but no structured vocabulary for such roles is specified. This technical specification identifies such a coded vocabulary.</li> </ol> <p>For more information visit <a href="http://www.iso.org">www.iso.org</a></p>
Internet Engineering Task Force (IETF) Tags for the Identification of Languages, "Request for Comment" (RFC) # 3066, January, 2001	<p>Describes a language tag for use in cases where it is desired to indicate the language used in an information object, how to register values for use in this language tag, and a construct for matching such language tags. For more information visit <a href="http://www.ietf.org">www.ietf.org</a></p>
Internet Engineering Task Force (IETF) The application/pdf Media Type (RFC 3778)	<p>PDF, the 'Portable Document Format', is a general document representation language that has been in use for document exchange on the Internet since 1993. This document provides an overview of the PDF format, explains the mechanisms for digital signatures and encryption within PDF files, and updates the media type registration of 'application/pdf'. For more information visit <a href="http://www.ietf.org">www.ietf.org</a></p>
Internet Engineering Task Force (IETF), HTTP HyperText Transfer Protocol HTTP/1.1 (RFC 2616)	<p>The Hypertext Transfer Protocol (HTTP) is an application-level protocol for distributed, collaborative, hypermedia information systems. It is a generic, stateless, protocol, which can be used for many tasks beyond its use for hypertext, such as name servers and distributed object management systems, through extension of its request methods, error codes and headers [47]. A feature of HTTP is the typing and negotiation of data representation, allowing systems to be built independently of the data being transferred. For more information visit <a href="http://www.ietf.org">www.ietf.org</a></p>
Internet Engineering Task Force (IETF), MIME Multipurpose Internet Message Extensions (RFC 2045 to RFC 2049)	<p>The first and second documents in this set define MIME header fields and the initial set of MIME media types. The third document describes extensions to RFC 822 formats to allow for character sets other than US-ASCII. The fourth document describes what portions of MIME must be supported by a conformant MIME implementation. It also describes various pitfalls of contemporary messaging systems as well as the canonical encoding model MIME is based on. For more information visit <a href="http://www.ietf.org">www.ietf.org</a></p>
Internet Engineering Task Force (IETF), SMTP Simple Mail Transfer Protocol (RFC 2821)	<p>The objective of the Simple Mail Transfer Protocol (SMTP) is to transfer mail reliably and efficiently. SMTP is independent of the particular transmission subsystem and requires only a reliable ordered data stream channel. While this document specifically discusses transport over TCP, other transports are possible. For more information visit <a href="http://www.ietf.org">www.ietf.org</a></p>





Standard	Description
Internet Engineering Task Force (IETF), The MIME Multipart/Related Content-type (RFC 2387)	The Multipart/Related content-type provides a common mechanism for representing objects that are aggregates of related MIME body parts. This document defines the Multipart/Related content-type and provides examples of its use. For more information visit <a href="http://www.ietf.org">www.ietf.org</a>
Internet Engineering Task Force (IETF), Transmission Control Protocol (TCP), DARPA Internet Program Protocol Specification (RFC 793)	The Transmission Control Protocol (TCP) is intended for use as a highly reliable host-to-host protocol between hosts in packet-switched computer communication networks, and in interconnected systems of such networks. This document describes the functions to be performed by the Transmission Control Protocol, the program that implements it and its interface to programs or users that require its services. For more information visit <a href="http://www.ietf.org">www.ietf.org</a>
Organization for the Advancement of Structured Information Standards (OASIS) Security Assertion Markup Language (SAML) Core v2.0 OASIS Standard; ITU-T X.1141	SAML, developed by the Security Services Technical Committee of OASIS, is an XML-based framework for communicating user authentication, entitlement, and attribute information. As its name suggests, SAML allows business entities to make assertions regarding the identity, attributes, and entitlements of a subject (an entity that is often a human user) to other entities, such as a partner company or another enterprise application. For more information visit <a href="http://www.oasis-open.org">www.oasis-open.org</a>
Organization for the Advancement of Structured Information Standards (OASIS) Web Services Security SOAP Message Security Version 1.0	Describes enhancements to SOAP messaging to provide message integrity and confidentiality. The specified mechanisms can be used to accommodate a wide variety of security models and encryption technologies. This specification also provides a general-purpose mechanism for associating security tokens with message content. No specific type of security token is required, the specification is designed to be extensible (i.e., support multiple security token formats. Additionally, this specification describes how to encode binary security tokens, a framework for XML-based tokens, and how to include opaque encrypted keys. It also includes extensibility mechanisms that can be used to further describe the characteristics of the tokens that are included with a message. For more information visit <a href="http://www.oasis-open.org">www.oasis-open.org</a>
Organization for the Advancement of Structured Information Standards (OASIS) Simple Object Access Protocol (SOAP) Version 1.1	SOAP is a protocol specification for invoking methods on servers, services, components and objects. SOAP codifies the existing practice of using XML and HTTP as a method invocation mechanism. The SOAP specification mandates a small number of HTTP headers that facilitate firewall/proxy filtering plus an XML vocabulary that is used for representing method parameters, return values, and exceptions." (DevelopMentor) SOAP consists of three parts: an envelope that defines a framework for describing what is in a message and how to process it, a set of encoding rules for expressing instances of application-defined data types, and a convention for representing remote procedure calls and responses. For more information visit <a href="http://www.oasis-open.org">www.oasis-open.org</a>
Organization for the Advancement of Structured Information Standards (OASIS) – ebRIM OASIS – ebXML Registry Information Model v2.1	The Registry Information Model provides a blueprint or high-level schema for the ebXML Registry. Its primary value is for implementers of ebXML Registries. It provides these implementers with information on the type of metadata that is stored in the Registry as well as the relationships among metadata Classes. The Registry information model: a) Defines what types of objects are stored in the Registry; b) Defines how stored objects are organized in the Registry. For more information visit <a href="http://www.oasis-open.org">www.oasis-open.org</a>





Standard	Description
Organization for the Advancement of Structured Information Standards (OASIS) – ebMS OASIS/ebXML Messaging Services Specifications v2.1	Defines a Message Service protocol for reliable Business-to-Business data interchange. ebMS v2.1 adds quality of service features on top of transfer protocols such as HTTP and SMTP. Key qualities of service features include guaranteed delivery and nonrepudiation of receipt. ebMS v2.1 can reliably transfer any data type including XML, X12, EDIFACT, or binary data between two parties over the Internet. For more information visit <a href="http://www.oasis-open.org">www.oasis-open.org</a>
Organization for the Advancement of Structured Information Standards (OASIS) –ebRS OASIS – ebXML Registry Services Specifications v2.1	The ebXML Registry provides a set of services that enable sharing of information between interested parties for the purpose of enabling business process integration between such parties based on the ebXML specifications. The shared information is maintained as objects in a repository and managed by the ebXML Registry Services defined in this document. For more information visit <a href="http://www.oasis-open.org">www.oasis-open.org</a>
Organization for the Advancement of Structured Information Standards (OASIS) – ebXML Registry Information Model (3.0)	The Registry Information Model provides a blueprint or high-level schema for the ebXML Registry. Its primary value is for implementers of ebXML Registries. It provides these implementers with information on the type of metadata that is stored in the Registry as well as the relationships among metadata Classes. The Registry information model: a) Defines what types of objects are stored in the Registry; b) Defines how stored objects are organized in the Registry. For more information visit <a href="http://www.oasis-open.org">www.oasis-open.org</a>
Organization for the Advancement of Structured Information Standards (OASIS) – ebXML Registry Services Specification (3.0)	The ebXML Registry provides a set of services that enable sharing of information between interested parties for the purpose of enabling business process integration between such parties based on the ebXML specifications. The shared information is maintained as objects in a repository and managed by the ebXML Registry Services defined in this document. For more information visit <a href="http://www.oasis-open.org">www.oasis-open.org</a>
VHA National Drug File Reference Terminology (NDF-RT) Formulary	Provides standard names for (1) mechanism of action, (2) Physiologic Effect and (3) Structural Class. NDF-RT is part of the Federal Medication Terminologies. For more information visit <a href="http://www.cancer.gov/cancertopics/terminologyresources/page5">www.cancer.gov/cancertopics/terminologyresources/page5</a>

## 4.2 GAPS WHERE THERE ARE NO STANDARDS

This section describes gaps in standards. Gaps occur in the following two cases, where HITSP has:

- Identified requirements derived from the context that have no standards that meet all tiers of HITSP criteria to merit selection for that context
- Identified a single standard that encompasses and singly fulfills a set of tightly-coupled standards from the given context, yet is lacking in fulfilling one or more of the tightly-coupled requirements

The gap is only relative to the specific Use Case requirement. Recommended resolutions were developed through a series of steps including the Technical Committee's initial recommendations, cross Technical Committee validation of the gap, provisional recommendations and peer review by the Technical Committee.

The table below identifies the Use Case requirements and known associated gaps, along with the recommended resolutions.



**Table 4.2-1 Use Case Requirements and Associated Standards Gaps**

Requirement Number	Summary Description	Identified Gaps	Recommended Resolution
DR17	Decision	8.1.1.1 Action: Request information from submitters of reports/information. In the PH side – an attempt is made to enumerate as much of the notifiable conditions possible – the opposite exists in AE reporting, but for AE the case is inverted – for PH it is doable, but for AE, it is not easily doable without tremendous human intervention to automate the classification; Alert may be programmable by class – trigger certain reporting events, but this is after the determination that this is an event	Work with SDOs to create a minimum number of standards for PH case reporting requests and AE reporting requests
DR17	Decision	8.1.1.2 Action: Request information from submitters of reports/information. Gap in identifying supplemental detail needed from standards (e.g. using patient anti-TB drug as an indication of active TB to compare to known TB patients) – what standardized questions to ask	Work with SDOs to create a minimum number of standards for PH case reporting and AE reporting
DR17	Decision	8.1.1.2 Action: Request information from submitters of reports/information GAP in the specifics of what should be requested	Leave to local definition via TP50
DR25	Case Report Content	Facility Identifier, Send Report to: Federal Project under way to used DUNS number for companies that import products – global business – Not sufficient for this Use Case – doesn't cover: PH Agency requesting information back PH Clinic – may not have one, manufacturers won't, food importers – DUNS Satellite clinic may not have a separate ID from Hospital May need to be more than one data element to distinguish the concept	Pending policy and assigning authority recommendations
DR25	Case Report Content	Event Device Problem Code : Not using a structured terminology; MedDRA/CDRH discussion to align terminologies; Overlap: Codelist GAP: Reconcile structured terminology for device AE reporting	Work with SDOs to update the standards to conform to the data requirements



Requirement Number	Summary Description	Identified Gaps	Recommended Resolution
DR25	Case Report Content	<p>Type of Reportable Event It should represent the coded adverse event term. Events/incidents for internal reporting (e.g. falls) Reportable events for non-FDA: WHO taxonomy Joint Commission list CDC FDA (form) VAERS – vaccine injury CMS Never list</p> <p>Terminology Service opportunity; Broadest list may reflect a GAP Multiple lists reflect OVERLAP It is a vocabulary issue to be addressed with ICSR 3.</p>	Work with SDOs to update the standards to conform to the data requirements
DR25	Case Report Content	<p>Type of Follow-Up MedWatch form – follow-up info – corrected, etc – no structured vocabulary</p>	Work with SDOs to update the standards to conform to the data requirements
DR25	Case Report Content	<p>Type of Remedial Action Not coded today; could be coded depending on type of report (e.g. medical device – refurbished);</p>	Work with SDOs to update the standards to conform to the data requirements
DR25	Case Report Content	<p>Occupational Risk Factors GAP for detail – some in, but not all in SNOMED-CT Y/N/U/Not Asked null flavor options</p>	Work with SDOs to update the standards to conform to the data requirements
DR25	Case Report Content	<p>Contact with confirmed or suspect HBV case – Need contact type coded</p>	Work with SDOs to update the standards to conform to the data requirements
DR25	Case Report Content	<p>Frequency of direct blood or body fluid exposure Frequent, several times/week, infrequent</p>	Work with SDOs to update the standards to conform to the data requirements



Requirement Number	Summary Description	Identified Gaps	Recommended Resolution
DR25	Case Report Content	<p>7.1.6.3 Action: Update PH Case Report or AE Report.</p> <p>7.1.7.2 Action: Transmit confirmed PH Case Reports or AE Reports to Public Health.</p> <p>7.2.1.4 Action: Communicate reporting criteria for both PH Cases and Aes. Reporting criteria include: trigger data and reporting specifications.</p> <p>8.1.1.2 Action: Receive additional information to assist in investigation activities.</p> <p>8.2.1.2 Action: Send information to Public Health related to previously reported PH Cases and/or other information.</p> <p>7.1.1.2 Action: Incorporate PH trigger data and reporting specifications.</p> <p>7.1.1.3 Action: Incorporate AE trigger data and reporting specifications.</p> <p>7.1.6.1 Action: Information related to possible PH Cases or Aes that is not available through an EHR is manually gathered.</p> <p>7.1.6.2 Action: Information related to possible PH Cases or Aes that is not available through an EHR may be gained through electronic information exchanges.</p> <p>8.1.1.1 Action: Request information from submitters of reports/information.</p> <p>8.2.1.1 Action: Receive request for additional information from Public Health.</p> <p>Need to refer maintenance of common data elements and harmonization effort</p>	Recommend that a body to maintain this be identified
DR25	Case Report Content	Concomitant Medical Products & Therapy Dates: Other medical products and treatment used proximal to the event: Non-medication product terms are to be represented with ICSR 3 and therefore, these are a GAP for this release. In the user interface, the user will need to select one or more (n) of a list.	Work with SDOs to update the standards to conform to the data requirements
DR25	Case Report Content	Type of Reporter: The role of the reporter with respect to the patient (e.g., treating or consulting clinician, case manager, etc.)	Work with SDOs to update the standards to conform to the data requirements
DR25	Case Report Content	Suspect Product Name: Product name - Medications should reference NDC and RxNorm as identified in C80. Vaccines are represented by CVX codes (also identified in C80). Non-medication product terms are to be represented with ICSR 3 and therefore, these are a GAP for this release. In the user interface, the user will need to select one or more (n) of a list.	Work with SDOs to update the standards to conform to the data requirements



Requirement Number	Summary Description	Identified Gaps	Recommended Resolution
DR25	Case Report Content	Patient Recovered Diagnosis: Final determination of reaction – diagnosis; Captures reported signs and symptoms that have been combined into a succinct diagnosis that captures the patient state at the end of the adverse event	Recovery terminology will be determined as part of the ICSR 3 effort. Some terms are identified in ICH which will be reviewed for ICSR 3. Some harmonization is also required with Public Health reporting for other uses of the term "recovered". For now, the vocabulary is a GAP.
DR25	Case Report Content	Name of Treatment	Medications should reference NDC and RxNorm as identified in C80. Vaccines are represented by CVX codes (also identified in C80). Non-medication product terms and actions are to be represented with ICSR 3 and therefore, these are a GAP for this release. In the user interface, the user will need to select one or more ( <i>n</i> ) of a list.
DR25	Case Report Content	7.1.1.2, 7.1.1.3 Incorporate PH/AE trigger data and reporting specifications. Not sufficient support yet	HL7 EDCI – standard under ballot in progress
DR25	Case Report Content	7.1.1.3 Incorporate AE trigger data and reporting specifications. FDA – forms for SPL; Form structure is there, but not the logic behind it	Work with SDOs to create a minimum number of standards for PH case reporting and AE reporting
DR25	Case Report Content	7.1.1.2, 7.1.1.3 Incorporate PH/AE trigger data and reporting specifications. Forms section- HITSP – the industry recognized need for development of standardized forms, but the forms development is an area of gaps. Forms sections have some things to start with. LOINC is not complete for this	Work with SDOs to create a minimum number of standards for PH case reporting and AE reporting
DR25	Case Report Content	8.2.2.2 Action: Communicate case or patient specific information. No Standards for structure Clinical Reports sent from PH to HC Provider	Work with SDOs to create a minimum number of standards for PH case reporting and AE reporting
DR25	Case Report Content	8.2.2.3 Action: Receive specific clinically relevant Public Health information No Standards for structure Reports sent from PH to Public	Work with SDOs to create a minimum number of standards for PH case reporting and AE reporting.
DR25	Case Report Content	8.3.1.2a Alternate Action: Send information related to previously reported PH Cases and/or other information may be sent to Public Health No standards for supplemental information reports	Work with SDOs to create a minimum number of standards for PH case reporting and AE reporting



Requirement Number	Summary Description	Identified Gaps	Recommended Resolution
DR25	Case Report Content	<p>7.1.6.3 Action: Update PH Case Report or AE Report.</p> <p>7.1.7.2 Action: Transmit confirmed PH Case Reports or AE Reports to Public Health.</p> <p>8.1.1.2 Action: Communicate reporting criteria for both PH Cases and Aes. Reporting criteria include: trigger data and reporting specifications.</p> <p>8.2.1.2 Action: Receive additional information to assist in investigation activities.</p> <p>Action: Send information to Public Health related to previously reported PH Cases and/or other information.</p> <p>No consolidation of overlapping methods for Case reporting and AE reporting</p>	<p>Better harmonize the data elements across the Use Case which will make the generation of the standards easier.</p> <p>AHRQ in partnership with FDA, CDC, DOD, IHS, and VA is developing and will publish a set of data safety data elements in common format for use by the PSOs to exchange data. This should be reconciled with the dataset that will inform the development of a construct for communication of the adverse event data.</p> <p>Support efforts currently underway to create within the SDOs harmonized standards for the adverse event reports. Recommend that the SDOs prepare standards for the transmission of this payload</p>
DR25	Case Report Content	<p>7.1.6.3 Action: Update PH Case Report or AE Report.</p> <p>7.1.7.2 Action: Transmit confirmed PH Case Reports or AE Reports to public health.</p> <p>7.2.1.4 Action: Communicate reporting criteria for both PH Cases and Aes. Reporting criteria include: trigger data and reporting specifications.</p> <p>8.1.1.2 Action: Receive additional information to assist in investigation activities.</p> <p>8.2.1.2 Action: Send information to public health related to previously reported PH Cases and/or other information</p> <p>There are gaps for standards for AE reporting – Vocabularies to describe the event for regulatory domain are MedDRA, but not used by EHR</p> <p>It is not clear what organization is the owner of non-drug, device, HAI or previously defined events</p>	<p>Refer to AHIC and ONC or other appropriate bodies to identify some organization within this group to help deal with the policy and data and reporting requirements.</p> <p>Evaluate harmonized cross-agency data set to determine whether the result will support these data and reporting requirements.</p> <p>Listed Never Events: the category to capture falls, sores, non-infectious surgical complications; criminal events. Incident categories are not fully defined – efforts with WHO patient safety taxonomy, NQF</p> <p>NOTE: Messaging – do not see the point of introducing another AE message – deferring because there are discussions under way to address this issue</p>



Requirement Number	Summary Description	Identified Gaps	Recommended Resolution
DR25	Case Report Content	<p>7.1.6.3 Action: Update PH Case Report or AE Report.</p> <p>7.1.7.2 Action: Transmit confirmed PH Case Reports or AE Reports to public health.</p> <p>7.2.1.4 Action: Communicate reporting criteria for both PH Cases and Aes. Reporting criteria include: trigger data and reporting specifications.</p> <p>8.1.1.2 Action: Receive additional information to assist in investigation activities.</p> <p>8.2.1.2 Action: Send information to Public Health related to previously reported PH Cases and/or other information.</p> <p>Vocabularies used across the models are not standardized in HL7</p>	<p>HL7 is looking to standardized the vocabularies across HL7 internal and external</p> <p>Adopt SDO-defined vocabularies where possible</p>
IER26	Identify communication recipients	<p>8.1.5.1 Action: Receive additional information to assist in investigation activities.</p> <p>Possible gap for identifying party to whom to communicate this information; Policy consideration</p>	Refer to policy specifications

### 4.3 STANDARD OVERLAPS

This section describes the instances where there are overlaps among standards for the Use Case requirements. The overlap is only relative to the specific Use Case requirement. Overlaps refer to instances wherein some of the requirements are met by multiple standards. Recommended resolutions were developed through a series of steps including the Technical Committee's initial recommendations, cross Technical Committee validation of the overlap, provisional recommendations and peer review by the Technical Committee's.

The table below presents the identified overlaps and the respective resolution plans.





**Table 4.3-1 Use Case Requirements and Associated Standard Overlaps**

Requirement Number	Summary Description	Standard Overlap	Recommended Resolution
DR25	Case Report Content	<p>7.1.6.3 Action: Update PH Case Report or AE Report.</p> <p>7.1.7.2 Action: Transmit confirmed PH Case Reports or AE Reports to public health.</p> <p>7.2.1.4 Action: Communicate reporting criteria for both PH Cases and Aes. Reporting criteria include: trigger data and reporting specifications.</p> <p>8.1.1.2 Action: Receive additional information to assist in investigation activities.</p> <p>8.2.1.2 Action: Send information to Public Health related to previously reported PH Cases and/or other information.</p> <p>7.1.1.2 Action: Incorporate PH trigger data and reporting specifications.</p> <p>7.1.1.3 Action: Incorporate AE trigger data and reporting specifications.</p> <p>7.1.6.1 Action: Information related to possible PH Cases or Aes that is not available through an EHR is manually gathered.</p> <p>7.1.6.2 Action: Information related to possible PH Cases or Aes that is not available through an EHR may be gained through electronic information exchanges.</p> <p>8.1.1.1 Action: Request information from submitters of reports/information.</p> <p>8.2.1.1 Action: Receive request for additional information from Public Health.</p> <p>CDISC Anatomical Site List – Overlap SNOMED</p>	Refer to Foundations



Requirement Number	Summary Description	Standard Overlap	Recommended Resolution
DR25	Case Report Content	<p>7.1.6.3 Action: Update PH Case Report or AE Report.</p> <p>7.1.7.2 Action: Transmit confirmed PH Case Reports or AE Reports to Public Health.</p> <p>7.2.1.4 Action: Communicate reporting criteria for both PH Cases and Aes. Reporting criteria include: trigger data and reporting specifications.</p> <p>8.1.1.2 Action: Receive additional information to assist in investigation activities.</p> <p>8.2.1.2 Action: Send information to Public Health related to previously reported PH Cases and/or other information.</p> <p>There is an active migration/harmonization to enable the adoption of the same standards across multiple organizations for Patient Safety:</p> <p>ISO ICSR : HL7 ICSR 3</p> <p>HL7 ICSR 2</p> <p>ICH-E2B</p> <p>Notifiable Disease Condition</p> <p>Generic Incident Notification (GIN)</p> <p>Root cause and Underlying factors Message (RUM)</p> <p>ICSR – 2 flavors:</p> <p>1) International conference of Harmonization E2B; does not cover vaccines, devices or food; does not include combination products (e.g. drug/device, drug/biologic) – only supports use of MEDRA; extends use of MEDRA to code surgical, disease conditions; discussion using to code lab; MEDRA has incorporated some of the lab code test names; AE; 2) HL7 ICSR – developed as a broader Use Case – next release is what FDA is trying to get international consensus; HL7 includes food, devices and medications, and vaccines</p>	<p>Harmonization effort is under way – Version 3 is expected to expand version 2 to include food, cosmetics, devices, drugs, and possibly veterinary. Work may be informed by ISO TR22224</p> <p>Once SDO harmonization is complete, we should incorporate the resulting work into a HITSP construct to communicate the payload</p>
DR25	Case Report Content	<p>7.1.6.3 Action: Update PH Case Report or AE Report.</p> <p>7.1.7.2 Action: Transmit confirmed PH Case Reports or AE Reports to Public Health</p> <p>7.2.1.4 Action: Communicate reporting criteria for both PH Cases and Aes. Reporting criteria include: trigger data and reporting specifications</p> <p>8.1.1.2 Action: Receive additional information to assist in investigation activities</p> <p>8.2.1.2 Action: Send information to Public Health related to previously reported PH Cases and/or other information</p> <p>Healthcare Associated Infections (HAI), CDC, CMS, AHRQ</p> <p>States don't necessarily align with the same definition and list of HAIs than those required by CDC</p> <p>Over the last decade, difficulty on agreeing on standards for harmonizing adverse event reporting</p>	<p>Request harmonization of state and federal definitions for HAIs from the CSTE</p> <p>HHS/PSOs may become appropriate bodies for managing standardization of reporting for Hospital/Institutional Acquired Infections</p>



Requirement Number	Summary Description	Standard Overlap	Recommended Resolution
DR25	Case Report Content	<p>7.1.6.3 Action: Update PH Case Report or AE Report.</p> <p>7.1.7.2 Action: Transmit confirmed PH Case Reports or AE Reports to Public Health</p> <p>7.2.1.4 Action: Communicate reporting criteria for both PH Cases and Aes. Reporting criteria include: trigger data and reporting specifications</p> <p>8.1.1.2 Action: Receive additional information to assist in investigation activities</p> <p>8.2.1.2 Action: Send information to public health related to previously reported PH Cases and/or other information.</p> <p>PH Case Reporting</p> <p>No official standard, but there are numerous attempts to create one</p> <p>See Appendix 6.2 for details</p>	<p>standardization workgroup within CSTE – body to adjudication PHCS reporting standards</p> <p>Case Reporting WG reports to Surveillance Coordination Group which in turn reports to PH Informatics Team. The PH Informatics team passes it on to CSTE membership for approval</p> <p>This should be reconciled with the dataset that will inform the development of a construct for communication of the public health case event data</p> <p>Recommend that the SDOs prepare standards for the transmission of this payload. Monitor and contribute to these efforts</p>
DR25	Case Report Content	<p>CDISC has started a list of ~300 anatomical sites; Looking for 100 +/- sites (e.g. upper right arm)</p> <p>Overlap possible – HL7 Bodysite/CDISC</p> <p>Want major gross anatomical sites involved with clinical procedures</p>	<p>Recommend harmonization between CDISC and HL7 (RCRIM, OO referral)</p>
DR25	Case Report Content	<p>Patient County: The county of the address of the subject of the case report - US-GNIS; 3166-2 or -3?</p>	<p>Selection deferred pending further analysis from CMHR</p>



## 5.0 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.

### 5.1 CONFORMANCE CRITERIA

In order to claim conformance to the specification, an implementation must satisfy all the requirements and mandatory statements listed in the HITSP Interoperability Specification, its associated construct specifications, as well as conformance criteria from the selected base and composite standards. A conformant system must be constrained as specified in Table 3.1.2-1, and implement all of the required actors from Table 3.2.3-1, within the scope, subset or implementation option that is selected from Section 5.2 below.

Claims of conformance to this specification must be made using the following language:

This product conforms to the HITSP Public Health Case Reporting Interoperability Specification, available at [www.hitsp.org](http://www.hitsp.org).

### 5.2 CONFORMANCE SCOPING, SUBSETTING AND OPTIONS

A HITSP Interoperability Specification can be implemented for individual business actors defined in the Interoperability Specification. An implementation claiming conformance to a specific business actor from the Interoperability Specification shall support all of the requirements associated to that business actor as described in Table 3.2.3-1.

This means that **for each implemented business actor**:

1. All Required or Conditionally Required technical actors listed for the business actor shall be supported as specified in the associated construct
2. Optional technical actors listed for the business actor may be supported as specified in the associated construct
3. All Required or Conditionally Required transactions and content subsets listed for each implemented technical actor assigned to the business actor shall be supported as specified in the associated construct
4. Optional transactions and content subsets listed for each implemented technical actor assigned to the business actor may be supported as specified in the associated construct

Implementers of this Interoperability Specification who follow the principles listed above are being provided a level of implementation flexibility, while maintaining interoperability.



### 5.3 TEST METHODS

HITSP relies on the conformance test methods, test tools and other test-related material produced by, or under the auspices, of standards developers, profiling organizations and Implementation Guide producers as part of its collaborative implementation testing effort. Efforts to produce conformance test methods, tools, etc. may be internal to the organization, or provided by an external organization.

A Health Information Technology (HIT) Implementation Testing website has been developed in collaboration with HITSP, the National Institute of Standards and Technology (NIST), the Certification Commission for Healthcare Information Technology (CCHIT), and the Office of the National Coordinator (ONC) to advance conformance and interoperability testing capabilities. This website provides HIT implementers with the necessary resources to support and test their implementation of standards-based health systems. For more information, visit NIST at [www.nist.gov](http://www.nist.gov).



## 6.0 APPENDIX

The following sections include relevant materials referenced throughout this document.

### 6.1 DESCRIPTION OF STANDARDS

The following table contains descriptions of the selected standards from Section 4.1.2 above:

**Table 6.1-1 Description of Standards**

Standard	Description
Accredited Standards Committee (ASC) X12 Standards Release 004010	Release (version) 004010 of the Accredited Standards Committee (ASC) X12 standards including the X12.5 Interchange Control, X12.6 Application Control Structure, 270 Eligibility, Coverage or Benefit Inquiry, 271 Eligibility, Coverage or Benefit Information and other control standards for the uniform electronic interchange of business transactions. Published by the Data Interchange Standards Association (DISA). For more information visit <a href="http://www.x12.org">www.x12.org</a> .
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 <a href="http://www.ama-assn.org">www.ama-assn.org</a> .
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 <a href="http://www.ama-assn.org">www.ama-assn.org</a> .
ASTM International Standard Guide for Electronic Authentication of Health Care Information: # E1762-95(2003)	Defines a document structure for use by electronic signature mechanisms, describes the characteristics of an electronic signature process. Defines minimum requirements for different electronic signature mechanisms, defines signature attributes for use with electronic signature mechanisms, describes acceptable electronic signature mechanisms and technologies, defines minimum requirements for user identification, access control, and other security requirements for electronic signatures, and outlines technical details for all electronic signature mechanisms in sufficient detail to allow interoperability between systems supporting the same signature mechanism. For more information visit <a href="http://www.astm.org">www.astm.org</a> .
CDC Race and Ethnicity Code Sets	The U.S. Centers for Disease Control and Prevention (CDC) has prepared a code set for use in coding race and ethnicity data. This code set is based on current federal standards for classifying data on race and ethnicity, specifically the minimum race and ethnicity categories defined by the U.S. Office of Management and Budget (OMB) and a more detailed set of race and ethnicity categories maintained by the U.S. Bureau of the Census (BC). The main purpose of the code set is to facilitate use of federal standards for classifying data on race and ethnicity when these data are exchanged, stored, retrieved, or analyzed in electronic form. At the same time, the code set can be applied to paper-based record systems to the extent that these systems are used to collect, maintain, and report data on race and ethnicity in accordance with current federal standards. For more information visit <a href="http://www.cdc.gov">www.cdc.gov</a> .



Standard	Description
Centers for Disease Control and Prevention Implementation Guide for Immunizations Data Transaction using Version 2.3.1 of the Health Level Seven (HL7) Standard Protocol. Implementation Guide Version 2.2 June 2006	This Guide is intended for use by immunization registries that want to participate in a strictly-defined record exchange agreement that limits the amount of optionality normally expected when using the HL7 standard. The Guide describes the most frequently used segments in their entirety, while giving a minimum description of segments containing only a few useful fields for registries. The Guide fully describes the fields within the segments used frequently by immunization registries, while the others are omitted in this document. With this limited scope, this <i>Guide</i> can in no way serve as a substitute for a thorough study of the entire set of HL7 specifications for electronic data interchange in health care environments. For more information visit <a href="http://www.cdc.gov/vaccines/programs/iis/stds/downloads/hl7guide.pdf">www.cdc.gov/vaccines/programs/iis/stds/downloads/hl7guide.pdf</a> .
Digital Imaging and Communications in Medicine (DICOM) Part 3.12: Media Formats and Physical Media for Media Interchange	This DICOM Standard describes the services and the data necessary for the interchange of information between digital imaging computer systems found in health care settings. PS 3.12 of the DICOM Standard articulates the structure between the Media Storage Model and specific media. Media physical characteristics are also covered. For more information visit <a href="http://medical.nema.org">medical.nema.org</a> .
European Telecommunications Standards Institute (ETSI) Technical Specification TS 101 903: XML Advanced Electronic Signatures (XadES)	Extends the IETF/W3CXML-Signature Syntax and Processing specification [XMLDSIG] into the domain of nonrepudiation by defining XML formats for advanced electronic signatures that remain valid over long periods and are compliant with the European Directive. This includes evidence as to its validity even if the signer or verifying party later attempts to deny (repudiates) the validity of the signature. An advanced electronic signature aligned with this document can, in consequence, be used for arbitration in case of a dispute between the signer and verifier, which may occur at some later time, even years later. For more information visit <a href="http://www.etsi.org">www.etsi.org</a> .
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 <a href="http://www.itl.nist.gov">www.itl.nist.gov</a> .  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.
Federal Medication Terminologies	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).  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). For more information visit <a href="http://www.cancer.gov/cancertopics/terminologyresources/page4">http://www.cancer.gov/cancertopics/terminologyresources/page4</a> .
Food and Drug Administration (FDA) - Unique Ingredient Identifier (UNII)	Provides codes developed by FDA to uniquely identify all ingredients used in marketed medications in the United States. Each UNII is assigned based on molecular structure, manufacturing process, or other characteristics. UNII is part of the Federal Medication Terminologies. For more information visit <a href="http://www.fda.gov/oc/datacouncil/SRS.htm">www.fda.gov/oc/datacouncil/SRS.htm</a>
Food and Drug Administration (FDA) - National Drug Code (NDC)	Provides drug codes for prescription medicine and insulin products. NDC is managed by the FDA and is part of the Federal Medication Terminologies. For more information visit <a href="http://www.fda.gov/cder/ndc/database/default.htm">www.fda.gov/cder/ndc/database/default.htm</a>





Standard	Description
Health Level Seven (HL7) Common Terminology Services (CTS) Release 1	<p>The HL7 Common Terminology Services (HL7 CTS) defines an Application Programming Interface (API) that can be used when accessing terminological content. The CTS specification was developed as an alternative to a common data structure. Instead of specifying what an external terminology must look like, HL7 has chosen to identify the common functional characteristics that an external terminology must be able to provide. As an example, an HL7 compliant terminology service will need to be able to determine whether a given concept code is valid within the particular resource. Instead of describing a table keyed by the resource identifier and concept code, the CTS specification describes an Application Programming Interface (API) call that takes a resource identifier and concept code as input and returns a true/false value. Each terminology developer is free to implement this API call in whatever way is most appropriate for them.</p> <p>It describes a set of API calls that represent the core functionality that will be needed by basic HL7 Version 3 applications.</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 <a href="http://www.hl7.org">www.hl7.org</a>.</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 <a href="http://www.hl7.org">www.hl7.org</a>.</p>
Health Level Seven (HL7) Implementation Guide for CDA Release 2.0: History and Physical (H&P) Notes	<p>The HL7 Implementation Guide for CDA Release 2.0: History and Physical (H&amp;P) Notes defines additional constraints on the CDA Header and Body used in a History and Physical document in the U.S. realm, and provides examples of conforming fragments in the body of the document and an example of a conforming XML instance. For more information visit <a href="http://www.hl7.org">www.hl7.org</a>.</p>
Health Level Seven (HL7) Implementation Guide for CDA Release 2.0: Consultation Note	<p>The HL7 Implementation Guide for CDA Release 2: Consultation Note defines additional constraints on the CDA Header and Body used in a Consultation document in the U.S. realm, and provides examples of conforming fragments in the body of the document and an example of a conforming XML instance. For more information visit <a href="http://www.hl7.org">www.hl7.org</a>.</p>
Health Level Seven (HL7) Implementation Guide: CDA Release 2.0 – Continuity of Care Document (CCD), April 01, 2007	<p>The Continuity of Care Document implementation guide describes constraints on the HL7 Clinical Document Architecture, Release 2 (CDA) specification in accordance with requirements set forward in ASTM E2369-05 Standard Specification for Continuity of Care Record (CCR). The resulting specification, known as the Continuity of Care Document (CCD), is developed as a collaborative effort between ASTM and HL7. It is intended as an alternate implementation to the one specified in ASTM ADJE2369 for those institutions or organizations committed to implementation of the HL7 Clinical Document Architecture. For more information visit <a href="http://www.hl7.org">www.hl7.org</a>.</p>



Standard	Description
Health Level Seven (HL7) U.S. Realm – Interoperability Specification: Lab Result Message to EHR (ORU^R01) (HL7 Version 2.5.1) September, 2007	This guide contains the necessary specifications for clinical laboratory results reporting to EHRs for use in the U.S. Realm. For more information visit <a href="http://www.hl7.org">www.hl7.org</a> .
Health Level Seven (HL7) V3 RBAC, R1-2008, HL7 Version 3 Standard: Role Based Access Control (RBAC) Healthcare Permissions Catalog, Release 1, February 2008	The Healthcare Permission Catalog provides the necessary content for creating interoperable roles facilitating inter-organizational communications and information sharing among healthcare organizations and their business partners. For more information visit <a href="http://www.hl7.org">www.hl7.org</a> .
Health Level Seven (HL7) Version 2.3.1 Chapter 2 – Control, Chapter 3 – Patient Administration	The HL7 Version 2.3.1 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. Both message formats and value sets/code tables are contained in the standard. For more information visit <a href="http://www.hl7.org">www.hl7.org</a> .
Health Level Seven (HL7) Version 2.5, Chapter 2 – Control, Chapter 3 – Patient Administration, Chapter 5 – Query	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. For more information visit <a href="http://www.hl7.org">www.hl7.org</a> .
Health Level Seven (HL7) Version 2.5.1	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. 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, 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 <a href="http://www.hl7.org">www.hl7.org</a> .
Health Level Seven (HL7) Version 2.5.1 – Vocabularies and Value Sets	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. 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, 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 <a href="http://www.hl7.org">www.hl7.org</a> .
Health Level Seven (HL7) Version 3.0	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 <a href="http://www.hl7.org">www.hl7.org</a> .
Health Level Seven (HL7) Version 3.0 – Vocabularies and Value Sets	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 <a href="http://www.hl7.org">www.hl7.org</a> .



Standard	Description
Health Level Seven (HL7) Version 3.0 Context-Aware Information Retrieval Specification: URL Implementation Guide	Informative implementation guide for URL-based implementations of the context-aware information retrieval ("Infobutton") The goal of this infobutton implementation guide is to recommend a URL-based implementation of the context-aware information retrieval ("infobutton") domain. The intent is to provide a simple way to implement infobuttons that is compatible with the current state of the market in this area. Most infobutton implementations to date, especially on the side of on-line information resources, rely on URL-based APIs. For more information visit <a href="http://www.hl7.org">www.hl7.org</a> .
Health Level Seven (HL7) Version 3.0 Infrastructure Management – Query Infrastructure, Release 2 DSTU Ballot 1 – September 2008	Query Infrastructure domain specifies the formation of information queries and the responses to these queries to meet the needs of healthcare applications using the HL7 version 3 messaging standard. For more information visit <a href="http://www.hl7.org">www.hl7.org</a> .
Health Level Seven (HL7) Version 3.0 Privacy Consent related specifications RCMR_RM010001 – Data Consent	The Data Consent RMIM captures the data and associations needed to (1) record or report a consumer's consent or dissent to authorize the access, collection, use, or disclosure of personally identifiable information; (2) convey a provider's request or intent to override a patient's recorded consent or dissent; (3) convey a type of consent directive associated with a privacy policy; or (4) to record or report a consumer's consent directive, which is to be applied to future access, collection, use or disclosure of personally identifiable information. For more information visit <a href="http://www.hl7.org">www.hl7.org</a> .
Health Level Seven (HL7) Version 3.0 Standard: Transport Specification – Web Services Profile, Release 2 Committee Ballot 1 – May 2008	The Web Services Profile for HL7 promotes the use of Web Services to exchange HL7 messages and to ease interoperability between implementations. The profile focuses on basic Web services protocols and technologies like SOAP (Simple Object Access Protocol) and WSDL (Web Services Description Language), which lay the groundwork for more complex interactions based on higher-level Web services specifications. For more information visit <a href="http://www.hl7.org">www.hl7.org</a> .
HUGO Gene Nomenclature Committee at the European Bioinformatics Institute – Gene Names	For each known human gene, HUGO approves a gene name and symbol (short-form abbreviation). All approved symbols are stored in the HGNC database. Each symbol is unique and HUGO ensures that each gene is only given one approved gene symbol. In preference each symbol maintains parallel construction in different members of a gene family and can also be used in other species, especially the mouse. For more information visit <a href="http://www.genenames.org">www.genenames.org</a> .
Human Genome Variation Society (HGVS) – Description of Sequence Variants – February, 20, 2008	Discussions regarding the uniform and unequivocal description of sequence variants in DNA and protein sequences (mutations, polymorphisms) were initiated by two papers published in 1993; Beaudet AL & Tsui LC and Beutler E.  Current rules (den Dunnen, JT and Antonarakis, SE [2000]) however do not extensively cover all types of variants and the more complex changes. These pages list, based on the last publication, the existing nomenclature recommendations as well as the most recent suggestions. The article <a href="http://denDunnenJTandAntonarakisSE(2000).Hum.Mutat.15:7-12">den Dunnen JT and Antonarakis SE (2000). Hum.Mutat. 15:7-12</a> provide more detail explanation. For more information visit <a href="http://www.hgvs.org/mutnomen/recs.html#intro">www.hgvs.org/mutnomen/recs.html#intro</a> .
Integrating the Healthcare Enterprise (IHE) Exchange of Personal Health Record Content (XPHR)	The Exchange of Personal Health Record Content (XPHR) Integration Profile describes the content and format of summary information extracted from a PHR system used by a patient for import into healthcare provider information systems, and visa versa. The purpose of this profile is to support interoperability between PHR systems used by patients and the information systems used by healthcare providers. This profile does not address all the data exchange requirements of PHR systems. For more information visit <a href="http://www.ihe.net">www.ihe.net</a> .



Standard	Description
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Volume 2 Supplement 2007 – 2008 Cross-Enterprise User Assertion (XUA)	The Cross-Enterprise User Assertion Integration Profile (XUA) provides a means to communicate claims about the user identity of an authenticated principal (user, application, system...) in transactions that cross enterprise boundaries. To provide accountability in these cross enterprise transactions there is a need to identify the requesting user in a way that the receiver can make access decisions and proper audit entries. The XUA Profile supports enterprises that have chosen to have their own user directory with their own unique method of authenticating the entities, and others that may have chosen to use a third party to perform the authentication. For more information visit <a href="http://www.ihe.net">www.ihe.net</a> .
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Supplement Volume 3 – Document Digital Signature (DSG) Content Profile	Specifies the use of digital signatures for documents that are shared between organizations. For more information visit <a href="http://www.ihe.net">www.ihe.net</a> .
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) – Revision 5.0 or later, Cross Enterprise Sharing of Scanned Documents (XDS-SD) Integration Profile	This defines how to store healthcare metadata in clinical documents, including patient identifiers, demographics, encounter, order or service information, represented within a structured HL7 CDA R2 header, with a PDF or plaintext formatted document containing clinical information with a non XML body. For more information visit <a href="http://www.ihe.net">www.ihe.net</a> to retrieve Volume 1, and Volume 2 of the framework.
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0 or later, Audit Trail and Node Authentication (ATNA)	Audit Trail and Node Authentication (ATNA) establishes the characteristics of a Basic Secure Node. It describes the security environment (user identification, authentication, authorization, access control, etc.) assumed for the node so that security reviewers may decide whether this matches their environments. It defines basic auditing requirements for the node. It defines basic security requirements for the communications of the node using TLS or equivalent functionality. It establishes the characteristics of the communication of audit messages between the Basic Secure Nodes and Audit Repository nodes that collect audit information. This integration profile has been designed so that specific domain frameworks may extend it through an option defined in the domain specific technical framework. Extensions are used to define additional audit event reporting requirements, especially actor specific requirements. For more information visit <a href="http://www.ihe.net">www.ihe.net</a> .
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0 or later, Consistent Time (CT) Integration Profile	The Consistent Time (CT) Integration Profile provides a means to ensure that the system clocks and time stamps of the many computers in a network are well synchronized. This profile specifies synchronization with a median error less than 1 second. This is sufficient for most purposes. The current version of the ITI-TF Final Text, specifies the IHE CT Integration Profile, and other transactions defined and implemented as of October 10, 2008. The latest version of the IHE Technical Framework is available at <a href="http://www.ihe.net">www.ihe.net</a> .
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0 or later, Audit Trail and Node Authentication (ATNA) Integration Profile, Section 9.1 Authentication	The Audit Trail and Node Authentication (ATNA) Integration Profile establishes the characteristics of a Basic Secure Node. It describes the security environment (user identification, authentication, authorization, access control, etc.) assumed for the node so that security reviewers may decide whether this matches their environments. It defines basic auditing requirements for the node. It defines basic security requirements for the communications of the node using TLS or equivalent functionality. It establishes the characteristics of the communication of audit messages between the Basic Secure Nodes and Audit Repository nodes that collect audit information. This Integration Profile has been designed so that specific domain frameworks may extend it through an option defined in the domain specific technical framework. Extensions are used to define additional audit event reporting requirements, especially actor specific requirements. The latest version of the IHE Technical Framework is available at <a href="http://www.ihe.net">www.ihe.net</a> .
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 5.0 or later, Patient Demographics Query (PDQ) Integration Profile	Provides ways for multiple distributed applications to query a central patient information server for a list of patients, based on user-defined search criteria, and retrieve a patient's demographic (and, optionally, visit or visit-related) information directly into the application. For more information visit <a href="http://www.ihe.net">www.ihe.net</a> .



Standard	Description
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Supplement 2008 – 2009, Pediatric Demographics, Draft for Trial Implementation (August 22, 2008)	The experience of immunization registries and other public health population databases has shown that matching and linking patient records from different sources for the same individual person in environments with large proportions of pediatric records requires additional demographic data. Pediatric Demographics makes use of the following six additional demographic fields to aid record matching in databases with many pediatric records. The latest version of the IHE Technical Framework is available at <a href="http://www.ihe.net">www.ihe.net</a> .
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (TF) Supplement 2007 – 2008, Notification of Document Availability (NAV) Integration Profile, Draft for Trial Implementation, October 10, 2008	The Notification of Document Availability Integration Profile (NAV) introduces a mechanism allowing notifications to be sent point-to-point to systems within a Cross-Enterprise Document Sharing affinity domain (See IHE IT Infrastructure XDS Integration Profile), eliminating the need for manual steps or polling mechanisms for a Document Consumer to be aware that documents that may be of interest have been registered with an XDS Document Registry Actor. For further information visit <a href="http://www.ihe.net">www.ihe.net</a> .
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) 2007-2008 Trial Implementation Supplement Cross-enterprise Document Reliable Interchange (XDR) Release 3	This Supplement to the IHE IT Infrastructure Technical Framework provides a generic, standards based mechanism for conveying a set of medical documents in a point-to-point networked based communication. The current version of the XDR is specified in the XDR Trial Implementation Supplement to the ITI-TF, rev. 5.0, which is consistent with IHE XDS.b Supplement in term of document entry metadata. For more information visit <a href="http://www.ihe.net/technical_framework">www.ihe.net/technical_framework</a> .  NOTE: Off-line mode transaction expected to be updated once standards are available for Web Services Off-line.
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 5.0 or later, Cross-Enterprise Document Media Interchange (XDM) Integration Profile	Provides document interchange using a common file and directory structure over several standard media types. This permits the patient to use physical media to carry medical documents. This also permits the use of person-to-person email to convey medical documents. XDM supports the transfer of data about multiple patients within one data exchange. For more information visit <a href="http://www.ihe.net">www.ihe.net</a> .
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework, Revision 4.0 or later, Personnel White Pages (PWP) Integration Profile	The Personnel White Pages (PWP) Integration Profile provides access to basic directory information on human workforce members to other workforce members within the enterprise. This information has broad use among many clinical and non-clinical applications across the healthcare enterprise. This Personnel White Pages Profile specifies a method of finding directory information on the User Identities (user@realm) supplied by the Enterprise User Authentication (EUA) Integration Profile. For more information, visit <a href="http://www.ihe.net">www.ihe.net</a> .
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Supplement 2008-2009 Sharing Value Sets (SVS) Integration Profile	The Sharing Value Sets (SVS) Integration Profile provides a means through which healthcare systems producing clinical or administrative data, such as diagnostic imaging equipment, laboratory reporting systems, primary care physician office EMR systems, or national healthcare record systems, can receive a common, uniform nomenclature managed centrally. Shared nomenclatures are essential to achieving semantic interoperability.
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0, Section 10 Cross-Enterprise Document Sharing (XDS.a) Integration Profile	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. Section 10, Cross-Enterprise Document Sharing facilitates the registration, distribution and access across health enterprises of patient electronic health records. 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 <a href="http://www.ihe.net">www.ihe.net</a> .





Standard	Description
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0 – Registry Stored Query Transaction for XDS Profile Supplement [ITI-18]	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 Registry Stored Query Transaction Trial Implementation Supplement specifies an IHE transaction that provides optimization and implementation simplification. For more information visit <a href="http://www.ihe.net">www.ihe.net</a> .
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Supplement 2008-2009, Cross-Community Access (XCA), Trial Implementation, October 10, 2008	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 trial implementation version of the XCA Supplement to the ITI-Technical Framework, specifies the IHE transactions that support access between communities in a manner compatible with the XDS Integration profile. For more information visit <a href="http://www.ihe.net">www.ihe.net</a> .
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Volume 2 Supplement 2007 – 2008 Cross-Enterprise Document Sharing-B (XDS.b) Integration Profile	The Cross-Enterprise Document Sharing-B (XDS.b) Integration Profile supplement provides a new implementation choice for the Cross-Enterprise Document Sharing (XDS) Integration Profile based on use of the Web Services and ebXML Reg/Rep standards that is consistent with current developments and best practices in the industry. For more information visit <a href="http://www.ihe.net">www.ihe.net</a> .
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0 XCA Supplement	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 trial implementation version of the XCA Supplement to the ITI-TF, rev. 4.0 Final Text, specifies the IHE transactions that support access between communities in a manner compatible with the XDS Integration profile. For more information visit <a href="http://www.ihe.net">www.ihe.net</a> .
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Supplement 2007 – 2008 Basic Patient Privacy Consents (BPPC) Integration Profile – Trial Implementation	The Basic Patient Privacy Consents (BPPC) Integration Profile provides a mechanism to record the patient privacy consent(s), a method to mark documents published to XDS with the patient privacy consent that was used to authorize the publication, and a method for XDS Consumers to use to enforce the privacy consent appropriate to the use. This profile complements XDS by describing a mechanism whereby an XDS Affinity Domain can develop and implement multiple privacy policies, and describes how that mechanism can be integrated with the access control mechanisms supported by the XDS Actors (e.g. systems). There are two key parts of the profile: 1) It provides a document content specification for capturing a patient acknowledgement of a privacy consent policy or policies. 2) It describes the method by which XD* Actors can enforce the privacy policies determined by the document confidentialityCode related to the patient privacy consents. For more information visit <a href="http://www.ihe.net">www.ihe.net</a> .
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0 or later, Patient Identifier Cross-Referencing (PIX) Integration Profile	The Patient Identifier Cross-referencing (PIX) Integration Profile is targeted at healthcare enterprises of a broad range of sizes (hospital, a clinic, a physician office, etc.). It supports the cross-referencing of patient identifiers from multiple Patient Identifier Domains via the following interactions: 1) The transmission of patient identity information from an identity source to the Patient Identifier Cross-reference Manager. 2) The ability to access the list(s) of cross-referenced patient identifiers either via a query/ response or via update notification.  By specifying the above transactions among specific actors, this integration profile does not define any specific enterprise policies or cross-referencing algorithms. By encapsulating these behaviors in a single actor, this integration profile provides the necessary interoperability while maintaining the flexibility to be used with any cross-referencing policy and algorithm as deemed adequate by the enterprise. For more information visit <a href="http://www.ihe.net">www.ihe.net</a> .



Standard	Description
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (TF) Supplement, Retrieve Form for Data Capture (RFD), Draft for Trial Implementation, October 10 2008	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 <a href="http://www.ihe.net">www.ihe.net</a> .
Integrating the Healthcare Enterprise (IHE) Laboratory Technical Framework Volume 3 (LAB TF-3) Document-based Transactions, Revision 2.0 – For Trial Implementation, August 16, 2007	The IHE Laboratory Technical Framework introduces a content Integration Profile Sharing Laboratory Reports (LAB TF-3) that describes a clinical laboratory report as a human-readable electronic document. This document, which may also contain data in a machine-readable format and contains the complete set of final results produced by a clinical laboratory in fulfillment of one or more test orders for a patient. This document is focused on the sharing of sets of laboratory results in the form of a laboratory report structured document, and is not intended to address ordering or return of laboratory results to the ordering provider. For more information visit <a href="http://www.ihe.net">www.ihe.net</a> .
Integrating the Healthcare Enterprise (IHE) Patient Care Coordination (PCC), Revision 4.0, 2008 – 2009, Cross-Enterprise Sharing of Medical Summaries (XDS-MS) Integration Profile	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 Cross Enterprise Document Sharing of Medical Summaries (XDS-MS) Integration Profile enables sharing of health information between enterprises of a regional health network, and further describes how to map content in a CDA medical document into registry metadata. In the registry, healthcare providers publish pointers to documents stored in distributed repositories. Other healthcare providers may search and retrieve these and other documents. For more information visit <a href="http://www.ihe.net">www.ihe.net</a> .
Integrating the Healthcare Enterprise (IHE) Patient Care Coordination (PCC) Technical Framework Supplement 2008 – 2009, Draft for Trial Implementation, August 22, 2008	The Query for Existing Data Profile (QED) supports dynamic queries for clinical data, including vital signs, problems, medications, immunizations, diagnostic results, procedures and visit history. This profile makes the information widely available to other systems within and across enterprises to support provision of better clinical care. The QED profile leverages the existing content modeling defined previously in other IHE document profiles and the HL7 CCD implementation guide to deliver information that is semantically equivalent as a web service using the IHE ITI web services and HL7 web services guidelines. For more information visit <a href="http://www.ihe.net">www.ihe.net</a> .
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 <a href="http://www.ihe.net">www.ihe.net</a> .
International Classification of Functioning, Disability and Health (ICF)	The International Classification of Functioning, Disability and Health, known more commonly as ICF, is a classification of health and health-related domains. These domains are classified from body, individual and societal perspectives by means of two lists: a list of body functions and structure, and a list of domains of activity and participation. Since an individual's functioning and disability occurs in a context, the ICF also includes a list of environmental factors. See <a href="http://www.who.int/classifications/icf/en/">www.who.int/classifications/icf/en/</a> .
International Health Terminology Standards Development Organisation (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 <a href="http://www.ihtsdo.com">www.ihtsdo.com</a> .





Standard	Description
International Organization for Standardization (ISO) Health Informatics – Pseudonymisation, Unpublished Technical Specification # 25237	Health Informatics – Pseudonymisation. Approved as a Technical Specification March, 2007. For more information visit <a href="http://www.iso.org">www.iso.org</a> .
International Organization for Standardization (ISO) Health Informatics – 9660 Level 1	Defines a common logical format for files and directories so discs written to ISO 9660 specifications can be read by a wide array of computer operating systems. For more information visit <a href="http://www.iso.org">www.iso.org</a> .
International Organization for Standardization (ISO) ISO 3166-1	The International Standard for country codes. The purpose of ISO 3166 is to establish codes for the representation of names of countries, territories or areas of geographical interest, and their subdivisions.
International Organization for Standardization (ISO) PDF/A ISO 19005-1b. Document management – Electronic document file format for long-term preservation – Part 1: Use of PDF (PDF/A)	Specifies how to use the Portable Document Format (PDF) 1.4 for long-term preservation of electronic documents. It is applicable to documents containing combinations of character, raster and vector data. For more information visit <a href="http://www.iso.org">www.iso.org</a> .
Internet Engineering Task Force (IETF) Network Time Protocol (Version 3) Specification, Implementation and Analysis, "Request for Comment" (RFC) #1305, March, 1992	Describes the Network Time Protocol (NTP): the mechanisms to synchronize time and coordinate time distribution in a large, diverse internet operating at rates from mundane to lightwave. For more information visit <a href="http://www.ietf.org">www.ietf.org</a> .
Internet Engineering Task Force (IETF) Simple Network Time Protocol (SNTP) Version 4, "Request for Comment" (RFC) #2030, October, 1996	Describes the Simple Network Time Protocol (SNTP) Version 4, which is an adaptation of the Network Time Protocol (NTP). SNTP can be used when the ultimate performance of the full NTP implementation is not needed or justified. When operating with current and previous NTP and SNTP versions, SNTP Version 4 involves no changes to the NTP specification or known implementations, but is rather a clarification of certain design features of NTP. For more information visit <a href="http://www.ietf.org">www.ietf.org</a> .
Internet Society – Tags for Identifying Languages – 2005	This document describes the structure, content, construction, and semantics of language tags for use in cases where it is desirable to indicate the language used in an information object. It also describes how to register values for use in language tags and the creation of user-defined extensions for private interchange. This document, in combination with RFC 4647, replaces RFC 3066, which replaced RFC 1766. For more information visit <a href="http://www.ietf.org/rfc/rfc4646.txt">www.ietf.org/rfc/rfc4646.txt</a> .
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 <a href="http://www.loinc.org">www.loinc.org</a> .
National Cancer Institute (NCI) Thesaurus	The NCI Thesaurus is a reference terminology and biomedical ontology used in a growing number of NCI and other systems. It covers vocabulary for clinical care, translational and basic research, and public information and administrative activities. The NCI Thesaurus provides definitions, synonyms, and other information on nearly 10,000 cancers and related diseases, 8,000 single agents and combination therapies, and a wide range of other topics related to cancer and biomedical research. It is part of the Federal Medication Terminologies. For more information visit <a href="http://www.cancer.gov">www.cancer.gov</a> .



Standard	Description
National Center for Biotechnology Information (NCBI) – Genetic Reference Sequences	Established in 1988 as a national resource for molecular biology information, NCBI creates public databases, conducts research in computational biology, develops software tools for analyzing genome data, and disseminates biomedical information – all for the better understanding of molecular processes affecting human health and disease. The Entrez Nucleotide database is a collection of sequences from several sources, including GenBank, RefSeq, and PDB. The number of bases in these databases continues to grow at an exponential rate. For more information visit <a href="http://www.ncbi.nlm.nih.gov">www.ncbi.nlm.nih.gov</a> .
National Center for Biotechnology Information (NCBI) – Single Nucleotide Polymorphisms	Established in 1988 as a national resource for molecular biology information, NCBI creates public databases, conducts research in computational biology, develops software tools for analyzing genome data, and disseminates biomedical information – all for the better understanding of molecular processes affecting human health and disease. A key aspect of research in genetics is associating sequence variations with heritable phenotypes. The most common variations are single nucleotide polymorphisms (SNPs), which occur approximately once every 100 to 300 bases. For more information visit <a href="http://www.ncbi.nlm.nih.gov">www.ncbi.nlm.nih.gov</a> .
National Library of Medicine (NLM) Unified Medical 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 <a href="http://www.nlm.nih.gov">www.nlm.nih.gov</a>
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 <a href="http://www.nubc.org">www.nubc.org</a> .
Organization for the Advancement of Structured Information Standards (OASIS) Common Alerting Protocol (CAP) V1.1, October 2005	This is a simple but general format for exchanging all-hazard emergency alerts and public warnings over all kinds of networks. CAP allows a consistent warning message to be disseminated simultaneously over many different warning systems, thus increasing warning effectiveness while simplifying the warning task. CAP also facilitates the detection of emerging patterns in local warnings of various kinds, such as might indicate an undetected hazard or hostile act. And CAP provides a template for effective warning messages based on best practices identified in academic research and real-world experience.–
Organization for the Advancement of Structured Information Standards (OASIS) Emergency Data Exchange Language (EDXL) Distribution Element (DE) Version 1.0	This is a standard message distribution framework for data sharing among emergency information systems using the XML-based Emergency Data Exchange Language (EDXL). This format may be used over any data transmission system, including but not limited to the SOAP HTTP binding. It is a routing element intended to route payloads of any kind, including other OASIS emergency message standards such as CAP, HAVE and Resource Messaging, but also any of the HITSP constructs, NIEM IEPDS, etc. It is designed to be provisioned by core services to route based on geography, incident type, agency type, or level of government. It can also be provisioned with access control and other security data. For more information visit <a href="http://docs.oasis-open.org/emergency/edxl-de/v1.0/EDXL-DE_Spec_v1.0.pdf">docs.oasis-open.org/emergency/edxl-de/v1.0/EDXL-DE_Spec_v1.0.pdf</a> .
Organization for the Advancement of Structured Information Standards (OASIS) Security Assertion Markup Language (SAML) Core V2.0 OASIS Standard; ITU-T X.1141	SAML, developed by the Security Services Technical Committee of OASIS, is an XML-based framework for communicating user authentication, entitlement, and attribute information. As its name suggests, SAML allows business entities to make assertions regarding the identity, attributes, and entitlements of a subject (an entity that is often a human user) to other entities, such as a partner company or another enterprise application. For more information visit <a href="http://www.oasis-open.org">www.oasis-open.org</a> .



Standard	Description
Organization for the Advancement of Structured Information Standards (OASIS) WS-Trust Version 1.3, March 2007	Defines extensions that build on [WS-Security] to provide a framework for requesting and issuing security tokens, and to broker trust relationships. Defines Security Token Service (STS) model for security tokens including requesting, issuing, renewing, canceling and validating. For more information visit <a href="http://www.oasis-open.org">www.oasis-open.org</a> .
Organization for the Advancement of Structured Information Standards (OASIS) eXtensible Access Control Markup Language (XACML), ITU-T Recommendation X.1142, February 2005	The Organization for the Advancement of Structured Information Standards (OASIS) standards group developed the eXtensible Access Control Markup Language (XACML) as a language to express and evaluate access decisions. The XACML technical specification includes a profile for RBAC using XACML that complies with the ANSI RBAC standard. The HL7 RBAC Permission Catalog provides a standard vocabulary that can be used for cross-enterprise access control. For more information visit <a href="http://www.oasis-open.org">www.oasis-open.org</a> .
Organization for the Advancement of Structured Information Standards (OASIS) Simple Object Access Protocol (SOAP) Version 1.1	SOAP is a protocol specification for invoking methods on servers, services, components and objects. SOAP codifies the existing practice of using XML and HTTP as a method invocation mechanism. The SOAP specification mandates a small number of HTTP headers that facilitate firewall/proxy filtering plus an XML vocabulary that is used for representing method parameters, return values, and exceptions." {DevelopMentor} SOAP consists of three parts: an envelope that defines a framework for describing what is in a message and how to process it, a set of encoding rules for expressing instances of application-defined data types, and a convention for representing remote procedure calls and responses. For more information visit <a href="http://www.oasis-open.org">www.oasis-open.org</a> .
Organization for the Advancement of Structured Information Standards (OASIS) Simple Object Access Protocol (SOAP) Version 1.2	SOAP is a protocol specification for invoking methods on servers, services, components and objects. SOAP codifies the existing practice of using XML and HTTP as a method invocation mechanism. The SOAP specification mandates a small number of HTTP headers that facilitate firewall/proxy filtering plus an XML vocabulary that is used for representing method parameters, return values, and exceptions." {DevelopMentor} SOAP consists of three parts: an envelope that defines a framework for describing what is in a message and how to process it, a set of encoding rules for expressing instances of application-defined data types, and a convention for representing remote procedure calls and responses. For more information visit <a href="http://www.oasis-open.org">www.oasis-open.org</a> .
U.S. National Uniform Claims Committee Health Care Provider Taxonomy Code Set	The Health Care Provider Taxonomy code set is a collection of unique alphanumeric codes, ten characters in length. The Health Care Provider Taxonomy code set includes specialty categories for individuals, groups of individuals, and non-individuals. The National Uniform Claims Committee maintains this code set. The complete code set is available from the Washington Publishing Company at <a href="http://www.wpc-edi.com">www.wpc-edi.com</a> .
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 <a href="http://aurora.regenstrief.org">aurora.regenstrief.org</a> .
United States Postal Service (USPS) – Postal Codes	List of United States postal codes (known in various countries as a post code, postcode, or ZIP code) appended to a postal address for the purpose of sorting mail. For more information visit <a href="http://www.usps.com">www.usps.com</a> .
USB Removable Device Type 2.0 (USB Implementers Forum)	The USB-IF was formed to provide a support organization and forum for the advancement and adoption of Universal Serial Bus technology. The Forum facilitates the development of high-quality compatible USB peripherals (devices), and promotes the benefits of USB and the quality of products that have passed compliance testing. For more information visit <a href="http://www.usb.org">www.usb.org</a> .
VHA National Drug File Reference Terminology (NDF-RT) Formulary	Provides standard names for (1) mechanism of action, (2) Physiologic Effect and (3) Structural Class. NDF-RT is part of the Federal Medication Terminologies. For more information visit <a href="http://www.cancer.gov/cancertopics/terminologyresources/page5">www.cancer.gov/cancertopics/terminologyresources/page5</a>



## 6.2 PUBLIC HEALTH CASE REPORTING DATA ELEMENTS

In fulfillment of data and information requirements for case reporting, the following provisional data dictionary was generated by the HITSP Population Perspective Technical Committee based upon analysis of minimally common data requirements provided by the AHIC Ad-Hoc Case Report Standardization workgroup for Initial Common Data Elements. Standards shown in the tables below were provided as part of the data requirements to ensure interoperability with industry systems and alignment with previously selected HITSP standards. Further analysis and review will be provided in the design of the IS. Options to be considered for these have been supplied by USHIK and can be found in the Appendix in Section 6.3 of this document. The list of constraints is harmonized with that provided by the existing 2006 and 2007 HITSP Interoperability Specifications. If there is a deviation from identified concepts and standards from data requirements, it is important to identify if there is a difference in terms or a difference in concepts. If there is a concept difference, it is important to determine whether the concept needs to be preserved. Some of the data elements have a legacy introduction that may not be needed.

Moving forward, the HITSP Population Perspective TC has identified active industry bodies to which we defer for data requirements for this Use Case:

For Public Health reporting, the Council of State and Territorial Epidemiologists (CSTE) should be the body to adjudicate the reporting content. CSTE has ongoing efforts to harmonize these data and reporting requirements across the state and territorial public health jurisdictions. These efforts will further inform the HITSP data requirements.

For Adverse Event Reporting, there are 3 bodies:

- 1) FDA, which has various groups within it depending upon the report type (e.g. drugs, food/dietary supplements, cosmetics, and devices)
- 2) Patient Safety Organizations or other professional organizations: in the future, PSOs may serve as a source for data elements and AE reporting, particularly in the area of AEs not related to drugs, devices, food/dietary supplements, cosmetics
- 3) Healthcare Associated Infections (HAI) has traditionally been CDC, but PSOs could eventually become a source for this as well

There are three tiers of data for case reporting. The first tier includes those data elements that are cross-cutting in nature across all case reports. These are identified in the tables below as 'Universal' (U). The Next Tier is a set of domain-specific common elements which are unique to the report type. In the tables below, these are identified as 'Adverse Events' (AE) and 'Public Health' (PH). For public health, these data elements include the non-condition specific data elements maintained by CSTE. The third tier of data includes data elements that are report-specific. This document includes examples of these for public health based upon disease specific data elements maintained also by CSTE. These are identified as 'Anthrax' (RSAX), 'Hepatitis B' (RSHB), Tuberculosis (RSTB), and 'Tularemia' (RSTU). Some of the data



elements included in these examples may be candidates for generalization resulting from the analysis for HITSP construct development.

Trigger rules and decision support rules should focus on the second tier of data elements. This second tier may be triaged further depending upon how general the trigger is. Once in the third tier, the context is known and detailed criteria may be applied. First tier trigger rules can leverage the following data elements:

- event status
- condition
- date/time
- public health event
- event outcome

**Table 6.2-1 Data Elements Cross Reference for High-level Cross-Cutting Tables**

DATA ELEMENTS CROSS REFERENCE	
Column	Definition
Data Element	Data element name/identifier as listed by the PH/CCC PH Initial Common Data Elements Ad-hoc workgroup
Definition	Data element description as listed by USHIK for the selected standard for the data element. NOTE: many of the Public Health-specific terms, defined or not in this table, are informative only in this document and will be maintained by CSTE
Data Type	Type of data that is collected with this data element (coded, numeric, text, date/time)
Usage	Indicates which case reporting purposes leverage the data variable: U=Universal PH=Unique to Public Health Reporting AE=Unique to Adverse Event Reporting RSTB=Report-specific Tuberculosis RSAX=Report-specific Anthrax RSHB=Report-specific Hep B RSTU=Report-specific Tularemia
Data Requirement Standards	Expected standards/data values if data element has finite values. CHI-domain recommendations were followed if available
Optionality	Indicates optionality of the attribute: (R=Required, O=Optional, RE=Required if known);
Comments	Pertinent comments and usage



**Table 6.2-2 Facility Data Elements**

Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality*	Comments
Facility Identifier	Unique facility identifier	Numeric	U	CMS IDs	O	Federal Project under way to use DUNS number for companies that import products – global business – Not sufficient for this Use Case – doesn't cover: PH Agency requesting information back PH Clinic – May not have one, manufacturers won't, food importers – DUNS Satellite clinic may not have a separate ID from Hospital May need to be more than one data element to distinguish the concept
Facility/Importer Name	The name of the facility that the healthcare provider diagnosed the subject of the Case Report	String	U PH		C	Manufacturer/processor organization placing the report; For PH, one of the minimum number of variables requested for initial case reporting
<b>Address</b>						
Address	The address (Street, City, State, Zip Code) of the person or facility that diagnosed the subject of the Case Report	XAD-106	U PH	FIPS for city/state	R	The electronic transmission of the minimum data set requests either facility/clinician telephone or address, preferably both, to be reported For PH, one of the minimum number of variables requested for initial case reporting Can be used for practice location
Telephone	The phone number of the person or facility that diagnosed the subject of the Case Report	XTN-40	U	HL7 Phone	O PH: R	The electronic transmission of the minimum data set requests either facility/clinician telephone or address, preferably both, to be report. For PH, one of the minimum number of variables requested for initial Case Reporting
<b>Contact</b>						
Contact Person	The name of the person to be contacted for further information		U	HL7	O	



Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality*	Comments
Contact Phone Number	The telephone number for the contact person	XTN-40	U PH	HL7	O PH: R	The electronic transmission of the minimum data set requests either facility/clinician telephone or address, preferably both, to be reported  For PH, one of the minimum number of variables requested for initial Case Reporting
Responsible clinician/ Healthcare provider name	The name of the person that diagnosed the subject		U PH	HL7	O PH: R	For PH, one of the minimum number of variables requested for initial Case Reporting

\* **NOTE:** Optionality = “R” for Required, “R2” for Required if Known or “O” for Optional, or “C” for Conditional. Conditional footnotes are further described below.

**Table 6.2-3 Report Data Elements**

Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality*	Comments
Date Report Sent	The date the report is submitted	Timestamp	U PH	HL7 Timestamp	O PH:R	For PH, one of the minimum number of variables requested for initial Case Reporting
Date Sent to FDA	The date the report was submitted to the FDA – U.S.	Timestamp	AE	HL7 Timestamp	O	
Date Sent to Manufacturer (Change to date report Sent)	Date report sent to manufacturer of suspected product.	Timestamp	U	HL7 Timestamp	O	
Date User Facility/Importer Became Aware of Event	The date the event was first recognized by an observer	Timestamp	U PH	HL7 Timestamp	O PH:R	For PH, one of the minimum number of variables requested for initial Case Reporting
Report Date	The date that the Case Report is being sent	Timestamp	U PH	HL7 Timestamp	O PH:R	For PH, one of the minimum number of variables requested for initial Case Reporting
Report Sent To	The organization to which the report is submitted		U		O	For PH – report sent to PH Entity – Facility Identifier (see above)





Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality*	Comments
Report Sent to FDA	Indication if the report is submitted to the Food and Drug Administration (FDA) – U.S.		AE	Y/N/U	O	
Report Source	The originator of the report		U	HL7 Table 0235 – Report source Value  C Clinical trial L Literature H Health professional R Regulatory agency D Database/registry/poison control center N Non-healthcare professional P Patient M Manufacturer/marketing authority holder E Distributor O Other	O	
Reported Previously	Indication if the information is supplemental to update in event already reported	Coded	U	Y/N/U	O	
Type of Report	The type of report (e.g., Drug Event Report, Healthcare Associated Infection Report, etc.)	Alphanumeric	U		O	List of report types – typically text (e.g. MedWatch, HAI, Case Notification) – may have formal number assigned by report recipient
User Facility//Importer Report Number	The number of the report assigned by the reporting facility		U		O	May be a standard way to constructing the ID (e.g. assigning authority:ID) – Candidate: HL7 Entity Identifier?  Need to be as neutral as possible  May need to identify an assigning authority  e.g. PH – CDC is an assigning authority for this element, statePH, LocalPH is an assigning authority



Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality*	Comments
<b>REPORTER INFORMATION</b>						
Occupation of Reporter	The role of the reporter (e.g., physician, nurse, administrator, etc.)		U	North American Industry Classification System – derived from the above –a formal name for the Census List	O	
Reporter Address (street name, city, state, zip code)	The address of the reporter		U PH	HL7	O PH: R	For PH, one of the minimum number of variables requested for initial Case Reporting
Reporter Email	The email contact information for the reporter		U	HL7	O	
Reporter Name	The name of the person or facility sending the Case Report		U PH AE		O PH:R AE:R	For PH, one of the minimum number of variables requested for initial Case Reporting  For AE, one of the minimum number of variables required for valid electronic report
Telephone	The phone number of the person or facility sending the Case Report	XTN-40	U PH	HL7	O PH:R	For PH, one of the minimum number of variables requested for initial Case Reporting
Type of Reporter	The role of the reporter with respect to the patient (e.g., treating or consulting clinician, case manager, etc.)		U	e.g. reported by self, clinician-reported, PH nurse,	O	

\* **NOTE:** Optionality = “R” for Required, “R2” for Required if Known or “O” for Optional, or “C” for Conditional. Conditional footnotes are further described below.

**Table 6.2-4 Patient Data Elements**

Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality*	Comments
Age	The age of the subject of the case report at time of diagnosis	Numeric	U PH	Unified Code for Units of Measure (UCUM) for Age Units	O PH: R	For PH, one of the minimum number of variables requested for initial Case Reporting
Birth Weight	The weight of the patient at birth		AE, PH	UCUM units,	O O	Only for certain reports (absolute)



Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality*	Comments
Date of Birth	Date of birth	Date field	U PH	HL7 Timestamp HL7 V3 flavors of null for DOB	O PH: R	NOTE: May not be passing DOB for age over 89 due to HIPAA requirements For PH, one of the minimum number of variables requested for initial Case Reporting
Date of Death	If patient has died, deceased date/time		U PH	HL7 date	O O	
Estimated Deliver Date	Estimated date of delivery (or est. date of confinement [EDC])		PH		O	Only for certain reports
Ethnicity	The ethnicity of the subject of the Case Report		U PH	Shall be coded as specified in HITSP/C80 Section 2.2.1.1.2.2 Ethnicity  CDC Race and Ethnicity Code Set	O O	May be restricted by jurisdiction NOTE: this may repeat
Number of Siblings	The number of siblings in a multiple birth	numeric	PH		O	Only for certain reports
Occupation	The occupation of subject of the case report. Enter as much detail as possible (e.g. Teacher in Pre-School facility)		PH	North American Industry Classification System – derived from the above –a formal name for the Census List	O	Only for certain reports
Patient Address (street name, city, state, zip code)	The address of the subject of the Case Report	XAD-106	U PH	FIPS	O PH: R	For PH, one of the minimum number of variables requested for initial Case Reporting
Patient Alias Name: First, Middle, Last	This field contains names by which the patient has been known at some time	XPN-48	U	HL7	O	(former names for management of adoptions and name changes)
Patient Country	The country of the address of the subject of the Case Report		U	ISO 3166-3	O	
Patient Country of Birth	The subject's country of birth		PH	ISO 3166-3	O	Only for certain reports; This may apply to specific conditions



Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality*	Comments
Patient Country of Origin	The subject's country of origin		PH	ISO 3166-3	O	Only for certain reports; This may apply to specific conditions. May not necessarily be the subject's country of birth
Patient County	The county of the address of the subject of the Case Report	String	U PH	FIPS	O O	
Patient Identifier	The identifier for the patient, may be a pseudonymized identifier	Alphanumeric	U AE		RE AE:R	RE; NOTE: For PHCR, the patient identifier may be a pseudo-id  For AE, one of the minimum number of variables required for valid electronic report
Patient Name (First, MI, Last)	The name (preferably legal) of the subject of the Case Report		U AE	HL7	O PH: R	For PH, one of the minimum number of variables requested for initial Case Reporting
Patient Telephone	The telephone of the subject of the Case Report	XTN-40	U PH	HL7	O PH: R	For PH, one of the minimum number of variables requested for initial Case Reporting
Physiologic al Sex	Patient sex	Coded	U PH	Full list of codes from CDC	O PH: R	For PH, one of the minimum number of variables requested for initial case reporting
Pregnancy Status	Whether the subject of the case report was pregnant at time of diagnosis		PH AE	Yes/No	O O	This may apply to specific conditions. Report-specific requirements; Public health only. For AE – part of relevant medical history
Race	The race(s) of the subject of the Case Report.		U PH	Shall be coded as specified in HITSP/C80 Section 2.2.1.1..2.7 RACE CDC Race and Ethnicity Code Set	O O	May be restricted by jurisdiction NOTE: this may repeat
Time arrived in the US	The date that the subject most recently arrived into the U.S.		PH	HL7 Timestamp	O	Only for certain reports; This may apply to specific conditions
Weight	The weight of the patient at the time of the report		AE	UCUM units	O	Only for certain reports (absolute)

\* **NOTE:** Optionality = “R” for Required, “R2” for Required if Known or “O” for Optional, or “C” for Conditional. Conditional footnotes are further described below.



**Table 6.3-5 Clinical Data Elements**

Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality*	Comments
<b>EVENT INFORMATION</b>						
Adverse Event Terms	Definition pending		AE		O	NOTE: Narrative description of the event – translate into coded value of the narrative;
Approximate Age of Device	The length of time the device has been in use for the patient		AE	UCUM + absolute	O	Same as Patient age –Can be derived from product manufacture date
Date of Event	The date the event first occurred	Date Field	U PH	HL7 Timestamp HL7 V3 flavors of null for DOB	U PH: R	For PH, one of the minimum number of variables requested for initial Case Reporting
Description of Event	A textual description of the event	Free Text	U		O	
Event Abated after use stopped or dose reduced?	Indication that the event resolved//abated after usage stopped or dose reduced		AE	Y/N/U	O	
Event Device Problem Code	The locally determined code to identify the problem for subsequent follow up		AE	See Gaps	O	Might be combined with the concept of 'description of event'
Event Patient Problem Code	The locally determined code to identify the problem for subsequent follow up		AE	Codes from center for devices;	O	Might be combined with the concept of 'description of event'
Event Reappeared after reintroduction	Indication if the reaction reoccurred after rechallenging the patient to the suspected substance		AE	Y/N/U	O	
Location where Event Occurred	The location of the event – e.g., home, hospital, other facility, etc.		AE	HAI Service Delivery Location – HL7, Home, Work	O	



Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality*	Comments
Name of Condition	The name of the condition diagnosed for the subject of the Case Report		U PH	SNOMED-CT (This HITSP Interoperability Specification will use the CHI recommended SNOMED CT as a reference terminology to communicate interoperable information among and between systems, with the HITSP Interoperability Specification Pre-condition that the sending and using systems must use formal coded nursing terminologies such as the Clinical Care Classification (CCC) System and the Omaha System that are integrated in SNOMED CT)	O PH: R	Might be combined with the concept of 'description of event' For PH, one of the minimum number of variables requested for initial case reporting
Outcome attributed to AE	Textual description of the outcome associated with the adverse event		AE	Terminology mapping to a constrained set. HL7 event outcome HL7 Table 0240	O	e.g. Died, Hospitalized, disabled/permanent injury;
Patient Recovered Diagnosis	Final determination of reaction – diagnosis		AE	ICH – B2B guide – short list	O	e.g. Patient recovered, recovering, recovered with sequella



Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality*	Comments
Type of Event and/or Issue	Definition pending		AE	See Gaps	O	<p>Might be combined with the concept of 'description of event'</p> <p>For AE, one of the minimum number of variables required for valid electronic report</p> <p>Next level detail from type of reportable event; Hierarchy type relationship; (e.g. a subset of TRLI, a lab error; )</p> <p>Expect the same standard set as selected for 'Type of Reportable Event'</p> <p>Could have a 1:1 match; to classify by incident type –</p> <p>Information model relationship between this term and 'Type of Reportable Event'</p>
Type of Reportable Event	Seriousness of the event		AE	See Gaps	O	<p>Might be combined with the concept of 'description of event'</p> <p>For AE, one of the minimum number of variables required for valid electronic report</p>
<b>MEDICATION HISTORY</b>						
AE Following Prior Vaccination	Description of the adverse event		AE	Y/N/Y with Freetext description	O	<p>Vaccination Only</p> <p>NOTE: Could say add free-text description or coded value from above selection; add a separate field for this – this could appear as part of the medical HX;</p>
Common Device Name	Common name of the device	Alphanumeric	AE		O	How referred to in institution; (e.g. MRI, CTScan);
Concomitant Medical Product Name	Other medical products in use for the patient to determine proximal relationships		AE	NDC; RxNorm; FDA lists; ISO Medicinal Product Identifiers – an international drug dictionary	O	<p>For AE, one of the minimum number of variables required for valid electronic report</p> <p>NOTE: Devices: Global Medical Device Nomenclature (Pending); licensing issues</p>
Concomitant Medical Products & Therapy Dates	Other medical products and treatment used proximal to the event		AE	HL7 Timestamp	O	Need to capture date+product





Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality*	Comments
Current Medications (Medwatch concomitant meds)	Other medications in use		AE	RxNorm (harmonize with other Use Cases)	O	
Date product returned to manuf.	If returned to the manufacturer, date of return		AE	HL7 Timestamp	O	
Expiration Date	The expiration date of the product		AE	HL7 Timestamp	O	
If explanted give date	Date device was removed (if removed)		AE	HL7 Timestamp	O	
If implanted give date	Date of implantation of the device (if implanted)		AE	HL7 Timestamp	O	
Immunization Services Funding Eligibility	Indication of vaccination source (e.g., special program such as Vaccine for Children, state or provincial programs, etc)		AE	HL7 2.5 Table 0064 – Financial class	O	Vaccination Only
Is this a single use device that was reprocessed and reused on patient?	Indication if the device is a single-use device that was cleaned/reprocessed and is reused on the affected patient		AE	Y/N/U	O	
Manuf. Name, City and State	Manufacturer of the device	XAD-106	AE	HL7	O	
Medical Device Catalog #	Catalog number of the device	Alphanumeric	AE		O	
Medical Device Lot #	Lot number of the device	Alphanumeric	AE		O	
Medical Device Model #	Model number of the device	Alphanumeric	AE		O	
Medical Device Other #	Other identifiers for the device	Alphanumeric	AE		O	
Medical Device Serial #	Serial number of the device	Alphanumeric	AE		O	



Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality*	Comments
Name and Address of Reprocessor	Name and address of the individual/organization reprocessing the single use device	XAD-106	AE	HL7	O	
NDC# or Unique ID	The unique identifier for the product		AE	Complete NDC number – down to the package level detail	O	
Operator of Device	The individual managing the device		AE	Health professional, lay user, patient, other	O	Aligns with occupation of operator (e.g. radiologist, radiation therapist, parent): Terminology mapping
Pre-existing clinician diagnosed allergies, birth defects. Medical conditions	Allergies, conditions existing prior to the use of the suspected agent		AE	SNOMED list harmonized with other Use Cases; CHI Allergies	O	
Previous Vaccine Date Given	The date the vaccination dose suspected was administered		AE	HL7 Timestamp	O	Vaccination Only
Previous Vaccine Lot #	The lot number of the vaccine dose	Alphanumeric	AE		O	Vaccination Only
Previous Vaccine Manufacturer	The manufacturer of the vaccine dose		AE	MVX	O	Vaccination Only
Previous Vaccine Route/Site	The route of administration of the vaccine dose		AE	HL7 V 2.5 Table 0163 – Administrative site	O	Vaccination Only NOTE: Need to distinguish route (e.g. intramuscular) and site (e.g. left hip)  Route may be determined by type of vaccine
Previous Vaccine Type	The type of vaccine		AE	CVX	O	Vaccination Only
Product available for evaluation?	Indication if the product is still available to be evaluated		AE	Y/N/U	O	
Product Diagnosis for Use	The reason the product was initially used		AE	SNOMED-CT	O	Condition for which the product was used  Align with med management 'Reason for use' – use the same term (check term)



Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality*	Comments
Product Dose	The dose of the product administered		AE	Align with med management dose	O	
Product Frequency	The frequency with which the product was administered		AE	Align with med management	O	
Product Lot #	The product lot number	Alphanumeric	AE		O	
Product Route Used	The route of administration of the product (e.g., oral, intravenous, intramuscular, etc.)		AE	Align with med management	O	
Product Therapy Dates	Duration of therapy with the product		AE	HL7 Timestamp	O	
Suspect Product Name	Product name		AE	CVX for vaccine, are for vaccine AE; NDC; Text description or brand name or trade name; Devices: GAP or possibly UPC codes	O	
Therapy Dates	Dates of treatment with the suspected agent		AE	HL7 timestamp	O	
Vaccine # Previous Doses	The number of previous doses of the vaccine type	numeric	AE		O	Vaccination Only
<b>PREVIOUS HISTORY</b>						
Anthrax Signs and Symptoms	The signs and symptoms experienced by the patient pertaining to Anthrax		RSAX	SNOMED-CT Question subset: Fever Chills Cough Chest pain Difficulty breathing Headache Vomiting Diarrhea Abdominal cramps or pain Edema Cutaneous ulcer with edema and black eschar Regional lymphadenopathy	R	Edema: Should be defined – pulmonary, lower extremity, and how does this differ from the ulcer definition  NOTE: Terminology Service mapping to SNOMED-CT terms; if there is a term not in SNOMED that the term be added. Not for HITSP to do the mapping. Point to CSTE to provide this mapping/value set for the SNOMED-CT codes



Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality*	Comments
Hep B Signs and Symptoms	The signs and symptoms experienced by the patient pertaining to Hep B		RSHB	SNOMED-CT Question Subset: Symptomatic Jaundice	R	NOTE: Terminology Service mapping to SNOMED-CT terms; if there is a term not in SNOMED that the term be added. Not for HITSP to do the mapping. Point to CSTE to provide this mapping/value set for the SNOMED-CT codes
Patient Class	General type of patient, e.g., Inpatient, Outpatient, Emergency	Coded	AE	HL7 2.5.5 Table 0004 Patient Class, ActEncounterCode subset of HL7 V3 ActCode, limited to IMP, AMB, EMER corresponding to HL7 V2.X I,O,E	O	
Signs and Symptoms	The signs and symptoms experienced by the patient		U PH	SNOMED-CT (This HITSP Interoperability Specification will use the CHI recommended SNOMED CT as a reference terminology to communicate interoperable information among and between systems, with the HITSP Interoperability Specification Pre-condition that the sending and using systems must use formal coded nursing terminologies such as the Clinical Care Classification (CCC) System and the Omaha System that are integrated in SNOMED CT)	O	This may apply to specific conditions. ICD9-CM – does not cover in sufficient detail
Symptom/Illness Onset Date/Time	This is the range of time of which the problem was active for the patient; for PH: The date that the subject began having symptoms of condition being reported	Date field	U	HL7 Timestamp	O	



Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality*	Comments
TB Major body site of TB	The subject's anatomic site where the disease is located		RSTB	See Overlaps	R	NOTE: One terminology for this IS, probably even across HITSP; may need expansion or constraint by  CHI standard is SNOMED, but recommended – table for body site comes from HL7 – HL7 value set be developed from SNOMED content – Use HL7 Body Site table; Possible Gap – need to check mapping to SNOMED – verify
TB Signs and Symptoms	The signs and symptoms experienced by the patient pertaining to TB		RSTB	SNOMED-CT Question Subset: Asymptomatic Fever Chills Cough Productive cough Hemoptysis Night sweat Weight loss Chest pain	R	NOTE: Terminology Service mapping to SNOMED-CT terms; if there is a term not in SNOMED that the term be added. Not for HITSP to do the mapping. Point to CSTE to provide this mapping/value set for the SNOMED-CT codes
TB Status of Patient at Diagnosis – Alive	At the time of diagnosis, was the subject alive or deceased?		RSTB	considere Y/N	R	
Tularemia Location of Lesion	Anatomical location of Tularemia lesion		RSTU	(See Overlaps) Value Set: Ulceroglandular Pneumonic Glandular Oropharyngeal Oculoglandular Typhoidal	R	CDISC has started a list of ~300 anatomical sites; Looking for 100 +/- sites (e.g. upper right arm)  Overlap possible – HL7 Bodysite/CDISC Want major gross anatomical sites involved with clinical procedures



Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality*	Comments
Tularemia signs and symptoms	The signs and symptoms experienced by the patient pertaining to Tularemia		RSTU	SNOMED-CT Question subset: Abdominal cramps or pain Bloody sputum Chest pain Chills Conjunctivitis Cough Cutaneous ulcer Diarrhea Fever Headache Joint pain Lymphadenopathy Malaise Meningitis Muscle aches Nausea Pharyngitis Pneumonia Sepsis Shortness of breath Sore throat Vomiting Weight loss	R	NOTE: Terminology Service mapping to SNOMED-CT terms; if there is a term not in SNOMED that the term be added. Not for HITSP to do the mapping. Point to CSTE to provide this mapping/value set for the SNOMED-CT codes
Types of Anthrax	Mode or site of the introduction of the anthrax bacilli		RSAX	SNOMED-CT Value Set: Cutaneous anthrax Inhalation anthrax Gastrointestinal anthrax	O	
<b>LAB RESULTS</b>						
Reporting Laboratory Identifier	Identifier for laboratory that is sending the result. This laboratory may be sending results received back from reference laboratories	Alphanumeric	AE	CLIA Unique Laboratory ID	O	
Performing Laboratory	Laboratory that produced the test result. This may be a reference laboratory identifier	Alphanumeric	AE	CLIA Unique Laboratory ID	O	



Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality*	Comments
Report Date/Time	Date/time of report	Date	AE	HL7 Timestamp	O	
Results Status	Status of report (preliminary, final, corrected)	Coded	AE	HL70123 Result Status	O	
Ordered Test Code	The identifier code for the requested observation/test/ battery	Coded	AE	Recommend SNOMED-CT, LOINC, CPT, HCPCS and others (encouraging commercial vendor participation) get together to establish a suitable vocabulary	O	Major GAP – lack of a universal vocabulary for identifying ordered tests; Referral made to SDOs by Population Perspective TC
Resulted Test	The identifier code for the specific test component resulted	Coded	AE	LOINC Laboratory Test Identifiers include analytes, specimen source, methods, and sensitivity tests for drugs.	O	
Result Unit	Unit for numeric result context	Alphanumeric	AE	Unified Code for Units of Measure (UCUM) Expressions	O	
Test Interpretation	Interpretation of test result, including the susceptibility test interpretation	Coded	AE	HL70078 Abnormal Flags	O	
Test Status	Status of the test result	Coded	AE	HL70123 Result Status	O	
<b>CLINICAL TEST (Different from Diagnostic)</b>						
TB Collection Date	Date TST was placed	Date	RSTB	HL7 Timestamp	R	
TB Test Method	Testing method used to arrive at the specific result: Tuberculin Skin Test (TST)	Alphanumeric	RSTB	HL7 V3 Observation Method as a starter set. May be extended locally	R	May also be referred as Purified Protein Derivative (Mantoux) NOTE: Need language from TB experts to differentiate this data element from diagnostic test method below  Clinical test may be a screening test; May need to select specific subset terms; need definition of terms for which tests can appear in which classification





Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality*	Comments
TB Test Result	Test result of TST	Coded	RSTB	Recommend SNOMED-CT	R	Includes all test results including susceptibilities, serologies, non-organisms; Additional value sets (e.g., +/-)
<b>DIAGNOSTIC INFORMATION</b> The following data element will include condition specific value sets						
Date of Test	The date that the laboratory test was performed for the subject of the Case Report	Date	AE, PH, RSAX, RSHB, RSTB, RSTU	HL7 Timestamp	O O R R R R	
Test Method	Testing method used to arrive at the specific result: The name of the laboratory test	Alphanumeric	AE, PH, RSAX, RSHB, RSTB, RSTU	HL7 V3 Observation Method as a starter set. May be extended locally	O O R R R R	LOINC – code may already indicate the method if already specified within LOINC that this field may be left unspecified (NOTE: HL7 Observation Method Table – refers to CDC maintained value set)
Anthrax Test Method	Testing method used to arrive at the specific result: The name of the laboratory test	Alphanumeric	RSAX	All select HL7 Observation Method for lab tests, including domain subsets. Value set: B. Anthracis culture Anthrax electrophoretic immunotransblot (EITB) reaction to protective antigen and/or lethal factor bands B. Anthracis direct fluorescent antibody assay (DFA) B. Anthracis time-resolved fluorescence (TRF) B. Anthracis by PCR x-ray	R	



Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality*	Comments
HepB Test Method	Testing method used to arrive at the specific result: The name of the laboratory test	Alphanumeric	RSHB	All select HL7 Observation Method for lab tests, including domain subsets. Value set: ALT (SGPT) AST (SGOT) Bilirubin IgM anti-HBc IgM anti-HAV Total anti-HBc Anti-HBs HbsAg HbeAg Anti-Hbe HBV-DNA	R	
TB Test Method	Testing method used to arrive at the specific result: The name of the laboratory test	Alphanumeric	RSTB	All select HL7 Observation Method for lab tests, including domain subsets. Value set: X-ray Smear – Acid fast bacilli Culture – Acid fast bacilli Nucleic Acid Amplification Test (NAAT) Polymerase chain reaction Interferon Gamma Release Assay (IGRA) QuantiFERON	R	
Tularemia Test Method	Testing method used to arrive at the specific result: The name of the laboratory test	Alphanumeric	RSTU	All select HL7 Observation Method for lab tests, including domain subsets. Value set: F. tularensis fluorescent assay F. tularensis antibody F. tularensis culture x-ray	R	



Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality*	Comments
Test Result	The test result of the laboratory test including any applicable result units of measure	Coded	AE, PH, RSAX, RSHB, RSTB, RSTU	SNOMED-CT	O O R R R R	
Specimen Collection Date	The date that the specimen for the laboratory test was taken from the subject of the Case Report	Date	AE, PH, RSAX, RSHB, RSTB, RSTU	HL7 Timestamp	O O R R R R	
Source of Specimen	The physical body location from where the specimen for the lab report was taken from the subject	Coded	AE, PH, RSAX, RSHB, RSTB, RSTU	SNOMED –CT	O O R R R R	
Anthrax Source of Specimen	The physical body location from where the specimen for the lab report was taken from the subject	Coded	RSAX	SNOMED –CT Value set: Blood Chest CSF Lesion swab Lymph node biopsy Skin biopsy Sputum Stool		Terminology Service mapping to SNOMED-CT terms: if there is a term not in SNOMED that the term be added. Not for HITSP to do the mapping  Point to CSTE to provide this mapping/value set for the SNOMED-CT codes
HepB Source of Specimen	The physical body location from where the specimen for the lab report was taken from the subject	Coded	RSHB	SNOMED –CT Value set: Blood	R	Terminology Service mapping to SNOMED-CT terms: if there is a term not in SNOMED that the term be added. Not for HITSP to do the mapping  Point to CSTE to provide this mapping/value set for the SNOMED-CT codes
TB Source of Specimen	The physical body location from where the specimen for the lab report was taken from the subject	Coded	RSTB	SNOMED –CT Value set: Chest Abdominal Sputum Cerebrospinal fluid Biopsied tissue		Terminology Service mapping to SNOMED-CT terms: if there is a term not in SNOMED that the term be added. Not for HITSP to do the mapping  Point to CSTE to provide this mapping/value set for the SNOMED-CT codes



Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality*	Comments
Tularemia Source of Specimen	The physical body location from where the specimen for the lab report was taken from the subject	Coded	RSTU	SNOMED –CT Value set: Blood Chest CSF Lesion swab Lymph node biopsy Skin biopsy Sputum Stool	R	Terminology Service mapping to SNOMED-CT terms; if there is a term not in SNOMED that the term be added. Not for HITSP to do the mapping  Point to CSTE to provide this mapping/value set for the SNOMED-CT codes
Name of Organization Collecting Specimen	Name of organization collecting specimen which may be different from the organization performing the laboratory analysis	Alphanumeric	AE, PH, RSAX, RSHB, RSTB, RSTU	Facility identifier as discussed above	O O R R R R	
HepB Lab Referencing Range	Upper limit normal?	Free-text	RSHB		O	This applies to liver enzyme levels, for the above test methods ALT and AST, at time of diagnosis
HepB Abnormal Flag	Interpretative result of HbsAg lab test		RSHB	(HL7 table) 0078	O	
HepB Previously tested HbsAg +	Has the subject previously tested positive for hepatitis B surface antigen?		RSHB	Y/N/U	R	Include date of test
HbsAg Date of test	Date of previous HbsAg test performed		RSHB	HL7 Timestamp	R	
Diagnosis/Injury Code	Diagnosis or diagnoses assigned as a result of the encounter	Coded	AE	ICD-9/10 CM Or SNOMED CT	O;	Only for certain Reports Review public health and AE use Constrain to ICD9/10 Would need good SNOMED CT to ICD maps
Diagnosis Type	Type of diagnosis being sent (admitting, working, final)	IS (coded)	AE	HL7 2.5 User-defined Table 0052 – Diagnosis Type	O	Only for certain Reports Review public health and AE use
Diagnosis Date/Time	The date that the subject of the Case Report was diagnosed with Condition above	Date field	AE, PH	HL7 Timestamp	O	Only for certain Reports Review public health and AE use



Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality*	Comments
Previous Event Report Details	Definition pending		AE	SNOMED-CT	O	
Reason for Non-Evaluation	Definition pending	Free-text	AE		O	
Type of Follow-Up	Definition pending		AE	See gaps	O	
Type of Remedial Action	Definition pending		AE	See Gaps	O	
<b>MEDICAL TREATMENT</b>						
Administration of Treatment	Was treatment administered?		AE, PH, RSAX, RSHB, RSTB, RSTU	PH: Y/N	O O R R R R	This may apply to specific conditions and may have different question sets applied. This can include administration of antibiotics, vaccine, or other substances used to treat for a specific condition
Admission Date	Enter the date that the subject of the Case Report was Admitted to the hospital	Date	U	HL7 Timestamp	O	
Anthrax Name of Treatment	Name of the treatment used to treat the Anthrax		RSAX	Subset of values for Name of treatment/intervention Value set: Amoxicillin Ciprofloxacin Doxycycline	O	
Anti HBs test 1-2 months after the last dose of vaccine	Was the patient tested for antibody to HbsAg (anti-HBs) [within 1-2 months] after the last dose?		RSHB	Y/N	O	
Date of Admin of Treatment	The date treatment was administered. For HepB, Date HBV vaccine administered	Date	AE, PH, RSAX, RSHB, RSTB, RSTU	HL7 Timestamp	O R O R R	This may apply to specific conditions
Death	Did the subject die as a result of the disease?	Boolean	PH	HL7 Table 0136Yes/No Indicator	O	



Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality*	Comments
Discharge Date	Enter the date that the subject of the Case Report was Discharged from the hospital		U	HL7 Timestamp	O	
HepB Name of Treatment	Name of HBV vaccine		RSHB	HBV Vaccine	O	Subset of values for Name of treatment/intervention
HepB Number of doses of HBV vaccine in the past	If yes, how many shots	numeric	RSHB		O	
HepB Positive anti-HBs	Did the patient test positive for Anti-HBs ("reactive", "positive", or anti-HBs $\geq 10$ mIU/ml) after the last dose of HBV vaccine?		RSHB	Y/N/U	O	Positive (or "reactive") for antibody HbsAg as defined by anti-HBs $\geq 10$ mIU/ml
HepB Serum anti-HBs $\geq 10$ mIU/ml	Was serum anti-HBs $\geq 10$ mIU/ml?		RSHB	Y/N/U	O	If patient tested positive for antibody to HbsAg (anti-HBs) after the last dose of HBV vaccine
HepB Year of last HBV Vaccine Dose	In what year was the last shot received?		RSHB	HL7 Timestamp	O	
Hospital Name	Name of hospital the case was admitted	String	PH	Same discussion as facility name/id	O	
Hospitalization	If the subject of the case report was hospitalized		U	Y/N/U	O	



Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality*	Comments
Name of Treatment	Name of the treatment		AE, PH, RSTU	SNOMED-CT; RxNorm; CVX	O R	<p>This may apply to specific conditions. This can include name of antibiotics, vaccine, or other substances used to treat for a specific condition</p> <p>NOTE: Patient may have received as a result of the harm/incident</p> <p>Context of use – may be 2 attributes – Intervention (substance intervention, clinical intervention) :</p> <p>What additional substances were administered (CVX, MVX) Name of treatment for clinical, dx, procedure (SNOMED)</p> <p>Actions take to mitigate harm (could be clinical procedure or substance administration)</p> <p>Actions taken with the drug (e.g. stop drug) – HL7 ICSR – not PH</p>
Recovered	Did the subject recover from the disease?		AE, PH	Recovered, recovered with sequelle	O	<p>Combine with Patient Recovered</p> <p>Diagnosis</p>





Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality*	Comments
TB Name of Treatment	The list of medications prescribed for the subject's treatment of TB		RSTB	Value set: Isonaizid (INH) Rifampin Rifamate Rifater Pyrazinamide Ethambutol Streptomycin Ethionamide Kanamycin Cycloserine Capreomycin Para-Amino Salicylic Acid Amikacin Rifabutin Ciprofloxacin Levofloxacin Moxifloxacin Ofloxacin Rifapentine Other	O	This data element is found in the non-condition specific list, but has specific value set associated with this condition Subset of values for Name of treatment/intervention
EPIDEMIOLOGIC INFORMATION						
Contact with Animal or Animal Products	Definition pending		RSAX	Y/N/U/Not Asked null flavor options Question Subset: Animal Exposure type Current location Exposure date	O	
Contact with Person with Similar Symptoms	Definition pending		RSAX	Y/N/U/Not Asked null flavor options	O	
Exposed to suspicious powder	Definition pending		RSAX	Y/N/U/Not Asked null flavor options	O	
Handled suspicious mail	Definition pending		RSAX	Y/N/U/Not Asked null flavor options	O	
Travel Information						
Date Travel	Definition pending	Date	RSAX	HL7 Timestamp	O	



Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality*	Comments
Location of Travel	Definition pending		RSAX	International – ISO country codes, Local – could be GPS location – situation dependent	O	
Occupational Risk Factors	Definition pending		RSAX	SNOMED-CT (See Gaps)	O	
<b>EPIDEMIOLOGIC DATA – HEP B</b>						
Environmental Risk Factors	Are environmental risk factors present?		RSHB	Y/N/U/Not Asked null flavor options	O	
<b>DURING 6 WEEKS-6MONTHS PRIOR TO ONSET OF SYMPTOMS</b>						
Acupuncture	Did the patient have puncture with a needle contaminated with blood?		RSHB	Y/N/U/Not Asked null flavor options	O	Terminology Service
Contact with confirmed or suspect HBV case	[During 6 weeks-6 months prior to onset of symptoms] was the patient a contact of a person with confirmed or suspected acute or chronic hepatitis B virus infection?		RSHB	Y/N/U/Not Asked null flavor options Question Subset: Casual Household [non-sexual] Sexual Needle use Perinatal Other	O	
Date of receiving blood or blood products	If yes [to receiving blood or blood products], date of transfusion		RSHB	HL7 Timestamp	O	
Dental work or oral surgery	Did the patient have dental work or oral surgery?		RSHB	Y/N/U/Not Asked null flavor options	O	Terminology Service
Hemodialysis	Did the patient undergo hemodialysis?		RSHB	Y/N/U/Not Asked null flavor options	O	
Hospitalized	Was the patient hospitalized?		RSHB	Y/N/U/Not Asked null flavor options	O	This is different from the data element hospitalization in the non-condition specific list
Incarcerated	Was the patient incarcerated for longer than 24 hours?		RSHB	Y/N/U/Not Asked null flavor options	O	



Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality*	Comments
IV infusion or injection in the outpatient setting	Did the patient receive any IV infusions and/or injections in the outpatient setting?		RSHB	Y/N/U/Not Asked null flavor options	O	Terminology Service
Long-term Care	Was the patient a resident of a long term care facility?		RSHB	Y/N/U/Not Asked null flavor options	O	
Organ or tissue transplant recipient	Did the patient have an organ or tissue transplant?		RSHB	Y/N/U/Not Asked null flavor options	O	Terminology Service
Receive blood or blood products	Did the patient receive blood or blood products [transfusion]?		RSHB	Y/N/U/Not Asked null flavor options	O	
Surgery	Did the patient have surgery?		RSHB	Y/N/U/Not Asked null flavor options	O	Terminology Service
<b>Medical Risk Factors</b>						
Diagnosed STD	Definition pending		RSHB	Y/N/U/Not Asked null flavor options	O	Terminology Service
History of Viral Hepatitis	Patient has a history of viral hepatitis?		RSHB	Y/N/U/Not Asked null flavor options Question Subset: Hepatitis A Hepatitis B Hepatitis C Hepatitis D Other viral hepatitis	O	Terminology Service
Perinatal	Definition pending		RSHB	Y/N/U/Not Asked null flavor options	O	
Treated STD	Was the patient EVER treated for a sexually transmitted disease?		RSHB	Y/N/U/Not Asked null flavor options	O	Terminology Service
Year of the most Recent Treatment	If yes to treated for STD, in what year was the most recent treatment		RSHB	HL7 Timestamp	O	
<b>Occupational Risk Factors</b>						
Female Sexual Partners	In the 6 months before symptom onset how many female sex partners did the patient have?		RSHB	Y/N/U/Not Asked null flavor options	O	Female sexual partners



Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality*	Comments
Frequency of direct blood or body fluid exposure	Frequency of direct blood contact or body fluids exposure?		RSHB	See gaps Value set: Frequent (several times weekly) Infrequent	O	This follow-up question applies to above questions for public safety worker, employed in medical or dental field, and generic question of job involving direct contact with human blood Frequent/several times per week, infrequent; GAP – CDC value set
Job involving direct contact with human blood	Definition pending		RSHB	Y/N/U/Not Asked null flavor options	O	Terminology Service CSTE mapping
Lifetime Total Sexual Partners	Definition pending	numeric	RSHB		O	Lifetime total sexual partners
Male Sexual Partners	In the 6 months before symptom onset how many male sex partners did the patient have?		RSHB	CDC 0 1 2-5 Unknown >5	O	Male sexual partners  Numeric or grouped CDC has a value set – number of sex partners SNOMED – incomplete – local CDC
Medical or Dental Field	Was the patient employed in a medical or dental field involving direct contact with human blood?		RSHB	Y/N/U/Not Asked null flavor options	O	Terminology Service
Public Safety Worker	Was the patient employed as a public safety worker (fire fighter, law enforcement or correctional officer) having direct contact with human blood?		RSHB	Y/N/U/Not Asked null flavor options	O	Terminology Service
Socio-behavioral Risk Factors	Are socio-behavioral risk factors present?		RSHB	Y/N/U/Not Asked null flavor options	O	Socio-behavioral risk factors
<b>DURING 6 WEEKS – 6 MONTHS PRIOR TO ONSET OF SYMPTOMS</b>						
An accidental stick or puncture with a needle or other object contaminated with blood	Definition pending		RSHB	Y/N/U/Not Asked null flavor options	O	



Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality*	Comments
Body Piercing (other than ear)	Did the patient have any part of their body pierced (other than ear)?		RSHB	Y/N/U/Not Asked null flavor options	O	
Exposure to some else's blood	Definition pending		RSHB	Y/N/U/Not Asked null flavor options	O	
Incarcerated	Incarcerated for longer than 24 hours?		RSHB	Y/N/U/Not Asked null flavor options	O	
Incarceration	During his/her lifetime, was the patient EVER incarcerated for longer than 6 months?		RSHB	Y/N/U/Not Asked null flavor options	O	
Physical assault on exposed person involving blood or semen	Definition pending		RSHB	Y/N/U/Not Asked null flavor options	O	
Place the body piercing was performed	Where was the piercing performed?		RSHB		O	
Place the tattoo placement was performed	Definition pending		RSHB	Standards to be selected pending further domain analysis – see appendix for detail to be considered	O	
Shared Injection Equipment	Definition pending		RSHB	Y/N/U/Not Asked null flavor options	O	
Shared razor, toothbrushes or nail care items	Definition pending		RSHB	Y/N/U/Not Asked null flavor options	O	
Tattooing	Definition pending		RSHB	Y/N/U/Not Asked null flavor options	O	
Use of Injection Street Drugs	During the 6 weeks- 6 months prior to onset of symptoms inject drugs not prescribed by a doctor?		RSHB	Y/N/U/Not Asked null flavor options	O	
Use of street drugs but not inject	During the 6 weeks- 6 months prior to onset of symptoms use street drugs but not inject?		RSHB	Y/N/U/Not Asked null flavor options	O	



Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality*	Comments
<b>EPIDEMIOLOGIC INFORMATION – TB</b>						
HIV Status	Does the patient have a history of being HIV positive?		RSTU	Y/N/U/Not Asked null flavor options	O	
Location of Probable Exposure	Places that the subject may have been exposed to TB		RSTU	HAI Service Delivery Location – HL7, Home, Work Question subset: Day care Home School College Workplace Long term care facility Type of long term care facility Hospital Correctional facility Type of correctional facility Airplane or Public transportation Homeless shelter Other public gathering place	Conditional: R for Correctional and Homeless, O for remainder	The location of a person when a person is diagnosed doesn't relate to the exposure site. Many of the cases are related to reactivation of latent TB infection and the exposure occurred many years before. These settings have more impact for the contact tracings to identify converts  NOTE: Workplace may include office; Airplane may include the parameter of 8 hour  NOTE: Repeat from location of event – remove /qualify subset in Appendix
Medical Risk Factors	Are medical risk factors present?		RSTU	Y/N/U/Not Asked null flavor options	O	
Occupational Risk Factors	Are occupational risk factors present?		RSTU	Y/N/U/Not Asked null flavor options Question Subset: Healthcare worker Correctional employee	O	CSTE – may want to spell this out for mapping
Sociobehavioral Risk Factors	Are sociobehavioral risk factors present?		RSTU	Y/N/U/Not Asked null flavor options Question Subset: Homeless within the past year Incarcerated Excess alcohol use within past year Injection drug use within past year Non-injection drug use within past year	O	CSTE – may want to spell this out for mapping



Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality*	Comments
EPIDEMIOLOGIC INFORMATION – TULAREMIA						
Animal/Insect	Type of animal/insect		RSTU	SNOMED-CT	O	
Contact with animal or animal products	Contact with livestock (dead or alive), animal products, insect		RSTU	Y/N/U/Not Asked null flavor options	O	Has the patient been bitten by ticks or deer flies in the three weeks prior to illness? May also ask if patient has consumed high-risk animal. (or this also define a recreational exposure)
Contact with person with similar symptoms	Definition pending		RSTU	Y/N/U/Not Asked null flavor options	O	
Current Location	Location of exposure		RSTU	Field, Zoo, descriptive location; may be in SNOMED-CT	O	Can include ticks or deer flies
Exposed to Suspicious Powder	Was the Subject exposed to suspicious powder		RSTU	Field, Zoo, descriptive location; may be in SNOMED-CT	O	
Exposure Date	Date of exposure		RSTU	HL7 Timestamp	O	Date of bite
Exposure Type	Exposure type		RSTU	SNOMED-CT	O	Also can be used to describe insect bite

\* **NOTE:** Optionality = “R” for Required, “R2” for Required if Known or “O” for Optional, or “C” for Conditional. Conditional footnotes are further described below.

### 6.3 USE CASE TO INFORMATION EXCHANGE AND DATA REQUIREMENTS

This section contains an extraction of business actors, required interactions and conditions/scenarios from the Use Case into a matrix/table.

**Table 6.3-1 Mapping of Use Case Actions to Information Exchange Requirements**

Event	Action	Information Exchange Requirement(s) (includes security requirements)	Data Requirements
Public Health Case Reporting Provider – Reporting from EHRs			





Event	Action	Information Exchange Requirement(s) (includes security requirements)	Data Requirements
7.1.1 Event: Receive and incorporate trigger data and reporting specifications	7.1.1.1 Action: Receive and incorporate reporting criteria for both PH Cases and AEs. Reporting criteria include: trigger data and reporting specifications	IER26 Identify communication recipients	DR17 Decision Support Data Content (PH,AE)
		IER27 Send non-patient notification message or alert	DR17 Decision Support Data Content (PH , AE) DR59 Generic Alert Data – Public Health
		IER42 Request/receive medical concept knowledge	DR17 Decision Support Data Content (PH , AE) DR8 Unstructured Data DR59 Generic Alert Data – Public Health
		IER13 Send/receive notification of document availability	DR8 Unstructured Data
		IER49 Report confirmation	
	7.1.1.2 Action: Incorporate PH trigger data and reporting specifications	IER42 Request/receive medical concept knowledge	DR17 Decision Support Data Content (PH, AE) DR8 Unstructured Data DR59 Generic Alert Data – Public Health
		IER29 Send/receive electronic form for data capture	DR17 Decision Support Data Content (PH) DR21 Terminology Data DR24 Case Report Pre-populate Data
	7.1.1.3 Action: Incorporate AE trigger data and reporting specifications	IER42 Request/receive medical concept knowledge	DR17 Decision Support Data Content (PH, AE) DR8 Unstructured Data DR59 Generic Alert Data – Public Health
		IER29 Send/receive electronic form for data capture	DR17 Decision Support Data Content (AE) DR21 Terminology Data DR24 Case Report Pre-populate Data
7.1.2 Event: Monitor EHR data and identify possible PH Cases or Aes	7.1.2.1 Action: Monitor EHR data for information matching inclusion/exclusion factors	IER29 Send/receive electronic form for data capture	DR17 Decision Support Data Content (PH, AE) DR21 Terminology Data DR24 Case Report Pre-populate Data



Event	Action	Information Exchange Requirement(s) (includes security requirements)	Data Requirements
		IER49 Report confirmation	
	7.1.2.2 Action: Identify, view, evaluate, and triage possible PH Cases and AEs	IER29 Send/receive electronic form for data capture	DR17 Decision Support Data Content (PH, AE) DR21 Terminology Data DR24 Case Report Pre-populate Data
		IER49 Report confirmation	
7.1.3 Event: View possible reports	7.1.3.1 Action: Select possible PH Cases or AEs	No Interoperability requirement – edge system function	DR17 Decision Support Data Content (PH, AE) DR25 Case Report Content
	7.1.3.2 Action: View report for selected possible PH Cases or AEs	IER29 Send/receive electronic form for data capture	DR21 Terminology Data DR24 Case Report Pre-populate Data
7.1.4 Event: May perform initial notification	7.1.4.1 Action: (If Applicable) Communicate initial notification to Public Health	IER29 Send/receive electronic form for data capture	DR17 Decision Support Data Content (PH, AE) DR21 Terminology Data DR24 Case Report Pre-populate Data
		IER18 Send/receive clinical document	DR25 Case Report Content
	7.1.4.2 Action: (If Applicable) Communicate initial notification to Manufacturers	IER29 Send/receive electronic form for data capture	DR17 Decision Support Data Content (AE) DR21 Terminology Data DR24 Case Report Pre-populate Data DR17 Decision Support Data Content (AE)
		IER55 Anonymize patient identifiable data (AE)	DR25 Case Report Content
		IER56 Pseudonymize patient identifying information (AE)	DR25 Case Report Content
		IER18 Send/receive clinical document	DR25 Case Report Content
		IER49 Report confirmation	
7.1.5 Event: Complete and/or queue report	7.1.5.1 Action: Automatically send PH Case Reports or AE Reports which meet all reporting criteria. Reporting criteria include: trigger data and reporting specifications	IER18 Send/receive clinical document	DR17 Decision Support Data Content (PH, AE) DR25 Case Report Content



Event	Action	Information Exchange Requirement(s) (includes security requirements)	Data Requirements
	7.1.5.2 Action: Send PH Case Reports or AE Reports which meet all reporting criteria to a review or approval queue. Reporting criteria include: trigger data and reporting specifications	IER29 Send/receive electronic form for data capture	DR17 Decision Support Data Content (PH, AE) DR21 Terminology Data DR24 Case Report Pre-populate Data DR25 Case Report Content
		IER49 Report confirmation	
	7.1.5.3 Action: Send PH Case Reports or AE Reports which do not meet all reporting criteria to a completion queue. Reporting criteria include: Trigger data and reporting specifications	IER29 Send/receive electronic form for data capture	DR17 Decision Support Data Content (PH, AE) DR21 Terminology Data DR24 Case Report Pre-populate Data DR25 Case Report Content
		IER49 Report confirmation	
7.1.6 Event: Augment EHR Information and update report	7.1.6.1 Action: Information related to possible PH Cases or AEs that is not available through an EHR is manually gathered	IER29 Send/receive electronic form for data capture	DR17 Decision Support Data Content Reporting supplement /trigger criteria for PH Reporting supplement /trigger criteria for AE DR21 Terminology Data DR25 Case Report Content
	7.1.6.2 Action: Information related to possible PH Cases or AEs that is not available through an EHR may be gained through electronic information exchanges	IER29 Send/receive electronic form for data capture	DR17 Decision Support Data Content (PH, AE) DR21 Terminology Data DR24 Case Report Pre-populate Data DR25 Case Report Content
		IER40 Query for existing data	DR25 Case Report Content
		IER18 Send/receive clinical document	DR25 Case Report Content
		IER10 Identify patient	DR25 Case Report Content
		IER1 Provide authorization and consent	
		IER5 Verify entity identity	
		IER2 Send data over secured communication channel	
		IER4 Synchronize system time	
		IER3 Create audit log entry	



Event	Action	Information Exchange Requirement(s) (includes security requirements)	Data Requirements
	7.1.6.3 Action: Update PH Case Report or AE Report	IER29 Send/receive electronic form for data capture	DR17 Decision Support Data Content (PH), AE) DR21 Terminology Data DR24 Case Report Pre-populate Data DR25 Case Report Content
		IER40 Query for existing data	DR25 Case Report Content
		IER18 Send/receive clinical document	DR25 Case Report Content
		IER10 Identify patient	DR25 Case Report Content
		IER1 Provide authorization and consent	
		IER5 Verify entity identity	
		IER2 Send data over secured communication channel	
		IER4 Synchronize system time	
		IER3 Create audit log entry	
7.1.7 Event: Finalize and Send Report	7.1.7.1 Action: Confirm PH Case Report or AE Report	IER49 Report confirmation	DR17 Decision Support Data Content Reporting supplement /trigger criteria for PH Reporting supplement /trigger criteria for AE DR21 Terminology Data DR25 Case Report Content
	7.1.7.2 Action: Transmit confirmed PH Case Reports or AE Reports to public health	IER18 Send/receive clinical document	DR17 Decision Support Data Content Reporting supplement /trigger criteria for PH Reporting supplement /trigger criteria for AE DR21 Terminology Data DR25 Case Report Content
Public Health Case Reporting Provider – Public Health Case Investigation and Information Sharing			
7.1.6 Event: Augment EHR Information and update report	7.1.6.1 Action: Information related to possible PH Cases or Aes that is not available through an EHR is manually gathered	IER29 Send/receive electronic form for data capture	DR17 Decision Support Data Content (PH, AE) DR21 Terminology Data DR24 Case Report Pre-populate Data DR25 Case Report Content



Event	Action	Information Exchange Requirement(s) (includes security requirements)	Data Requirements
	7.1.6.2 Action: Information related to possible PH Cases or Aes that is not available through an EHR may be gained through electronic information exchanges	IER29 Send/receive electronic form for data capture	DR17 Decision Support Data Content (PH, AE) DR21 Terminology Data DR24 Case Report Pre-populate Data DR25 Case Report Content
		IER40 Query for existing data	DR25 Case Report Content
		IER18 Send/receive clinical document	DR25 Case Report Content
		IER10 Identify patient	DR25 Case Report Content
		IER1 Provide authorization and consent	
		IER5 Verify entity identity	
		IER2 Send data over secured communication channel	
		IER4 Synchronize system time	
		IER3 Create audit log entry	
	7.1.6.3 Action: Update PH Case Report or AE Report	IER29 Send/receive electronic form for data capture	DR17 Decision Support Data Content (PH, AE) DR21 Terminology Data DR24 Case Report Pre-populate Data DR25 Case Report Content
		IER40 Query for existing data	DR25 Case Report Content
		IER18 Send/receive clinical document	DR25 Case Report Content
		IER10 Identify patient	DR25 Case Report Content
		IER1 Provide authorization and consent	
		IER5 Verify entity identity	
		IER2 Send data over secured communication channel	
		IER4 Synchronize system time	
		IER3 Create audit log entry	



Event	Action	Information Exchange Requirement(s) (includes security requirements)	Data Requirements
8.2.1 Event: Send Additional Information	8.2.1.1 Action: Receive request for additional information from Public Health	IER26 Identify communication recipients	DR8 Unstructured Data DR59 Generic Alert Data – Public Health
		IER27 Send non-patient notification message or alert	DR59 Generic Alert Data – Public Health
		IER42 Request/receive medical concept knowledge	DR8 Unstructured Data DR59 Generic Alert Data – Public Health DR21 Terminology Data
		IER6 Provide proof of document integrity and origin	DR8 Unstructured Data DR59 Generic Alert Data – Public Health
		IER13 Send/receive notification of document availability	DR8 Unstructured Data
		IER18 Send/receive clinical document)	DR8 Unstructured Data DR59 Generic Alert Data – Public Health
	8.2.1.2 Action: Send information to public health related to previously reported PH Cases and/or other information	IER29 Send/receive electronic form for data capture	(PH, AE) DR21 Terminology Data DR24 Case Report Pre-populate Data DR25 Case Report Content
		IER49 Report confirmation	
		IER1 Provide authorization and consent	
		IER5 Verify entity identity	
8.2.2 Event: Receive Public Health Information	8.2.2.1 Action: Receive case or patient specific information	IER29 Send/receive electronic form for data capture	DR21 Terminology Data DR24 Case Report Pre-populate Data DR25 Case Report Content
		IER18 Send/receive clinical document	DR25 Case Report Content
		IER49 Report confirmation	
		IER1 Provide authorization and consent	
		IER5 Verify entity identity	



Event	Action	Information Exchange Requirement(s) (includes security requirements)	Data Requirements
	8.2.2.2 Action: Receive specific clinically relevant Public Health information	IER29 Send/receive electronic form for data capture	DR21 Terminology Data DR24 Case Report Pre-populate Data DR25 Case Report Content
		IER 26 Identify communication recipients	DR8 Unstructured Data DR59 Generic Alert Data – Public Health
		IER27 Send non-patient notification message or alert	DR59 Generic Alert Data – Public Health
		IER42 Request/receive medical concept knowledge	DR8 Unstructured Data DR59 Generic Alert Data – Public Health
		IER6 Provide proof of document integrity and origin	DR8 Unstructured Data DR59 Generic Alert Data – Public Health
		IER13 Send/receive notification of document availability	DR8 Unstructured Data
		IER18 Send/receive clinical document	
		IER2 Send data over secured communication channel	
		IER4 Synchronize system time	
		IER3 Create audit log entry	
	8.2.2.3 Action: Receive Publicly Available Information	IER18 Send/receive clinical document	DR59 Generic Alert Data – Public Health
		IER26 Identify communication recipients	DR59 Generic Alert Data – Public Health
		IER27 Send non-patient notification message or alert	DR59 Generic Alert Data – Public Health
		IER42 Request/receive medical concept knowledge	DR59 Generic Alert Data – Public Health
		IER6 Provide proof of document integrity and origin	DR8 Unstructured Data DR59 Generic Alert Data – Public Health





Event	Action	Information Exchange Requirement(s) (includes security requirements)	Data Requirements
8.2.3 Event: Manage and treat PH Cases	8.2.3.1 Action: Identify and manage additional possible PH Cases	Not applicable to AE No interoperability issue Edge System Workflow considerations	
	8.2.3.2 Action: Treat confirmed and additional possible PH Cases	Not applicable to AE No interoperability issue Edge System Workflow considerations	
Public Health Case Reporting: Laboratory - Public Health Case Investigation and Information Sharing			
8.3.1 Event: Send information/report	8.3.1.1 Action: Incorporate and utilize Public Health reporting specifications	NOTE: Not currently done electronically	DR17 Decision Support Data Content Reporting supplement /trigger criteria for PH
	8.3.1.2 Action: Identify and send information/report	IER13 Send/receive notification of document availability	DR25 Case Report Content (Lab feed) DR17 Decision Support Data Content (identify reportable information: Report lab results on patients where test results meet criteria:)
	8.3.1.2a Alternate Action: Send information related to previously reported PH Cases and/or other information may be sent to Public Health	NOTE: May be a non-data request (e.g. send isolate)	DR25 Case Report Content (Lab feed)
8.3.2 Event: Receive Public Health Information	8.3.2.1 Action: Receive specimen status information or patient specific information	IER27 Send non-patient notification message or alert	DR59 Generic Alert Data – Public Health
		IER13 Send/receive notification of document availability	DR8 Unstructured Data
	8.3.2.1a Alternate Action: Receive specific clinically relevant public health information or publicly available information	IER27 Send non-patient notification message or alert	DR59 Generic Alert Data – Public Health
		IER13 Send/receive notification of document availability	DR8 Unstructured Data
Public Health Case Reporting: Public Health – Reporting from EHRs			
7.2.1 Event: Determine and communicate reporting criteria including: trigger data and reporting specifications	7.2.1.1 Action: Determine PH Case Criteria	IER26 Identify communication recipients	DR17 Decision Support Data Content Disease-specific Reporting /trigger criteria for PH DR59 Generic Alert Data – Public Health



Event	Action	Information Exchange Requirement(s) (includes security requirements)	Data Requirements
		IER27 Send non-patient notification message or alert	DR17 Decision Support Data Content Disease-specific Reporting /trigger criteria for PH DR59 Generic Alert Data – Public Health
		IER42 Request/receive medical concept knowledge	DR17 Decision Support Data Content Disease-specific Reporting /trigger criteria for PH DR8 Unstructured Data DR59 Generic Alert Data – Public Health
		IER13 Send/receive notification of document availability	DR8 Unstructured Data
		IER49 Report confirmation	
	7.2.1.2 Action: Determine PH trigger data and reporting specifications	IER29 Send/receive electronic form for data capture	DR17 Decision Support Data Content (PH) DR21 Terminology Data DR24 Case Report Pre-populate Data DR25 Case Report Content
		IER26 Identify communication recipients	DR17 Decision Support Data Content Disease-specific Reporting /trigger criteria for PH DR59 Generic Alert Data – Public Health
	7.2.1.3 Action: Determine AE trigger data and reporting specifications	IER29 Send/receive electronic form for data capture	DR17 Decision Support Data Content Disease/treatment-specific or Event-type drug/drug-class; DR21 Terminology Data DR24 Case Report Pre-populate Data DR25 Case Report Content
		IER26 Identify communication recipients	DR17 Decision Support Data Content Disease/treatment-specific or Event-type DR59 Generic Alert Data – Public Health



Event	Action	Information Exchange Requirement(s) (includes security requirements)	Data Requirements
	7.2.1.4 Action: Communicate reporting criteria for both PH Cases and Aes. Reporting criteria include: trigger data and reporting specifications	IER26I identify communication recipients	DR17 Decision Support Data Content (PH, AE) DR8 Unstructured Data DR59 Generic Alert Data – Public Health DR26 Reporting Criteria Content
		IER27 Send non-patient notification message or alert	DR17 Decision Support Data Content (PH, AE) DR59 Generic Alert Data – Public Health DR26 Reporting Criteria Content
		IER42 Request/receive medical concept knowledge	DR17 Decision Support Data Content (PH, AE) DR8 Unstructured Data DR59 Generic Alert Data – Public Health DR26 Reporting Criteria Content DR21 Terminology Data
		IER6 Provide proof of document integrity and origin	DR17 Decision Support Data Content (PH, AE) DR8 Unstructured Data DR59 Generic Alert Data – Public Health DR26 Reporting Criteria Content
		IER13 Send/receive notification of document availability	DR17 Decision Support Data Content (PH, AE) DR8 Unstructured Data DR26 Reporting Criteria Content
		IER18 Send/receive clinical document	DR17 Decision Support Data Content (PH, AE) DR26 Reporting Criteria Content
7.2.2 Event: May receive initial notification	7.2.2.1 Action: (If Applicable) Receive initial notification from Providers	IER29 Send/receive electronic form for data capture	DR17 Decision Support Data Content (PH, AE) DR21 Terminology Data DR24 Case Report Pre-populate Data
		IER18 Send/receive clinical document	DR25 Case Report Content



Event	Action	Information Exchange Requirement(s) (includes security requirements)	Data Requirements
		IER26 Identify communication recipients (e.g. border state)	DR25 Case Report Content
		IER5 Verify entity identity	
	7.2.2.2 Action: (If Applicable) Respond to initial notifications requiring immediate attention	No interoperability requirement. NOTE: Depends upon information received in 7.2.2.1	DR17 Decision Support Data Content prioritize/report prioritization
7.2.3 Event: Receive report and determine need for further action	7.2.3.1 Action: Public Health receives and evaluates reports	No interoperability requirement. NOTE: Depends upon information received in 7.2.2.1	DR17 Decision Support Data Content prioritize/response time criticality
	7.2.3.2 Action: Public Health determines need for further action	No Interoperability Requirement	
Public Health Case Reporting: Public Health – Public Health Case Investigation and Information Sharing			
7.2.3 Event: Receive report and determine need for further action	7.2.3.1 Action: Public Health receives and evaluates reports	No Interoperability Requirement. NOTE: Depends upon information received in 7.2.2.1	DR17 Decision Support Data Content prioritize/response time criticality
	7.2.3.2 Action: Public Health determines need for further action	NOTE: No Interoperability Requirement;	
8.1.1 Event: Access additional information and investigate	8.1.1.1 Action: Request information from submitters of reports/information	IER29 Send/receive electronic form for data capture	DR21 Terminology Data DR24 Case Report Pre-populate Data DR25 Case Report Content
		IER13 Send/receive notification of document availability	DR21 Terminology Data DR8 Unstructured Data DR59 Generic Alert Data – Public Health DR26 Reporting Criteria Content
	8.1.1.1a Alternate Action: Request information by utilizing information exchanges. Public Health may query for existing public health reportable data	IER29 Send/receive electronic form for data capture	DR21 Terminology Data DR24 Case Report Pre-populate Data DR25 Case Report Content
		IER18 Send/receive clinical document	DR8 Unstructured Data DR59 Generic Alert Data – Public Health DR26 Reporting Criteria Content



Event	Action	Information Exchange Requirement(s) (includes security requirements)	Data Requirements
	8.1.1.2 Action: Receive additional information to assist in investigation activities	IER29 Send/receive electronic form for data capture	DR21 Terminology Data DR8 Unstructured Data DR59 Generic Alert Data – Public Health
	8.1.1.3 Action: Perform investigation activities	No interoperability requirement	
8.1.2 Event: Determine Case Status	8.1.2.1 Action: Evaluate and classify PH Cases	IER49 Report confirmation	DR17 Decision Support Data Content Case Classification
	8.1.2.2 Action: Determine status of PH Case reports	IER18 Send/receive clinical document	DR17 Decision Support Data Content Case Classification Data Input
8.1.3 Event: Perform Contact Tracing	8.1.3.1 Action: Identify those who may have come in contact.	IER18 Send/receive clinical document	DR17 Decision Support Data Content Levels of contact tracing
	8.1.3.2 Action: Identify additional possible PH Cases	No specific interoperability requirement	DR17 Decision Support Data Content Reporting supplement /trigger criteria for PH Reporting supplement /trigger criteria for AE
8.1.4 Event: Assess Impact and Determine Management Plan	8.1.4.1 Action: Assess and understand impact	No interoperability requirement	NOTE: CDS – is a local consideration
	8.1.4.2 Action: Determine management plan	No interoperability requirement	DR17 Decision Support Data Content Management plan
8.1.5 Event: Communicate public health information	8.1.5.1 Action: Communicate case or patient specific information	IER26 Identify communication recipients	DR8 Unstructured Data DR17 Decision Support Data Content responsible party
		IER42 Request/receive medical concept knowledge	DR8 Unstructured Data DR59 Generic Alert Data – Public Health
		IER6 Provide proof of document integrity and origin	DR8 Unstructured Data
		IER13 Send/receive notification of document availability	DR17 Decision Support Data Content (AE) DR8 Unstructured Data DR26 Reporting Criteria Content



Event	Action	Information Exchange Requirement(s) (includes security requirements)	Data Requirements
		IER2 Send data over secured communication channel	
		IER4 Synchronize system time	
		IER3 Create audit log entry	
		IER56 Pseudonymize patient identifying information (re-identification)	DR8 Unstructured Data
		IER27 Send non-patient notification message or alert	DR59 Generic Alert Data – Public Health
	8.1.5.2 Action: Communicate specific clinically relevant Public Health information	IER26 Identify communication recipients	DR8 Unstructured Data DR17 Decision Support Data Content responsible party
		IER42 Request/receive medical concept knowledge	DR8 Unstructured Data DR59 Generic Alert Data – Public Health
		IER6 Provide proof of document integrity and origin	DR8 Unstructured Data
		IER13 Send/receive notification of document availability	DR17 Decision Support Data Content (AE) DR8 Unstructured Data DR26 Reporting Criteria Content
		IER56 Pseudonymize patient identifying information (re-identification)	DR8 Unstructured Data
		IER27 Send non-patient notification message or alert	DR59 Generic Alert Data – Public Health
		IER1 Provide authorization and consent	
		IER5 Verify entity identity	
		IER2 Send data over secured communication channel	
		IER4 Synchronize system time	
		IER3 Create audit log entry	



Event	Action	Information Exchange Requirement(s) (includes security requirements)	Data Requirements
		IER55 Anonymize patient identifiable data (AE)	
		IER56 Pseudonymize patient identifying information (AE)	
	8.1.5.3 Action: Communicate publicly available information	IER6 Provide proof of document integrity and origin	DR59 Generic Alert Data – Public Health
		IER55 Anonymize patient identifiable data (AE)	
		IER56 Pseudonymize patient identifying information (AE)	
		IER1 Provide authorization and consent	
		IER5 Verify entity identity	
		IER26 Identify communication recipients	DR59 Generic Alert Data – Public Health DR17 Decision Support Data Content – authorized recipient
		IER42 Request/receive medical concept knowledge	DR59 Generic Alert Data – Public Health
		IER2 Send data over secured communication channel	
		IER4 Synchronize system time	
		IER3 Create audit log entry	
		IER27 Send non-patient notification message or alert	DR59 Generic Alert Data – Public Health
		IER18 Send/receive clinical document	
Public Health Case Reporting: Information Exchange – Reporting from EHRs			
9.1 Data provisioning – including support for secondary uses – data provisioning and distribution of data transmission	IER29 Send/receive electronic form for data capture	DR21 Terminology Data DR24 Case Report Pre-populate Data DR25 Case Report Content	





Event	Action	Information Exchange Requirement(s) (includes security requirements)	Data Requirements
	parameters	IER55 Anonymize patient identifiable data (AE)	DR8 Unstructured Data DR59 Generic Alert Data – Public Health DR24 Case Report Pre-populate Data DR25 Case Report Content
		IER56 Pseudonymize patient identifying information	DR8 Unstructured Data DR25 Case Report Content
		IER18 Send/receive clinical document	DR8 Unstructured Data DR25 Case Report Content
	9.2 Data pseudonymization and re-identification as well as HIPAA de-identification	IER55 Anonymize patient identifiable data (AE)	DR8 Unstructured Data DR59 Generic Alert Data – Public Health DR24 Case Report Pre-populate Data DR25 Case Report Content
		IER56 Pseudonymize patient identifying information (AE)	DR8 Unstructured Data DR25 Case Report Content
	9.3 Data delivery – including secure data delivery, data receipt and confirmation of delivery to EHRs, personally controlled health records, other systems and networks	IER26 Identify communication recipients	DR8 Unstructured Data DR59 Generic Alert Data – Public Health
		IER49 Report confirmation	
		IER27 Send non-patient notification message or alert	DR8 Unstructured Data
		IER42 Request/receive medical concept knowledge	DR24 Case Report Pre-populate Data DR25 Case Report Content
		IER29 Send/receive electronic form for data capture	DR25 Case Report Content
		IER18 Send/receive clinical document	DR17 Decision Support Data Content DR25 Case Report Content DR8 Unstructured Data DR59 Generic Alert Data – Public Health
		IER18 Send/receive clinical document	
		IER10 Identify patient	



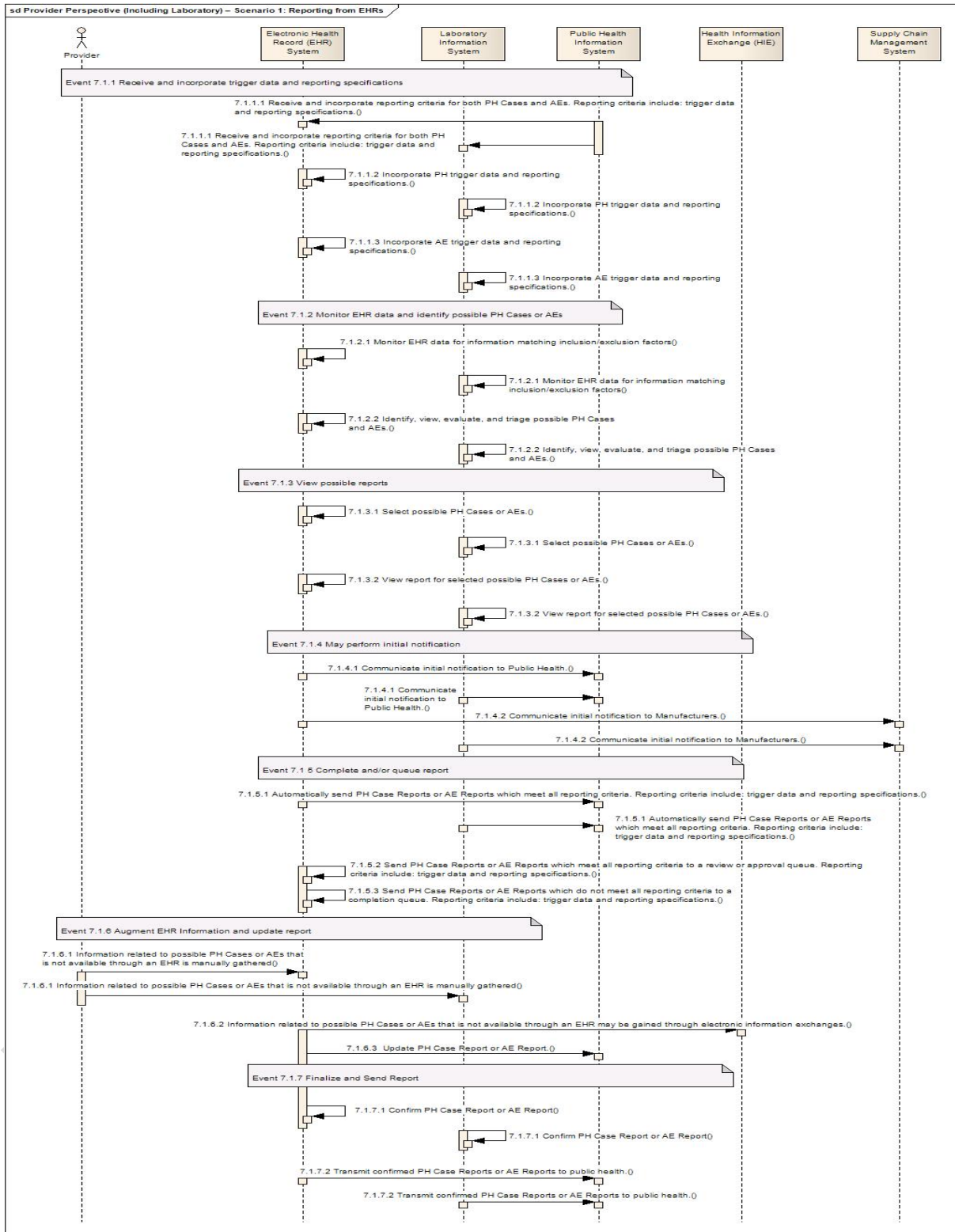
Event	Action	Information Exchange Requirement(s) (includes security requirements)	Data Requirements
		IER1 Provide authorization and consent	
		IER5 Verify entity identity	
		IER2 Send data over secured communication channel	
		IER4 Synchronize system time	
		IER3 Create audit log entry	
		IER6 Provide proof of document integrity and origin	
		IER13 Send/receive notification of document availability	DR8 Unstructured Data

#### 6.4 USE CASE SEQUENCE DIAGRAMS

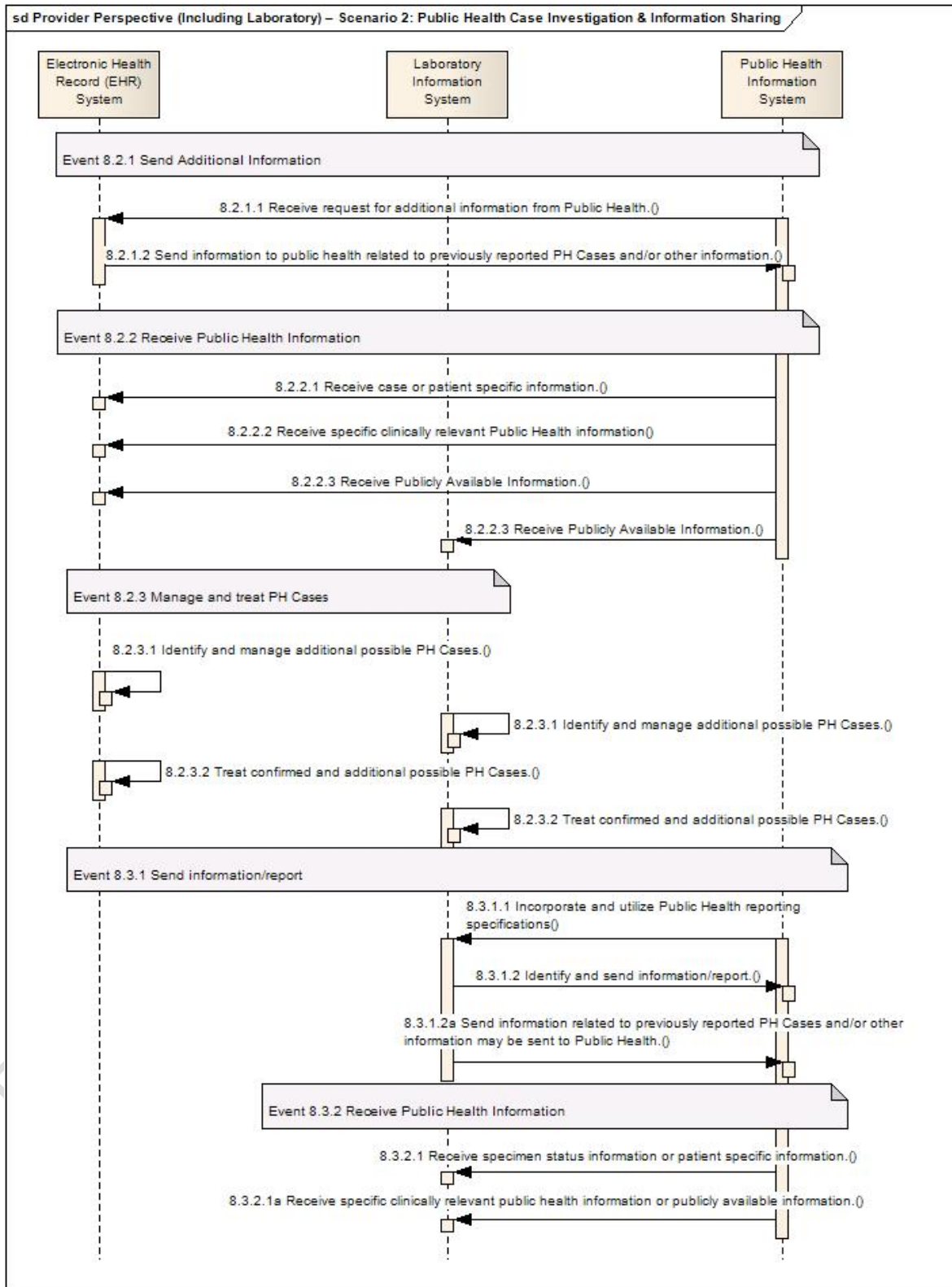
The high level sequence diagrams illustrate each Use Case scenario with a representation of a normal sequence of exchange between the primary actors. The event codes from the Use Case are annotated on the diagrams to show how the interactions relate to the Use Case. The interactions are supported by the various constructs which will be introduced in Section 3 of this Interoperability Specification.



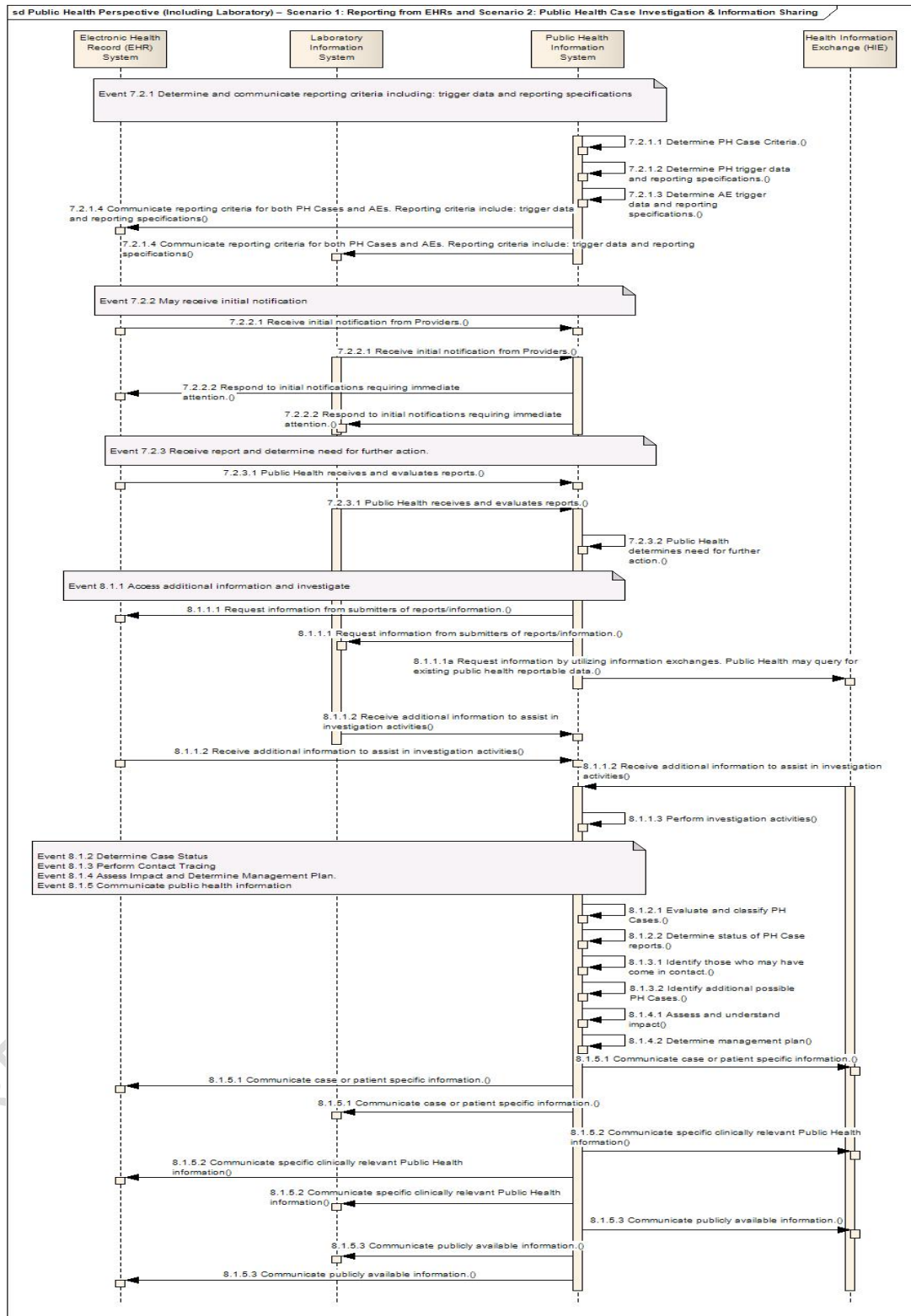
**Figure 6.4-1 Public Health Case Reporting (PHCR) High Level Sequence Diagram – Part 1 – Provider Perspective (Including Laboratory) – Scenario 1: Reporting from Electronic Health Records**



**Figure 6.4-2 Public Health Case Reporting (PHCR) High Level Sequence Diagram – Part 2 – Provider Perspective (Including Laboratory) – Scenario 2: Alert Functionality**



**Figure 6.4-3 Public Health Case Reporting (PHCR) High Level Sequence Diagram – Part 3 – Public Health Perspective (Including Laboratory) – Scenario 1: Reporting from EHRs and Scenario 2: Public Health Case Investigation & Information Sharing**



## 6.5 MAPPING OF CONSTRUCTS TO INFORMATION EXCHANGE AND DATA REQUIREMENTS

Table 6.5-1 below provides a mapping of the HITSP constructs that will be used in the design of the Interoperability Specification, and the data and information exchange requirements that are being satisfied by the construct. These requirements are limited to those that are deemed within scope for this Interoperability Specification, which are described in Section 3.1.

Construct Name	Information Exchange Requirement Number (IER#)	Data Requirement Number (DR#)
HITSP/C19 – Entity Identity Assertion	IER5 Verify entity identity	
HITSP/C26 – Nonrepudiation of Origin	IER6 Provide proof of document integrity and origin	
HITSP/C32 – Summary Documents Using HL7 Continuity of Care Document (CCD)		DR24 Case Report Pre-populate Data
HITSP/C35 – Lab Result Terminology		DR25 Case Report Content
HITSP/C36 – Lab Result Message		DR25 Case Report Content
HITSP/C37 – Lab Report Document Component		DR25 Case Report Content
HITSP/C48 – Encounter Document Using IHE Medical Summary (XDS-MS)		DR24 Case Report Pre-populate Data
HITSP/C62 – Unstructured Document		DR8 Unstructured Data
HITSP/C63 – Non Patient Notification Alert/Text Message	IER27 Send non-patient notification message or alert	DR59 Generic Alert Data – Public Health NOTE: This cannot be a targeted communication as this would be PHI NOTE: Coupled with Identify communication recipients for this Design
HITSP/C75 – Healthcare Associated Infection (HAI) Report: CDC – Healthcare Associated Infection Reporting		DR25 Case Report Content HAI) NOTE: HL7 Structured Documents; Provisional
HITSP /C76 – Case Report Pre-Populate		DR24 Case Report Pre-populate Data
HITSP/C80 - Clinical Document and Message Terminology		DR25 Case Report Content DR24 Case Report Pre-populate Data
HITSP/C82 - Emergency Common Alerting Protocol		DR59 Generic Alert Data – Public Health NOTE: This cannot be a targeted communication as this would be PHI





Construct Name	Information Exchange Requirement Number (IER#)	Data Requirement Number (DR#)
HITSP/C83 - CDA Content Modules		DR25 Case Report Content DR24 Case Report Pre-populate Data
HITSP/ T14 – Send Laboratory Result Message	IER18 Send/receive clinical document	
HITSP/C87 – Anonymize	IER55 Anonymize patient identifiable data	
HITSP/T15 - Collect and Communicate Security Audit Trail	IER3 Create audit log entry	
HITSP/T16 - Consistent Time	IER4 Synchronize system time	
HITSP/T17 - Secured Communication Channel	IER2 Send data over secured communication channel	
HITSP/T23 - Patient Demographics Query	IER10 Identify patient	
HITSP/T24 – Pseudonymize	IER56 Pseudonymize patient identifying information	
HITSP/T29 - Notification of Document Availability	IER13 Send/receive notification of document availability	
HITSP/T31 - Document Reliable Interchange	IER18 Send/receive clinical document	
HITSP/T33 - Transfer of Documents on Media	IER18 Send/receive clinical document	
HITSP/T63 - Emergency Message Distribution Element	IER27 Send non-patient notification message or alert	
HITSP/T64 - Identify Communication Recipients	IER26 Identify communication recipients	
HITSP/T66 - Retrieve Value Set		DR21 Terminology Data
HITSP/T81 - Retrieval of Medical Knowledge	IER42 Request/receive medical concept knowledge	
HITSP/TP13 - Manage Sharing of Documents	IER18 Send/receive clinical document	
HITSP/TP21 - Query for Existing Data	IER40 Query for existing data	
HITSP/TP22 - Patient ID Cross-Referencing	IER10 Identify patient	
HITSP/TP20 - Access Control	IER1 Provide authorization and consent	
HITSP/TP30 - Manage Consent Directives	IER1 Provide authorization and consent	
HITSP/TP50 - Retrieve Form for Data Capture	IER29 Send/receive electronic form for data capture	





## 7.0 CHANGE HISTORY

The following sections provide the history of changes made to this document.

### 7.1 DECEMBER 10, 2008

The changes in this construct address the following comments received during the Public Comment and Inspection Testing period (September 29 – October 24, 2008).

5154, 5391, 5453, 5529, 5530, 5659, 5660, 5661, 5662, 5672, 5673, 5674, 5675, 5676, 5677, 5678, 5679, 6641

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

Changes also reflect the following:

- Renamed Business actors and adopted cross-IS harmonized descriptions, adjusting diagrams to align with the renaming
- Adjusted all Data Requirements and IERs to use cross-IS harmonized concepts and descriptions
- Moved the Detailed Data Requirements table to the Appendix as an informative reference and propagated the data elements to the Data Requirements Table
- Modified descriptions of constructs in Table 1.2.1-1
- Added HITSP/C80, HITSP/C83, HITSP/C37, HITSP/C32 and HITSP/C48 to Table 3.2.3-1 and made several updates to optionality in this table as well
- Updated the technical actor role descriptions in Table 3.2.1-1
- Updated the Business Actor table to include IER03 and IER04
- Updated Table 3.2.3-1 to correct references to HITSP/TP20 and HITSP/C19
- Updated HITSP/TP21 Technical Actors and references to reflect updated HITSP/TP21

Minor editorial changes were made to this construct.

### 7.2 DECEMBER 18, 2008

Upon approval by the HITSP Panel on December 18, 2008, this document is now Released for Implementation.

