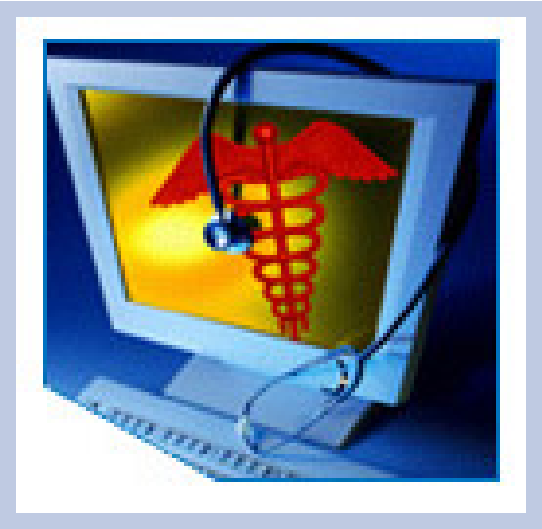
December 18, 2008
Version 1.0

HITSP Personalized Healthcare Interoperability Specification

HITSP/IS08



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FIGURES AND TABLES

1.0 INTRODUCTION

As an introduction to the Healthcare Information Technology Standards Panel (HITSP) Personalized Healthcare 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

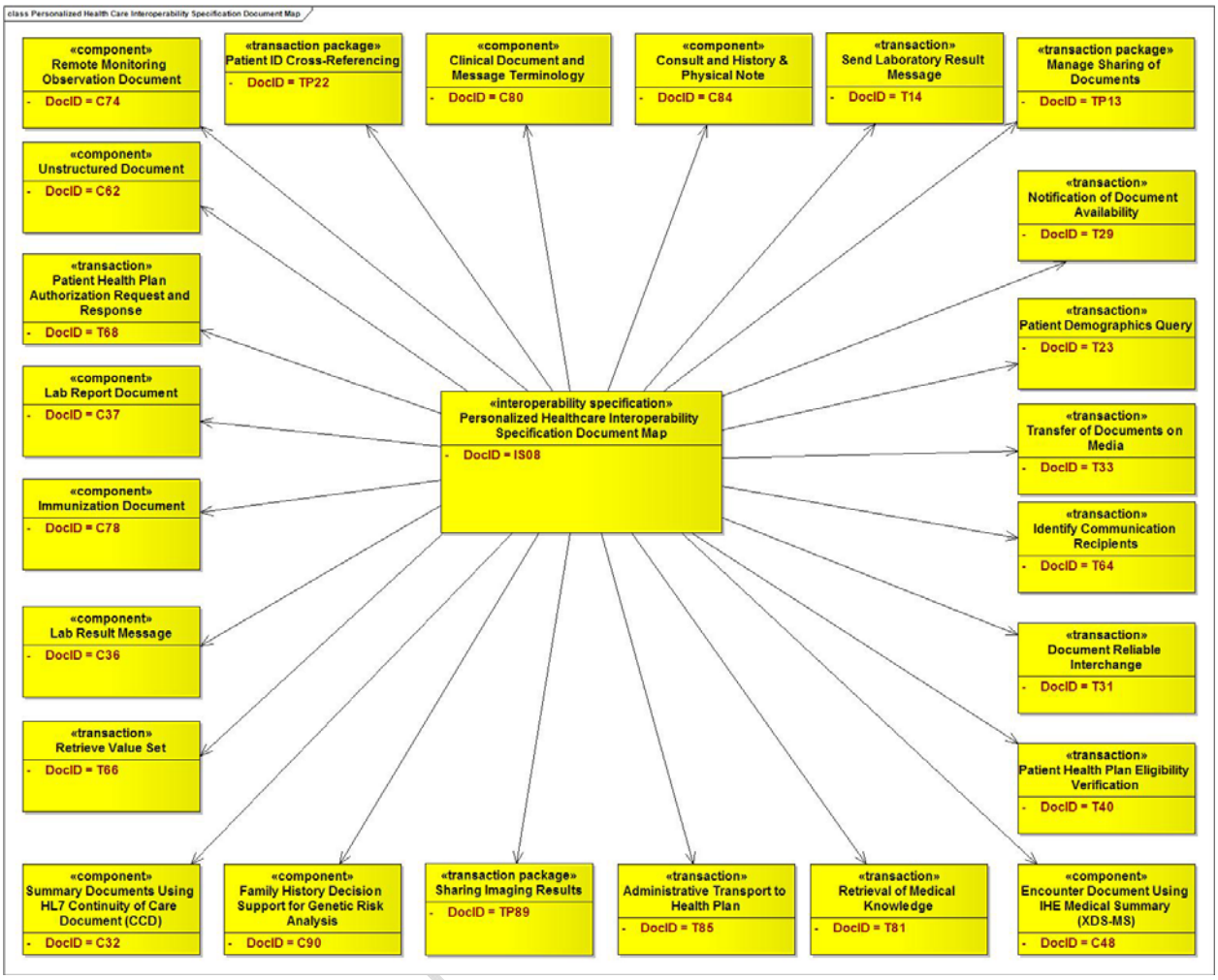
This section provides a high level definition of this Interoperability Specification and background information about the underlying Use Case that it is based upon.

The HITSP Personalized Healthcare Interoperability Specification describes family history and genetic/genomic lab order and results which are used to provide personalized treatment specific to genetic makeup.

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 the www.hitsp.org Web Site.

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).

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/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/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/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/C84 - Consult and History & Physical Note	The Consult and History & Physical Note Component supports two types of commonly used clinical notes, a consult note, and a history and physical note. It is intended for use to support the exchange of information from a consulting provider to a referring provider; and may also be used to provide background information from a referring provider to a consulting provider (e.g., prior reports).
HITSP/C90 - Clinical Genomic Decision Support	The Family History Decision Support for Genetic Risk Analysis Component is used to communicate genetic and family history information from healthcare IT applications to a clinical decision support system that provides an assessment of genetic risk of disease for a patient. It uses the HL7 Version 3 Standard: Clinical Genomics; Pedigree, Release 1 to support the communication of genetic and family history information to the clinical decision support system, and to support the communication of risk information from that system back to the originator.

Construct	Description
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.
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^Q22, 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/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.

Construct	Description
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/T40 - Patient Health Plan Eligibility Verification Transaction	The Patient Health Plan Eligibility Verification Transaction is intended to provide the status of a health plan covering the individual, along with details regarding patient liability for deductible, co-pay and co-insurance amounts for a defined base set of generic benefits or services. The base set of benefits includes, but is not limited to, coverage status and patient liability for medical, chiropractic, dental, hospital inpatient, hospital outpatient, emergency, physician office visit, pharmacy and vision services that are included in the patient's generic health plan benefit.
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/T68 - Patient Health Plan Authorization Request and Response	The Patient Health Plan Authorization Request and Response Transaction provides a mechanism for a healthcare provider (other than a retail pharmacy) to request approval from a health plan to authorize certain healthcare services, when required by the patient's health plan contract. The information exchanged includes, but is not limited to, approval status for coverage, allowed service provider(s), and certification dates for services that are included in the patient's health plan benefits. The response from the health plan indicates that the health plan has determined that the particular service(s) will or will not be covered, and what is the level of coverage if that information is available from the health plan.
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/T85 - Administrative Transport to Health Plan	The Administrative Transport to Health Plan Transaction will be used as the transport for administrative transactions between a provider and a health plan. Examples include a pharmacy obtaining health plan eligibility, and a physician requesting referral or authorization information from a health plan. This construct is based on the CAQH Phase II CORE #270 Connectivity Rule v2.0.0, which addresses the message envelope metadata, the message envelope standards, and the submitter authentication standards for administrative transactions, as well as communications-level errors, and acknowledgements.

Construct	Description
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/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.
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/TP89 - Sharing Imaging Results	The Sharing Imaging Results Transaction Package supports the process of sharing medical imaging results data. Imaging results data are captured as part of the normal process of care performed by healthcare providers. This data can be made available through document sharing for both clinical care and public health purposes.

1.3 COPYRIGHT PERMISSIONS

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 2.0.

A list of key reference documents and background material is provided in the table below. These documents can be retrieved from www.hitsp.org.

Table 1.4-1 Reference Documents

Reference Document	Document Description
HITSP Acronyms List	Lists and defines the acronyms used in this document
HITSP Conventions List	Describes the conventions that are used to convey the full descriptions and usage of standards in the HITSP specifications
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
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
Personalized Healthcare Detailed Use Case, March 21, 2008 Harmonized	AHIC Use Case that is the basis of this HITSP Interoperability Specification
TN900 - Security and Privacy Technical Note	Developed as a reference document to provide the overall context for use of the HITSP Security and Privacy constructs. It includes the following: • The scope, reference policy background, and Security and Privacy principles used in the development of the constructs • A detailed description and schematics of the conceptual relationship between the Security and Privacy constructs • A mapping of existing standards and constructs to be used in meeting the stated requirements of the AHIC Use Cases • A list of identified gaps and the recommended approaches to resolving those gaps • A roadmap for how the Security and Privacy constructs will evolve and eventually align with other HITSP Interoperability Specifications • A conceptual framework for Security and Privacy management, including reference information on privacy policies, risk assessment, and risk management • 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 HITSP will periodically update this Technical Note as required by the introduction of new contexts for use.
TN901 – Technical Note for Clinical Documents	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: • The scope, background, and principles for use in the development of the CMHR constructs • A detailed description and schematics of the relationship between CMHR constructs • A conceptual framework for the construction of clinical documents • An overview of Clinical Document concepts • An overview of Vocabulary concepts

2.0 REQUIREMENTS

This section provides a high level description of the Personalized Healthcare 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 AHIC Personalized Healthcare Use Case, including any applicable scenarios that are part of the Use Case.

The Personalized Healthcare Use Case focuses on the exchange of clinically useful genetic/genomic test information, personal and family health history, and the use of analytical tools in Electronic Health Records (EHRs) to support clinical decision-making. Family health history requires gathering data from disparate sources, increasing the need for interoperability. A complete record of all genetic/genomic tests performed for a consumer, regardless of the ordering clinician, are important parts of a patient's healthcare record and should be available for view by the consumer.

The Personalized Healthcare Use Case focuses on the exchange of family and personal health history and genetic/genomic testing information between stakeholders in two scenarios:

- **Clinical Assessment.** A family health history is gathered from or by the consumer in an interoperable form to be used by consumers and clinicians. This information is accessed by clinicians and used in conjunction with personal medical history, current health status, and personal preferences to develop a diagnostic plan.
- **Genetic Testing, Reporting, and Clinical Management.** A medical testing laboratory performs genetic or genomic testing after it receives genetic/genomic test orders and any accompanying information necessary for the testing in an interoperable form. The testing laboratory performs the tests, develops the patient report, and transmits this information back to authorized providers.

Clinicians utilize this new diagnostic information for the management of their patients. Both clinicians and consumers have access to this information via the PHR. The findings require both narrative and structured form in reporting.

2.2 USE CASE REQUIREMENTS

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

The Personalized Healthcare Use Case focuses on the exchange of personal health, family health history, and genetic/genomic testing information between consumers and clinicians in two scenarios.

Scenario 1: Clinical Assessment
The Clinical Assessment scenario is focused on gathering past medical history, current medical status, and family health history information (including important genetic mutations that may be known to run in the family) from the consumer in an interoperable form to be used by consumers and clinicians. This information collection focuses on heritable conditions and is different from a full medical history. Scenario 1 is viewed from two perspectives, which are intended to indicate roles and functions rather than organizations or physical locations:

- Clinician perspective includes family physicians, pediatricians, obstetricians, oncologists, internists, clinical specialists, nurses, physician assistants, genetic counselors, medical geneticists, pathologists, psychologists, and other personnel that conduct clinical assessment, clinical management and evaluation activities. This includes the gathering of a patient's personal and family heath history information, diagnostic planning, genetic/genomic test ordering, and result interpretation activities. The clinician may also be working from within the testing laboratory

- Consumer perspective includes members of the public who receive healthcare services, as well as caregivers, patient advocates or surrogates, family members, and other parties who may be acting for, or in support of, a patient. The consumer reports family health history information, requests and views available family health history and genetic/genomic testing information, and considers personalized prevention messages and/or treatment information

Scenario 2: Genetic Testing, Reporting and Clinical Management
The Genetic Testing, Reporting, and Clinical Management scenario highlights the genetic/genomic testing and reporting functions as well as the clinical management that follows the receipt of information from the testing. Part of this scenario is focused on a testing laboratory receiving and capturing genetic/genomic test orders and any accompanying information necessary for the testing, as well as the ability to exchange genetic/genomic laboratory test results among laboratories and ordering clinicians with appropriate security and privacy considerations. The testing laboratory which performs the tests, analyzes the test data using genetic/genomic databases and repositories, and interprets the data. In addition, the testing laboratory considers other personal and family health information by performing a risk assessment, develops a patient report including fully structured results (and interpretation), and transmits

the report back to the authorized providers. The other part of this scenario focuses on determining appropriate preventative action, treatment protocol, messaging, and clinical interpretation of test results and analysis utilizing decision support tools, and genetic/genomic knowledge repositories, as well as the consumer's ability to permit designated individuals to request and view information in their PHR.

Scenario 2 is viewed from the perspective of the testing laboratory:

- Testing laboratories include medical laboratory personnel such as the laboratory director, laboratory supervisor, laboratory technicians, or other relevant staff. These personnel perform genetic/genomic and other laboratory tests ordered by clinicians to assess the genetic status of patients, generate test data, interpret the data in the context of other personal and family health information, perform a risk assessment in the context of family history information if needed, develop the patient report (including structured results), and send the report to the ordering clinician

During the review of this Use Case the HITSP Administrative and Financial Domain Technical Committee expanded the Use Case to include a requirement for authorization and verification of eligibility for the genetic/genomic test. See Table 2.2.2-2, IER14 and IER15 for inclusion.

The HITSP Provider Perspective Technical Committee also ruled that the following communications were out of scope:

1. Communications with EHR system suppliers for table updates
2. Communications with Genetic/Genomic Knowledge Repositories for looking up reference information

2.2.1 MAPPING OF USE CASE ACTIONS TO INFORMATION EXCHANGE REQUIREMENTS

Section 6.2 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 2.2.1-1 provided in Section 6.2.

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

Data Requirement Number (DR)	Description
Data Requirement 1	Demographic Data, including (but not limited to):
	• Name • Unique identifier • Race • Ethnicity • Occupation
Data Requirement 3	Clinical History, including (but not limited to):
	• History of specific disorder • Age of condition onset and/or death of various family members • Environmental exposure data • Any prior treatment for specific disorders • Relevant non-genetic laboratory, radiology and pathology data • Relevant social data
Data Requirement 4	Personal genetic/genomic data, including (but not limited to):
	• Prior genetic/genomic laboratory test results • Prior genetic status for specific disease • Full genome scan: deoxyribonucleic acid (DNA) • Risk Analysis relative to family history
Data Requirement 5	Family genetic/genomic information, including (but not limited to):
	• Genetic/genomic data of family members • History of consanguinity • Pedigree in structured form when available • Consent/access allowance information
Data Requirement 6	Health Plan Eligibility Information, including (but not limited to):
	• Health Plan related patient demographics (First name, last name, date of birth, health plan member ID) • Co-pay • Deductibles • Limits, and exclusions • Procedure or services coded values • Effective date of health insurance coverage actually in operation and in force Note: DR6 is only for the purposes of verifying eligibility and authorization.
Data Requirement 7	Genomic Laboratory registry

	• Name
	• CLIA certification (as appropriate)
	• Location
	• Contact information
	• Insurance Plan Associations
	• Facilities association
	• Specialties/Capabilities
	• Genome specific capabilities, such as:
	  • Diseases covered
	  • Tests covering pharmacogenomic applications
	  • Genome region
	  • Testing platform (Gene test, sequencing test, etc)
	Note: Similar to www.genetests.org but in structured form.

Data Requirement 8	Unstructured Data
	• Unstructured data as a supplement to order clarification, lab results clarification, or other additional interchange Note: This DR will become less necessary and less used as the order information and results information become more structured.

Table 2.2.2-2 below contains an extraction of the Information Exchange Requirements from the Use Case. These requirements are referenced from the Information Exchange Requirements column of the Use Case Mapping Table 6.2-1 provided in Section 6.2.

Table 2.2.2-2 Information Exchange Requirements (IER)

Information Exchange Requirement Number (IER)	Description
IER 1	Provide authorization and consent: Consumers authorize clinicians and other individuals (e.g., family members) to access/view PHR information (a.k.a., proxy access)
IER 12	Identify laboratory: Identify and select a particular laboratory based upon the patient's insurance coverage network and/or preferences
IER 14	Send/receive health plan eligibility: Identify and verify eligibility from Health Plan
IER 15	Send/receive health plan authorization: Obtain authorization for service from Health Plan
IER 19	Send/receive genetic/genomic test results: Lab sends and clinician or patient receives the genetic/genomic test results and associated narratives via an EHR, PHR or other clinical data system
IER 20	Send/receive genomic information: The ability of EHR, PHR and Data Bank providing systems to send/receive/store genomic information (in whole or in part) store textual report as a minimum
IER 21	Receive updated clinical information: Patient receives newly validated and updated personal and family health history information and pedigree, if appropriate, via an interoperable PHR
IER 23	Request/provide additional information: Send/receive a request for additional information, or send/receive additional information in unstructured format.
IER 25	Send/receive decision support data: Send /receive information from genetic/genomic knowledge sources and/or decision support modules within EHRs (including Fx HX and Test Results)
IER 41	Receive risk analysis report: Receive report including analysis of risk from a Genetic Clinical Decision Support System
IER 44	Send/receive genetic test order: Send/receive genetic test orders
IER 58	Send/receive patient health history: EHR or PHR systems send/receive patient personal health history, family health history, family pedigree, past genetic/genomic and other diagnostic testing information
IER 62	Send/receive encounter or full episode of care record: The ability to send/receive encounter or full episode of care record

2.2.3 IDENTIFICATION OF BUSINESS ACTORS, MAPPED TO REQUIREMENTS

A Business Actor is an abstraction instantiated as an IT system application used by a Stakeholder in the exchange of data necessary 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 application 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	Stakeholders	Use Case Scenario	Information Exchange Requirement Numbers (IER)	Data Requirement Numbers (DR)
Clinical Genetic Databases	Online servers and databases which provide detailed contextual knowledge specific to genetic diseases and the impact of genetic status on medical treatments. These databases may also provide references to the relevant medical literature	Registries Health Researchers Knowledge Engineers	1, 2	Out of Scope	Out of Scope
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	Patients Clinicians Consumers HIE Public Health Agencies Healthcare Entities	1, 2	IER23 Request or provide additional information	DR1 Demographic Data DR3 Clinical History DR4 Personal genetic/genomic data DR5 Family genetic/genomic information DR8 Unstructured Data
				IER58 Send/receive patient health history	DR1 Demographic Data DR3 Clinical History DR4 Personal genetic/genomic data DR5 Family genetic/genomic information
				IER1 Provide authorization and consent	DR1 Demographic Data
				IER62 Send/receive encounter or full episode of care record	DR1 Demographic Data DR3 Clinical History DR4 Personal genetic/genomic data
				IER20 Send/receive genomic information	DR1 Demographic Data DR3 Clinical History DR4 Personal genetic/genomic data
				IER12 Identify Laboratory	DR7 Genomic Laboratory Registry

Business Actor	Description	Stakeholders	Use Case Scenario	Information Exchange Requirement Numbers (IER)	Data Requirement Numbers (DR)
				IER44 Send/receive genetic test orders	DR1 Demographic Data DR3 Clinical History DR4 Personal genetic/genomic data
				IER25 Send/receive decision support data	DR1 Demographic Data DR3 Clinical History DR4 Personal genetic/genomic data DR5 Family genetic/genomic information DR8 Unstructured Data
				IER21 Receive updated clinical information	DR3 Clinical History
				IER19 Send/receive genetic/genomic test results	DR1 Demographic Data DR4 Personal genetic/genomic data
				IER41 Receive Risk Analysis Report	DR4 Personal genetic/genomic data
Genetic Clinical Decision Support (systems)	Systems that enable improved analysis and conclusions of genetic data based on related information, recent research, algorithms or other resources	Genetic Specialists Health Researchers Knowledge Engineers	1, 2	IER23 Request or provide additional information	DR1 Demographic Data DR3 Clinical History DR4 Personal genetic/genomic data DR5 Family genetic/genomic information DR8 Unstructured Data
				IER58 Send/receive patient health history	DR1 Demographic Data DR3 Clinical History DR4 Personal genetic/genomic data DR5 Family genetic/genomic information

Business Actor	Description	Stakeholders	Use Case Scenario	Information Exchange Requirement Numbers (IER)	Data Requirement Numbers (DR)
				IER1 Provide authorization and consent	DR1 Demographic Data
				IER62 Send/receive encounter or full episode of care record	DR1 Demographic Data DR3 Clinical History DR4 Personal genetic/genomic data
				IER20 Send/receive genomic information	DR1 Demographic Data DR3 Clinical History DR4 Personal genetic/genomic data
				IER44 Send/receive genetic test orders	DR1 Demographic Data DR3 Clinical History DR4 Personal genetic/genomic data
				IER25 Send/receive decision support data	DR1 Demographic Data DR3 Clinical History DR4 Personal genetic/genomic data DR5 Family genetic/genomic information DR8 Unstructured Data
				IER21 Receive updated clinical information	DR3 Clinical History
				IER19 Send/receive genetic/genomic test results	DR1 Demographic Data DR4 Personal genetic/genomic data
				IER41 Receive Risk Analysis Report	DR4 Personal genetic/genomic data

Business Actor	Description	Stakeholders	Use Case Scenario	Information Exchange Requirement Numbers (IER)	Data Requirement Numbers (DR)
Genetic/Genomic Knowledge Repositories	Organizations that maintain resources which provide raw genetic/genomic information. The information may include human genetic sequence data, structured nomenclature regarding specific genetic disease, or other similar data types	Health Researchers Knowledge Engineers Health Care Entities	1, 2	IER23 Request or provide additional information	DR1 Demographic Data DR3 Clinical History DR4 Personal genetic/genomic data DR5 Family genetic/genomic information DR8 Unstructured Data
				IER44 Send/receive genetic test orders	DR1 Demographic Data DR3 Clinical History DR4 Personal genetic/genomic data
Health Plan System	Systems used by health plans that include administrative and financial functions associated with the coverage and financing of healthcare for the health plan's enrolled members. These functions include information regarding the individual's enrollment, eligibility, coverage and benefits, authorizations, claims, care coordination and other information related to the member	Administrative and Financial staff Health Information Management Healthcare Entities	2	IER14 Send/receive health plan eligibility	DR6 Health Plan Eligibility Information
				IER15 Send/receive health plan authorization	DR6 Health Plan Eligibility Information
				IER12 Identify Laboratory	DR7 Genomic Laboratory Registry
Personal Health Record (PHR) Systems	A healthcare record system used to create, review, annotate and maintain records by the patient or the caregiver for a patient. The PHR may include any aspect(s) of the health condition, medications, medical problems, allergies, vaccination history, visit history or communications with healthcare providers	Patients Clinicians Consumers HIE Registries Public Health Agencies Healthcare Entities	1, 2	IER23 Request or provide additional information	DR1 Demographic Data DR3 Clinical History DR4 Personal genetic/genomic data DR5 Family genetic/genomic information DR8 Unstructured Data

Business Actor	Description	Stakeholders	Use Case Scenario	Information Exchange Requirement Numbers (IER)	Data Requirement Numbers (DR)
				IER58 Send/receive patient health history	DR1 Demographic Data DR3 Clinical History DR4 Personal genetic/genomic data DR5 Family genetic/genomic information
				IER1 Provide authorization and consent	DR1 Demographic Data
				IER62 Send/receive encounter or full episode of care record	DR1 Demographic Data DR3 Clinical History DR4 Personal genetic/genomic data
				IER20 Send/receive genomic information	DR1 Demographic Data DR3 Clinical History DR4 Personal genetic/genomic data
				IER12 Identify Laboratory	DR7 Genomic Laboratory Registry
				IER44 Send/receive genetic test orders	DR1 Demographic Data DR3 Clinical History DR4 Personal genetic/genomic data
				IER25 Send/receive decision support data	DR1 Demographic Data DR3 Clinical History DR4 Personal genetic/genomic data DR5 Family genetic/genomic information DR8 Unstructured Data
				IER21 Receive updated clinical information	DR3 Clinical History

Business Actor	Description	Stakeholders	Use Case Scenario	Information Exchange Requirement Numbers (IER)	Data Requirement Numbers (DR)
				IER19 Send/receive genetic/genomic test results	DR1 Demographic Data DR4 Personal genetic/genomic data
				IER41 Receive Risk Analysis Report	DR4 Personal genetic/genomic data
Provider Administrative and Financial Systems	Systems used by healthcare providers that include administrative and financial functions associated with the delivery of healthcare. These functions support the delivery and optimization of care, but generally do not impact the direct care of an individual patient	Administrative and financial staff Healthcare Entities	1, 2	IER15 Send/Receive health plan authorization	DR6 Health Plan Eligibility Information
				IER14 Send/Receive health plan eligibility	DR6 Health Plan Eligibility Information
Laboratory 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	Patient Consumer Healthcare Entities Public Health Agencies Registries HIE Clinicians	1, 2	IER23 Request or provide additional information	DR1 Demographic Data DR3 Clinical History DR4 Personal genetic/genomic data DR5 Family genetic/genomic information DR8 Unstructured Data
				IER58 Send/receive patient health history	DR1 Demographic Data DR3 Clinical History DR4 Personal genetic/genomic data DR5 Family genetic/genomic information
				IER1 Provide authorization and consent	DR1 Demographic Data
				IER62 Send/receive encounter or full episode of care record	DR1 Demographic Data DR3 Clinical History DR4 Personal genetic/genomic data

Business Actor	Description	Stakeholders	Use Case Scenario	Information Exchange Requirement Numbers (IER)	Data Requirement Numbers (DR)
				IER20 Send/receive genomic information	DR1 Demographic Data DR3 Clinical History DR4 Personal genetic/genomic data
				IER12 Identify Laboratory	DR7 Genomic Laboratory Registry
				IER44 Send/receive genetic test orders	DR1 Demographic Data DR3 Clinical History DR4 Personal genetic/genomic data
				IER25 Send/receive decision support data	DR1 Demographic Data DR3 Clinical History DR4 Personal genetic/genomic data DR5 Family genetic/genomic information DR8 Unstructured Data
				IER21 Receive updated clinical information	DR3 Clinical History
				IER19 Send/receive genetic/genomic test results	DR1 Demographic Data DR4 Personal genetic/genomic data

Business Actor	Description	Stakeholders	Use Case Scenario	Information Exchange Requirement Numbers (IER)	Data Requirement Numbers (DR)
Infrastructure Services	This business actor groups the services that are necessary to support the Use Case, such as: • PID service • Locator service • Registry service • Data repository • Security and privacy services These services don't need to be implemented in any one particular location. The actual deployment of the services would be highly influenced by implementation needs and policies.	All	All	All	All

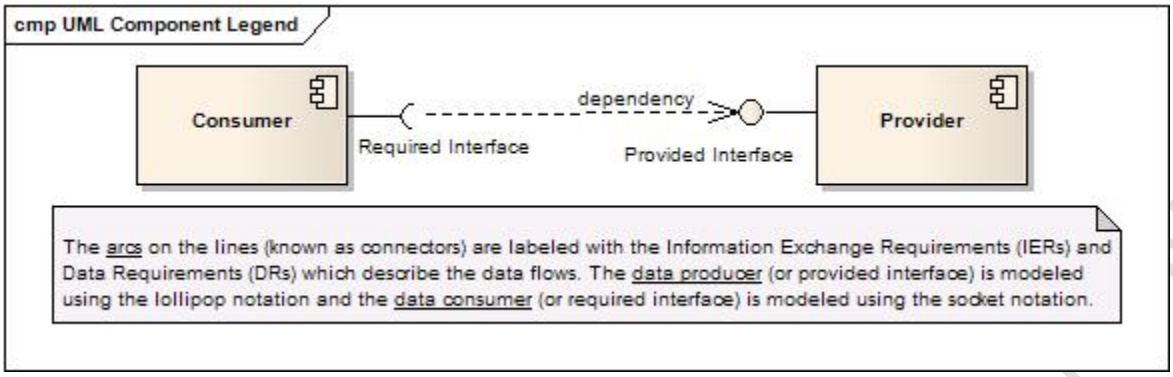
2.2.4 HIGH-LEVEL DIAGRAMS

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 6.3 that illustrates 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.

The figures below are Component Data Flow diagrams that illustrate the data flow and information exchanges between the primary HITSP Business 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 is a legend for reading the Component Data Flow diagrams.

Figure 2.2.4-1 Legend for Component Diagrams



Note that the infrastructure services business actor groups the services that are necessary to support the Use Case but don't need to be implemented in any one particular location (e.g., security). The actual deployment of the services would be highly influenced by implementation needs and policies. They are NOT shown on the Figure 2.2.4 diagrams, because they can be placed anywhere.

Figure 2.2.4-2 is a Component Data Flow diagram that illustrates the data flow and information exchanges between the primary actors in scenario 1, Clinical Assessment. 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 2.2.4-2 Scenario 1: Clinical Assessment Component Data Flow Diagram

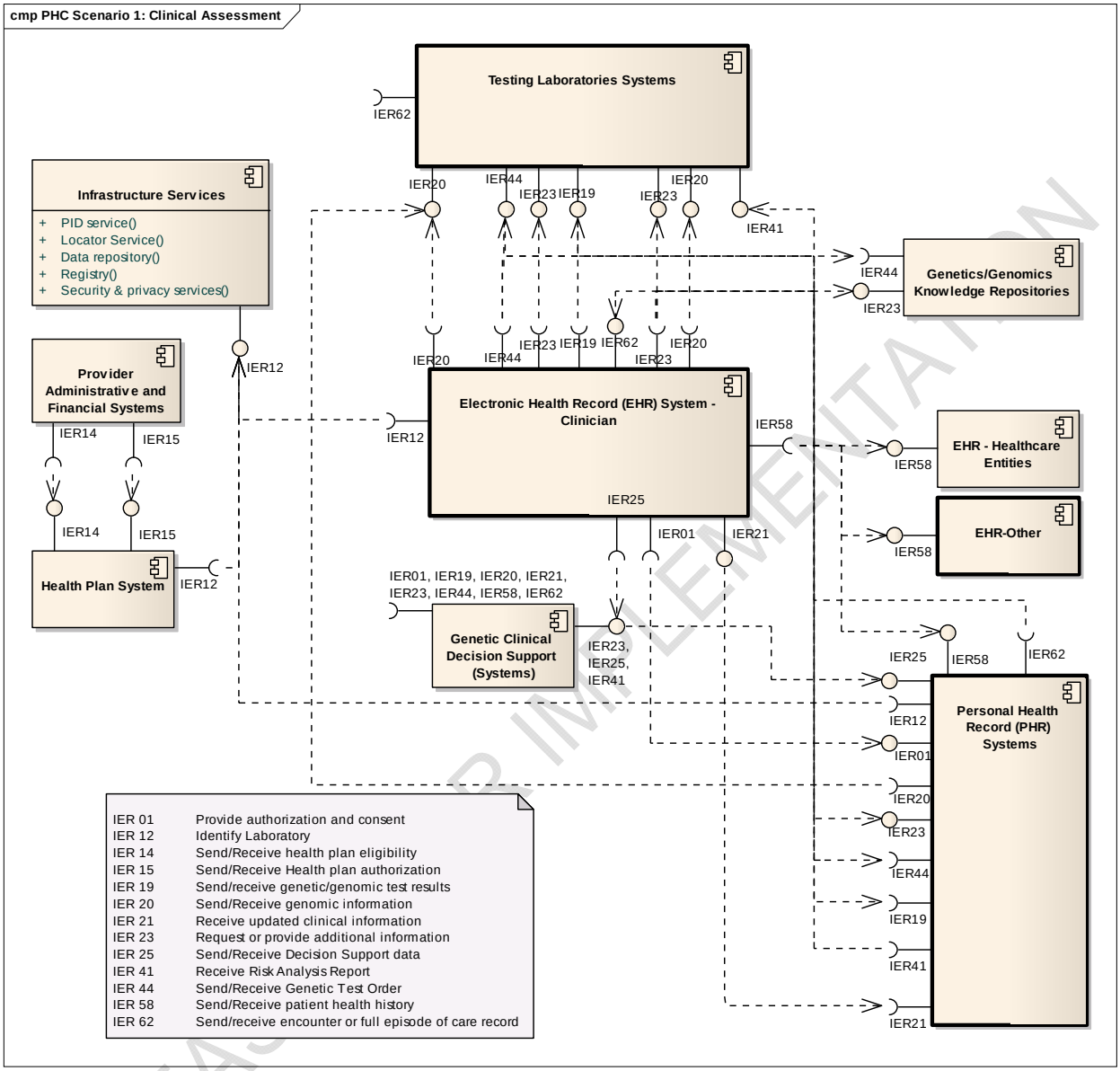
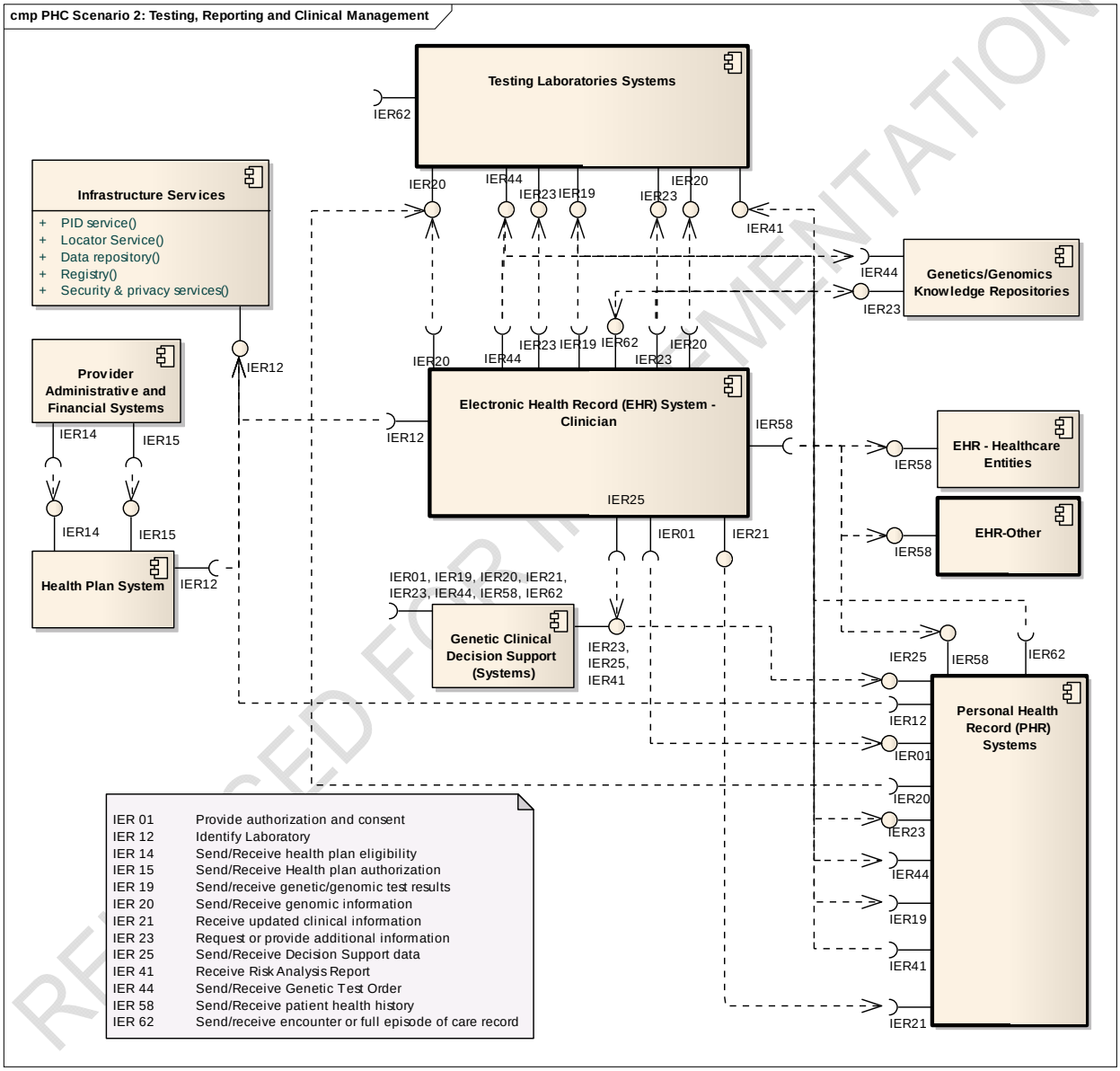


Figure 2.2.4-3 is a Component Data Flow diagram that illustrates the data flow and information exchanges between the primary actors in Scenario 2: Testing, Reporting and Clinical Management. The information exchange and data requirement numbers from tables in Section 2.2.2 are annotated on the diagrams 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 2.2.4-3 Scenario 2: Testing, Reporting and Clinical Management 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. 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.

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
Interactions between the testing laboratories and genetic repositories are out of scope	1
Updates to genomic decision support are not provided by the laboratory	2
Table (e.g. codes, reference values) updates from EHR systems suppliers are out of scope	1, 2

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
No applicable constraints	

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
Assume that all pre-conditions from the lower level constructs (Transaction Packages, etc.) are incorporated	All
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
Support the following HITSP Security and Privacy constructs: HITSP/C19 – Entity Identity Assertion HITSP/T16 - Consistent Time HITSP/T17 - Secured Communication Channel HITSP/T15 - Collect and Communicate Security Audit Trail HITSP/TP30 - Manage Consent Directives HITSP/TP20 - Access Control	All

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
Assume that all scenario post-conditions from the lower level constructs (Transaction Package, etc.) are incorporated	All
Information sent for research or public health is covered by HITSP/IS02 – Biosurveillance	All
Communications with pharmacies for medication is covered by HITSP/IS07 – Medication Management	All

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
No applicable process triggers	

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 basic 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).

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	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

Technical Actor(s)	Actor Role	Construct
Administrative Transport Client	A provider sending a request to a health plan has a client role	HITSP/T85
Administrative Transport Server	A Health Plan responding to a request from a healthcare provider has a Server role	HITSP/T85
Audit Record Repository	Provides a repository for audit events	HITSP/T15
Audit Record Source	Creates and communicates an Audit Record to the Audit Record Repository on behalf of another actor that performs an action requiring logging	HITSP/T15
Consent Directive Requestor	Accesses Consent Directives located through a Consent Registry from Consent Repositories	HITSP/TP30
Consent Registry	Responsible for providing location information and sender notification regarding consent directive. The Consent Registry receives a Manage Consent Directive Metadata Request	HITSP/TP30
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, importing, or other processing of content created by a Content Creator Actor	HITSP/C32 HITSP/C36 HITSP/C37 HITSP/C48 HITSP/C62 HITSP/C80 HITSP/C84 HITSP/TP30 HITSP/C90
Content Creator	Responsible for the creation of content and transmission to a Content Consumer	HITSP/C32 HITSP/C36 HITSP/C37 HITSP/C48 HITSP/C62 HITSP/C80 HITSP/C84 HITSP/TP30
DNS Server	This actor has authoritative location information	HITSP/T64
Document Consumer	Queries a Document Registry Actor for documents meeting certain criteria and retrieves selected documents from one or more Document Repository actors	HITSP/TP13 HITSP/TP89
Document Recipient	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/T31
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 HITSP/TP89

Technical Actor(s)	Actor Role	Construct
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 HITSP/TP89
Document Source	The 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/TP89 HITSP/T31
Eligibility Information Receiver	The system that initiates an inquiry to the Eligibility Information Source about an individual's insurance eligibility, coverage and benefits	HITSP/T40
Eligibility Information Source	The system which holds and maintains the information regarding the individual's insurance eligibility, coverage and benefits, and responds to the queries initiated by the Eligibility Information Receiver	HITSP/T40
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
Information Receiver for Health Plan Authorization	The system that initiates a request to the Health Plan Authorization Information Source about an individual's insurance requirements to obtain an authorization approval for purposes of benefit coverage determination in order to refer a patient for healthcare services	HITSP/T68
Information Source for Health Plan Authorization	The system which holds and maintains the information regarding the individual's insurance requirements related to an authorization for benefit coverage	HITSP/T68
Initiating Gateway	Support all outgoing inter-community communications	HITSP/TP13
Knowledge Requestor	A 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
Node	The originating or terminating point of information or signal flow in a telecommunications network	HITSP/T17
Notification Receiver	Receives notifications of availability for documents in an XDS registry and may optionally send acknowledgements	HITSP/T29
Notification Sender	Sends notifications of availability for documents in an XDS registry and receives acknowledgements 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 and maintains one or more Patient Information Sources of patient demographics data	HITSP/T23

Technical Actor(s)	Actor Role	Construct
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 Data when requested, assigns a unique identifier to each instance of a patient, and maintains a collection of identity traits	HITSP/TP22 HITSP/TP89
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 XDM	HITSP/T33
Portable Media Importer	Media Importer reads the selected information from media (CD-ROM, USB-Memory, e-Mail) following the directory structure outlined by XDM	HITSP/T33
Responding Gateway	Supports all incoming inter-community communications	HITSP/TP13
Service Provider	Represents the system providing a service to all entities that need an assertion or authentication. The service (or assertion) provider is the trusted third party issuer of the trustable identity assertion	HITSP/C19
Service User	Represents any individual entity (such as a clinician or a 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 transactions	HITSP/TP20 HITSP/C19
Time Client	Establishes time synchronization with one or more Time Servers using either the Network Time Protocol (NTP) or Simple Network Time Protocol (SNTP) algorithms. Maintains the local computer system clock synchronization with Coordinated Universal Time (UTC) based on synchronization with the Time Servers	HITSP/T16
Time Server	Provides Network Time Protocol (NTP) time services to Time Clients. It is either directly synchronized to a Coordinated Universal Time (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	An actor that has the role of providing the Resolved Value Sets	HITSP/T66

3.2.2 CONSTRUCT REQUIREMENTS

This section incorporates the comprehensive business and technical requirements and a detailed specification of the actions and decisions undertaken for the primary actions in each Use Case scenario

Table 6.4-1 (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. These 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 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.

Figure 3.2.2-1 Clinical Assessment Scenario 7.1.1

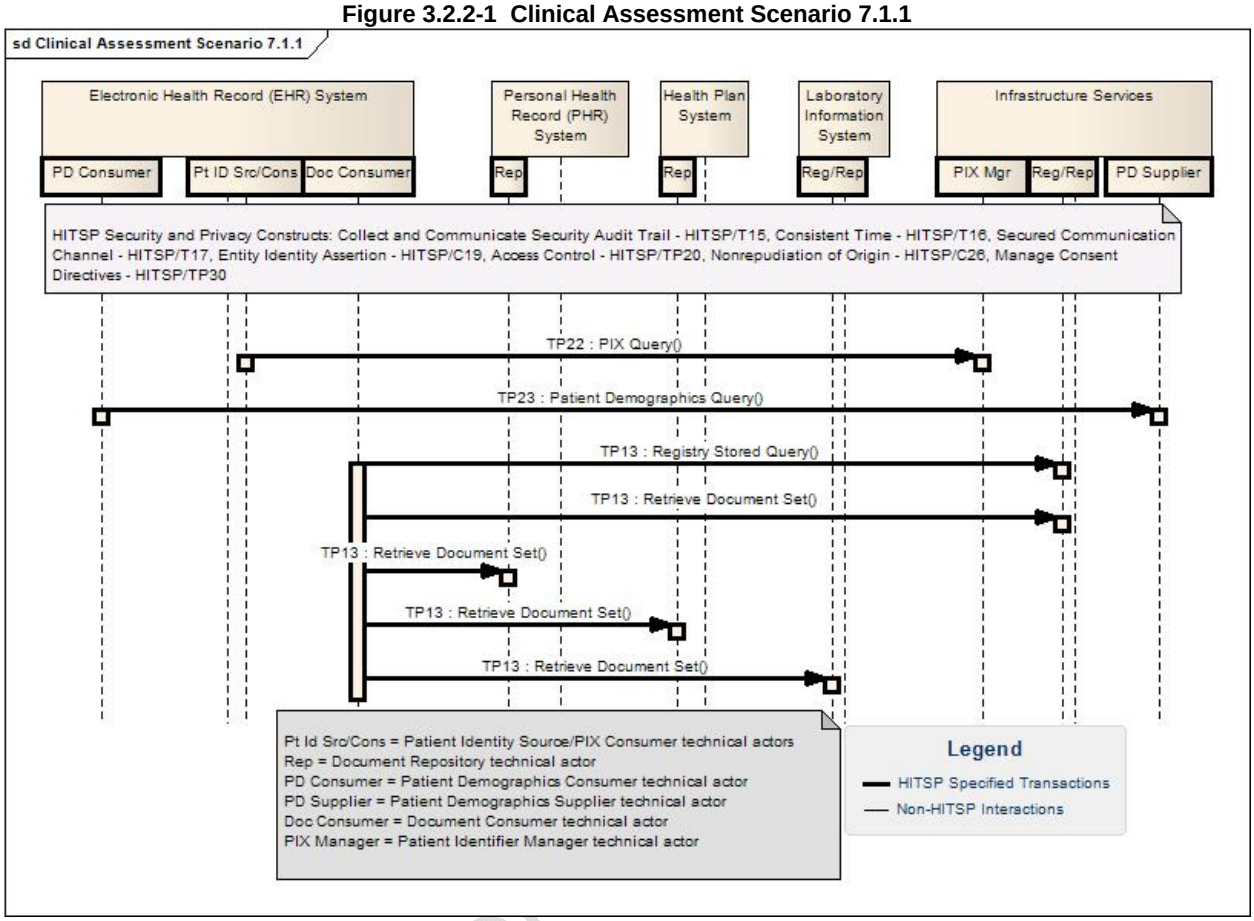


Figure 3.2.2-2 Clinical Assessment Scenario 7.1.2 and 7.1.3

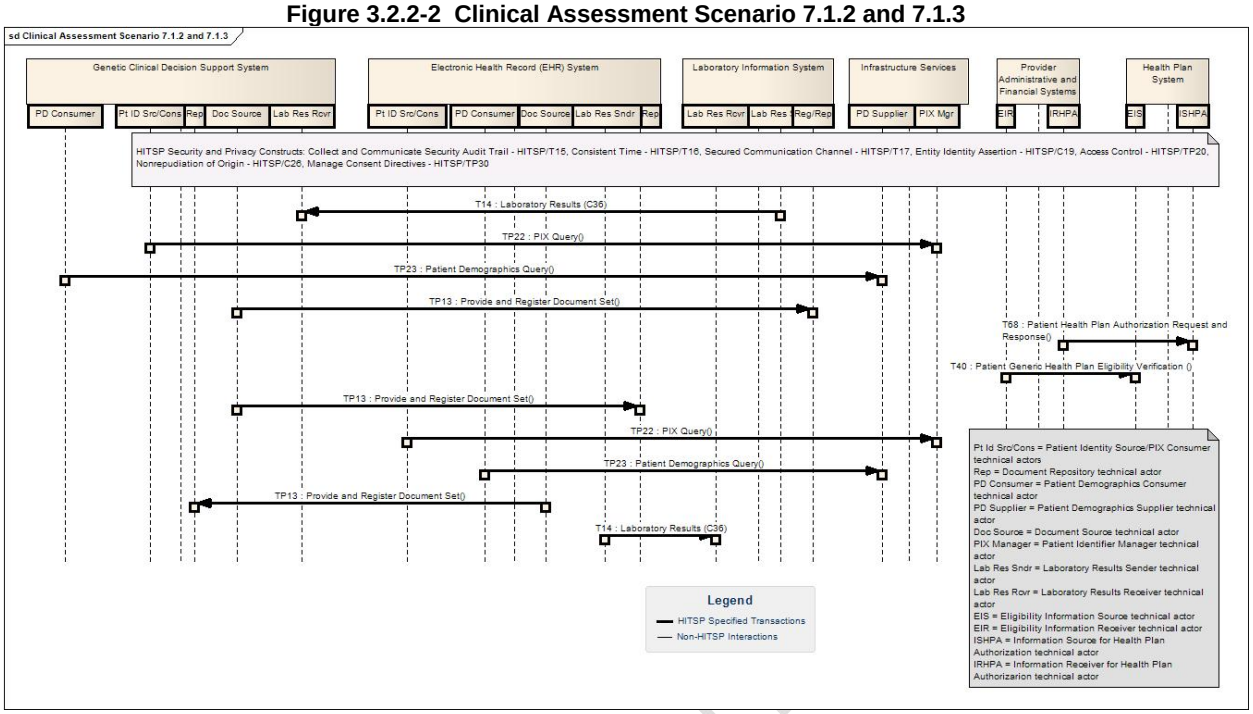


Figure 3.2.2-3 Clinical Assessment Scenario 7.3.1 and 7.3.2

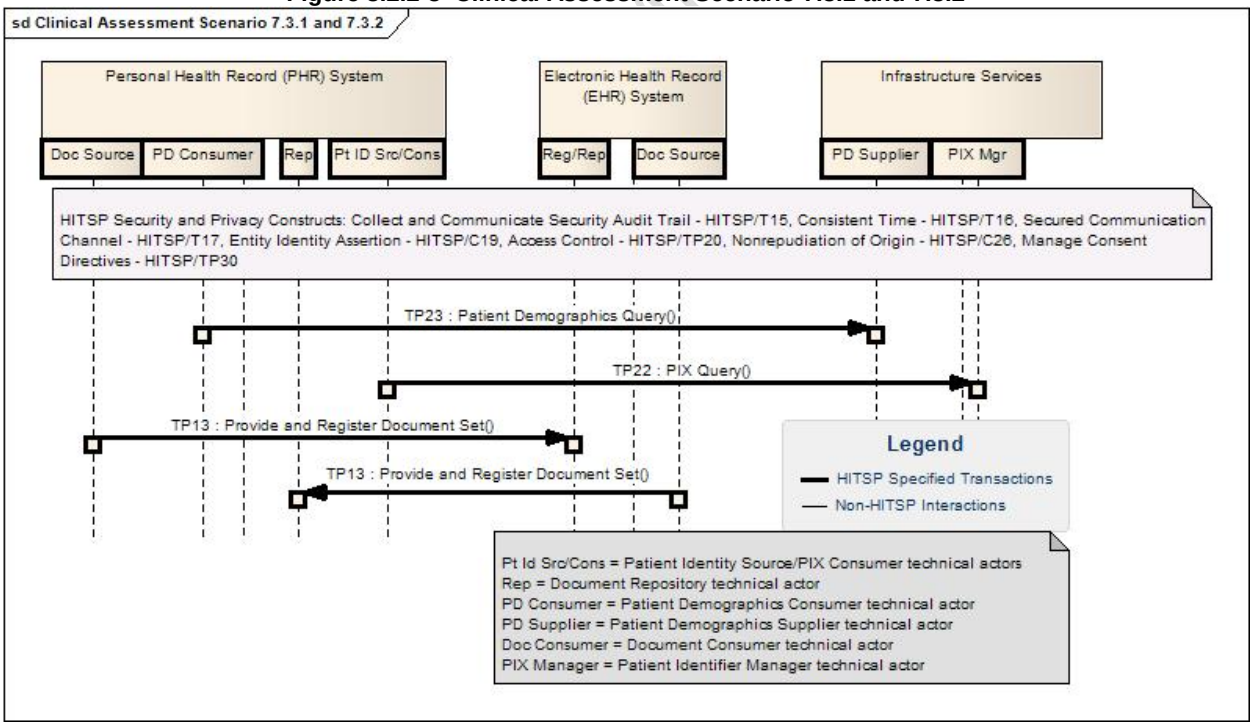


Figure 3.2.2-4 Genetic Testing, Reporting, and Clinical Management Scenario 8.1.1

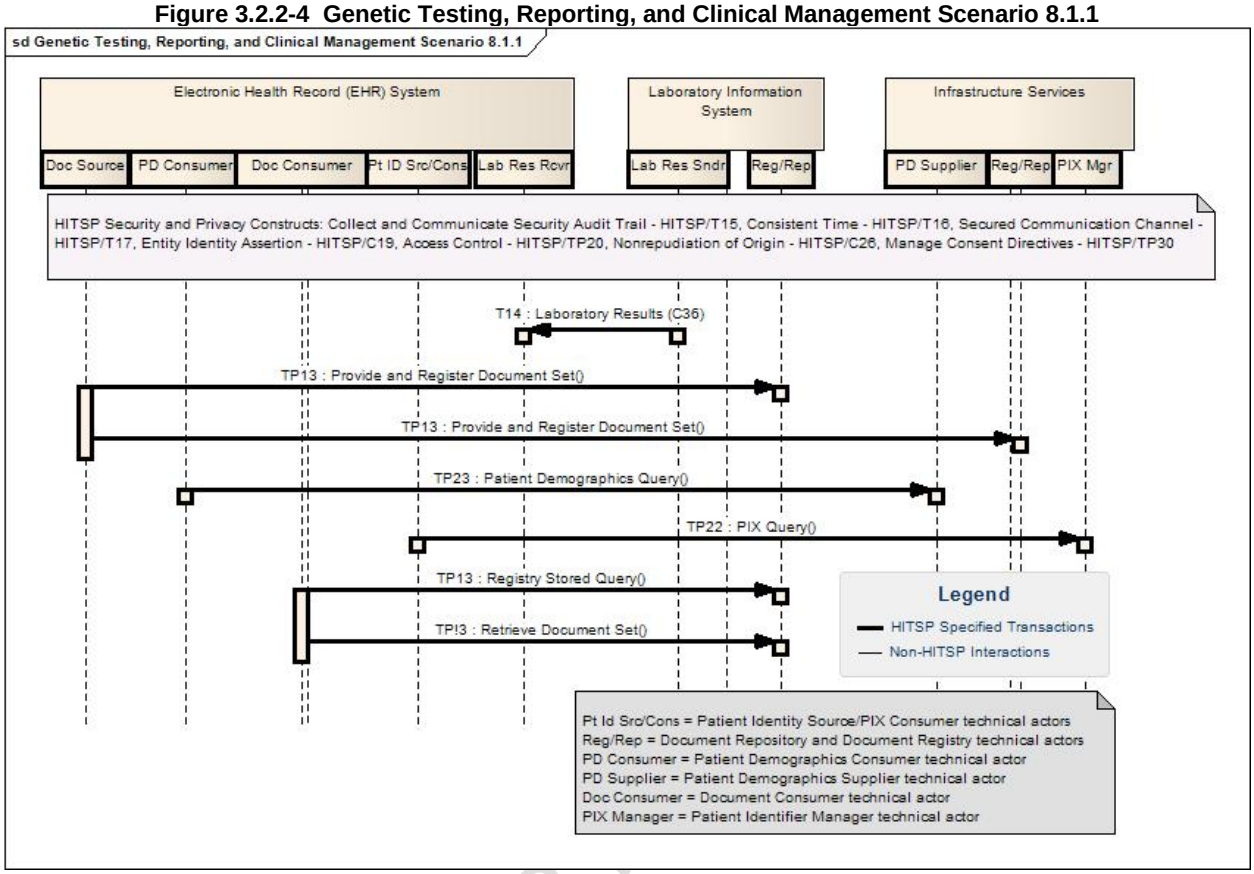


Figure 3.2.2-5 Genetic Testing, Reporting, and Clinical Management Scenario 8.1.3

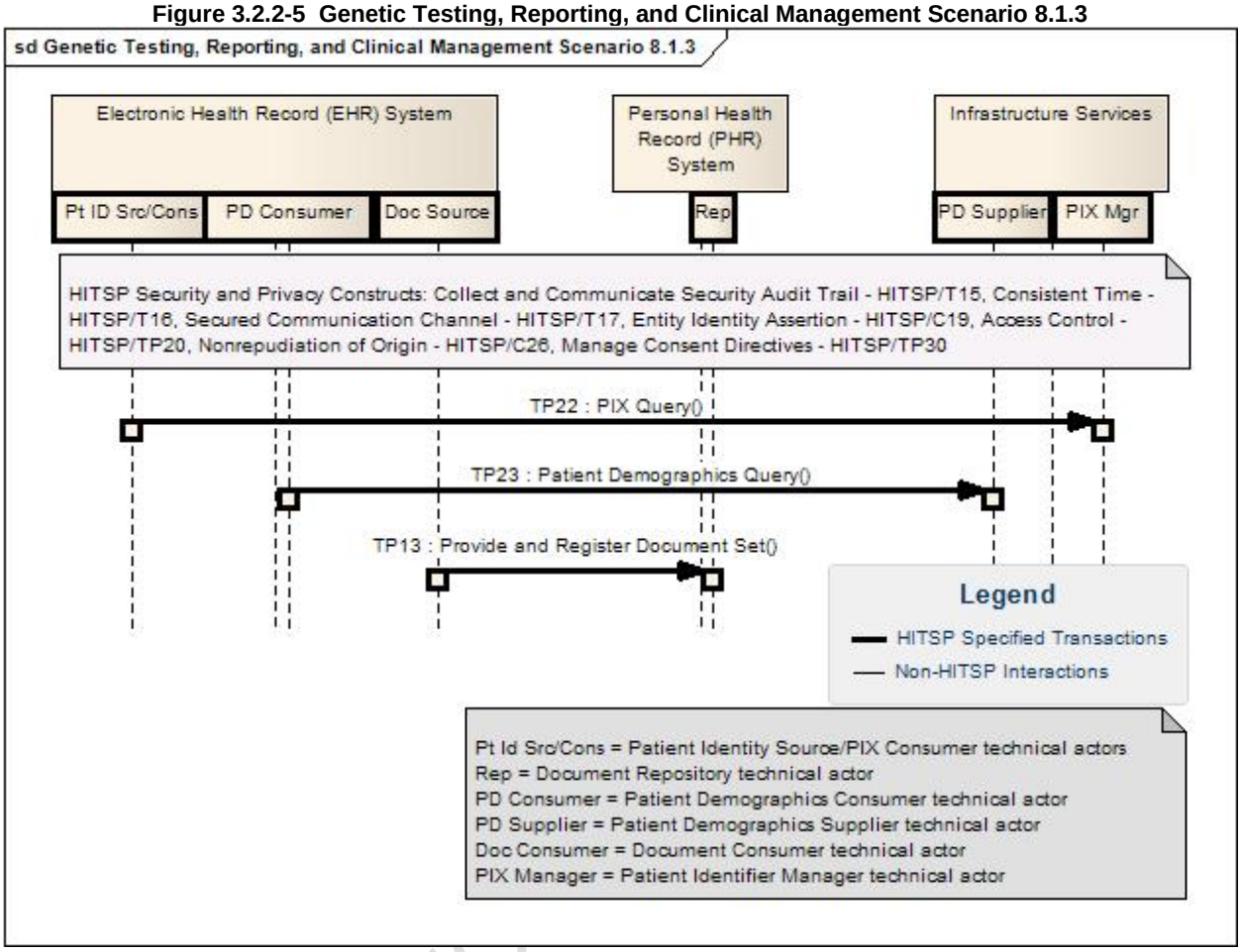


Figure 3.2.2-6 Genetic Testing, Reporting, and Clinical Management Scenario 8.2.1 and 8.2.3

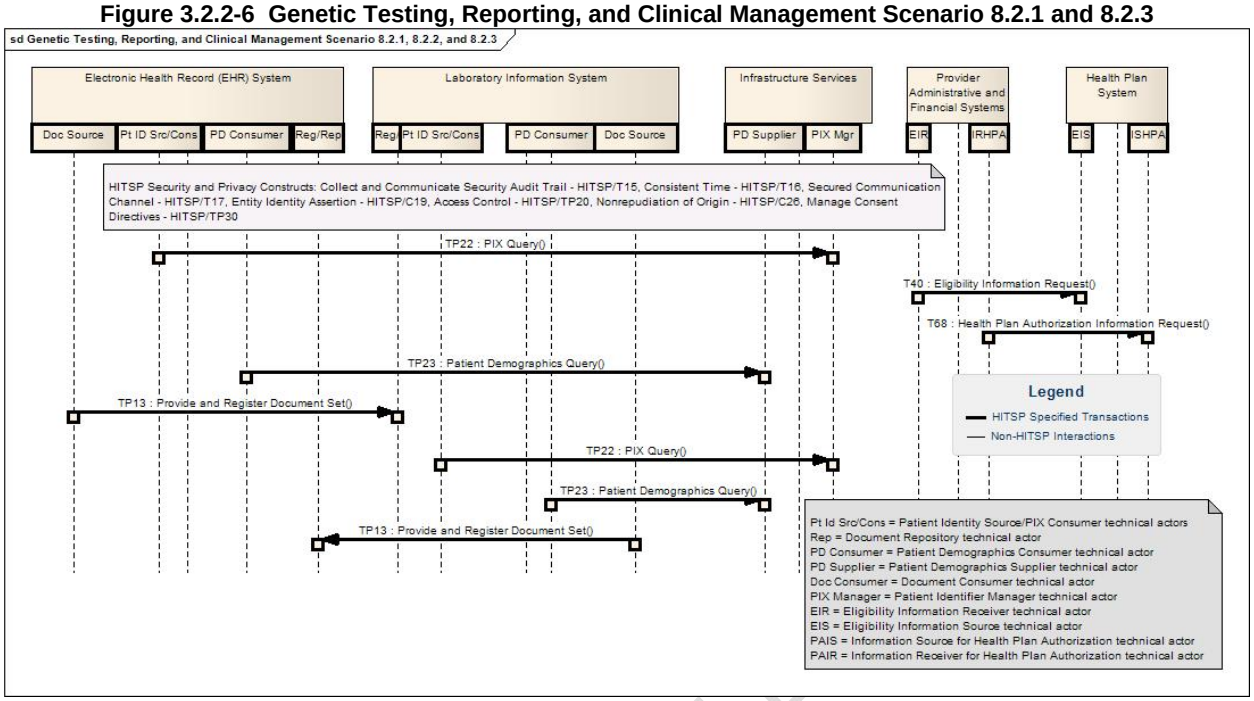


Figure 3.2.2-7 Genetic Testing, Reporting, and Clinical Management Scenario 8.2.4 and 8.2.5

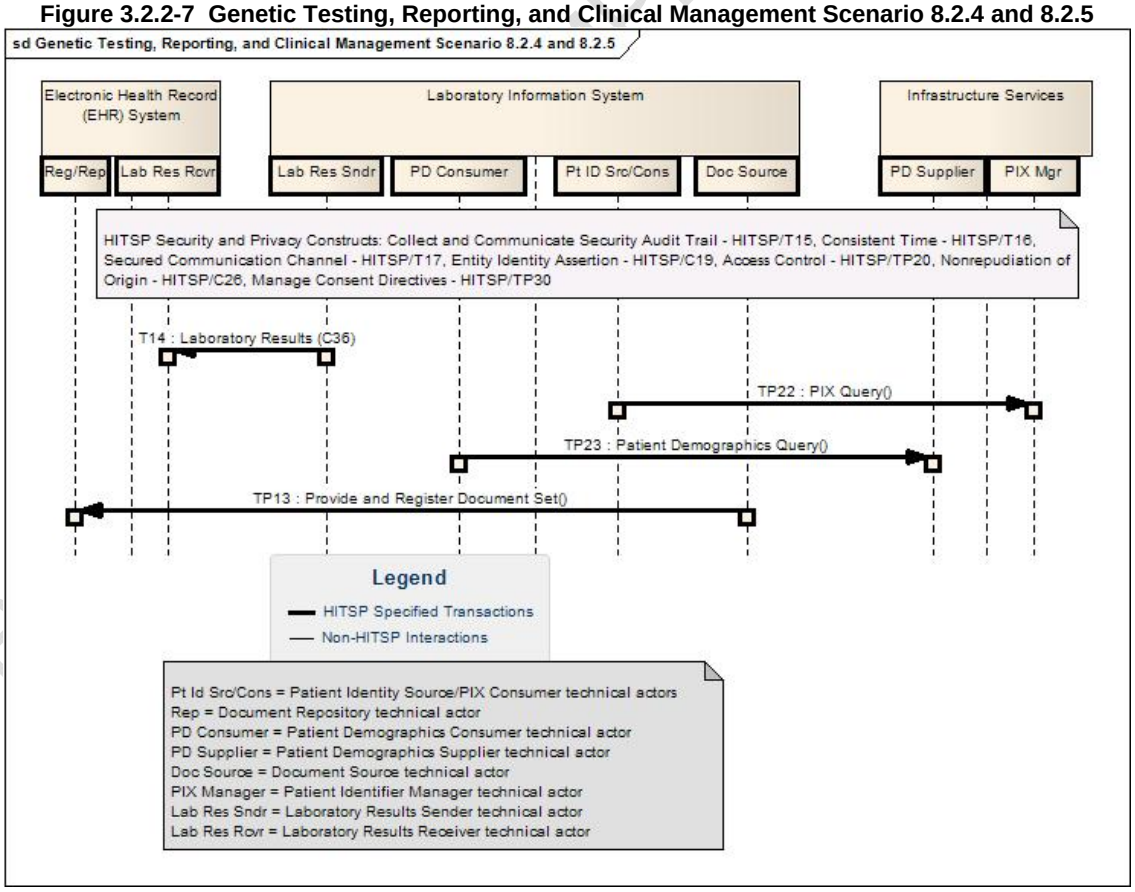
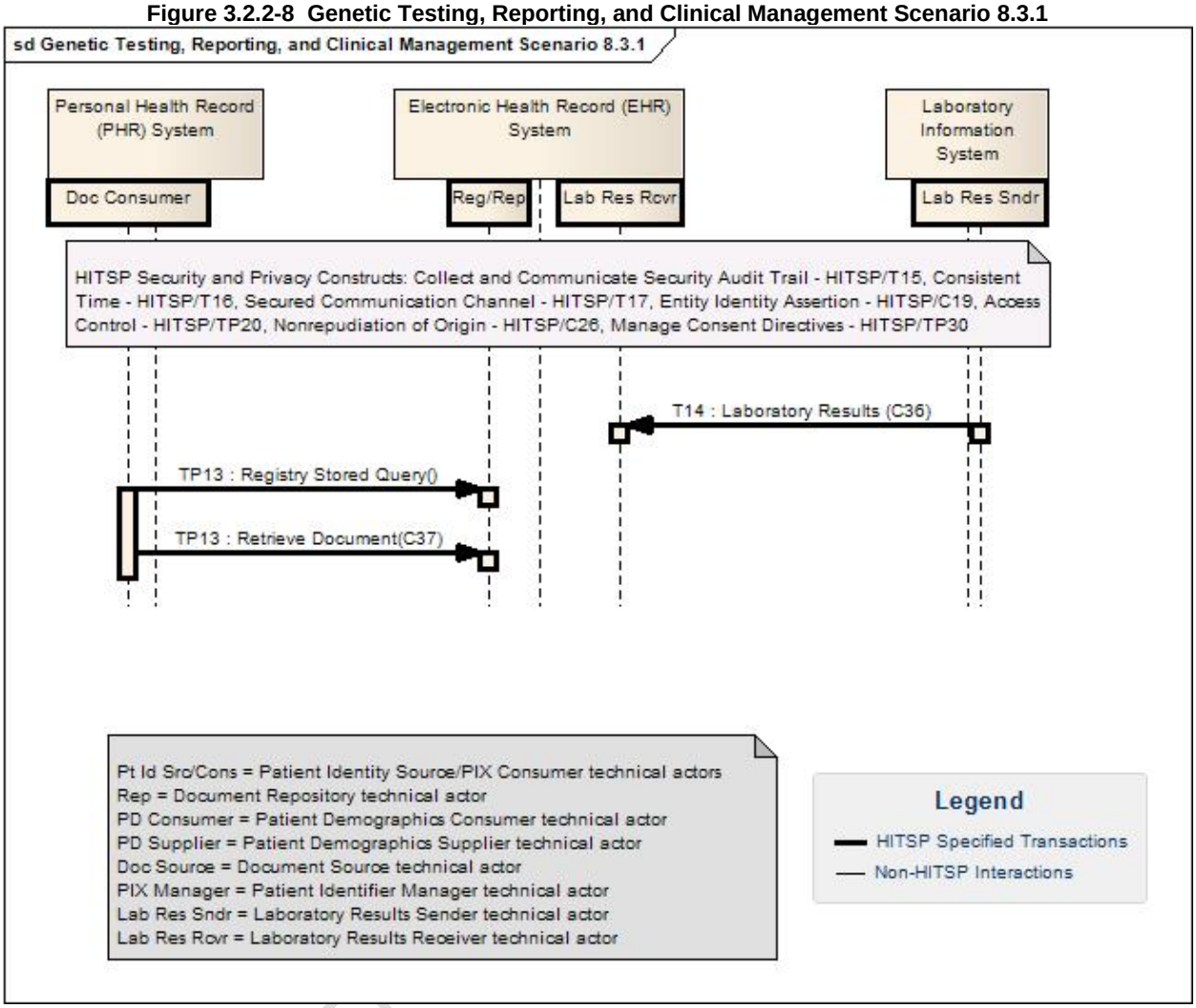


Figure 3.2.2-8 Genetic Testing, Reporting, and Clinical Management Scenario 8.3.1



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.

Note that all the business actors in the table below use the services provided by the Infrastructure Services business actor. Technical actors that are listed in the Infrastructure Services business actor are grouped there for convenience but may be implemented centrally in one place or distributed across several other business actors or edge systems.

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

Business Actor	Technical Actor(s)	Actor Optionality*	Construct	Transaction/Content (T/C)	T/C Optionality*
Electronic Health Record (EHR) System	Service User	R	HITSP/TP20	Access Control Request	O
	Identity Provider	C[102]	HITSP/C19	Provide Assertion	R
				Verify Assertion	O
	Content Creator	R	HITSP/C48	Structured Family History Creator-Structured Family History subset	R[111]
			HITSP/C37	Creator-Lab Report Document Component	R
			HITSP/TP30	Consent Document	R
			HITSP/C62	Unstructured Document	C[103]

Business Actor	Technical Actor(s)	Actor Optionality*	Construct	Transaction/Content (T/C)	T/C Optionality*
		C [103]	HITSP/C84	Structured Family History - Content Creator	R[111]
			HITSP/C90	Content Creator-Family History	R
	Content Consumer	R	HITSP/C32	Structured Family History Consumer-Document Display	R[111]
				Structured Family History Consumer-Document Import	O
				Structured Family History Consumer-Document Discrete Data Import	R[111]
			HITSP/TP30	Consent Document	R
			HITSP/C37	Consumer Document Display	R
				Consumer-Document Import	O
				Consumer-Document Discrete Data Import	R
			HITSP/C36	Lab Result Message	R
			HITSP/C48	Structured Family History Consumer-Document Display	R[111]
				Structured Family History Consumer-Document Import	O
				Structured Family History Consumer-Document Discrete Data Import	R[111]
			HITSP/C62	Unstructured Document	O
			HITSP/C84	Structured Family History Consumer-Document Display	R[111]
				Structured Family History Consumer-Document Import	O
				Structured Family History Consumer-Document Discrete Data Import	R[111]
			HITSP/C90	Content Consumer Genetic Risk Analysis	C [103]
	Document Repository	O [107]	HITSP/TP13	Provide & Register Document Set-b (XDS.b)	R
				Register Document Set-b (XDS.b)	R
				Retrieve Document Set	R
			HITSP/C19	Convey Assertion	O
	Audit Record Source	R[107]	HITSP/T15	Record Audit Event in Repository	R
	Audit Record Repository	O	HITSP/T15	Record Audit Event in Repository	R
	Time Client	R [107]	HITSP/T16	Maintain Time	R
	Node	R [107]	HITSP/T17	Secured Communication Channel	R
	Patient Demographics Consumer	C [101], [109]	HITSP/T23	Patient Demographics Query	R

Business Actor	Technical Actor(s)	Actor Optionality*	Construct	Transaction/Content (T/C)	T/C Optionality*
	Patient Identity Source	C [101]	HITSP/T22	Patient Identity Management	O
			HITSP/TP22	Patient Identity Feed	O
	Patient Identifier Cross Reference (PIX) Consumer	C[101]	HITSP/TP22	PIX Query	R
	Notification Receiver	C [109]	HITSP/T29	Receive Notification	R
				Send Acknowledgement	R
	Notification Sender	R	HITSP/T29	Send Notification	R
				Receive Acknowledgement	R
	Document Recipient	C [104]	HITSP/T31	Provide & Register Document Set.b	R
			HITSP/C19	Convey Assertion	O
	Document Source	C [105]	HITSP/T31	Provide & Register Document Set.b	R
			HITSP/TP13	Provide & Register Document Set-b (XDS.b)	R
			HITSP/C19	Convey Assertion	O
	Portable Media Creator	C [105]	HITSP/T33	Distribute Document Set on Media	R
	Portable Media Importer	C [104]	HITSP/T33	Distribute Document set on Media	R
	Document Consumer	C [106], [110], [104]	HITSP/TP13	Registry Stored Query	R
				Retrieve Document Set	R
			HITSP/C19	Convey Assertion	O
	Initiating Gateway	O	HITSP/TP13	ITI-38: Cross Gateway Query	R
				ITI-39: Cross Gateway Query	R
	Responding Gateway	O	HITSP/TP13	ITI-38: Cross Gateway Query	R
				ITI-39: Cross Gateway Retrieve	R
	Access Control Service	O	HITSP/TP20	Access Control Request	O
	Patient Identifier Cross Reference (PIX) Consumer	C [101]	HITSP/TP22	PIX Query	R
	Consent Directive Requester	O [108]	HITSP/TP30	Stored Query	R
				Retrieve Document Set	R
	Consent Repository	O	HITSP/TP30	Register Document Set	R
				Provide and Register Document Set	R
				Retrieve Document	R
	Personnel White Pages Consumer	O	HITSP/T64	Find Personnel White Pages	O
				Query Personnel White Pages	R
	Value Set Consumer	R	HITSP/T66	Retrieve Value Set	R
	Laboratory Result Message Receiver	R	HITSP/T14	Laboratory Results	R
	Laboratory Result Message Sender	R	HITSP/T14	Send Laboratory Results	R

Business Actor	Technical Actor(s)	Actor Optionality*	Construct	Transaction/Content (T/C)	T/C Optionality*
	Knowledge Resource	R	HITSP/T81	Retrieve Topic Medical Knowledge	R
				Retrieve Sub-Topic Medical Knowledge	R
	Knowledge Requestor	R	HITSP/T81	Retrieve Topic Medical Knowledge	R
				Retrieve Sub-Topic Medical Knowledge	R
PHR Systems	Service User	R	HITSP/TP20	Access Control Request	O
	Identity Provider	C [102]	HITSP/C19	Provide Assertion	R
				Verify Assertion	R
	Audit Record Source	R [107]	HITSP/T15	Record Audit Event in Repository	R
	Audit Record Repository	O	HITSP/T15	Record Audit Event in Repository	R
	Time Client	R [107]	HITSP/T16	Maintain Time	R
	Node	R [107]	HITSP/T17	Secured Communication Channel	R
	Access Control Service	O	HITSP/TP20	Access Control Request	O
	Content Creator	R	HITSP/C48	Structured Family History Creator-Structured Family History Subset	R[111]
			HITSP/C37	Creator-Lab Report Document	O
			HITSP/TP30	Consent Document	R
			HITSP/C62	Unstructured Document	C[103]
		C [103]	HITSP/C84	Structured Family History Content Creator	R[111]
			HITSP/C32	Structured Family History Creator-Structured Family History subset	R[111]
	Content Consumer	R	HITSP/TP30	Consent Document	R
			HITSP/C37	Consumer Document Display	R
				Consumer-Document Import	O
				Consumer-Document Discrete Data Import	R
			HITSP/C32	Structured Family History Consumer-Document Display	R[111]
				Structured Family History Consumer-Document Import	O
				Structured Family History Consumer-Document Discrete Data Import	R[111]
			HITSP/C48	Structured Family History Consumer-Document Display	R[111]
				Structured Family History Consumer-Document Import	O
				Structured Family History Consumer-Document Discrete Data Import	R[111]
			HITSP/C62	Unstructured Document	O

Business Actor	Technical Actor(s)	Actor Optionality*	Construct	Transaction/Content (T/C)	T/C Optionality*
			HITSP/C84	Structured Family History Consumer-Document Display	R[111]
				Structured Family History Consumer-Document Import	O
				Structured Family History Consumer-Document Discrete Data Import	R
	Consent Directive Requester	O [108]	HITSP/TP30	Stored Query	R
				Retrieve Document Set	R
	Document Repository	O [107]	HITSP/TP13	Provide & Register Document Set-b	R
				Register Document Set-b	R
				Retrieve Document	R
			HITSP/C19	Convey Assertion	O
	Document Recipient	C [104]	HITSP/T31	Provide & Register Document Set.b (XDS.b)	R
			HITSP/C19	Convey Assertion	O
	Document Consumer	C [106], [110], [104]	HITSP/TP13	Registry Stored Query	R
				Retrieve Document Set	R
			HITSP/C19	Convey Assertion	O
	Laboratory Result Message Receiver	R	HITSP/T14	Laboratory Results	R
	Portable Media Creator	C [105]	HITSP/T33	Distribute Document Set on Media	R
	Portable Media Importer	C [104]	HITSP/T33	Distribute Document Set on Media	R
	Personnel White Pages Consumer	O	HITSP/T64	Find Personnel White Pages	O
				Query Personnel White Pages	R
	Value Set Consumer (user)	R	HITSP/T66	Retrieve Value Set	R
	Initiating Gateway	O	HITSP/TP13	ITI-38: Cross Gateway Query	R
				ITI-39: Cross Gateway Retrieve	R
	Knowledge Requestor	R	HITSP/T81	Retrieve Topic Medical Knowledge	R
				Retrieve Sub-Topic Medical Knowledge	R
	Responding Gateway	O	HITSP/TP13	ITI-38: Cross Gateway Query	R
				ITI-39: Cross Gateway Retrieve	R
Laboratory Information Systems	Service User	R	HITSP/TP20	Access Control Request	O
	Identity Provider	C [102]	HITSP/C19	Provide Assertion	R
				Verify Assertion	R
	Audit Record Source	R [107]	HITSP/T15	Record Audit Event in Repository	R
	Audit Record Repository	O	HITSP/T15	Record Audit Event in Repository	R
	Time Client	R [107]	HITSP/T16	Maintain Time	R
	Node	R [107]	HITSP/T17	Secured Communication Channel	R

Business Actor	Technical Actor(s)	Actor Optionality*	Construct	Transaction/Content (T/C)	T/C Optionality*
	Access Control Service	O	HITSP/TP20	Access Control Request	O
	Content Creator	R	HITSP/TP30	Consent Document	O
			HITSP/C37	Creator-Lab Report Document	R
			HITSP/C36	Content Creator	R
	Content Consumer	R	HITSP/C32	Structured Family History Consumer-Document Display	R[111]
				Structured Family History Consumer-Document Import	O
				Structured Family History Consumer-Document Discrete Data Import	R[111]
			HITSP/TP30	Consent Document Component	R
			HITSP/C37	Consumer Document Display	R
				Consumer-Document Import	O
				Consumer-Document Discrete Data Import	R
			HITSP/C36	Lab Result Message	R
			HITSP/C48	Structured Family History Consumer-Document Display	R[111]
				Structured Family History Consumer-Document Import	O
				Structured Family History Consumer-Document Discrete Data Import	R[111]
			HITSP/C62	Unstructured Document	O
			HITSP/C84	Structured Family History Consumer-Document Display	R[111]
				Structured Family History Consumer-Document Import	O
				Structured Family History Consumer-Document Discrete Data Import	R[111]
			HITSP/C62	Unstructured Document	O
		C [103]	HITSP/C90	Content Consumer-Genetic Risk Analysis	R
	Consent Directive Requester	O [108]	HITSP/TP30	Stored Query	R
				Retrieve Document Set	R
	Document Repository	O [107]	HITSP/TP13	Provide & Register Document Set-b	R
				Register Document Set-b	R
				Retrieve Document	R
			HITSP/C19	Convey Assertion	O
	Document Recipient	C [104]	HITSP/T31	Provide & Register Document Set.b (XDS.b)	R
			HITSP/C19	Convey Assertion	O
	Document Consumer	C [106], [110],	HITSP/TP13	Registry Stored Query	R

Business Actor	Technical Actor(s)	Actor Optionality*	Construct	Transaction/Content (T/C)	T/C Optionality*
		[104]		Retrieve Document Set	R
			HITSP/C19	Convey Assertion	O
	Portable Media Creator	C [105]	HITSP/T33	Distribute Document Set on Media	R
	Portable Media Importer	C [104]	HITSP/T33	Distribute Document Set on Media	R
	Initiating Gateway	O	HITSP/TP13	ITI-38: Cross Gateway Query	R
				ITI-39: Cross Gateway Retrieve	R
	Responding Gateway	O	HITSP/TP13	ITI-38: Cross Gateway Query	R
				ITI-39: Cross Gateway Retrieve	R
	Personnel White Pages Consumer	O	HITSP/T64	Find Personnel White Pages	O
				Query Personnel White Pages	R
	Value Set Consumer (user)	R	HITSP/T66	Retrieve Value Set	R
	Laboratory Result Message Receiver	R	HITSP/T14	Laboratory Results	R
	Laboratory Result Message Sender	R	HITSP/T14	Send Laboratory Results	R
	Knowledge Resource	R	HITSP/T81	Retrieve Topic Medical Knowledge	R
				Retrieve Sub-Topic Medical Knowledge	R
	Knowledge Requestor	R	HITSP/T81	Retrieve Topic Medical Knowledge	R
				Retrieve Sub-Topic Medical Knowledge	R
Health Plan System	Service User	R	HITSP/TP20	Access Control Request	O
	Identity Provider	C [102]	HITSP/C19	Provide Assertion	R
				Verify Assertion	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
	Access Control Service	R	HITSP/TP20	Access Control Request	O
	Content Creator	R	HITSP/TP30	Consent Document	R
	Content Consumer	R	HITSP/TP30	Consent Document	R
	Consent Directive Requester	O [108]	HITSP/TP30	Stored Query	R
				Retrieve Document Set	R
	Eligibility Information Source	R	HITSP/T40	Eligibility Information Request	R
				Eligibility Information Response	R
	Information Source for Health Plan Authorization	R	HITSP/T68	Health Plan Authorization Information Request	R
				Health Plan Authorization Information Response	R

Business Actor	Technical Actor(s)	Actor Optionality*	Construct	Transaction/Content (T/C)	T/C Optionality*
	Administrative Transport Service	R	HITSP/T85	Any ASC X 12 transaction	R
Genetic / Genomic Knowledge Repositories	Knowledge Resource	R	HITSP/T81	Retrieve Topic Medical Knowledge	R
				Retrieve Sub-Topic Medical Knowledge	R
	Knowledge Requestor	R	HITSP/T81	Retrieve Topic Medical Knowledge	R
				Retrieve Sub-Topic Medical Knowledge	R
	Service User	R	HITSP/TP20	Access Control Request	O
	Identity Provider	C [102]	HITSP/C19	Provide Assertion	R
				Verify Assertion	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
	Access Control Service	R	HITSP/TP20	Access Control Request	O
	Content Creator	R	HITSP/TP30	Consent Document	R
	Content Consumer	R	HITSP/TP30	Consent Document	R
	Consent Directive Requester	O [108]	HITSP/TP30	Stored Query	R
				Retrieve Document Set	R
	Personnel White Pages Consumer	O	HITSP/T64	Find Personnel White Pages	O
				Query Personnel White Pages	R
	Value Set Consumer (user)	R	HITSP/T66	Retrieve Value Set	R
Provider Administrative and Financial System	Eligibility Information Receiver	R	HITSP/T40	Eligibility Information Request	R
				Eligibility Information Response	R
	Information Receiver for Health Plan Authorization	R	HITSP/T68	Health Plan Authorization Information Request	R
				Health Plan Authorization Information Response	R
	Administrative Transport (Client)	R	HITSP/T85	Any ASC X12 transaction	R
	Consent Directive Requester	O	HITSP/TP30	Stored Query	R
				Retrieve Document Set	R
	Content Consumer	R	HITSP/TP30	Consent Document	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
	Node	R	HITSP/T17	Secured Communication Channel	R

Business Actor	Technical Actor(s)	Actor Optionality*	Construct	Transaction/Content (T/C)	T/C Optionality*
	Service User	R	HITSP/TP20	Access Control Request	O
	Identity Provider	C [102]	HITSP/C19	Provide Assertion	R
				Verify Assertion	R
	Access Control Service	R	HITSP/TP20	Access Control Request	O
	Personnel White Pages Consumer	O	HITSP/T64	Find Personnel White Pages	O
				Query Personnel White Pages	R
	Knowledge Resource	O	HITSP/T81	Retrieve Topic Medical Knowledge	R
				Retrieve Sub-Topic Medical Knowledge	R
	Knowledge Requestor	O	HITSP/T81	Retrieve Topic Medical Knowledge	R
				Retrieve Sub-Topic Medical Knowledge	R
	Value Set Consumer (user)	R	HITSP/T66	Retrieve Value Set	R
Genetic Clinical Decision Support (systems)	Content Creator	R	HITSP/C90	Content Creator-Genomic Risk Analysis	R
	Content Consumer	R	HITSP/C90	Content Consumer-Family History	R
	Personnel White Pages Consumer	O	HITSP/T64	Find Personnel White Pages	O
				Query Personnel White Pages	R
	Value Set Consumer (user)	R	HITSP/T66	Retrieve Value Set	R
	Consent Directive Requester	O	HITSP/TP30	Stored Query	R
				Retrieve Document Set	R
	Content Consumer	R	HITSP/TP30	Consent Document	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
	Node	R	HITSP/T17	Secured Communication Channel	R
	Service User	R	HITSP/TP20	Access Control Request	O
	Identity Provider	C [102]	HITSP/C19	Provide Assertion	R
				Verify Assertion	R
	Knowledge Resource	R	HITSP/T81	Retrieve Topic Medical Knowledge	R
				Retrieve Sub-Topic Medical Knowledge	R
	Knowledge Requestor	R	HITSP/T81	Retrieve Topic Medical Knowledge	R
				Retrieve Sub-Topic Medical Knowledge	R
	Access Control Service	R	HITSP/TP20	Access Control Request	O
Infrastructure Services	Patient Identifier Cross Reference (PIX) Manager	C [102]	HITSP/TP22	Patient Identity Feed	R
				PIX Query	R
				PIX Update Notification	R
	Patient Demographics Supplier	C [102]	HITSP/T23	Patient Demographics Query	R
	Document Registry	C [112]	HITSP/TP13	PIX Identity Feed	R

Business Actor	Technical Actor(s)	Actor Optionality*	Construct	Transaction/Content (T/C)	T/C Optionality*
				Registry Stored Query	R
				Register Document Set-b	R
			HITSP/C19	Convey Assertion	O
	Document Repository	C [102]	HITSP/TP13	Retrieve Document	R
				Retrieve Document Set-b	R
				Provide & Register Document Set-b	R
			HITSP/C19	Convey Assertion	O
	Initiating Gateway	O	HITSP/TP13	Cross Gateway Query	R
				Cross Gateway Retrieve	R
	Responding Gateway	O	HITSP/TP13	Cross Gateway Query	R
				Cross Gateway Retrieve	R
	Audit Record Source	R	HITSP/T15	Record Audit Event in Repository	R
	Audit Record Repository	C [102]	HITSP/T15	Record Audit Event in Repository	R
	Time Client	R	HITSP/T16	Maintain Time	R
	Time Server	C [102]	HITSP/T16	Maintain Time	R
	Node	R	HITSP/T17	Secured Communication Channel	R
	Identity Provider	C [102]	HITSP/C19	Provide Assertion	R
				Verify Assertion	O
	Service User	R	HITSP/TP20	Access Control Request	O
	Service Provider	R[102]	HITSP/TP20	Access Control Request	O
	Access Control Service	C [102]	HITSP/TP20	Access Control Request	R
	Consent Registry	C [112]	HITSP/TP30	Register Document Set	R
				Stored Query	R
	Consent Repository	C [102]	HITSP/TP30	Provide and Register Document Set	R
				Register Document Set	R
				Retrieve Document	R
	Consent Directive Requester	R	HITSP/TP30	Stored Query	R
				Retrieve Document Set	R
	DNS Server	R[102]	HITSP/T64	Find Personnel White Pages	R
	Personnel White Pages Directory	C [102]	HITSP/T64	Query Personnel White Pages	R
	Personnel White Pages Consumer	O	HITSP/T64	Find Personnel White Pages	O
				Query Personnel White Pages	R
	Value Set Consumer (user)	R	HITSP/T66	Retrieve Value Set	R
	Value Set Repository	R[102]	HITSP/T66	Retrieve Value Set	R

***NOTE:** Optionality = "R" for Required, "R2" for Required if Known, or "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 [105] [106] 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
102	There should be at least one in a group of business actors
103	Shall be supported if this business actor is being used to provide genetic counseling
104	Business actor shall support at least one of these technical actors to receive or retrieve inbound content
105	Business actor shall support at least one of these technical actors to communicate outbound content
106	Document Source or Consent Directive Consumer Technical Actors shall support either the XDS.b option or the XCA option or both options
107	Shall be grouped with (used by) Laboratory Results Receiver and Document Consumer
108	Shall be grouped with (used by) Document Consumer
109	Shall only be implemented when supporting a Document Consumer Technical Actor
110	Document Source, Document Consumer, Document Repository, and Document Registry shall support the XDS.b option
111	These documents SHALL conform to the following constraints: Documents conforming to the Structured Family History constraints shall contain a templateId element under the Clinical Document element whose root attribute is 2.16.840.1.113883.3.88.11.8.1 to indicate conformance These documents shall contain a Family History section conforming to the requirements specified in Section 2.2.1.25 of C83 CDA Content Modules These documents shall contain an Allergies and Adverse Reactions section conforming to the requirements specified in Section 2.2.1.2 of C83 CDA Content Modules These documents shall contain an Active Problems section conforming to the requirements specified in Section 2.2.1.3 of C83 CDA Content Modules When known, these documents shall contain a History of Past Illness section conforming to the requirements specified in section 2.2.1.4 of C83 CDA Content Modules When known, these documents shall contain a Diagnostic Results section conforming to the requirements specified in Section 2.2.1.22 of C83 CDA Content Modules
112	There should be ONLY one in a group of business actors

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/T40 - Patient Health Plan Eligibility Verification HITSP/T68 – Patient Health Plan Authorization Request and Response	HITSP/T85 – Administrative Transport to Health Plan	Pre-condition	HITSP/T85 is the transport mechanism for HITSP/T40 and HITSP/T68

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.

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)
No applicable additional constraints				

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 AND GUIDANCE STANDARDS

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 and Guidance Standards

Standard	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 www.fda.gov and www.cms.hhs.gov

Standard	Description
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. For more information see the Code of Federal Regulations, Title 45, Parts 160, et. Seq

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 as defined in Section 4.0 above.

Table 4.1.2-1 Selected Standards Linked to HITSP Constructs

Standard Name	HITSP Construct	Remarks/ Minor Gaps
Accredited Standards Committee (ASC) X12 270 and 271 transaction standards version 4010, using the Insurance Subcommittee (X12N) Implementation Guides Version Reference Numbers 004010X92	HITSP/T40 - Patient Health Plan Eligibility Verification	
Accredited Standards Committee (ASC) X12 270 and 271 transaction standards version 4010, using the Insurance Subcommittee (X12N) Addenda 004010X92A1	HITSP/T40 - Patient Health Plan Eligibility Verification	
Accredited Standards Committee (ASC) X12 270 Transaction Version Standards Release 004010	HITSP/T40 - Patient Health Plan Eligibility Verification	
Accredited Standards Committee (ASC) X12 271 Transaction Version Standards Release 004010	HITSP/T40 - Patient Health Plan Eligibility Verification	
Accredited Standards Committee (ASC) X12 278 Transaction Version Standards Release 004010	HITSP/T68 - Patient Health Plan Authorization Request and Response	
Accredited Standards Committee (ASC) X12 278 Transactions Standard Version 4010, using the Insurance Subcommittee (X12N) Implementation Guides Version Reference Numbers 004010X94	HITSP/T68 - Patient Health Plan Authorization Request and Response	
Accredited Standards Committee (ASC) X12 278 Transactions Standard Version 4010, using the Insurance Subcommittee (X12N) Addenda 004010X94A1	HITSP/T68 - Patient Health Plan Authorization Request and Response	
Accredited Standards Committee (ASC) X12 Standards Release 004010	HITSP/C80 - Clinical Document and Message Terminology	Vocabularies are enabled via HITSP/C32 and HITSP/C84

Standard Name	HITSP Construct	Remarks/ Minor Gaps
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 and HITSP/C84
CDC Race and Ethnicity Code Sets	HITSP/C80 - Clinical Document and Message Terminology	Vocabularies are enabled via HITSP/C32, HITSP/C48, HITSP/C84 and HITSP/C90
Council for Affordable Quality Health Care (CAQH) Committee on Operating Rules for Information Exchange (CORE) Phase I Operating Rules	HITSP/T40 - Patient Health Plan Eligibility Verification	
Council for Affordable Quality Healthcare (CAQH) Committee on Operating Rules for Information Exchange (CORE) Phase II #258 Normalizing Last Name Rule v2.0.0	HITSP/T40 - Patient Health Plan Eligibility Verification	
Council for Affordable Quality Healthcare (CAQH) Committee on Operating Rules for Information Exchange (CORE) Phase II #259 AAA Error Code Reporting Rule v2.0.0	HITSP/T40 - Patient Health Plan Eligibility Verification Transaction	
Council for Affordable Quality Healthcare (CAQH) Committee on Operating Rules for Information Exchange (CORE) Phase II #260 Eligibility Data Content Rule v2.0.0	HITSP/T40 - Patient Health Plan Eligibility Verification Transaction	
Council for Affordable Quality Healthcare (CAQH) Phase II Core #270 Connectivity Rule v2.0.0	HITSP/T85 – Administrative Transport to Health Plan	
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	
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, HITSP/C84 and HITSP/C90
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/C84
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/C84

Standard Name	HITSP Construct	Remarks/ Minor Gaps
Health Level Seven (HL7) HL7 Version 3 Standard: Clinical Document Architecture (CDA), Release 2	HITSP/C84 - Consult and History & Physical Note HITSP/C37 - Lab Report Document HITSP/C48 - Encounter Document Using IHE Medical Summary (XDS-MS)	
Health Level Seven (HL7) Implementation Guide for CDA Release 2: History and Physical (H&P) Notes	HITSP/C84 - Consult and History & Physical Note	
Health Level Seven (HL7) Implementation Guide for CDA Release 2: Consultation Note	HITSP/C84 - Consult and History & Physical Note	
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)	
Health Level Seven (HL7) Standard Code Set CVX - Vaccines Administered	HITSP/C80 - Clinical Document and Message Terminology	Vocabularies are enabled via HITSP/C32
Health Level Seven (HL7) Standard Code Set MVX - Manufacturers of Vaccines	HITSP/C80 - Clinical Document and Message Terminology	Vocabularies are enabled via HITSP/C32
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	
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/TP22 - Patient ID Cross-Referencing HITSP/T23 - Patient Demographics Query	
Health Level Seven (HL7) Version 2.5.1	HITSP/ T14 - Send Laboratory Result Message HITSP/C36 - Lab Result Message Component	
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, HITSP/C84 and HITSP/C90
Health Level Seven (HL7) Version 3.0 Clinical Genomics; Pedigree, Release 1	HITSP/C90 – Clinical Genomic Decision Support	
Health Level Seven (HL7) Version 3.0 Context-Aware Information Retrieval Specification: URL Implementation Guide	HITSP/ T81 - Retrieval of Medical Knowledge	

Standard Name	HITSP Construct	Remarks/ Minor Gaps
Health Level Seven (HL7) Version 3.0 Privacy Consent related specifications RCMR_RM010001 - Data Consent	HITSP/TP30 - Manage Consent Directives	
HUGO Gene Nomenclature Committee at the European Bioinformatics Institute - Gene Names	HITSP/C80 - Clinical Document and Message Terminology	Vocabularies are enabled via HITSP/C90
Human Genome Variation Society (HGVS) - Description of Sequence Variants – February, 20, 2008	HITSP/C80 - Clinical Document and Message Terminology	Vocabularies are enabled via HITSP/C90
Integrating the Healthcare Enterprise (IHE) Exchange of Personal Health Record Content (XPHR)	HITSP/C32 - Summary Documents Using HL7 Continuity of Care Document (CCD)	
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) –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 (ATNA) Integration Profile	HITSP/T15 - Collect and Communicate Security Audit Trail	
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 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 5.0 or later, Patient Demographics Query (PDQ) Integration Profile	HITSP/T23 - Patient Demographics Query	
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework Supplement 2008 - 2009, Pediatric Demographics, Draft for Trial Implementation (August 22, 2008)	HITSP/T23 - Patient Demographics Query	

Standard Name	HITSP Construct	Remarks/ Minor Gaps
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	
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/TP13 - Manage Sharing of Documents HITSP/TP30 - Manage Consent Directives	
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) ITI Technical Framework Supplement 2008-2009 Sharing Value Sets (SVS)	HITSP/T66 – Retrieve Value Set	
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 Name	HITSP Construct	Remarks/ Minor Gaps
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) Radiology Technical Framework Revision 8.0	HITSP/TP89 – Sharing Imaging Results	
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/C36 - Lab Result Message HITSP/C80 - Clinical Document and Message Terminology	HITSP/C80 Vocabularies are enabled via HITSP/C32, HITSP/C48, HITSP/C84 and HITSP/C90
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/C84
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/C84
Logical Observation Identifiers Names and Codes (LOINC®)	HITSP/C80 - Clinical Document and Message Terminology	Vocabularies are enabled via HITSP/C32, HITSP/C48, HITSP/C84 and HITSP/C90

Standard Name	HITSP Construct	Remarks/ Minor Gaps
National Cancer Institute (NCI) Thesaurus	HITSP/C80 - Clinical Document and Message Terminology	Vocabularies are enabled via HITSP/C32, HITSP/C48 and HITSP/C84
National Center for Biotechnology Information (NCBI) - Genetic Reference Sequences	HITSP/C80 - Clinical Document and Message Terminology	Vocabularies are enabled via HITSP/C90
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/C84
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 and HITSP/C48
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	
Unified Code for Units of Measure (UCUM)	HITSP/C80 - Clinical Document and Message Terminology	Vocabularies are enabled via HITSP/C32, HITSP/C48, HITSP/C84 and HITSP/C90
United States Postal Service (USPS) – Postal Codes	HITSP/C80 - Clinical Document and Message Terminology	Vocabularies are enabled via HITSP/C32, HITSP/C48, HITSP/C84 and HITSP/C90
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/C84

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 Name	Reason for Use
No applicable informative reference standards	

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
IER41	Ability to receive report including analysis of risk from a Genetic Clinical Decision Support System	No way to receive a Risk Analysis report into an EHR/PHR	Care Management and Health Records Domain TC will investigate current standards The resulting Risk Analysis report should use standard Interoperable Clinician/Nursing Terminology with the following local/Interoperable language agreed to by HITSP: This 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

Requirement Number	Summary Description	Identified Gaps	Recommended Resolution
IER44	Ability to: Send/receive genetic test orders	No way to send a lab order to a genetic/genomic testing laboratory	Evaluating the creation of construct for lab orders is on the Care Management and Health Records Domain TC 2009 roadmap
IER44 IER23	Ability to: Send/receive genetic test orders, and Request or provide additional information	No way to receive genetic results. The HL7 standard is still under development	The intent is to constrain HITSP/C36 – Lab Result Message and HITSP/C37 – Lab Report Document usage here to the HL7 standard once it is ready
IER25	Send/receive Decision Support data	The component for clinical decision support does not exist in HITSP	Track HL7 work in this area
DR4 DR5 IER20 IER19	Personal genetic/genomic data Family genetic/genomic information Send/receive genomic information Send/receive genetic/genomic test results	HITSP/C36 – Lab Result Message is necessary but not sufficient to communicate genomic lab results. More detailed implementation guidance is necessary to satisfy the requirements.	Pending approval of 2009 HL7 2.5.1 ballot

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
No applicable overlaps			

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 HITSP's Personalized Healthcare specification, available at the www.hitsp.org Web Site.

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 Healthcare Information Technology Standards Panel (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.

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:

Table 6.1-1 Description of Standards

Standard	Description
Accredited Standards Committee (ASC) X12 270 and 271 Transaction Standards Version 4010, using the Insurance Subcommittee (X12N) Implementation Guides Version Reference Numbers 004010X92	Detailed Implementation Guides based on release 004010 of the X12 standards. These Implementation Guides provide details on the use of X12 standards to accomplish specific transaction functions. Some of the version 004010 Implementation Guides, but not all, have been adopted as Implementation Specifications under HIPAA. Implementation Guides are published by Washington Publishing Company. For more information visit www.wpc-edi.com.
Accredited Standards Committee (ASC) X12 270 and 271 Transaction Standards Version 4010, using the Insurance Subcommittee (X12N) Addenda 004010X92A1	Many of the version X12N 004010 Implementation Guides, including all of those adopted under HIPAA, have Addenda that contain updates -- only -- to the original Implementation Guides. These Addenda are identified as version 004010A1. Implementation Guide 004010X092A1 describes transactions for Health Care Eligibility Benefit Inquiry and Response. Implementation Guides are published by Washington Publishing Company. For more information visit www.wpc-edi.com.
Accredited Standards Committee (ASC) X12 270 Transaction Version Standards Release 004010	The objective of the Health Care Eligibility/Benefit Inquiry (270) is to provide for the exchange of eligibility inquiry to individuals within a health plan. This transaction can be used by health care providers to request coverage and payment information on the member/insured in a batch environment where real time processing is not required. This transaction is also used to provide additional patient eligibility information to support administrative reimbursement for health care products and services. This standard is required by HIPAA.
Accredited Standards Committee (ASC) X12 271 Transaction Version Standards Release 004010	The objective of the Health Care Eligibility, Coverage, or Benefit Information (271) is to provide for the response to eligibility inquiries about individuals within a health plan. This transaction can be used to receive coverage and payment information on a member/insured in a batch environment where real time processing is not required. This transaction is also used to provide additional patient eligibility information to support administrative reimbursement for health care products and services. This standard is required by HIPAA.
Accredited Standards Committee (ASC) X12 278 Transaction Version Standards Release 004010	The objective of the Health Care Service Review – Request for Review and Response (278) is to provide for the exchange of service review requests from a healthcare provider to a health plan, and a corresponding response from the health. plan to that healthcare provider. This transaction can be used by health care providers to request approval and coverage information on the patient for a particular service type or service. This standard is required by HIPAA. This standard is required by regulatory guidance.
Accredited Standards Committee (ASC) X12 278 transactions standard version 4010, using the Insurance Subcommittee (X12N) Implementation Guides Version Reference Numbers 004010X94	Detailed Implementations Guide based on release 004010 of the X12 standards. These Implementation Guides provide details on the use of X12 standards to accomplish specific transaction functions. Some of the version 004010 Implementation Guides, but not all, have been adopted as Implementation Specifications under HIPAA. This standard is required by regulatory guidance. Implementation Guides are published by Washington Publishing Company. For more information visit www.wpc-edi.com.

Standard	Description
Accredited Standards Committee (ASC) X12 278 Transactions Standard Version 4010, using the Insurance Subcommittee (X12N) Addenda 004010X94A1	Many of the version X12N 004010 Implementation Guides, including all of those adopted under HIPAA, have Addenda that contain updates -- only -- to the original Implementation Guides. These Addenda are identified as version 004010A1. Implementation Guide 004010X0941 describes transactions for Health Care Service Review – Request for Review and Response. Implementation Guides are published by Washington Publishing Company. For more information visit www.wpc-edi.com. This standard is required by regulatory guidance.
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 www.x12.org.
American Medical Association (AMA) Current Procedural Terminology (CPT®) Fourth Edition (CPT-4); CPT Evaluation and Management Codes	A uniform coding system used primarily to identify medical services and procedures furnished by physicians and other healthcare professionals. For more information visit www.ama-assn.org.
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 www.cdc.gov.
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 www.caqh.org.
Council for Affordable Quality Healthcare (CAQH) Committee on Operating Rules for Information Exchange (CORE) Phase II #258 Normalizing Last Name Rule v2.0.0	Provides 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 www.caqh.org.
Council for Affordable Quality Healthcare (CAQH) Committee on Operating Rules for Information Exchange (CORE) Phase II #259 AAA Error Code Reporting Rule v2.0.0	Provides 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 www.caqh.org.
Council for Affordable Quality Healthcare (CAQH) Committee on Operating Rules for Information Exchange (CORE) Phase II #260 Eligibility Data Content Rule v2.0.0	Provides 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 www.caqh.org.

Standard	Description
Council for Affordable Quality Healthcare (CAQH) Phase II Core #270 Connectivity Rule v2.0.0	The CORE #270 Connectivity Rule v2.00 developed by CAQH/CORE Connectivity Subgroup. It includes the following: Scope definition, rationale and policy guidelines Message envelope and submitter authentication standards (payload agnostic) Basic conformance requirements for stakeholders in terms of the chosen standards Message envelope metadata names, syntax and semantics Message envelope schemas and examples of use Error handling Glossary of terms For further information visit www.caqh.org.
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 medical.nema.org.
Federal Information Processing Standards (FIPS) Codes for the Identification of the States, the District of Columbia and the Outlying Areas of the United States, and Associated Areas Publication # 5-2, May, 1987	A set of two-digit numeric codes and a set of two-letter alphabetic codes for representing the 50 states, the District of Columbia and the outlying areas of the United States, and associated areas. The standard covers all land areas under the sovereignty of the United States, the freely associated states of Federated States of Micronesia and Marshall Islands, and the trust territory of Palau. For more information visit www.itl.nist.gov. NOTE: ASC X12 transactions and ASC X12N Implementation Guides do not allow use of this standard; instead they require use of the U.S. Postal Service's National Zip Code and Post Office Directory -- which provides similar alphabetic code values.
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 www.fda.gov/oc/datacouncil/SRS.htm
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 www.fda.gov/cder/ndc/database/default.htm
Health Level Seven (HL7) HL7 Version 3 Standard: Clinical Document Architecture (CDA), Release 2	The HL7 Clinical Document Architecture is an XML-based document markup standard that specifies the structure and semantics of clinical documents for the purpose of exchange. CDA is one instantiation of HL7's Version 3.0 Reference Information Model (RIM) into a specific message format. Of particular focus for HITSP Interoperability Specifications are message formats for Laboratory Results and Continuity of Care (CCD) documents. Release 2 of the HL7 Clinical Document Architecture (CDA) is an extension to the original CDA document markup standard that specifies the structure and semantics of clinical documents for the purpose of exchange. CDA R2 includes a prose document in HTML, XML schemas, data dictionary, and sample CDA documents. CDA R2 further builds upon other HL7 standards beyond just the Version 3.0 Reference Information Model (RIM) and incorporates Version 3.0 Data Structures, Vocabulary, and the XML Implementation Technology Specifications for Data Types and Structures. For more information visit www.hl7.org.
Health Level Seven (HL7) Implementation Guide for CDA Release 2: Consultation Note	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.

Standard	Description
Health Level Seven (HL7) Implementation Guide for CDA Release 2: History and Physical (H&P) Notes	The HL7 Implementation Guide for CDA Release 2: History and Physical (H&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.
Health Level Seven (HL7) Implementation Guide: CDA Release 2 – Continuity of Care Document (CCD), April 01, 2007	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 www.hl7.org.
Health Level Seven (HL7) Standard Code Set CVX - Vaccines Administered	The CDC's National Center of Immunization and Respiratory Diseases (NCIRD) maintains the HL7 external code set CVX. The implementation of the HL7 standard for immunization data exchange is described in Chapter 4 of the HL7 standard. The codes in HL7 Version 2.3 table 0292, represented the initial content of the external CVX code set. Since vaccines have to be added to this table more quickly than new versions of HL7 are released, this document represents the most up-to-date version of the CVX code set. Items have been added. Others have been added for planning purposes, pending FDA approval. For more information visit http://www.cdc.gov/vaccines/programs/iis/stds/cvx.htm
Health Level Seven (HL7) Standard Code Set MVX - Manufacturers of Vaccines	The CDC's National Center for Immunization and Respiratory Diseases (NCIRD) maintains the HL7 external code set MVX. The implementation of the HL7 standard for immunization data exchange is described in Chapter 4 of the HL7 standard. The codes in HL7 Version 2.3 table 0227 represent the initial content of the external MVX code set. This document represents the most up-to-date version of the MVX code set. For more information visit http://www.cdc.gov/vaccines/programs/iis/stds/mvx.htm
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 www.hl7.org.
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 www.hl7.org.
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 www.hl7.org.
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 www.hl7.org.

Standard	Description
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 www.hl7.org.
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 www.hl7.org
Health Level Seven (HL7) Version 3.0 Clinical Genomics; Pedigree, Release 1	The HL7 Clinical Genomic Pedigree is an XML-based message markup standard that specifies the structure and semantics of family history for the purpose of exchange. The Pedigree model is one instantiation of HL7's Version 3.0 Reference Information Model (RIM) into a specific message format. This model further builds upon other HL7 standards beyond just the Version 3.0 Reference Information Model (RIM) and incorporates Version 3.0 Data Structures, Vocabulary, and the XML Implementation Technology Specifications for Data Types and Structures. For more information visit www.hl7.org.
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.
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 www.hl7.org.
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 www.genenames.org.
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 *den Dunnen JT and Antonarakis SE (2000). Hum.Mutat. 15:7-12* provide more detail explanation. For more information visit www.hgvs.org/mutnomen/recs.html#intro.

Standard	Description
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.
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 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 www.ihe.net.
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 profile 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. For more information visit www.ihe.net.
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0 or later, Audit Trail and Node Authentication Profile (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. For more information visit www.ihe.net.
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0 or later, Consistent Time (CT) Integration Profile	The Consistent Time Integration Profile (CT) 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 www.ihe.net.
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	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 www.ihe.net.

Standard	Description
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 www.ihe.net.
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 www.ihe.net.
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	The Notification of Document Availability 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 www.ihe.net.
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 www.ihe.net/technical_framework. 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, Revision 4.0 or later, Personnel White Pages profile	The Personnel White Pages (PWP) 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 www.ihe.net.
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Supplement 2008-2009 Sharing Value Sets (SVS)	The Sharing Value Sets (SVS) 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)	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 www.ihe.net.

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 www.ihe.net.
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 www.ihe.net.
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Volume 2 Supplement 2007 – 2008 Cross-Enterprise Document Sharing-B (XDS.b)	The Cross-Enterprise Document Sharing-B Profile (XDS.b) 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 www.ihe.net.
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0 or later, Patient Identifier Cross-Referencing Integration Profile (PIX)	The Patient Identifier Cross-referencing Integration Profile (PIX) 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 www.ihe.net.
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 www.ihe.net.
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Supplement 2007 - 2008 Basic Patient Privacy Consents (BPPC) – Trial Implementation	The Basic Patient Privacy Consents (BPPC) 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 www.ihe.net.

Standard	Description
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 www.ihe.net.
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 www.ihe.net.
Integrating the Healthcare Enterprise (IHE) Radiology Technical Framework Revision 8.0	The IHE Radiology Technical Framework specifies the Cross-Enterprise Document Sharing for Imaging (XDS-I) Integration Profile which enables sharing of imaging documents such as radiology images and reports across healthcare enterprises. XDS-I extends XDS by sharing, locating and accessing DICOM instances from its original local sources, e.g. for radiologists or oncologists. For more information visit www.ihe.net .
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 www.who.int/classifications/icf/en/.
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 www.ihtsdo.com.
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 www.iso.org.
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 www.iso.org.

Standard	Description
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 www.ietf.org.
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 www.ietf.org.
Internet Engineering Task Force (IETF) Tags for Identifying Languages, "Request for Comment" (RFC) # 4646, September, 2006	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 www.ietf.org/rfc/rfc4646.txt.
Logical Observation Identifiers Names and Codes (LOINC®)	A database of universal identifiers for laboratory and other clinical observations. The laboratory portion of the LOINC database contains the usual categories of chemistry, hematology, serology, microbiology (including parasitology and virology), and toxicology; as well as categories for drugs and the cell counts typically reported on a complete blood count or a cerebrospinal fluid cell count. Antibiotic susceptibilities are a separate category. The clinical portion of the LOINC database includes entries for vital signs, hemodynamics, intake/output, EKG, obstetric ultrasound, cardiac echo, urologic imaging, gastroendoscopic procedures, pulmonary ventilator management, selected survey instruments, and other clinical observations. For more information visit www.loinc.org.
National 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 www.cancer.gov.
National Cancer Institute (NCI) Thesaurus: Route of Administration	Route of Administration is the path by which a particular drug product is introduced on or into the body. The medication terminology is maintained by the NCI Thesaurus, 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 www.cancer.gov.
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 www.ncbi.nlm.nih.gov.

Standard	Description
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 www.nlm.nih.gov
National Uniform Billing Committee (NUBC) Uniform Bill Version 2007 (UB-04) Current UB Data Specification Manual Field 22, Patient Discharge Status, Codes	A code set identifying status of patient discharge on an institutional claim (e.g., inpatient, outpatient, hospice, home care). For more information visit www.nubc.org.
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 www.oasis-open.org.
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 Toke Service (STS) model for security tokens including requesting, issuing, renewing, canceling and validating. For more information visit www.oasis-open.org.
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 XCML 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 www.oasis-open.org.
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 www.wpc-edi.com.
Unified Code for Units of Measure (UCUM)	A code system intended to include all units of measures being contemporarily used in international science, engineering, and business. The purpose is to facilitate unambiguous electronic communication of quantities together with their units. The focus is on electronic communication, as opposed to communication between humans. For more information visit aurora.regenstrief.org.
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 www.usps.com.
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 www.usb.org.
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 www.cancer.gov/cancertopics/terminologyresources/page5

6.2 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 6.2-1 Mapping of Use Case Actions to Information Exchange Requirements

Event	Action	Information Exchange Requirement(s) (includes security requirements)	Data Requirements
Personalized Healthcare: Clinician Perspective – Scenario 1 Clinical Assessment			
7.1.1 Construct a personal and family health history & pedigree	7.1.1.1 Request and gather available personal and family health history information in interoperable electronic form	IER58 Send/receive patient health history	DR1 Demographic Data DR3 Clinical History DR4 Personal genetic/genomic data DR5 Family genetic/genomic information
	7.1.1.1a Alternative Action: Request and gather available personal and family health history information in viewable electronic form	IER58 Send/receive patient health history	DR1 Demographic Data DR3 Clinical History DR4 Personal genetic/genomic data DR5 Family genetic/genomic information
	7.1.1.1b Alternative Action: Gather personal and family health history information via interview	None	None
	7.1.1.2 View consolidated available personal and family health history information	None	None
	7.1.1.3 Select personal and family health history information	None	None
	7.1.1.4 Incorporate personal and family health history information	None	None

Event	Action	Information Exchange Requirement(s) (includes security requirements)	Data Requirements
7.1.2 Evaluate relevant genetic testing references and guidelines	7.1.2.1 Receive information from genetic/genomic knowledge repositories and /or decision support modules within EHRs	IER25 Send/receive Decision Support data	DR1 Demographic Data DR3 Clinical History DR4 Personal genetic/genomic data DR5 Family genetic/genomic information DR8 Unstructured Data
	7.1.2.2 Perform interpretation, assembly, validation, and evaluation activities	IER25 Send/receive Decision Support data	DR1 Demographic Data DR3 Clinical History DR4 Personal genetic/genomic data DR5 Family genetic/genomic information DR8 Unstructured Data
7.1.3 Order genetic/genomic tests	7.1.3.1 Write genetic/genomic test order	IER12 Identify Laboratory	DR7 Genomic Laboratory Registry
		IER14 Send/receive health plan eligibility	DR6 Health Plan Eligibility Information
		IER15 Send/receive health plan authorization	DR6 Health Plan Eligibility Information
	7.1.3.2 Communicate genetic/genomic test order to the medical laboratory performing the genetic/genomic testing	IER44 Send/receive genetic test orders	DR1 Demographic Data DR3 Clinical History DR4 Personal genetic/genomic data

Event	Action	Information Exchange Requirement(s) (includes security requirements)	Data Requirements
Personalized Healthcare: Consumer Perspective – Scenario 1 Clinical Assessment			
7.3.1 Share available family health history information	7.3.1.1 Patient may self-report personal and family health history information	IER58 Send/receive patient health history	DR1 Demographic Data DR3 Clinical History DR4 Personal genetic/genomic data DR5 Family genetic/genomic information
	7.3.1.1a Alternative action: Patient uses an interoperable PHR to share his/her medical and family history with the clinician	IER58 Send/receive patient health history	DR1 Demographic Data DR3 Clinical History DR4 Personal genetic/genomic data DR5 Family genetic/genomic information
	7.3.1.1b Alternative action: Patient self-reports personal medical and family history through an electronic portal	None	None
	7.3.1.1c Alternative Action: Patient reports personal medical and family history by interview	None	None
7.3.2 Receive family health history information & pedigree	7.3.2.1 Patient receives newly validated and updated personal and family health history information and pedigree, if appropriate, from clinician	IER21 Receive updated clinical information	DR3 Clinical History
	7.3.2.1a Alternative Action: Patient receives newly validated and updated personal and family health history information and pedigree, if appropriate, via an interoperable PHR	IER21 Receive updated clinical information	DR3 Clinical History
	7.3.2.1b Alternative Action: Clinician reports newly validated and updated personal and family health history information and pedigree, if appropriate, via patient consultation	None	None

Event	Action	Information Exchange Requirement(s) (includes security requirements)	Data Requirements
Personalized Healthcare: Clinician Perspective – Scenario 2 Genetic Testing, Reporting and Clinical Management			
8.1.1 Receive results	8.1.1.1 The ordering clinician receives results from the testing laboratory	IER19 Send/receive genetic/genomic test results	DR1 Demographic Data DR4 Personal genetic/genomic data
		IER23 Request or provide additional information Note: The need for this consultative interchange will be reduced as the field matures and clinicians become more accustomed to genomic testing (Long Form: Consultative interchange directly between the laboratory director/pathologist/medical geneticist and the ordering clinician)	DR1 Demographic Data DR3 Clinical History DR4 Personal genetic/genomic data DR8 Unstructured Data
8.1.2 Perform interpretation and care planning activities	8.1.2.1 Perform interpretation and care planning activities	None	None
	8.1.2.2 Request and view additional information from the testing laboratory	IER23 Request or provide additional information Note: During care plan development the only reason for consultative interchange would be to follow up on mutation. As the system matures this change in interpretation would be flagged and communicated automatically	DR1 Demographic Data DR3 Clinical History DR4 Personal genetic/genomic data DR8 Unstructured Data
		IER41 Receive Risk Analysis Report	DR4 Personal genetic/genomic data
8.1.3 Provide results to consumer and/or next provider	8.1.3.1 Communicate results and additional interpretation from the testing laboratory to the next provider of care	IER20 Send/receive genomic information	DR1 Demographic Data DR3 Clinical History DR4 Personal genetic/genomic data
		IER19 Send/receive genetic/genomic test results	DR1 Demographic Data DR4 Personal genetic/genomic data

Event	Action	Information Exchange Requirement(s) (includes security requirements)	Data Requirements
	8.1.3.2 Communicate results and additional interpretation from the testing laboratory to the patient and other authorized family members	IER20 Send/receive genomic information	DR1 Demographic Data DR3 Clinical History DR4 Personal genetic/genomic data
		IER19 Send/receive genetic/genomic test results	DR1 Demographic Data DR4 Personal genetic/genomic data
Personalized Healthcare: Testing Laboratory Perspective – Scenario 2 Genetic Testing, Reporting and Clinical Management			
8.2.2 Prepare for appropriate test	8.2.2.1 Prepare for and perform the appropriate test based on the genetic/genomic testing orders received	IER14 Send/receive health plan eligibility	DR6 Health Plan Eligibility Information
		IER15 Send/receive health plan authorization	DR6 Health Plan Eligibility Information
	8.2.2.1a Communicate with the ordering clinician to get clarification	IER20 Send/receive genomic information	DR1 Demographic Data DR3 Clinical History DR4 Personal genetic/genomic data
		IER44 Send/receive genetic test orders	DR1 Demographic Data DR3 Clinical History DR4 Personal genetic/genomic data
	8.2.2.2 Make revisions to orders, as necessary	None	None
	8.2.2.3 Return information on order status or any order changes	IER20 Send/receive genomic information	DR1 Demographic Data DR3 Clinical History DR4 Personal genetic/genomic data

Event	Action	Information Exchange Requirement(s) (includes security requirements)	Data Requirements
		IER44 Send/receive genetic test orders	DR1 Demographic Data DR3 Clinical History DR4 Personal genetic/genomic data
8.2.3 Perform the genetic/genomic test	8.2.3.1 Execute the steps required to perform the genetic/genomic test	None	None
8.2.4 Develop and transmit the laboratory result report	8.2.4.1 Develop and transmit the laboratory result report	IER19 Send/receive genetic/genomic test results	DR1 Demographic Data DR4 Personal genetic/genomic data
8.2.5 Provide supplemental information	8.2.5.1 Provide supplemental information to the ordering clinician	IER23 Request or provide additional information	DR1 Demographic Data DR3 Clinical History DR4 Personal genetic/genomic data DR5 Family genetic/genomic information DR8 Unstructured Data
Personalized Healthcare: Consumer Perspective – Scenario 2 Genetic Testing, Reporting and Clinical Management			
8.3.1 Receive results and interpretation	8.3.1.1 Consumer receives laboratory results and clinical interpretation	IER19 Send/receive genetic/genomic test results	DR1 Demographic Data DR4 Personal genetic/genomic data
	8.3.1.2 Consumer provides consent and authorization to share information Note: A consumer may authorize an entity such as a health plan or primary physician or both to share the genetic testing results, the family history, and facts derived from the Clinical Decision Support System with specific care providers as the consumer may designate. Separate approvals should be in place for this subset of data.	IER1 Provide authorization and consent	DR1 Demographic Data
		IER62 Send/receive encounter or full episode of care record	DR1 Demographic Data DR3 Clinical History DR4 Personal genetic/genomic data

6.3 USE CASE SEQUENCE DIAGRAMS

The Use Case 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 are introduced in Section 3.0 of this Interoperability Specification.

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 6.3-1 represents the UML interaction diagram for the Clinical Assessment Scenario 1 from the perspective of the Clinician for Event 7.1.1. The clinician will request the patient's personal and family history and pedigree, preferably in an interoperable form. The clinician will also gather any previous genetic/genomic test results.

Figure 6.3-1 Construct Personal and Family Health History & Pedigree (event 7.1.1)

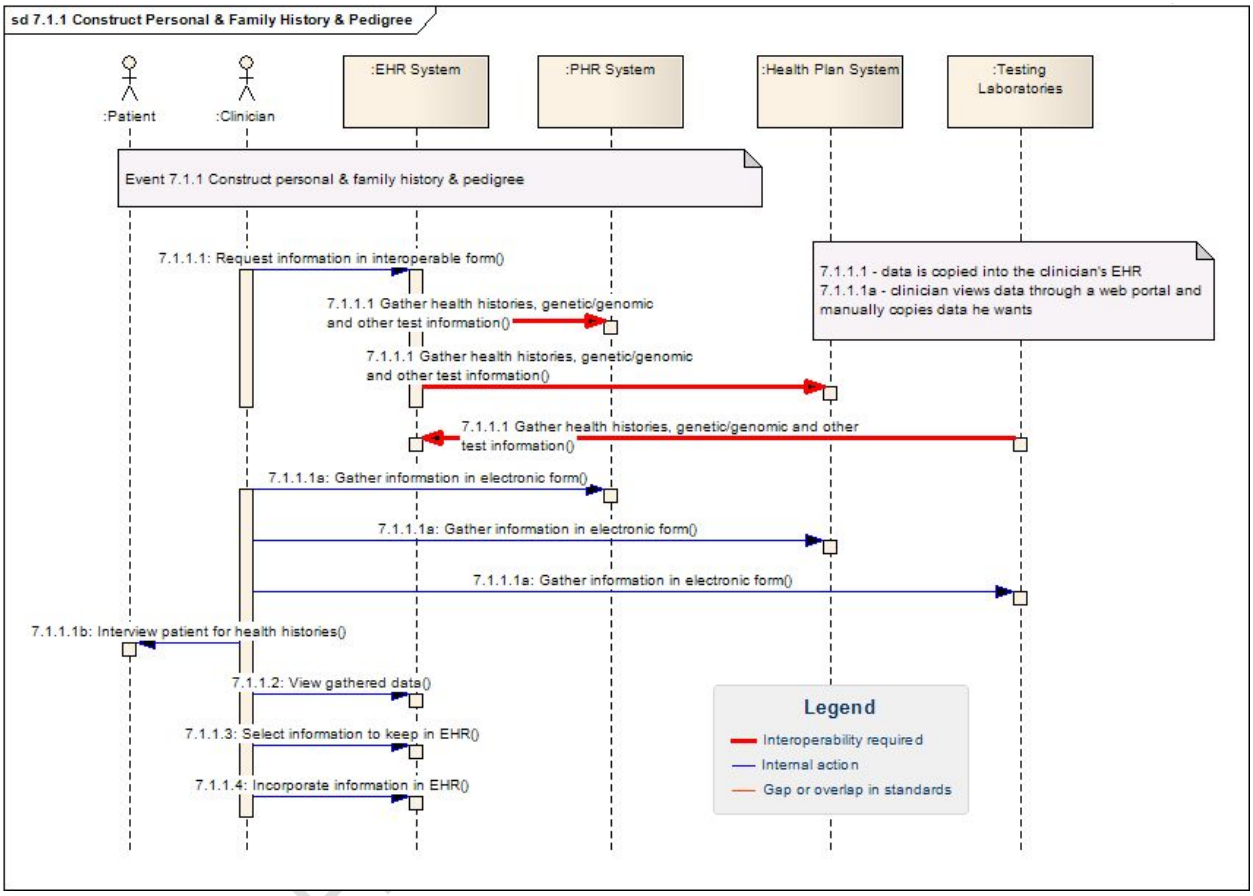


Figure 6.3-2 represents the UML interaction diagram for the Clinical Assessments scenario from the perspective of the Clinician for Events 7.1.2 and 7.1.3. The clinician will gather any genetic/genomic information related to the patient, evaluate this information, and then order the appropriate tests. Prior to ordering any tests the clinician will verify the patient's eligibility with their healthcare Health Plan.

Figure 6.3-2 Evaluate Reference Data and Order Tests (events 7.1.2, 7.1.3)

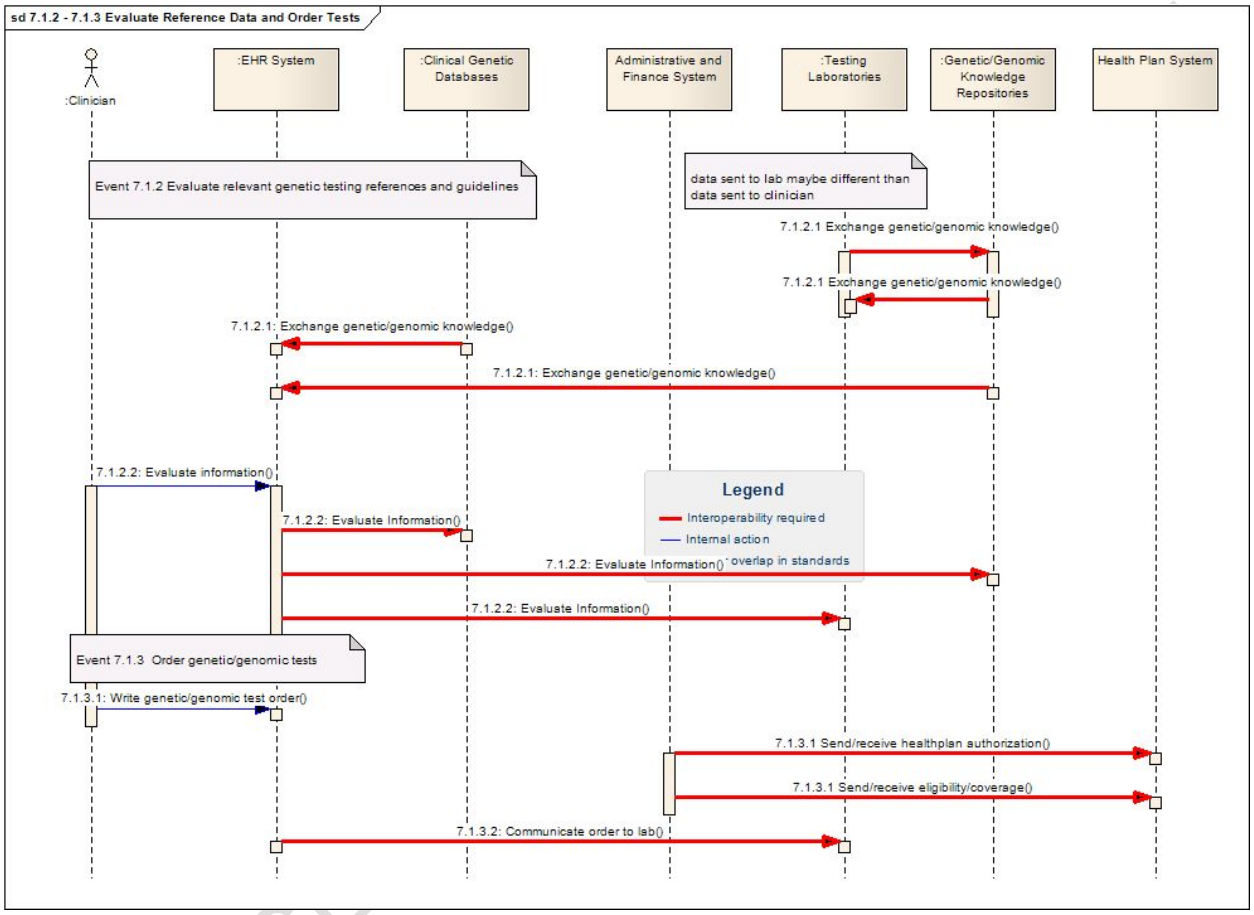


Figure 6.3-3 represents the UML diagram for the Clinical Assessments scenario from the perspective of the Patient for Events 7.3.1 and 7.3.2. The patient will share available health and family history with the clinician and will receive updated information from the clinician.

Figure 6.3-3 Share and Receive Family Health History and Pedigree (events 7.3.1, 7.3.2)

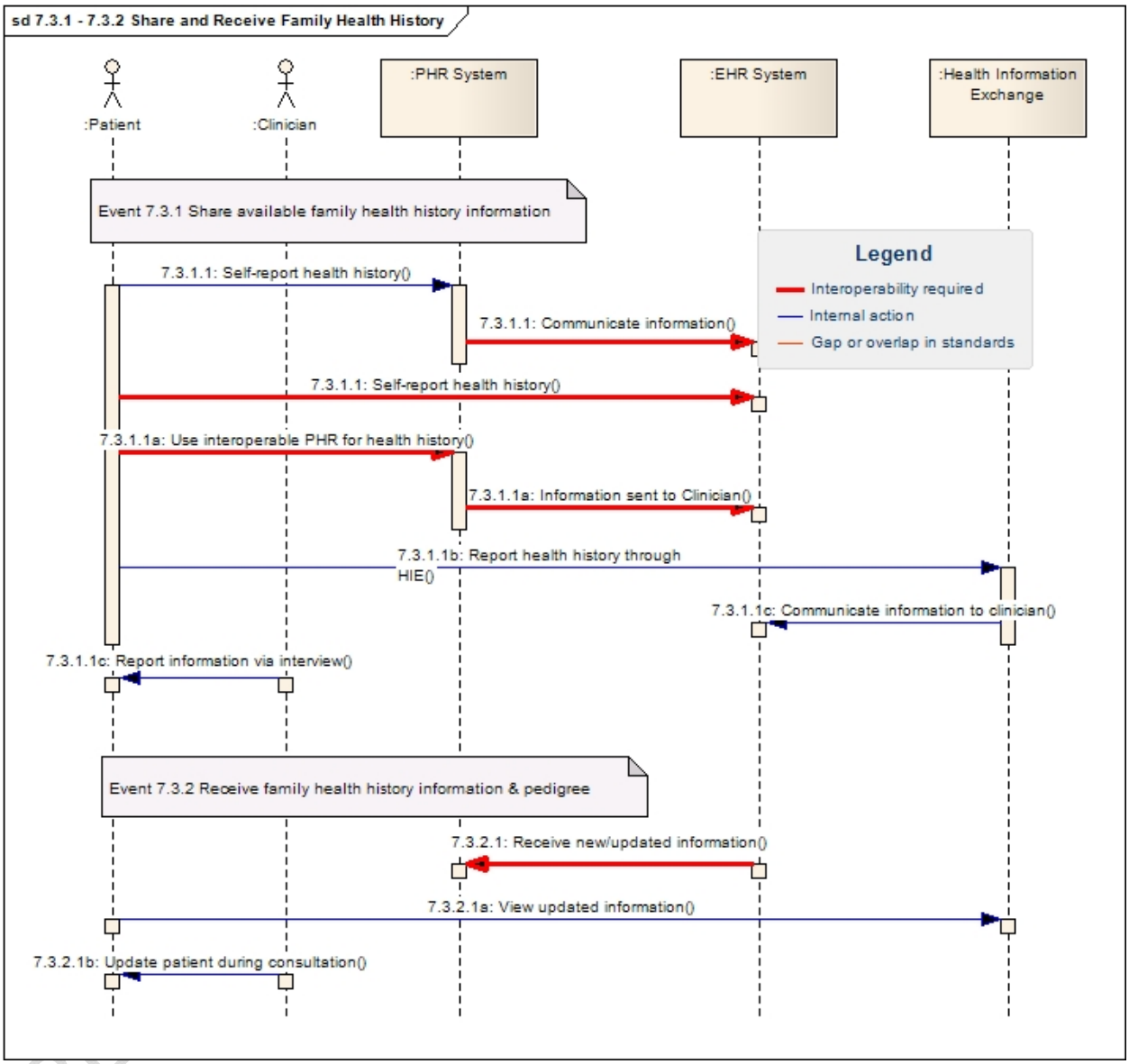


Figure 6.3-4 represents the UML interaction diagram for the Genetic Testing, Reporting and Clinical Management from the perspective of the Clinician for Events 8.1.1 and 8.1.2. The clinician will receive the test results from the Testing Laboratory and will interpret the results, possibly requesting additional information from the Laboratory, and decide on the patient care plan.

Figure 6.3-4 Receive Results and Perform Interpretation (events 8.1.1, 8.1.2)

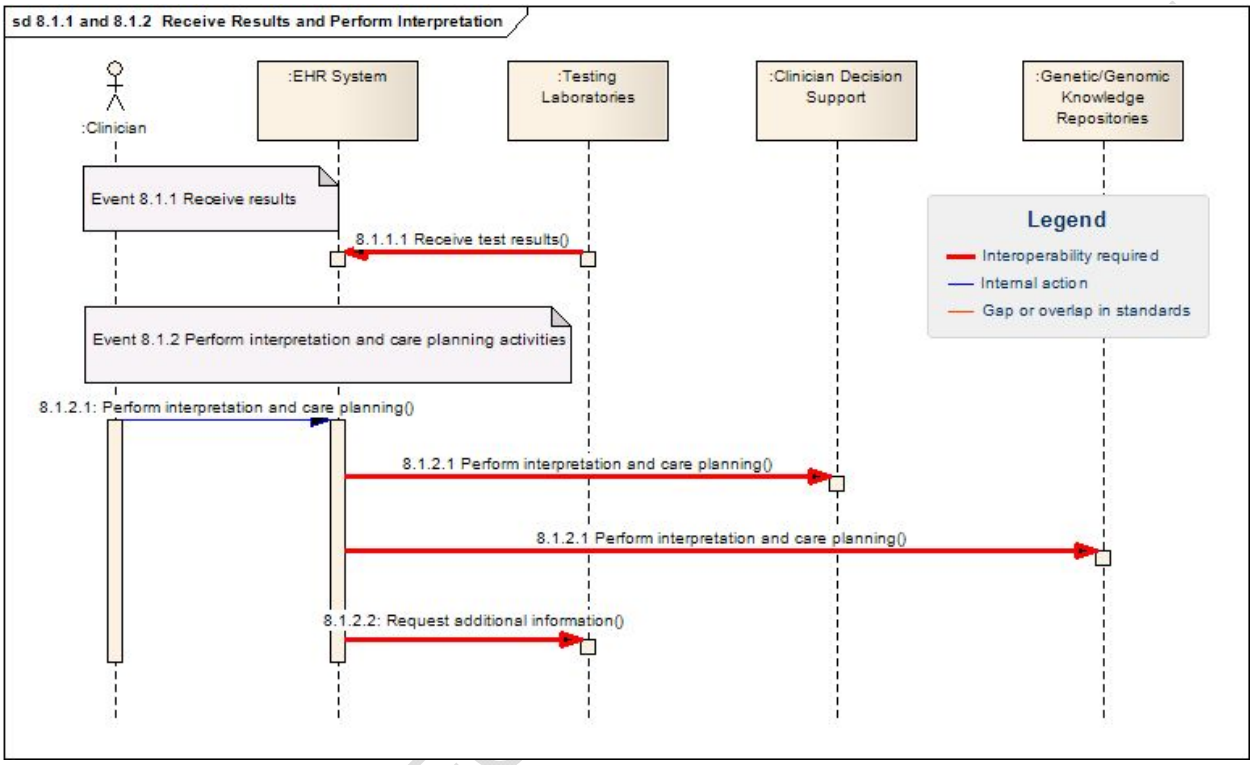


Figure 6.3-5 represents the UML interaction diagram for the Genetic Testing, Reporting and Clinical Management from the perspective of the Clinician for Event 8.1.3. The clinician will forward the results of the genetic/genomic test to the next provider of care and to the patient.

Figure 6.3-5 Provide Results to Patient (event 8.1.3)

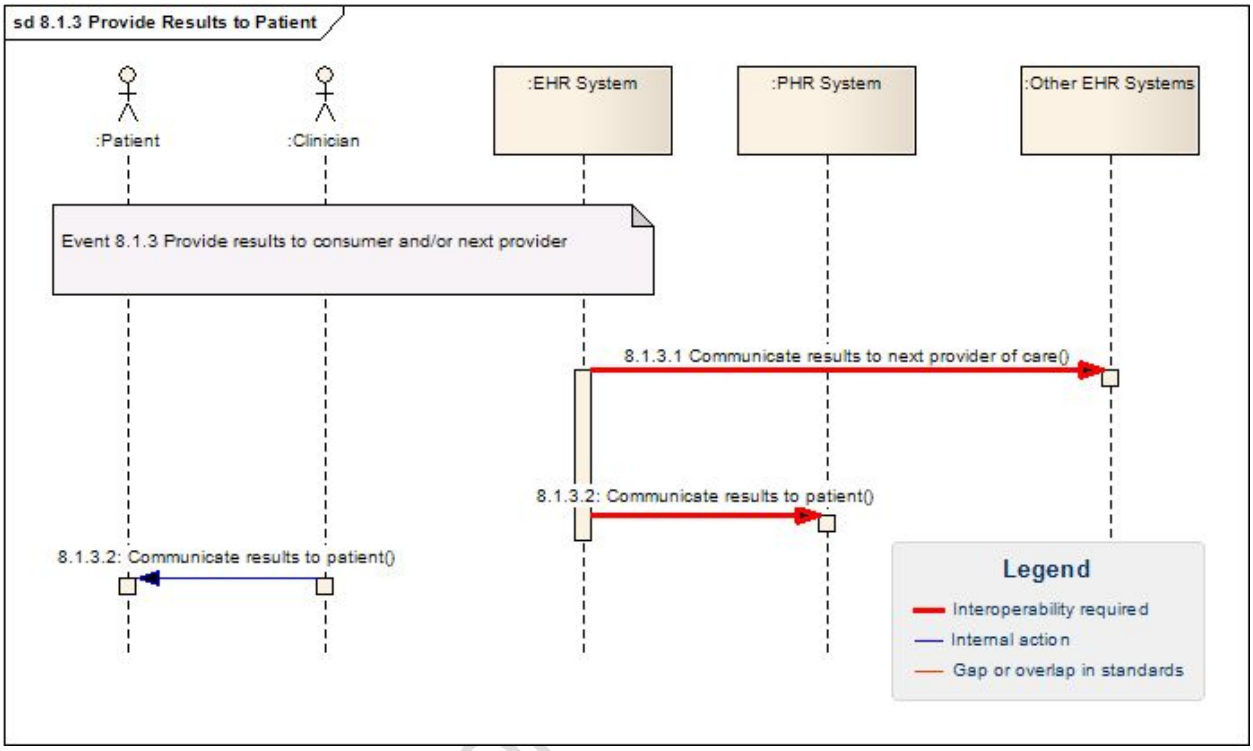


Figure 6.3-6 represents the UML interaction diagram for the Genetic Testing, Reporting and Clinical Management from the perspective of the Testing Laboratory for Events 8.2.1, 8.2.2 and 8.2.3. The Testing Laboratory receives an order from the Clinician. The Laboratory will verify the patient's eligibility and then prepare to perform the test. The Laboratory may need to communicate with the ordering clinician before performing the test.

Figure 6.3-6 Receive Genetic Test Order & Prepare for Test (events 8.2.1, 8.2.2 and 8.2.3)

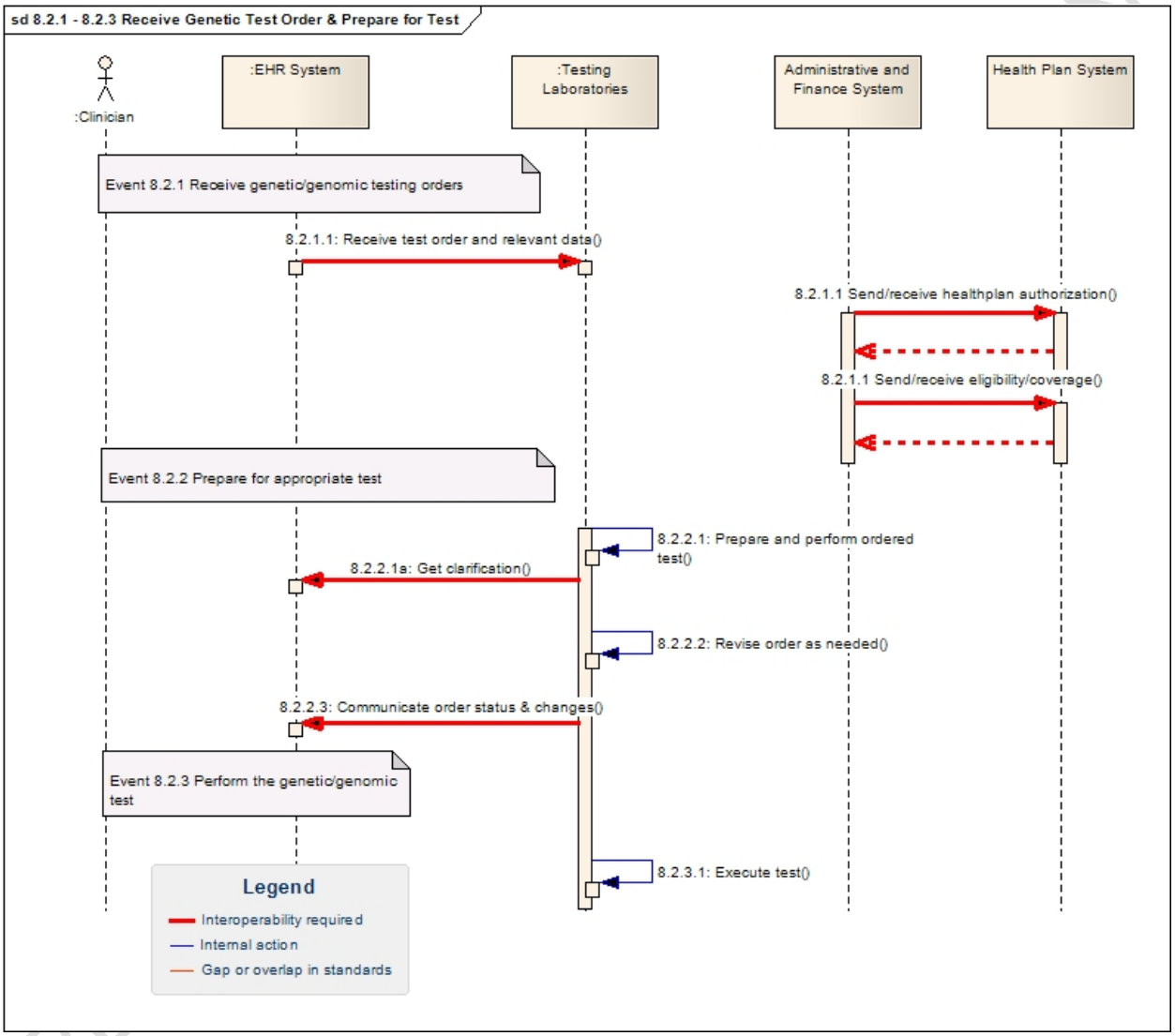


Figure 6.3-7 represents the UML interaction diagram for the Genetic Testing, Reporting and Clinical Management from the perspective of the Testing Laboratory for Events 8.2.4 and 8.2.5. After completing the test, the Laboratory will prepare and transmit a Laboratory Report of the test results to the ordering clinician. The Ordering Clinician may request additional information from the lab after reviewing the report.

Figure 6.3-7 Send Lab Result and Answer Questions (events 8.2.4, 8.2.5)

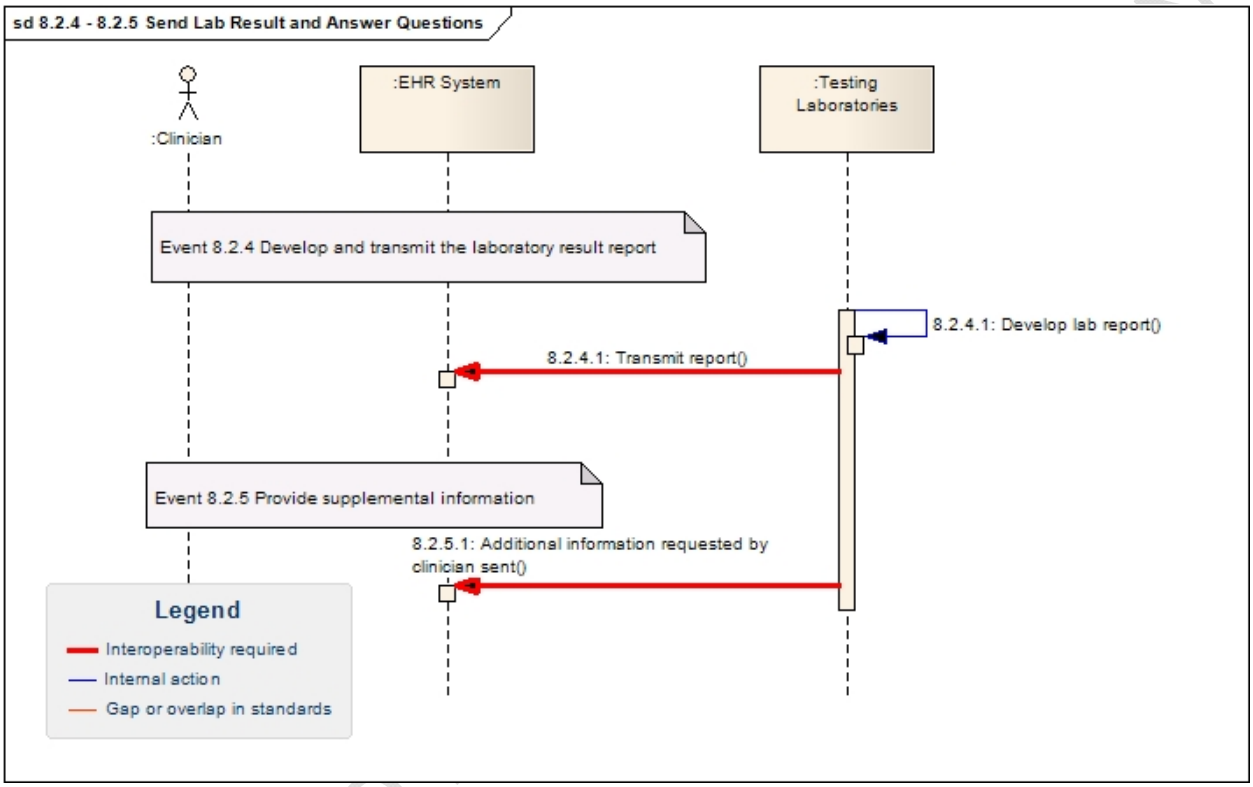
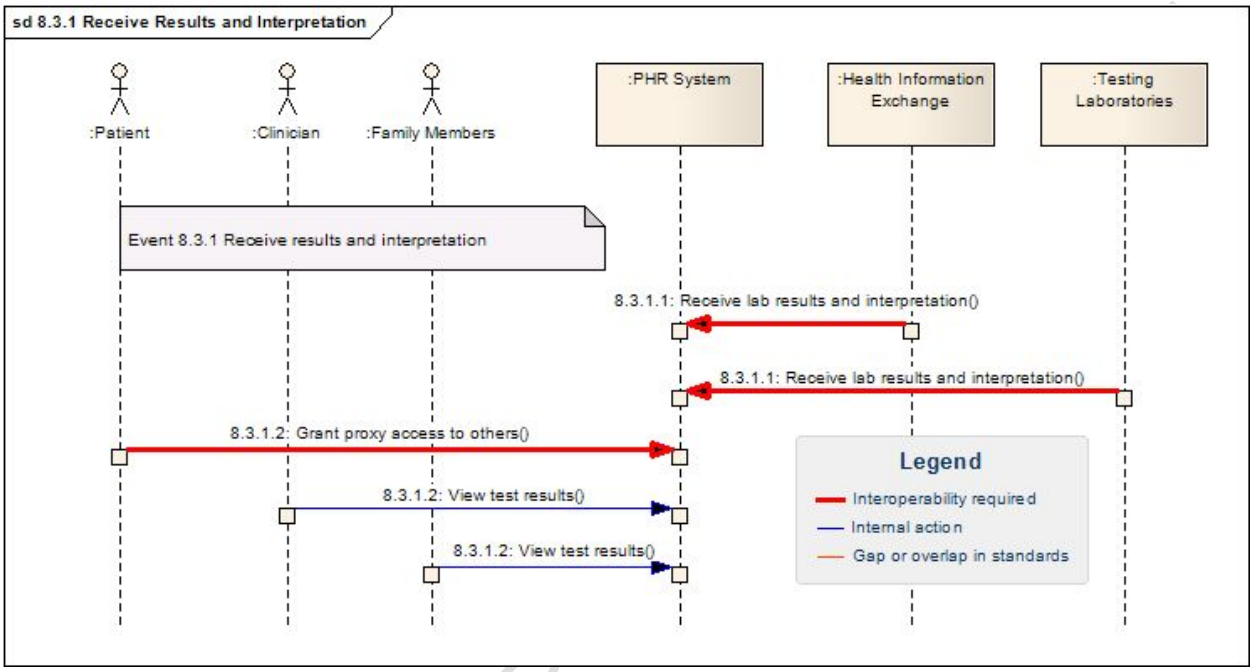


Figure 6.3-8 represents the UML interaction diagram for the Genetic Testing, Reporting and Clinical Management from the perspective of the Patient for Event 8.3.1. After the test has been performed and the report generated, the patient's PHR is updated with the results and interpretations. The patient may then decide to share this information with other providers or family members.

Figure 6.3-8 Receive Results and Interpretation (event 8.3.1)



6.4 MAPPING OF CONSTRUCTS TO INFORMATION EXCHANGE AND DATA REQUIREMENTS

Table 6.4-1 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.

Table 6.4-1 Mapping of Requirements to HITSP Constructs

Information Exchange Requirement Number (IER#)	Data Requirement Number (DR#)	Construct Name
IER23 Request or provide additional information	DR1 Demographic Data DR3 Clinical History DR4 Personal genetic/genomic data DR5 Family genetic/genomic information DR8 Unstructured Data	GAP – HITSP/C36 - Lab Result Message is necessary but not sufficient
		HITSP/C80 - Clinical Document and Message Terminology
		HITSP/C36 - Lab Result Message
		HITSP/C62 - Unstructured Document
		HITSP/T15 - Collect and Communicate Security Audit Trail

Information Exchange Requirement Number (IER#)	Data Requirement Number (DR#)	Construct Name
		HITSP/T16 - Consistent Time
		HITSP/T17 - Secured Communication Channel
		HITSP/T23 - Patient Demographics Query
		HITSP/T31 - Document Reliable Interchange
		HITSP/TP13 - Manage Sharing of Documents
		HITSP/TP20 - Access Control
		HITSP/TP22 - Patient ID Cross-Referencing
		HITSP/TP30 - Manage Consent Directives
		HITSP/T29 - Notification of Document Availability
		HITSP/C19 - Entity Identity Assertion
		HITSP/T66 - Retrieve Value Set
IER58 Send/receive patient health history	DR1 Demographic Data DR3 Clinical History DR4 Personal genetic/genomic data DR5 Family genetic/genomic information	HITSP/C19 - Entity Identity Assertion
		HITSP/C32 - Summary Documents Using HL7 Continuity of Care Document (CCD)
		HITSP/C80 - Clinical Document and Message Terminology
		HITSP/C36 - Lab Result Message
		HITSP/C48 Encounter Document Using IHE Medical Summary (XDS-MS)
		HITSP/C62 - Unstructured Document
		HITSP/C84 - Consult and History & Physical Note
		HITSP/T15 - Collect and Communicate Security Audit Trail
		HITSP/T16 - Consistent Time
		HITSP/T17 - Secured Communication Channel
		HITSP/T23 - Patient Demographics Query
		HITSP/T29 - Notification of Document Availability
		HITSP/T31 - Document Reliable Interchange
		HITSP/T33 - Transfer of Documents on Media
		HITSP/T64 - Identify Communication Recipients
		HITSP/TP13 - Manage Sharing of Documents
		HITSP/TP20 - Access Control
		HITSP/TP22 - Patient ID Cross-Referencing
IER1 Provide authorization and consent	DR1 Demographic Data	HITSP/C19 - Entity Identity Assertion
		HITSP/T15 - Collect and Communicate Security Audit Trail
		HITSP/T16 - Consistent Time

Information Exchange Requirement Number (IER#)	Data Requirement Number (DR#)	Construct Name
		HITSP/T17 - Secured Communication Channel
		HITSP/T64 - Identify Communication Recipients (service)
		HITSP/TP13 - Manage Sharing of Documents
		HITSP/TP20 - Access Control
		HITSP/TP30 - Manage Consent Directives
IER62 Send/receive encounter or full episode of care record	DR1 Demographic Data DR3 Clinical History DR4 Personal genetic/genomic data	HITSP/C19 - Entity Identity Assertion
		HITSP/C48 - Encounter Document Using IHE Medical Summary (XDS-MS)
		HITSP/C84 – Consult and History & Physical Note
		HITSP/T15 - Collect and Communicate Security Audit Trail
		HITSP/T16 - Consistent Time
		HITSP/T17 - Secured Communication Channel
		HITSP/T23 - Patient Demographics Query
		HITSP/T29 - Notification of Document Availability
		HITSP/T31 - Document Reliable Interchange
		HITSP/T64 - Identify Communication Recipients
		HITSP/TP13 - Manage Sharing of Documents
		HITSP/TP20 - Access Control
		HITSP/TP22 - Patient ID Cross-Referencing
		HITSP/TP30 - Manage Consent Directives
IER20 Send/receive genomic information	DR1 Demographic Data DR3 Clinical History DR4 Personal genetic/genomic data	HITSP/C19 - Entity Identity Assertion
		HITSP/C32 - Summary Documents Using HL7 Continuity of Care Document (CCD)
		HITSP/C80 - Clinical Document and Message Terminology
		HITSP/C36 - Lab Result Message
		HITSP/C37 - Lab Report Document
		HITSP/C48 - Encounter & Discharge Document Using IHE Medical Summary (XDS-MS)
		HITSP/C84 - Consult and History & Physical Note
		HITSP/T15 - Collect and Communicate Security Audit Trail
		HITSP/T16 - Consistent Time
		HITSP/T17 - Secured Communication Channel
		HITSP/T23 - Patient Demographics Query
		HITSP/T29 - Notification of Document Availability

Information Exchange Requirement Number (IER#)	Data Requirement Number (DR#)	Construct Name
		HITSP/T31 - Document Reliable Interchange
		HITSP/T33 - Transfer of Documents on Media
		HITSP/T64 - Identify Communication Recipients
		HITSP/T66 - Retrieve Value Set
		HITSP/TP13 - Manage Sharing of Documents
		HITSP/TP20 - Access Control
		HITSP/TP22 - Patient ID Cross-Referencing
		HITSP/TP30 - Manage Consent Directives
IER15 Send/receive health plan authorization	DR6 Health Plan Eligibility Information	HITSP/T85 – Administrative Transport to Health Plan
		HITSP/T40 - Patient Health Plan Eligibility Verification Transaction
		HITSP/T68 - Patient Health Plan Authorization Request and Response
		HITSP/C19 - Entity Identity Assertion
		HITSP/T15 - Collect and Communicate Security Audit Trail
		HITSP/T16 - Consistent Time
		HITSP/T17 - Secured Communication Channel
		HITSP/TP20 - Access Control
		HITSP/TP30 - Manage Consent Directives
		HITSP/T64 - Identify Communication Recipients
IER14 Send/receive health plan eligibility	DR6 Health Plan Eligibility Information	HITSP/T40 - Patient Health Plan Eligibility Verification Transaction
		HITSP/T68 - Patient Health Plan Authorization Request and Response
		HITSP/T85 – Administrative Transport to Health Plan
		HITSP/C19 - Entity Identity Assertion
		HITSP/T15 - Collect and Communicate Security Audit Trail
		HITSP/T16 - Consistent Time
		HITSP/T17 - Secured Communication Channel
		HITSP/TP20 - Access Control
		HITSP/TP30 - Manage Consent Directives
		HITSP/T64 - Identify Communication Recipients
IER12 Identify Laboratory	DR7 Genomic Laboratory Registry	HITSP/T64 - Identify Communication Recipients
		HITSP/C19 - Entity Identity Assertion
		HITSP/T15 - Collect and Communicate Security Audit Trail
		HITSP/T16 - Consistent Time

Information Exchange Requirement Number (IER#)	Data Requirement Number (DR#)	Construct Name
		HITSP/T17 - Secured Communication Channel
		HITSP/TP20 - Access Control
		HITSP/TP30 - Manage Consent Directives
IER44 Send/receive genetic test orders	DR1 Demographic Data DR3 Clinical History DR4 Personal genetic/genomic data	GAP
		HITSP/C19 - Entity Identity Assertion
		HITSP/C62 – Unstructured Document
		HITSP/T15 - Collect and Communicate Security Audit Trail
		HITSP/T16 - Consistent Time
		HITSP/T17 - Secured Communication Channel
		HITSP/T23 - Patient Demographics Query
		HITSP/T29 - Notification of Document Availability
		HITSP/T31 - Document Reliable Interchange
		HITSP/T64 - Identify Communication Recipients
		HITSP/TP13 - Manage Sharing of Documents
		HITSP/TP20 - Access Control
		HITSP/TP22 - Patient ID Cross-Referencing
		HITSP/TP30 - Manage Consent Directives
IER25 Send/receive Decision Support data	DR1 Demographic Data DR3 Clinical History DR4 Personal genetic/genomic data DR5 Family genetic/genomic information DR8 Unstructured Data	GAP
		HITSP/C84 - Consult and History & Physical Note
		HITSP/C90 - Clinical Genomic Decision Support
		HITSP/T15 - Collect and Communicate Security Audit Trail
		HITSP/T16 - Consistent Time
		HITSP/T17 - Secured Communication Channel
		HITSP/T23 - Patient Demographics Query
		HITSP/T29 - Notification of Document Availability
		HITSP/T31 - Document Reliable Interchange
		HITSP/T64 - Identify Communication Recipients
		HITSP/TP13 - Manage Sharing of Documents
		HITSP/TP30 - Manage Consent Directives
		HITSP/C19 - Entity Identity Assertion
		HITSP/TP20 - Access Control
		HITSP/TP22 - Patient ID Cross-Referencing
IER21 Receive	DR3 Clinical History	HITSP/C19 - Entity Identity Assertion

Information Exchange Requirement Number (IER#)	Data Requirement Number (DR#)	Construct Name
updated clinical information		HITSP/C62 - Unstructured Document
		HITSP/C84 – Consult and History & Physical Note
		HITSP/T15 - Collect and Communicate Security Audit Trail
		HITSP/T16 - Consistent Time
		HITSP/T17 - Secured Communication Channel
		HITSP/T23 - Patient Demographics Query
		HITSP/T29 - Notification of Document Availability
		HITSP/T31 - Document Reliable Interchange
		HITSP/T64 – Identify Communication Recipients
		HITSP/TP13 - Manage Sharing of Documents
		HITSP/TP20 - Access Control
		HITSP/TP22 - Patient ID Cross-Referencing
		HITSP/TP30 - Manage Consent Directives
IER19 Send/receive genetic/genomic test results	DR1 Demographic Data DR4 Personal genetic/genomic data	HITSP/C80 - Clinical Document and Message Terminology
		HITSP/C37 - Lab Report Document
		HITSP/C19 - Entity Identity Assertion
		HITSP/C36 - Lab Result Message
		HITSP/C62 - Unstructured Document
		HITSP/T15 - Collect and Communicate Security Audit Trail
		HITSP/T16 - Consistent Time
		HITSP/T17 - Secured Communication Channel
		HITSP/T23 - Patient Demographics Query
		HITSP/T29 - Notification of Document Availability
		HITSP/T31 - Document Reliable Interchange
		HITSP/T33 - Transfer of Documents on Media
		HITSP/T64 - Identify Communication Recipients
		HITSP/T66 – Retrieve Value Set
		HITSP/TP13 - Manage Sharing of Documents
		HITSP/TP20 - Access Control
		HITSP/TP22 - Patient ID Cross-Referencing
		HITSP/TP30 - Manage Consent Directives
IER41 Receive Risk Analysis Report	DR4 Personal genetic/genomic data	Gap (use HITSP/C62 - Unstructured Document until construct is developed)

Information Exchange Requirement Number (IER#)	Data Requirement Number (DR#)	Construct Name
		HITSP/C80 - Clinical Document and Message Terminology
		HITSP/C37 - Lab Report Document
		HITSP/C62 - Unstructured Document
		HITSP/C19 - Entity Identity Assertion
		HITSP/T15 - Collect and Communicate Security Audit Trail
		HITSP/T16 - Consistent Time
		HITSP/T17 - Secured Communication Channel
		HITSP/TP20 - Access Control
		HITSP/TP30 - Manage Consent Directives
		HITSP/T64 - Identify Communication Recipients
		HITSP/T66 – Retrieve Value Set

Table 6.4-2 provides the mapping sorted by constructs.

Table 6.4-2 Mapping of HITSP Constructs to Requirements

Construct Name	Information Exchange Requirement Number (IER#)	Data Requirement Number (DR#)
HITSP/C19 - Entity Identity Assertion	IER23 Request or provide additional information	DR1 Demographic Data DR3 Clinical History DR4 Personal genetic/genomic data DR5 Family genetic/genomic information DR8 Unstructured Data
	IER58 Send/receive patient health history	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data DR5 Family Genetic/genomic information
	IER1 Provide authorization and consent	DR1 Demographic Data
	IER62 Send/receive encounter or full episode of care record	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data
	IER20 Send/receive genomic information	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data
	IER14 Send/receive health plan eligibility	DR6 Health Plan Eligibility Information
	IER15 Send/receive health plan authorization	DR6 Health Plan Eligibility Information

Construct Name	Information Exchange Requirement Number (IER#)	Data Requirement Number (DR#)
	IER12 Identify Laboratory	DR7 Genomic Laboratory Registry
	IER44 Send/receive genetic test orders	DR1 Demographic Data DR3 Clinical History DR4 Personal genetic/genomic data
	IER25 Send/receive Decision Support data	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data DR5 Family Genetic/genomic information DR8 Unstructured Data
	IER21 Receive updated clinical information	DR3 Clinical History
	IER19 Send/receive genetic/genomic test results	DR1 Demographic Data DR4 Personal Genetic/genomic data
	IER41 Receive Risk Analysis Report	DR4 Personal Genetic/genomic data
HITSP/C32 - Summary Documents Using HL7 Continuity of Care Document (CCD)	IER58 Send/receive patient health history	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data DR5 Family Genetic/genomic information
	IER20 Send/receive genomic information	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data
	IER25 Send/receive Decision Support data	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data DR5 Family Genetic/genomic information DR8 Unstructured Data
HITSP/C80 - Clinical Document and Message Terminology	IER23 Request or provide additional information	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data DR5 Family Genetic/genomic information DR8 Unstructured Data
	IER58 Send/receive patient health history	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data DR5 Family Genetic/genomic information
	IER20 Send/receive genomic information	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data
	IER19 Send/receive genetic/genomic test results	DR1 Demographic Data DR4 Personal Genetic/genomic data

Construct Name	Information Exchange Requirement Number (IER#)	Data Requirement Number (DR#)
	IER41 Receive Risk Analysis Report	DR4 Personal Genetic/genomic data
	IER25 Send/receive Decision Support data	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data DR5 Family Genetic/genomic information DR8 Unstructured Data
HITSP/C36 - Lab Result Message	IER23 Request or provide additional information	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data DR5 Family Genetic/genomic information DR8 Unstructured Data
	IER58 Send/receive patient health history	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data DR5 Family Genetic/genomic information
	IER20 Send/receive genomic information	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data
	IER19 Send/receive genetic/genomic test results	DR1 Demographic Data DR4 Personal Genetic/genomic data
HITSP/C37 - Lab Report Document	IER20 Send/receive genomic information	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data
	IER19 Send/receive genetic/genomic test results	DR1 Demographic Data DR4 Personal Genetic/genomic data
	IER41 Receive Risk Analysis Report	DR4 Personal Genetic/genomic data
	IER25 Send/receive Decision Support data	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data DR5 Family Genetic/genomic information DR8 Unstructured Data
HITSP/C48 – Encounter Document Using IHE Medical Summary (XDS-MS)	IER58 Send/receive patient health history	DR1 Demographic Data DR3 Clinical History DR4 Personal genetic/genomic data DR5 Family genetic/genomic information
	IER62 Send/receive encounter or full episode of care record	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data
	IER20 Send/receive genomic information	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data

Construct Name	Information Exchange Requirement Number (IER#)	Data Requirement Number (DR#)
HITSP/C62 Unstructured Document	IER23 Request or provide additional information	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data DR5 Family Genetic/genomic information DR8 Unstructured Data
	IER58 Send/receive patient health history	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data DR5 Family Genetic/genomic information
	IER21 Receive updated clinical information	DR3 Clinical History
	IER19 Send/receive genetic/genomic test results	DR1 Demographic Data DR4 Personal Genetic/genomic data
	IER41 Receive Risk Analysis Report	DR4 Personal Genetic/genomic data
HITSP/C84 - Consult and History & Physical Note	IER58 Send/receive patient health history	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data DR5 Family Genetic/genomic information
	IER62 Send/receive encounter or full episode of care record	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data
	IER20 Send/receive genomic information	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data
HITSP/C90 – Clinical Genomic Decision Support	IER25 Send/receive Decision Support data	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data DR5 Family Genetic/genomic information DR8 Unstructured Data
HITSP/T15 - Collect and Communicate Security Audit Trail	IER23 Request or provide additional information	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data DR5 Family Genetic/genomic information DR8 Unstructured Data
	IER58 Send/receive patient health history	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data DR5 Family Genetic/genomic information
	IER1 Provide authorization and consent	DR1 Demographic Data

Construct Name	Information Exchange Requirement Number (IER#)	Data Requirement Number (DR#)
	IER62 Send/receive encounter or full episode of care record	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data
	IER20 Send/receive genomic information	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data
	IER14 Send/receive health plan eligibility	DR6 Health Plan Eligibility Information
	IER15 Send/receive health plan authorization	DR6 Health Plan Eligibility Information
	IER12 Identify Laboratory	DR7 Genomic Laboratory Registry
	IER44 Send/receive genetic test orders	DR1 Demographic Data DR3 Clinical History DR4 Personal genetic/genomic data
	IER25 Send/receive Decision Support data	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data DR5 Family Genetic/genomic information DR8 Unstructured Data
	IER21 Receive updated clinical information	DR3 Clinical History
	IER19 Send/receive genetic/genomic test results	DR1 Demographic Data DR4 Personal Genetic/genomic data
	IER41 Receive Risk Analysis Report	DR4 Personal Genetic/genomic data
HITSP/T16 - Consistent Time	IER23 Request or provide additional information	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data DR5 Family Genetic/genomic information DR8 Unstructured Data
	IER58 Send/receive patient health history	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data DR5 Family Genetic/genomic information
	IER1 Provide authorization and consent	DR1 Demographic Data
	IER62 Send/receive encounter or full episode of care record	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data
	IER20 Send/receive genomic information	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data
	IER14 Send/receive health plan eligibility	DR6 Health Plan Eligibility Information
	IER15 Send/receive health plan authorization	DR6 Health Plan Eligibility Information

Construct Name	Information Exchange Requirement Number (IER#)	Data Requirement Number (DR#)
	IER12 Identify Laboratory	DR7 Genomic Laboratory Registry
	IER44 Send/receive genetic test orders	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data
	IER25 Send/receive Decision Support data	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data DR5 Family Genetic/genomic information DR8 Unstructured Data
	IER21 Receive updated clinical information	DR3 Clinical History
	IER19 Send/receive genetic/genomic test results	DR1 Demographic Data DR4 Personal Genetic/genomic data
	IER41 Receive Risk Analysis Report	DR4 Personal Genetic/genomic data
HITSP/T17 - Secured Communication Channel	IER23 Request or provide additional information	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data DR5 Family Genetic/genomic information DR8 Unstructured Data
	IER58 Send/receive patient health history	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data DR5 Family Genetic/genomic information
	IER1 Provide authorization and consent	DR1 Demographic Data
	IER62 Send/receive encounter or full episode of care record	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data
	IER20 Send/receive genomic information	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data
	IER14 Send/receive health plan eligibility	DR6 Health Plan Eligibility Information
	IER15 Send/receive health plan authorization	DR6 Health Plan Eligibility Information
	IER12 Identify Laboratory	DR7 Genomic Laboratory Registry
	IER44 Send/receive genetic test orders	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data

Construct Name	Information Exchange Requirement Number (IER#)	Data Requirement Number (DR#)
	IER25 Send/receive Decision Support data	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data DR5 Family Genetic/genomic information DR8 Unstructured Data
	IER21 Receive updated clinical information	DR3 Clinical History
	IER19 Send/receive genetic/genomic test results	DR1 Demographic Data DR4 Personal Genetic/genomic data
	IER41 Receive Risk Analysis Report	DR4 Personal Genetic/genomic data
HITSP/T23 - Patient Demographics Query	IER23 Request or provide additional information	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data DR5 Family Genetic/genomic information DR8 Unstructured Data
	IER58 Send/receive patient health history	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data DR5 Family Genetic/genomic information
	IER62 Send/receive encounter or full episode of care record	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data
	IER20 Send/receive genomic information	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data
	IER44 Send/receive genetic test orders	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data
	IER25 Send/receive Decision Support data	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data DR5 Family Genetic/genomic information DR8 Unstructured Data
	IER21 Receive updated clinical information	DR3 Clinical History
	IER19 Send/receive genetic/genomic test results	DR1 Demographic Data DR4 Personal Genetic/genomic data
HITSP/T29 - Notification of Document Availability	IER23 Request or provide additional information	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data DR5 Family Genetic/genomic information DR8 Unstructured Data

Construct Name	Information Exchange Requirement Number (IER#)	Data Requirement Number (DR#)
	IER58 Send/receive patient health history	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data DR5 Family Genetic/genomic information
	IER62 Send/receive encounter or full episode of care record	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data
	IER20 Send/receive genomic information	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data
	IER44 Send/receive genetic test orders	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data
	IER25 Send/receive Decision Support data	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data DR5 Family Genetic/genomic information DR8 Unstructured Data
	IER21 Receive updated clinical information	DR3 Clinical History
	IER19 Send/receive genetic/genomic test results	DR1 Demographic Data DR4 Personal Genetic/genomic data
HITSP/T31 - Document Reliable Interchange	IER23 Request or provide additional information	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data DR5 Family Genetic/genomic information DR8 Unstructured Data
	IER58 Send/receive patient health history	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data DR5 Family Genetic/genomic information
	IER62 Send/receive encounter or full episode of care record	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data
	IER20 Send/receive genomic information	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data
	IER44 Send/receive genetic test orders	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data

Construct Name	Information Exchange Requirement Number (IER#)	Data Requirement Number (DR#)
	IER25 Send/receive Decision Support data	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data DR5 Family Genetic/genomic information DR8 Unstructured Data
	IER21 Receive updated clinical information	DR3 Clinical History
	IER19 Send/receive genetic/genomic test results	DR1 Demographic Data DR4 Personal Genetic/genomic data
HITSP/T33 - Transfer of Documents on Media	IER58 Send/receive patient health history	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data DR5 Family Genetic/genomic information
	IER20 Send/receive genomic information	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data
	IER19 Send/receive genetic/genomic test results	DR1 Demographic Data DR4 Personal Genetic/genomic data
HITSP/T40 - Patient Health Plan Eligibility Verification Transaction	IER14 Send/receive health plan eligibility	DR6 Health Plan Eligibility Information
	IER15 Send/receive health plan authorization	DR6 Health Plan Eligibility Information
HITSP/T64 – Identify Communication Recipients	IER23 Request or provide additional information	DR1 Demographic Data DR3 Clinical History DR4 Personal genetic/genomic data DR5 Family genetic/genomic information DR8 Unstructured Data
	IER58 Send/receive patient health history	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data DR5 Family Genetic/genomic information
	IER1 Provide authorization and consent	DR1 Demographic Data
	IER62 Send/receive encounter or full episode of care record	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data
	IER20 Send/receive genomic information	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data
	IER14 Send/receive health plan eligibility	DR6 Health Plan Eligibility Information
	IER15 Send/receive health plan authorization	DR6 Health Plan Eligibility Information
	IER12 Identify Laboratory	DR7 Genomic Laboratory Registry

Construct Name	Information Exchange Requirement Number (IER#)	Data Requirement Number (DR#)
	IER44 Send/receive genetic test orders	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data
	IER25 Send/receive Decision Support data	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data DR5 Family Genetic/genomic information DR8 Unstructured Data
	IER21 Receive updated clinical information	DR3 Clinical History
	IER19 Send/receive genetic/genomic test results	DR1 Demographic Data DR4 Personal Genetic/genomic data
	IER41 Receive Risk Analysis Report	DR4 Personal Genetic/genomic data
HITSP/T66 – Retrieve Value Set	IER23 Request or provide additional information	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data DR5 Family Genetic/genomic information DR8 Unstructured Data
	IER20 Send/receive genomic information	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data
	IER19 Send/receive genetic/genomic test results	DR1 Demographic Data DR4 Personal Genetic/genomic data
	IER41 Receive Risk Analysis Report	DR4 Personal Genetic/genomic data
HITSP/T68 - Patient Health Plan Authorization Request and Response	IER14 Send/receive health plan eligibility	DR6 Health Plan Eligibility Information
	IER15 Send/receive health plan authorization	DR6 Health Plan Eligibility Information
HITSP/T85 – Administrative Transport to Health Plan	IER14 Send/receive health plan eligibility	DR6 Health Plan Eligibility Information
	IER15 Send/receive health plan authorization	DR6 Health Plan Eligibility Information
HITSP/TP13 - Manage Sharing of Documents	IER23 Request or provide additional information	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data DR5 Family Genetic/genomic information DR8 Unstructured Data
	IER58 Send/receive patient health history	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data DR5 Family Genetic/genomic information
	IER62 Send/receive encounter or full episode of care record	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data

Construct Name	Information Exchange Requirement Number (IER#)	Data Requirement Number (DR#)
	IER20 Send/receive genomic information	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data
	IER44 Send/receive genetic test orders	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data
	IER25 Send/receive Decision Support data	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data DR5 Family Genetic/genomic information DR8 Unstructured Data
	IER21 Receive updated clinical information	DR3 Clinical History
	IER19 Send/receive genetic/genomic test results	DR1 Demographic Data DR4 Personal Genetic/genomic data
HITSP/TP20 - Access Control	IER23 Request or provide additional information	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data DR5 Family Genetic/genomic information DR8 Unstructured Data
	IER58 Send/receive patient health history	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data DR5 Family Genetic/genomic information
	IER1 Provide authorization and consent	DR1 Demographic Data
	IER62 Send/receive encounter or full episode of care record	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data
	IER20 Send/receive genomic information	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data
	IER14 Send/receive health plan eligibility	DR6 Health Plan Eligibility Information
	IER15 Send/receive health plan authorization	DR6 Health Plan Eligibility Information
	IER12 Identify Laboratory	DR7 Genomic Laboratory Registry
	IER44 Send/receive genetic test orders	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data

Construct Name	Information Exchange Requirement Number (IER#)	Data Requirement Number (DR#)
	IER25 Send/receive Decision Support data	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data DR5 Family Genetic/genomic information DR8 Unstructured Data
	IER21 Receive updated clinical information	DR3 Clinical History
	IER19 Send/receive genetic/genomic test results	DR1 Demographic Data DR4 Personal Genetic/genomic data
	IER41 Receive Risk Analysis Report	DR4 Personal Genetic/genomic data
HITSP/TP22 - Patient ID Cross-Referencing	IER23 Request or provide additional information	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data DR5 Family Genetic/genomic information DR8 Unstructured Data
	IER58 Send/receive patient health history	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data DR5 Family Genetic/genomic information
	IER62 Send/receive encounter or full episode of care record	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data
	IER20 Send/receive genomic information	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data
	IER44 Send/receive genetic test orders	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data
	IER25 Send/receive Decision Support data	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data DR5 Family Genetic/genomic information DR8 Unstructured Data
	IER21 Receive updated clinical information	DR3 Clinical History
	IER19 Send/receive genetic/genomic test results	DR1 Demographic Data DR4 Personal Genetic/genomic data
HITSP/TP30 - Manage Consent Directives	IER23 Request or provide additional information	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data DR5 Family Genetic/genomic information DR8 Unstructured Data

Construct Name	Information Exchange Requirement Number (IER#)	Data Requirement Number (DR#)
	IER58 Send/receive patient health history	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data DR5 Family Genetic/genomic information
	IER1 Provide authorization and consent	DR1 Demographic Data
	IER62 Send/receive encounter or full episode of care record	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data
	IER20 Send/receive genomic information	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data
	IER14 Send/receive health plan eligibility	DR6 Health Plan Eligibility Information
	IER15 Send/receive health plan authorization	DR6 Health Plan Eligibility Information
	IER12 Identify Laboratory	DR7 Genomic Laboratory Registry
	IER44 Send/receive genetic test orders	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data
	IER25 Send/receive Decision Support data	DR1 Demographic Data DR3 Clinical History DR4 Personal Genetic/genomic data DR5 Family Genetic/genomic information DR8 Unstructured Data
	IER21 Receive updated clinical information	DR3 Clinical History
	IER19 Send/receive genetic/genomic test results	DR1 Demographic Data DR4 Personal Genetic/genomic data
	IER41 Receive Risk Analysis Report	DR4 Personal Genetic/genomic data

7.0 DOCUMENT UPDATES

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).

5032, 5033, 5106, 5183, 5184, 5186, 5187, 5188, 5189, 5190, 5191, 5334, 5336, 5340, 5343, 5347, 5354, 5360, 5365

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

Minor editorial changes were made to this construct.

7.1.1 UPDATES FROM PUBLIC COMMENT

- Incorporated all of the 27 Public Comment TC dispositions into the document
- Added the following gap in Section 4.2
    - HITSP/C36 Lab Result Message is necessary but not sufficient to communicate genomic lab results
- Updated UML diagrams
    - Updated document map
    - Corrected use of HITSP/TP13 Manage Sharing of Documents where it is used
    - Added HITSP/T31 Document Reliable Interchange as an option where HITSP/TP13 is used
    - Updated Figure 6.3-8 so that the lab results go from the Lab to the EHR, and from the EHR to the PHR
    - Updated construct names where needed
    - Updated component diagrams to match IER and DR harmonized numbering
    - Updated diagrams for clarity
- Made editorial changes as suggested by public comments
    - Updated construct names and descriptions
    - Updated business actors and stakeholders as per HITSP Harmonized Data Set spreadsheet
    - Corrected use of IERs and DRs as per public comments
    - Corrected discussion language for clarity
- Updated Table 3.2.3-1 to include correct optionalities and constraints as per public comments
- Moved the following tables and figures to the Appendix to allow easier access to the Design Section 3.0 of the Interoperability Specification:

- Section 6.2 – All the tables that provided the Mapping of Use Case Actions to Information Exchange Requirements
- Section 2.2.4 – All the High Level UML Sequence Diagrams
- Table 6.4-2 – Mapping of HITSP constructs to Requirements

7.1.2 GLOBAL CHANGES

The following changes were applied through-out the document for clarification and consistency.

- Added IS business actor in order to consolidate use of Security, Privacy & Infrastructure constructs
  - Removed Locator Service, Data Repository, Patient Identification Service and Registries from UML diagrams, business actor tables and Table 3.2.3-1 and replaced them with Infrastructure Services business actor
- Renumbered IERs and DRs as part of HITSP IER and DR Harmonization Data Set
  - Updated Component diagrams in Section 2.2.4
  - Updated IER and DR numbers and names in Tables: 2.2.2-1, 2.2.2-2, 2.2.3-1, 6.2-1, 6.4-1

7.2 DECEMBER 18, 2008

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