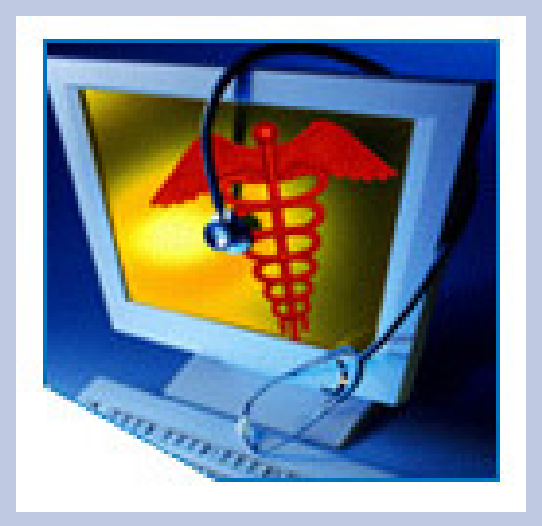
June 27, 2008
Version 1.0

HITSP Personalized Healthcare Use Case Requirements, Design and Standards Selection

HITSP/RDSS58



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Submitted to:

Healthcare Information Technology Standards Panel

Submitted by:
Provider Perspective Technical Committee
(Formerly Care Delivery Technical Committee)

With input from:
Administrative and Finance Domain Technical Committee
Care Management and Health Records Domain Technical Committee
Security, Privacy and Infrastructure Domain Technical Committee (Formerly Security and Privacy Technical Committee)

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1.0 INTRODUCTION

As an introduction to the HITSP Personalized Healthcare Use Case Requirements, Design and Standards Selection, this section describes the purpose of the document, the intended audience for the technical content of the document, and how to use this document. It acknowledges the copyright protections that pertain, and provides a list of key reference documents and background material. If you are already familiar with this information, proceed to Section 2.0 Requirements Analysis.

1.1 PURPOSE

The Requirements, Design and Standards Selection document is used to define the requirements for the Use Case and the detailed HITSP Interoperability Specification design map of existing standards and specifications that will be used to meet the stated requirements. It is intended to describe the process by which the Use Case was analyzed, standards were selected and the design was developed.

1.2 AUDIENCE

The Requirements, Design and Standards Selection document is designed to be used by the HITSP Technical Committees or Work Groups to document their analysis and decisions, other analysts who need to understand and evaluate the requirements, design and selected standards, and by those intending to test the resulting Interoperability Specifications against the Use Case requirements. Understanding and using the relevant set of Interoperability Specifications is a key requirement for establishing interoperability compliance.

1.3 HOW TO USE THIS REQUIREMENTS, DESIGN AND STANDARDS SELECTION DOCUMENT

The Requirements, Design and Standards Selection document is divided into five main related sections. Each section provides background information for the Interoperability Specification. Section 1.0 provides a brief introduction to the document. Users of this document who are familiar with the content may choose to proceed to Section 2.0. In Section 2.0, the Requirements Analysis provides a general overview of the Use Case and the specific requirements of the Use Case including a mapping of the Use Case requirements to the extracted interoperability requirements, the data requirements of the Use Case, and an identification of the scenarios, business actors, their interactions, and data elements used in those interactions. The design for the Interoperability Specification is provided in Section 3.0. This includes the scope of the design, mapping of interoperability requirements to the specific technical requirements, actor interactions and groupings, detailed descriptions of data used by the Use Case actors, and a description of existing or new HITSP constructs that will be used by the Interoperability Specification. Section 4.0 describes the Standards Selection process, provides a table of the selected and candidate standards, a gaps and overlaps discussion and plan for resolution. Section 5.0 describes the next steps in the HITSP standards harmonization process and Section 6.0 provides relevant appendix material.

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1.3.1 CONVENTIONS, ACRONYMS AND RESOURCES/REFERENCES

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

Table 1.3.1-1 Reference Documents

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

1.4 COPYRIGHT PERMISSIONS

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NOTE: HITSP will work with the appropriate standards organizations to obtain applicable copyright information for candidate standards.

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2.0 REQUIREMENTS ANALYSIS

This section provides a high level description of the Personalized Healthcare Use Case as well as the specific requirements that are extracted from the Use Case. It includes the following information:

- Mapping from the Use Case Requirements to the Derived Interoperability Requirements – this table lists the requirements grouped by actor for each event and related action
- Data Element Requirements – this table further describes the data requirements for each specified interoperability requirement and the business actor that is responsible for the data
- Business Actors – this table defines the business actors that are included for the Interoperability Specification
- High-Level Unified Modeling Language (UML) Business Sequence 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

The Personalized Healthcare Use Case Synopsis 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.

The AHIC Detailed 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.

2.2 USE CASE REQUIREMENTS

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

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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 from 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.

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, advance practice 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 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 both 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, 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:

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- 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, and send the report to the ordering clinician

During the review of this Use Case the HITSP Administrative and Financial Domain Technical Committee did not find a requirement for authorization and verification of eligibility for the genetic/genomic test. See Table 2.2.2-2, IER#8 for inclusion.

The HITSP Provider Perspective Technical Committee also ruled out of scope communications with EHR system suppliers for table updates and communications with Genetic/Genomic Knowledge Repositories for looking up reference information.

2.2.1 MAPPING OF USE CASE REQUIREMENTS TO INTEROPERABILITY REQUIREMENTS

This section contains an extraction of business actors, required interactions and conditions/scenarios from the Use Case into a matrix/table. The descriptions for the corresponding requirement numbers are provided in subsequent tables in this section.

Table 2.2.1-1 Mapping of Use Case Requirements to Interoperability Requirements

Use Case	Perspective/ Business Actor	Scenario	Event	Action	Interoperability Requirement(s) (includes security requirements)	Data Requirement Number
Personalized Healthcare	Clinician Perspective	1: Clinical Assessment	7.1.1 Construct a personal & family health history & pedigree	Action 7.1.1.1 Request and gather available personal and family health history information in interoperable electronic form	2	1, 2, 3, 4, 5
				Action 7.1.1.1a Alternative Action: Request and gather available personal and family health history information in viewable electronic form	2	1, 2, 3, 4, 5

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Use Case	Perspective/ Business Actor	Scenario	Event	Action	Interoperability Requirement(s) (includes security requirements)	Data Requirement Number
				Action 7.1.1.1b Alternative Action: Gather personal and family health history information via interview	No interoperability requirements	1, 2, 3, 4, 5
				Action 7.1.1.2 View consolidated available personal and family health history information	No interoperability requirements	1, 2, 3, 4, 5
				Action 7.1.1.3 Select personal and family health history information	No interoperability requirements	1, 2, 3, 4, 5
				Action 7.1.1.4 Incorporate personal and family health history information	No interoperability requirements	1, 2, 3, 4, 5
			7.1.2 Evaluate relevant genetic testing references and guidelines	Action 7.1.2.1 Receive information from genetic/genomic knowledge repositories and /or decision support modules within EHRs	11	Reference only
				Action 7.1.2.2 Perform interpretation, assembly, validation, and evaluation activities	11	Reference only
			7.1.3 Order genetic/genomic tests	Action 7.1.3.1 Write genetic/genomic test order	8, 9, 28, 29	1, 2, 3, 4

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Use Case	Perspective/ Business Actor	Scenario	Event	Action	Interoperability Requirement(s) (includes security requirements)	Data Requirement Number
				Action 7.1.3.2 Communicate genetic/genomic test order to the medical laboratory performing the genetic/genomic testing	9	1, 2, 3, 4
	Consumer perspective	1: Clinical Assessment	7.3.1 Share available family health history information	Action 7.3.1.1 Patient may self-report personal and family health history information	2, 12	1, 2, 5
				Action 7.3.1.1a Alternative action: Patient uses an interoperable PHR to share his/her medical and family history with the clinician	2, 12	1, 2
				Action 7.3.1.1b Alternative action: Patient self-reports personal medical and family history through an electronic portal	2, 12	1, 2
				Action 7.3.1.1c Alternative Action: Patient reports personal medical and family history by interview	No interoperability requirements	1, 2
			7.3.2 Receive family health history information & pedigree	Action 7.3.2.1 Patient receives newly validated and updated personal and family health history information and pedigree, if appropriate, from clinician	13	3

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Use Case	Perspective/ Business Actor	Scenario	Event	Action	Interoperability Requirement(s) (includes security requirements)	Data Requirement Number
				Action 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	13	3
				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	No interoperability requirements	3
	Clinician perspective	2: Genetic Testing, Reporting and Clinical Management	8.1.1 Receive results	Action: 8.1.1.1 The ordering clinician receives results from the testing laboratory	14, 15	1, 4
			8.1.2 Perform interpretation and care planning activities	Action 8.1.2.1 Perform interpretation and care planning activities	15, 16	2, 3, 4
				Action 8.1.2.2 Request and view additional information from the testing laboratory	15, 16, 26, 27	2, 3, 4

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Use Case	Perspective/ Business Actor	Scenario	Event	Action	Interoperability Requirement(s) (includes security requirements)	Data Requirement Number
			8.1.3 Provide results to consumer and/or next provider	Action 8.1.3.1 Communicate results and additional interpretation from the testing laboratory to the next provider of care	5, 14, 17	1, 2, 3, 4
				Action 8.1.3.2 Communicate results and additional interpretation from the testing laboratory to the patient and other authorized family members	5, 14, 17	1, 2, 3, 4
	Testing Laboratory perspective	2: Genetic Testing, Reporting and Clinical Management	8.2.1 Receive genetic/genomic testing orders	Action 8.2.1.1 Receive and capture the genetic/genomic testing order	5, 9, 10	1, 2, 3, 4
			8.2.2 Prepare for appropriate test	Action 8.2.2.1 Prepare for and perform the appropriate test based on the genetic/genomic testing orders received	5, 8, 10, 19	1, 2, 3, 4
				Action: 8.2.2.1a Communicate with the ordering clinician to get clarification	5, 10, 19	1, 2, 3, 4
				Action 8.2.2.2 Make revisions to orders, as necessary	5, 10, 19	1, 2, 3, 4
				Action 8.2.2.3 Return information on order status or any order changes	5, 10, 19	1, 2, 3, 4

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Use Case	Perspective/ Business Actor	Scenario	Event	Action	Interoperability Requirement(s) (includes security requirements)	Data Requirement Number
			8.2.3 Perform the genetic/genomic test	Action 8.2.3.1 Execute the steps required to perform the genetic/genomic test	No interoperability requirements	1, 2, 3, 4
			8.2.4 Develop and transmit the laboratory result report	Action 8.2.4.1 Develop and transmit the laboratory result report	14, 17	1, 4
			8.2.5 Provide supplemental information	Action 8.2.5.1 Provide supplemental information to the ordering clinician	16, 20	1, 4
	Consumer perspective	2: Genetic Testing, Reporting and Clinical Management	8.3.1 Receive results and interpretation	Action 8.3.1.1 Consumer receives laboratory results and clinical interpretation	3, 5, 14	1, 2, 3, 4
				Action 8.3.1.2 Consumer provides consent and authorization to share information	3, 5, 14	1, 2, 3, 4

2.2.2 DATA AND INFORMATION REQUIREMENTS MATRIX

This section contains an extraction of data and information requirements with a listing of the actual data elements and information that meet the described data requirements.

Table 2.2.2-1 provides the Data requirement numbers and descriptions that map to the Data Requirement Number column of table 2.2.1-1 above.

Table 2.2.2-1 Data Element and Information Requirements

Requirement Number	Description
Data Requirement 1	Demographic information, including (but not limited to): • Name • Unique identifier • Race/Ethnicity • Occupation

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Requirement Number	Description
Data Requirement 2	Personal health information, including (but not limited to): • History of specific disorder • Environmental exposure data • Any prior treatment for specific disorders • Relevant non-genetic laboratory test and pathology data • Other clinical data such as radiology study results
Data Requirement 3	Family history information, including (but not limited to): • Disorders of family members • Relevant social data • Environmental exposure data • Ages of condition onset and/or death of various family members • Pedigree in structured form
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)
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 appropriate • Consent/access allowance information

Table 2.2.2-2 below contains an extraction of the interoperability requirements from the Use Case. Interoperability requirements map to the Interoperability Requirements column in table 2.2.1-1 above.

Table 2.2.2-2 Interoperability Exchange Requirements (IER)

Requirement Number	Description
IER 1	The ability to exchange EHR clinical summaries
IER 2	Clinician's system send/receive patient personal health history, family health history, past genetic/genomic and other diagnostic testing information
IER 3	Consumers authorize clinicians and other individuals (e.g., family members) to access/view PHR information (a.k.a., proxy access)
IER 4	The ability to send/receive encounter or full Episode of Care record
IER 5	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 6	The ability to provide decision support software at each step of consultation, which may include algorithms, dashboards, status reports and views
IER 7	The ability of genomic device data to be entered automatically into an EHR/PHR and/or encounter record and provide alerts based upon triggers
IER 8	The ability to identify and appropriately select a particular laboratory based upon the patient's insurance coverage network and/or preferences
IER 9	Send/receive genetic test orders
IER 10	Send/receive requests for clarification of clinician genetics orders
IER 11	Send/receive information from genetic/genomic knowledge repositories and/or decision support modules within EHRs
IER 12	Patient uses an interoperable PHR to share his/her medical and family history (pedigree) with the clinician

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Requirement Number	Description
IER 13	Patient receives newly validated and updated personal and family health history information and pedigree, if appropriate, via an interoperable PHR
IER 14	LIS sends and clinician receives the genetic/genomic test results and associated narratives via an EHR or other clinical data system
IER 15	Consultative interchange directly between the laboratory director/pathologist/medical geneticist and the ordering clinician
IER 16	Send/receive request for additional information from the testing laboratory, such as genomic sequence information
IER 17	Communicate results, interpretations and risk from the testing laboratory to the patient and other authorized providers and family members
IER 18	Send/receive genetic/genomic testing orders, other important clinical information, and any previously reported genetic test results deemed necessary for the testing from a structured, standards-based electronic message
IER 19	Send/receive updated genomic test order
IER 20	Clinician requests additional test results information
IER 21	Data delivery
IER 22	Data retrieval
IER 23	Subject-data matching
IER 24	Support for personally controlled health records
IER 25	Consumer-controlled access decisions
IER 26	Ability to send structured family history and genetic test results to a Genetic Clinical Decision Support System
IER 27	Ability to receive report including analysis of risk from a Genetic Clinical Decision Support System
IER 28	Ability to identify and verify eligibility from payor
IER 29	Ability to obtain authorization for service from payor

Finally, Table 2.2.2-3 below provides a mapping of the business actors from the Use Case, to the interoperability requirements from Table 2.2.2-2. Business Actors with no interoperability requirements are noted as not applicable.

Table 2.2.2-3 Business Actors to Interoperability Exchange Requirements

Business Actor	Interoperability Exchange Requirements
Clinical Genetic Databases	NA
Clinicians	NA
Consumers	NA
Electronic Health Record (EHR) System Suppliers	NA
Genetic Specialists	NA
Genetic/Genomic Knowledge Repositories	16, 18, 20, 21, 22
Health Information Management (HIM) Personnel	NA
Health Researchers	NA
Healthcare Entities	NA
Healthcare Payor Systems	1, 4, 6, 8, 16, 21, 22, 23
Knowledge Engineers	NA
Laboratory Organizations	NA

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Business Actor	Interoperability Exchange Requirements
Manufacturers/Distributors	NA
Patients	NA
Personal Health Record (PHR) System Suppliers	NA
Public Health Agencies/Organizations	1, 2, 3, 4, 9, 10, 11, 15, 16, 17, 18, 19, 20, 21, 22, 23
Registries	1, 3, 4, 11, 16, 21, 22, 23
System Vendors	NA
Testing Laboratories	1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23

2.2.3 IDENTIFICATION OF BUSINESS ACTORS, AND SCENARIOS

This section describes the business actors that impact interoperability requirements for each scenario. A HITSP business actor should generally be an IT system that is directly engaged, and benefits from the real world information interchange defined within a business Use Case action. A business actor may also be a person or organization, however, only IT systems have associated technical actors (see Section 3.2 for technical actors). The table below identifies the significant Use Case business actors, their descriptions and the Use Case scenarios in which they are used.

Table 2.2.3-1 Business Actors

Business Actor	Description	Use Case Scenario
Clinical Genetic Databases	Organizations that maintain resources, such as 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	1, 2
Clinicians	Healthcare providers with patient care responsibilities, including physicians, advance practice nurses, physician assistants, nurses, psychologists, pharmacists, medical geneticists, genetic counselors, pathologists, and other licensed and credentialed personnel involved in treating patients	1, 2
Consumers	Members of the public that include patients as well as caregivers, patient advocates, surrogates, family members, and other parties who may be acting for, or in support of, a patient receiving or potentially receiving healthcare services	2
Data Repository	The system that provides the laboratory test results	1, 2

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Business Actor	Description	Use Case Scenario
Electronic Health Record (EHR) System Suppliers	Organizations which provide systems that are an electronic, cumulative record of information on an individual across more than one healthcare setting that is collected, managed, and consulted by professional involved in the individual's healthcare	1, 2 (out of scope)
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	1, 2
Genetic Specialists	Medical geneticists, genetic counselors, and clinicians (including pathologists) who participate in evaluation, diagnostic planning, and genetic/genomic test ordering and result interpretation activities	2
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	1, 2 (out of scope)
Health Information Exchange (HIE)	The specific organizations that provide the electronic movement of health-related data and information among organizations such as RHIOs and Health Information Exchange Organizations	1, 2
Healthcare Entities	Organizations that are engaged in or support the delivery of healthcare. These organizations could include hospitals, ambulatory clinics, long-term care facilities, community-based healthcare organizations, employers/occupational health programs, school health programs, dental clinics, psychology clinics, care delivery organizations, pharmacies, home health agencies, hospice care providers, and other healthcare facilities	2
Healthcare Payer Systems	Insurers, including health plans, self-insured employer plans, and third party administrators, providing healthcare benefits to enrolled members and reimbursing provider organizations. As part of this role, they provide information on eligibility and coverage for individual consumers, as well as claims-based information on consumer health history. Case management or disease management may also be supported	2
Locator Service	Responds to queries for the test results by providing the list of available test results and their locations within data repositories	1, 2
Patients	Members of the public who receive healthcare services	1, 2

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Business Actor	Description	Use Case Scenario
Personal Health Record (PHR) Systems	Organizations which provide specific PHR solutions to clinicians and patients such as software applications and software services. These suppliers may include developers, providers, resellers, operators, and others who may provide these or similar capabilities	1, 2
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	1, 2
Public Health Agencies/Organizations (federal/state/local/territorial/tribal)	Federal, state, local, territorial, and tribal government organizations and clinical care personnel that exist to help protect and improve the health of their respective constituents	2
Registries	Organized systems for the collection, storage, retrieval, analysis, and dissemination of information to support health needs. This also includes government agencies and professional associations which define, develop, and support registries. These may include registries of phenotypic and genotypic information	2
Testing Laboratory Systems	Medical testing laboratories, either within a hospital, ambulatory, or clinician office environment and/or operating as a free-standing entity, which meet regulatory standards for clinical laboratories and analyze specimens as ordered by providers to assess the health status of patients. Specifically, testing laboratories perform genetic/genomic and other laboratory tests ordered by genetic specialists and clinicians to assess the genetic status of patients	1, 2

2.2.4 HIGH-LEVEL UML BUSINESS SEQUENCE DIAGRAM

This section contains an explanation of the relationship between the business actors and data interactions between the primary actors and alternative actors for each Use Case scenario. The UML diagrams that follow illustrate each scenario with a representation of a normal sequence of exchange between the primary actors.

Figure 2.2.4-1 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.

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Figure 2.2.4-1 7.1.1 Construct Personal and Family Health History & Pedigree

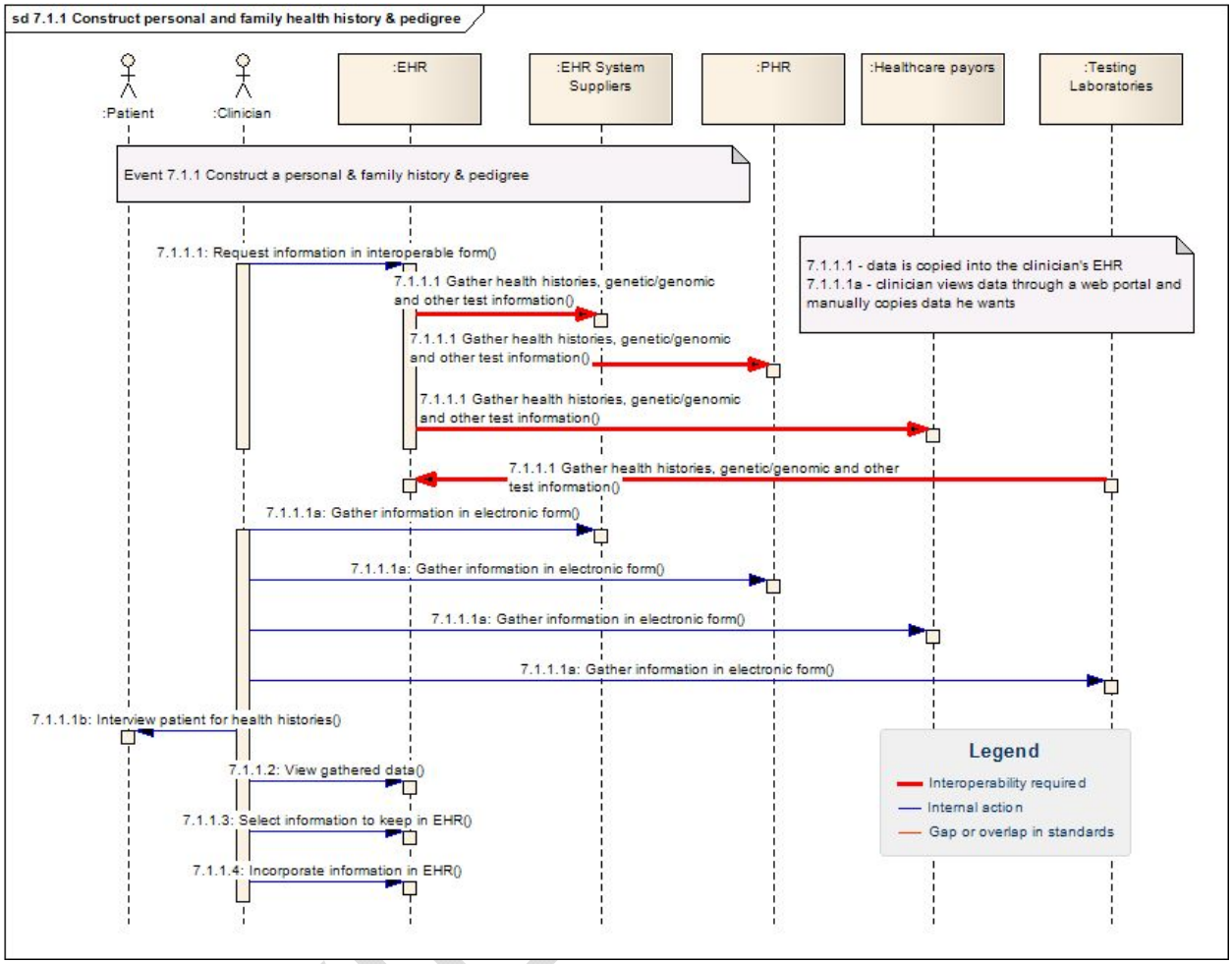

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Figure 2.2.4-2 represents the UML interaction diagram for the Clinical Assessments scenario from the perspective of the Clinician for Events 7.1.2 and 7.1.3. The clinician will gather any genetic/genomic information related to the patient, evaluate this information, and then order the appropriate tests. Prior to ordering any tests the clinician will verify the patient's eligibility with their healthcare payor.

Figure 2.2.4-2 7.1.2 – 7.1.3 Evaluate Reference Data and Order Tests

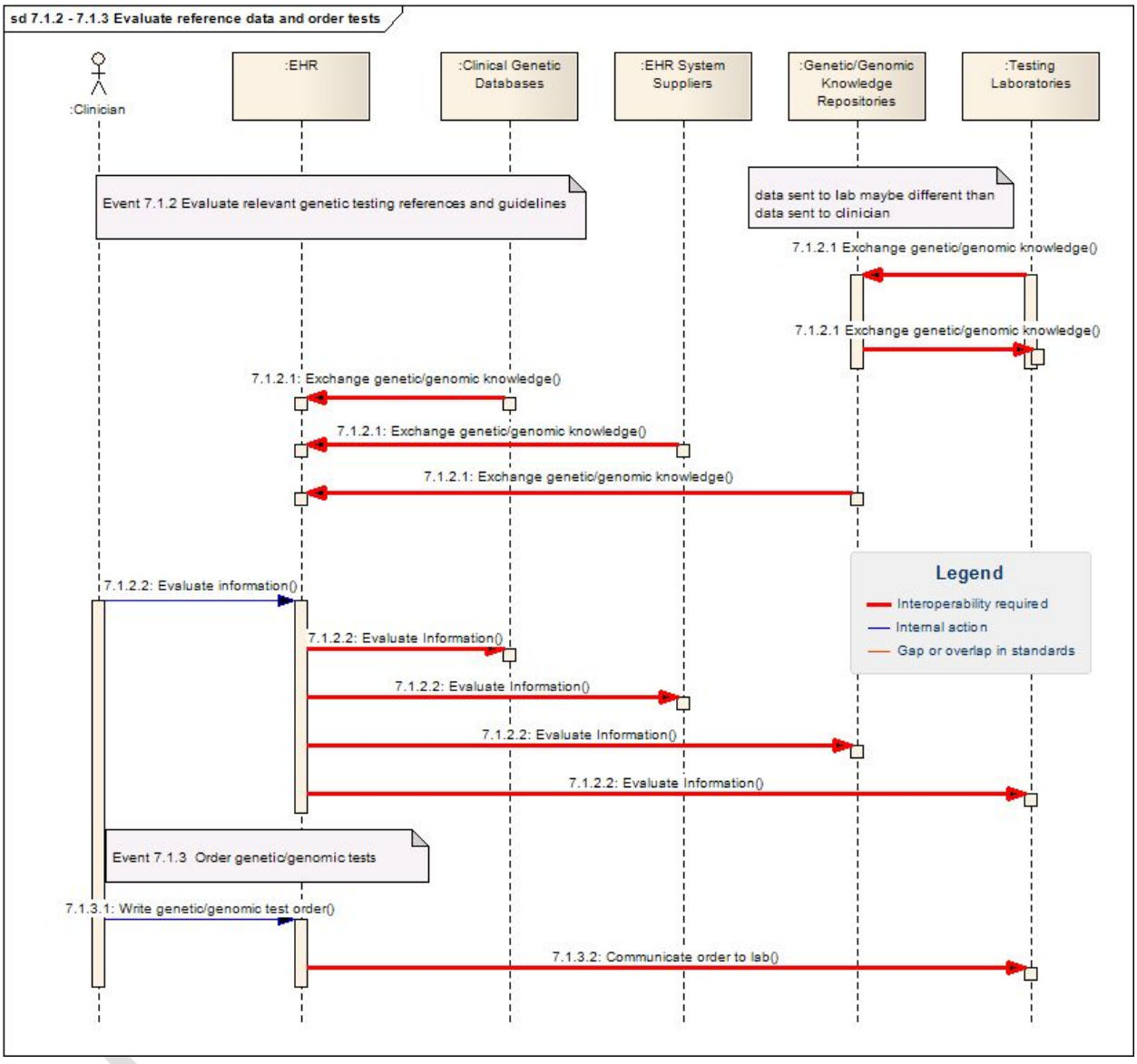

Figure 2.2.4-3 represents the UML interaction diagram for the Clinical Assessments scenario from the perspective of the Patient for Events 7.3.1 and 7.3.2. The patient will share available health and family history with the clinician and will receive updated information from the clinician.

Figure 2.2.4-3 7.3.1 – 7.3.2 Share and Receive Family Health History and Pedigree

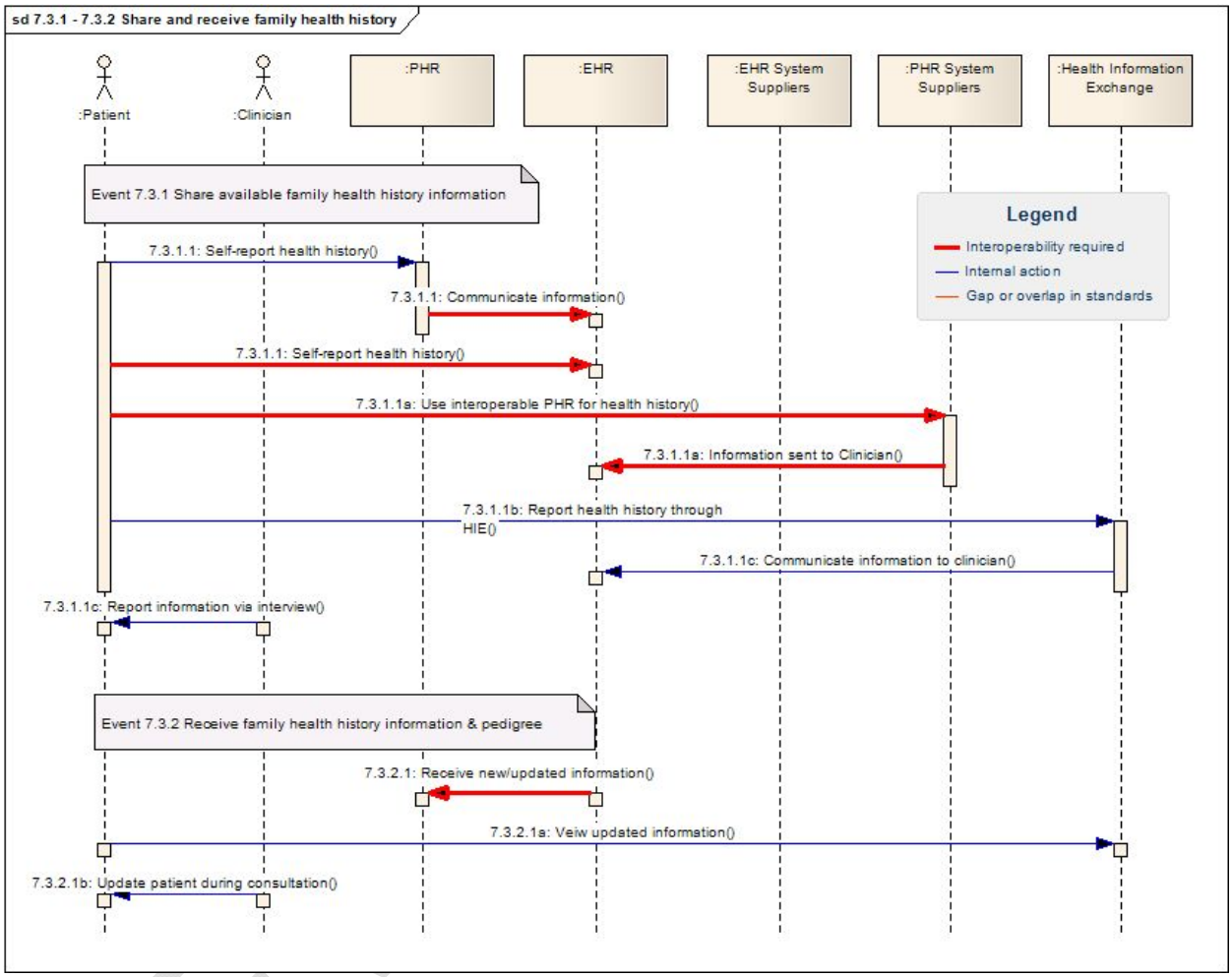

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Figure 2.2.4-4 represents the UML interaction diagram for the Genetic Testing, Reporting and Clinical Management from the perspective of the Clinician for Events 8.1.1 and 8.1.2. The clinician will receive the test results from the Testing Laboratory and will interpret the results, possibly requesting additional information from the Laboratory, and decide on the patient care plan.

Figure 2.2.4-4 8.1.1 – 8.1.2 Receive Results and Perform Interpretation

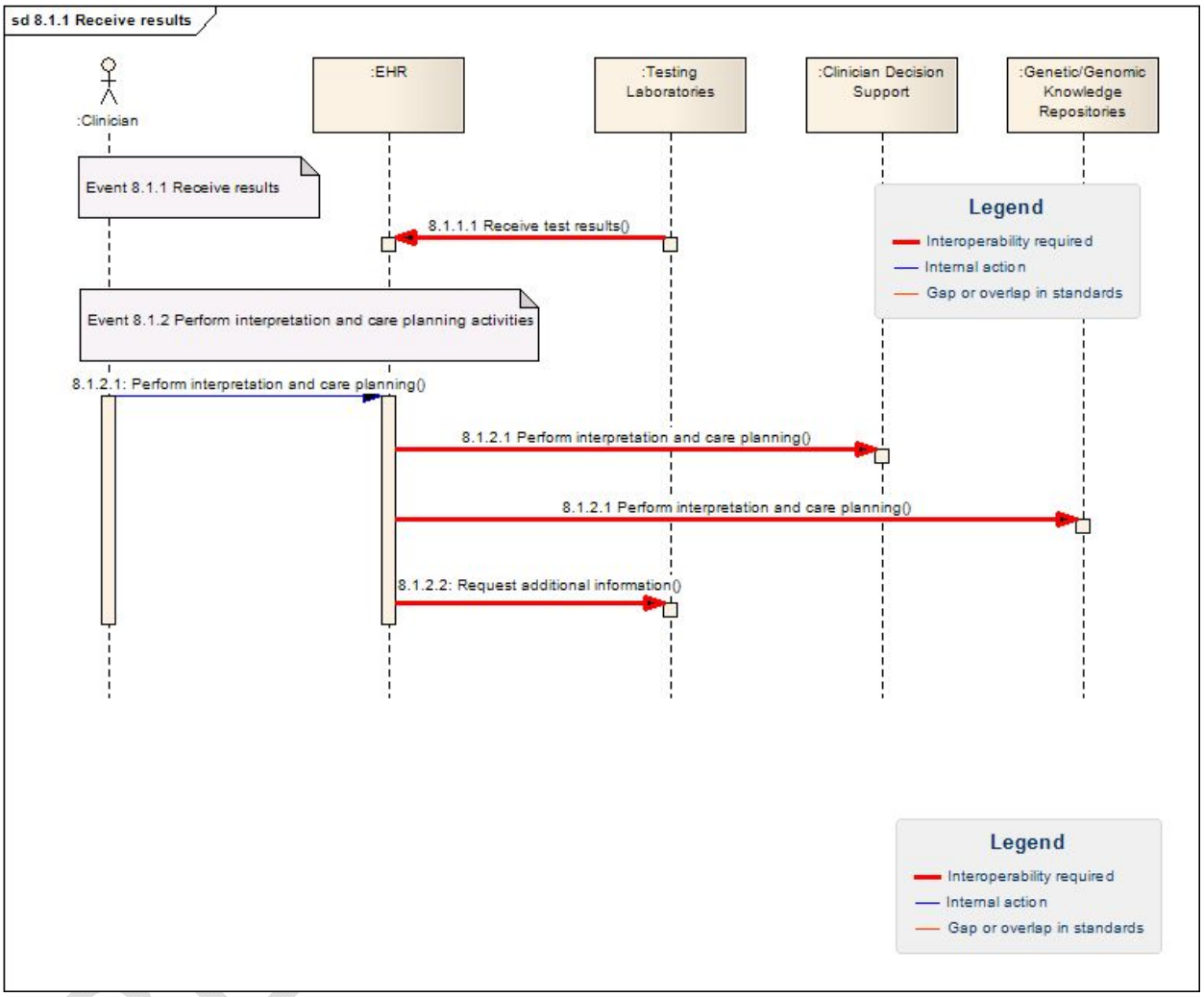

Figure 2.2.4-5 represents the UML interaction diagram for the Genetic Testing, Reporting and Clinical Management from the perspective of the Clinician for Event 8.1.3. The Clinician will forward the results of the genetic/genomic test to the next provider of care and to the patient.

Figure 2.2.4-5 8.1.3 Provide Results to Patient

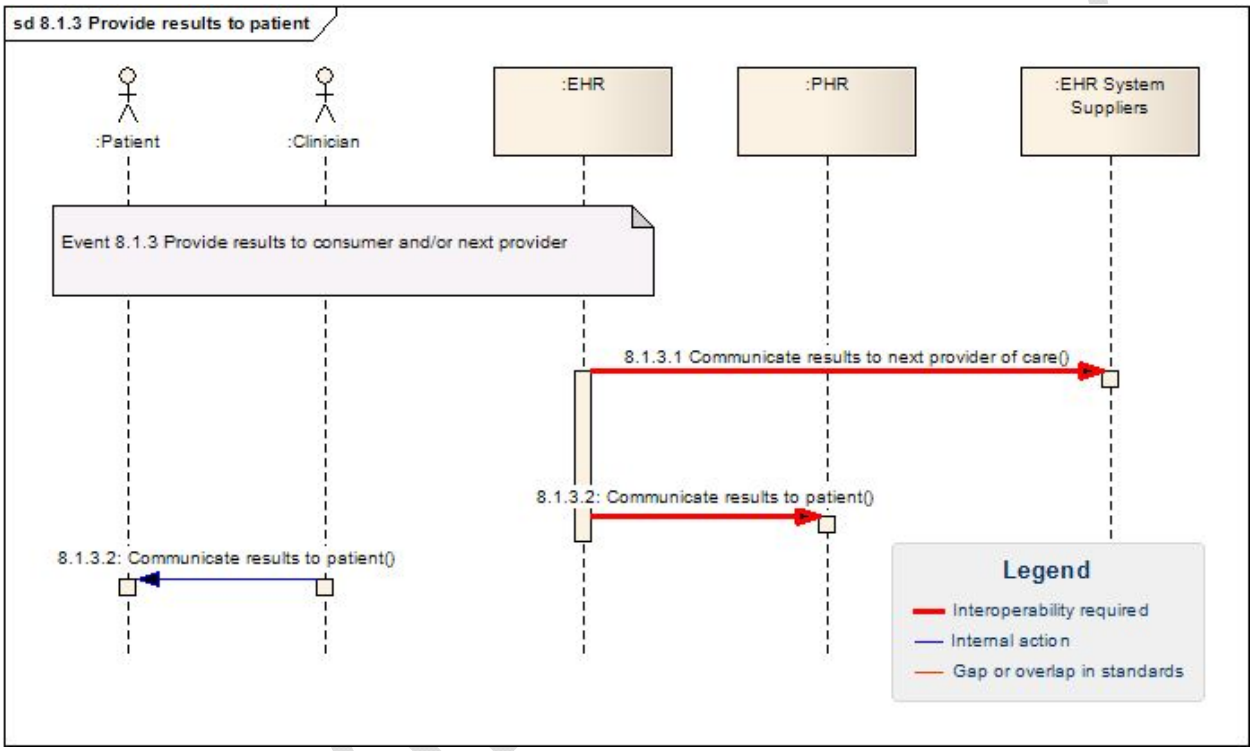

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Figure 2.2.4-6 represents the UML interaction diagram for the Genetic Testing, Reporting and Clinical Management from the perspective of the Testing Laboratory for Events 8.2.1, 8.2.2 and 8.2.3. The Testing Laboratory receives an order from the Clinician. 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 2.2.4-6 8.2.1 – 8.2.3 Receive Genetic Test Order & Prepare for Test

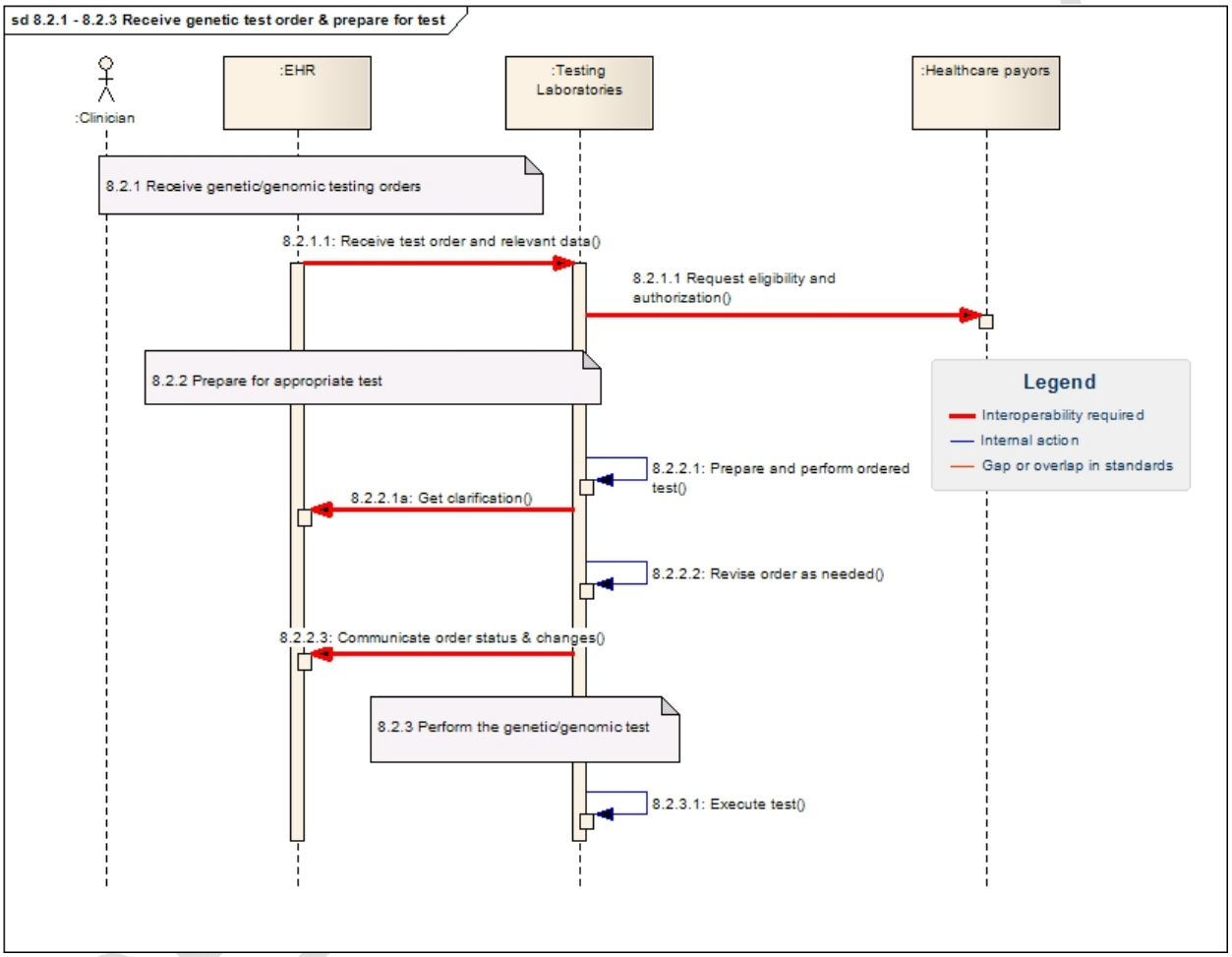

Figure 2.2.4-7 represents the UML interaction diagram for the Genetic Testing, Reporting and Clinical Management from the perspective of the Testing Laboratory for Events 8.2.4 and 8.2.5. After completing the test, the Laboratory will prepare and transmit a Laboratory Report of the test results to the ordering clinician. The Ordering Clinician may request additional information from the lab after reviewing the report.

Figure 2.2.4-7 8.2.4 – 8.2.5 Send Lab Result and Answer Questions

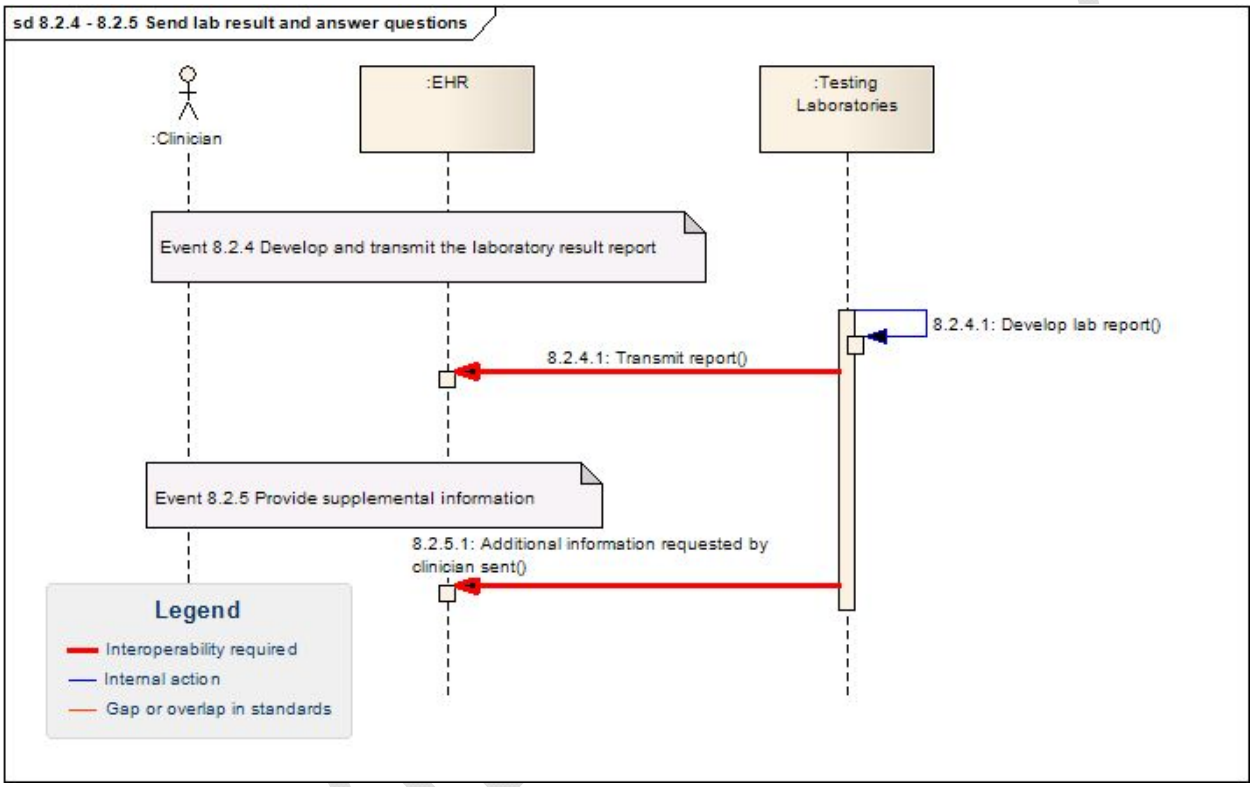

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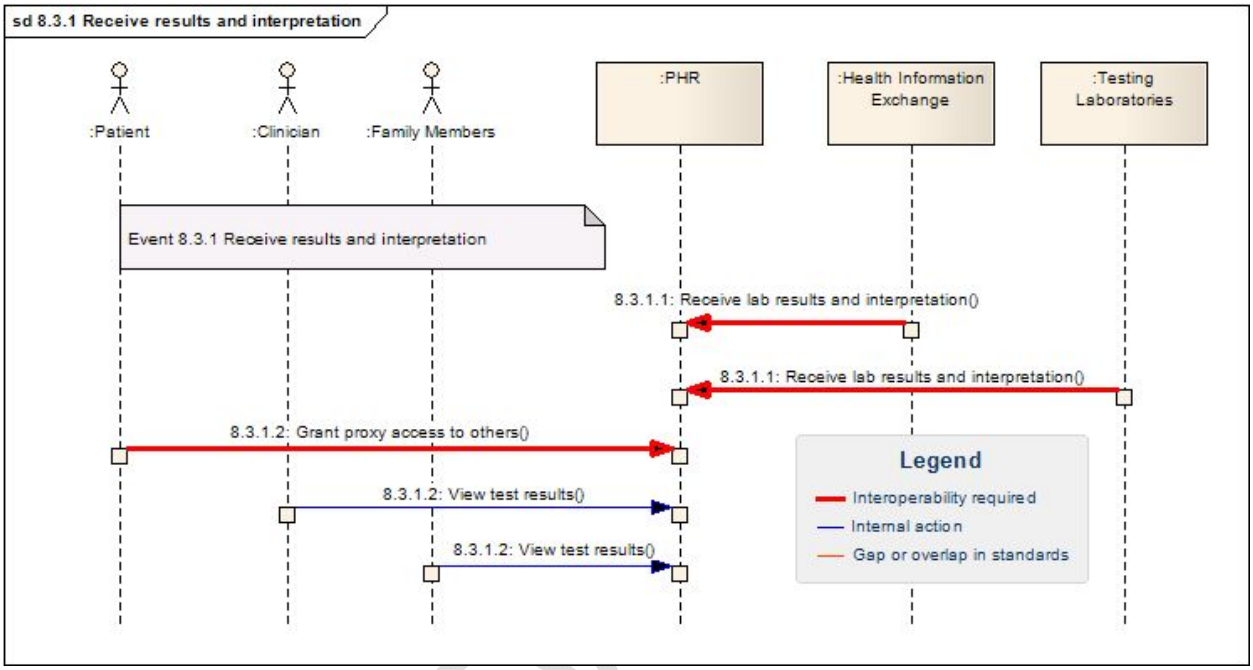
Figure 2.2.4-8 represents the UML interaction diagram for the Genetic Testing, Reporting and Clinical Management from the perspective of the Patient for Event 8.3.1. After the test has been performed and the report generated, the patient's PHR is updated with the results and interpretations. The patient may then decide to share this information with other providers or family members.

Figure 2.2.4-8 8.3.1 Receive Results and Interpretation



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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 events and actions of the design from the specified requirements. It also provides a detailed mapping of the specified requirements to the business and technical actors, and data elements. Groupings of specific actions and actors are illustrated to further describe the relevant interactions as existing or new HITSP constructs required for interoperability.

3.1 SCOPE OF DESIGN

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

In Section 2.2 we noted that the Use Case does not address authorization for testing from a Health Plan perspective and is considered a gap. It is determined in collaboration with the Administrative and Finance Domain Technical Committee (TC) that there needs to be the ability to identify and verify eligibility from payer and ability to obtain authorization for service. Further, it was determined in collaboration with the Care Management and Health Records Domain TC that there needs to be the ability to send structured and genetic test results to a Clinical Decision Support System and for the ability to receive a report of risk to a consumer based on the analysis results and interpretation of a test study.

As for Interoperability Exchange Requirements, we identified the need for the ability to identify and appropriately select a particular laboratory based upon the patient's insurance coverage network and/or preferences.

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.

We identified that interactions between the testing laboratories and genetic repositories are out of scope, updates to genomic decision support are not provided by the laboratory and that EHR systems suppliers are out of scope.

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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 updates from EHR systems suppliers are out of scope	1, 2

3.1.2 CONSTRAINTS

This section describes the constraints that limit the use of the Requirements and Design, or to which the design must conform in order to be used within the described context. 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 scenario. 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 Use Case scenario.

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

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Pre-condition	Use Case Scenario
Support the following HITSP Security and Privacy constructs: HITSP/C19 Entity Identity Assertion – Provide assertion HITSP/T16 Consistent Time – Maintain time HITSP/T17 Secured Communication Channel – Authenticate node HITSP/T15 Collect and Communicate Security Audit Trail – Record audit event in repository HITSP/TP30 Manage Consent Directives – Capture/Request consent directive HITSP/TP20 Access Control – Access control request	All
All pre-conditions from the lower level constructs are incorporated	All
When needed, the patient is uniquely registered with the Patient Identity Cross-Referencing service	All

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 will provide 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 planned constructs used to meet the business and technical requirements for this Use

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Case. Opportunities for reuse of existing HITSP constructs are outlined, along with a description of any necessary updates to existing constructs. Any variances in the Security and Privacy implementation are also described here.

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 of assurance is offered by the basic use of HITSP/TP13 Manage Sharing of Documents construct. A medium level of assurance is offered by 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 PKIs).

The detailed applications of the main HITSP constructs required by this Interoperability Specification are shown in the steps below. It is important to recognize the three transport methods that will support a wide variety of environmental factors:

a) HITSP/TP13 - Manage Sharing of Documents is needed to provide the ability to share documents among Health Information Exchange (HIE) members, and additionally to support a longitudinal health record
b) HITSP/T31 - Document Reliable Interchange is needed for situations where the consultation is to be forwarded to a particular designated recipient, without the need/desire to upload the information into the HIE

HITSP/T33 - Transfer of Documents on Media is needed for cases where the consulting individual is not known, or is known to be outside of a document sharing arrangement. This enables consumer choice by allowing the consumer to transport the information. The receiving physician may want to read the physical media to incorporate the information into their PHR/EHR.

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 implement real world business actor information interchanges (see Section 2.2.3). The table below identifies the technical actors and gives 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
Patient Identity Source	Sends patient demographic information to the Patient Identifier Cross-Reference Manager
PIX Consumer	The Patient Identifier Cross-Reference Consumer either queries for sets of Cross-Reference Patient Identifiers. It may also receive notifications about cross-reference changes
Content Creator	The Content Creator is responsible for the creation of content and transmission to a Content Consumer

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Technical Actor(s)	Actor Role
Content Consumer	A Content Consumer is responsible for viewing, import, or other processing of content created by a Content Creator Actor
Audit Record Source	The actor that, on behalf of another actor that performs an action requiring logging, creates and communicates an Audit Record to the Audit Record Repository
Audit Record Repository	This actor provides a repository for audit events
Time Client	Establishes time synchronization with one or more Time Servers using the NTP protocol and either the NTP or SNTP algorithms. Maintains the local computer system clock synchronization with UTC based on synchronization with the Time Servers
Time Server	Provides NTP time services to Time Clients. It is either directly synchronized to a UTC master clock (e.g. satellite time signal) or is synchronized by being grouped with a Time Client to other Time Server(s)
Eligibility Information Receiver	The system that initiates an inquiry to the Eligibility Information Source about an individual's insurance eligibility, coverage and benefits
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
Payor Authorization Information Receiver	The system that initiates a request to the Authorization Information Source about an individual's insurance requirements to obtain an authorization approval for purposes of benefit coverage determination and reimbursement in order to refer a patient for care or services to another clinician or providers of care
Payor Authorization Information Source	The system which holds and maintains the information regarding the individual's insurance requirements related to an authorization for benefit coverage determination and reimbursement purposes when a patient is referred for care or services, and responds to the query initiated by the Authorization Information Receiver
Service User	The entity that takes on the actor role of initiator or claimant. This is an initiator actor
Service Provider	This is the information resource, representing the information repositories and all capabilities that receive, process and fulfill authorized request. The Service Provider includes any local access decision and enforcement components that are part of the distributed capabilities
Identity Provider	The 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).
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.
Node	The originating or terminating point of information or signal flow in a telecommunications network
Patient Demographics Consumer	Queries the Patient Demographics Supplier for a list of patient demographic information
Person Identification Service	System that maintains a cross-domain person and/or patient index including all known identifiers (real and pseudo) for each person and/or patient within all domains with which it communicates
Notification Receiver	Receives notifications of availability for documents in an XDS registry and may optionally send acknowledgements to them
Notification Sender	Sends notifications of availability for documents in an XDS registry and receives acknowledgements of these notifications
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
Document Source	The Document Source Actor is 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
Portable Media Creator	The Portable Media Creator writes the selected information from a consumer's PHR to media following the directory structure outlined by XDM

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Technical Actor(s)	Actor Role
Portable Media Importer	The Portable Media Importer processes all the contents written by a Portable Media Creator on the physical media. The Portable Media Importer must successfully process all documents
Document Consumer	Queries a Document Registry Actor for documents meeting certain criteria and retrieves selected documents from one or more Document Repository actors
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
Initiating Gateway	Support all outgoing inter-community communications
Responding Gateway	Supports all incoming inter-community communications
Access Control Service	The UACS is the enterprise security service that supports and implements user-side access control capabilities. This is an initiator actor
Service Provider Access Control Service	The SPACS service supports and implements the service-side access control capabilities. This is a service provider actor
PIX 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
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
Consent Directive Requestor	The Consent Directive Requester accesses Consent Directives located through a Consent Registry from Consent Repositories
Consent Registry	The Consent Registry is responsible for providing location information and sender notification regarding consent directive. The Consent Registry receives a Manage Consent Directive Metadata Request
Consent Repository	The Consent Repository is responsible for both the persistent storage of Consent Directives as will 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

3.2.2 SEQUENCE DIAGRAM FOR PROCESS FLOW

This section incorporates the comprehensive business and technical requirements and a detailed analysis of the interactions and decisions undertaken for the primary actions in each Use Case scenario. 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 HITSP constructs). The detailed actor Transactions described in these diagrams show all common or independent actors, data, and the actual transactions from the HITSP constructs that are used for the Interoperability Specification.

Transactions that make use of existing HITSP constructs are shown explicitly, indicating opportunities for reuse. Table 3.2.2-1 provides the tabular representation of the interactions shown in the UML diagrams below.

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Figure 3.2.2-1 Clinical Assessment Scenario 7.1.1

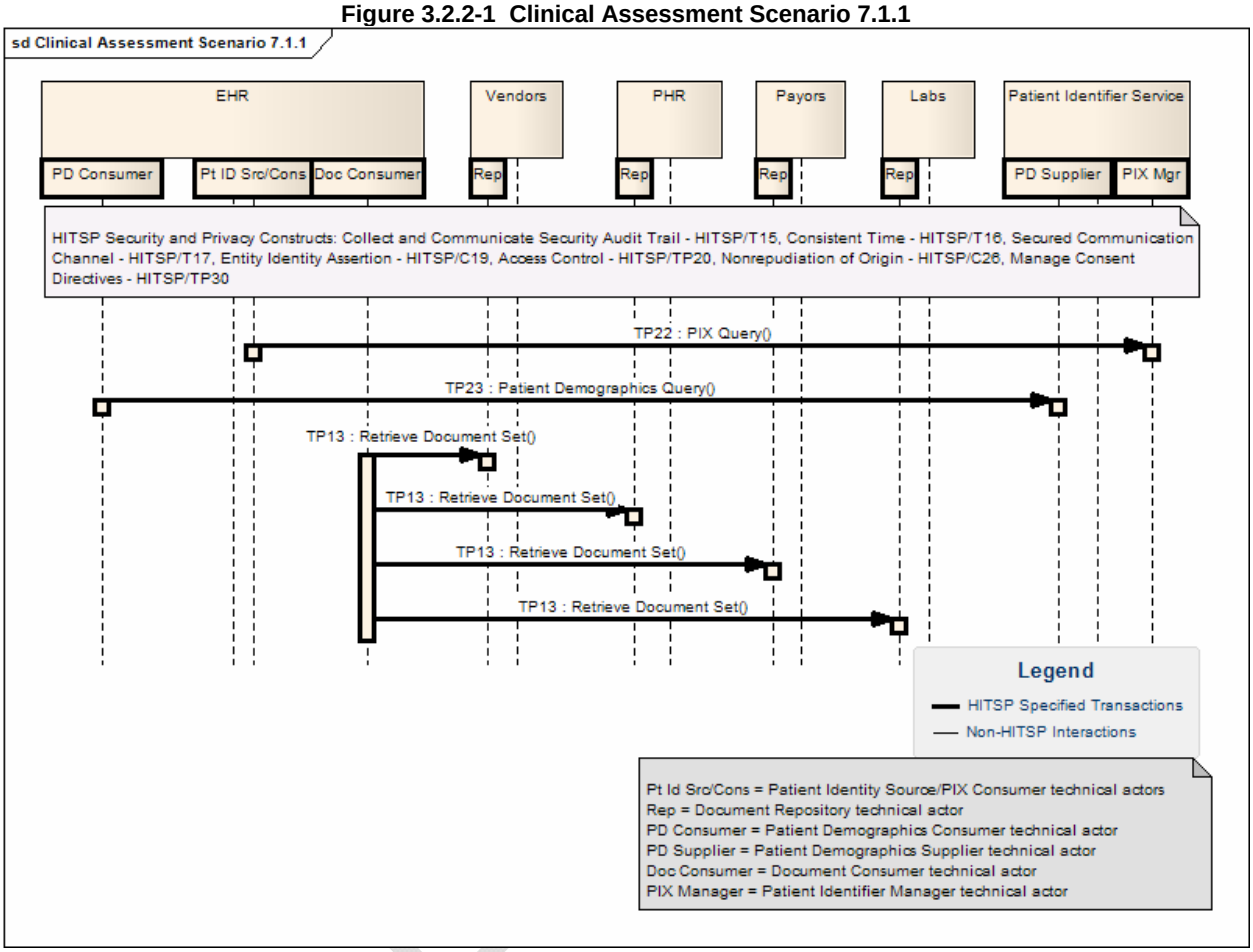

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Figure 3.2.2-2 Clinical Assessment Scenario 7.1.2 and 7.1.3

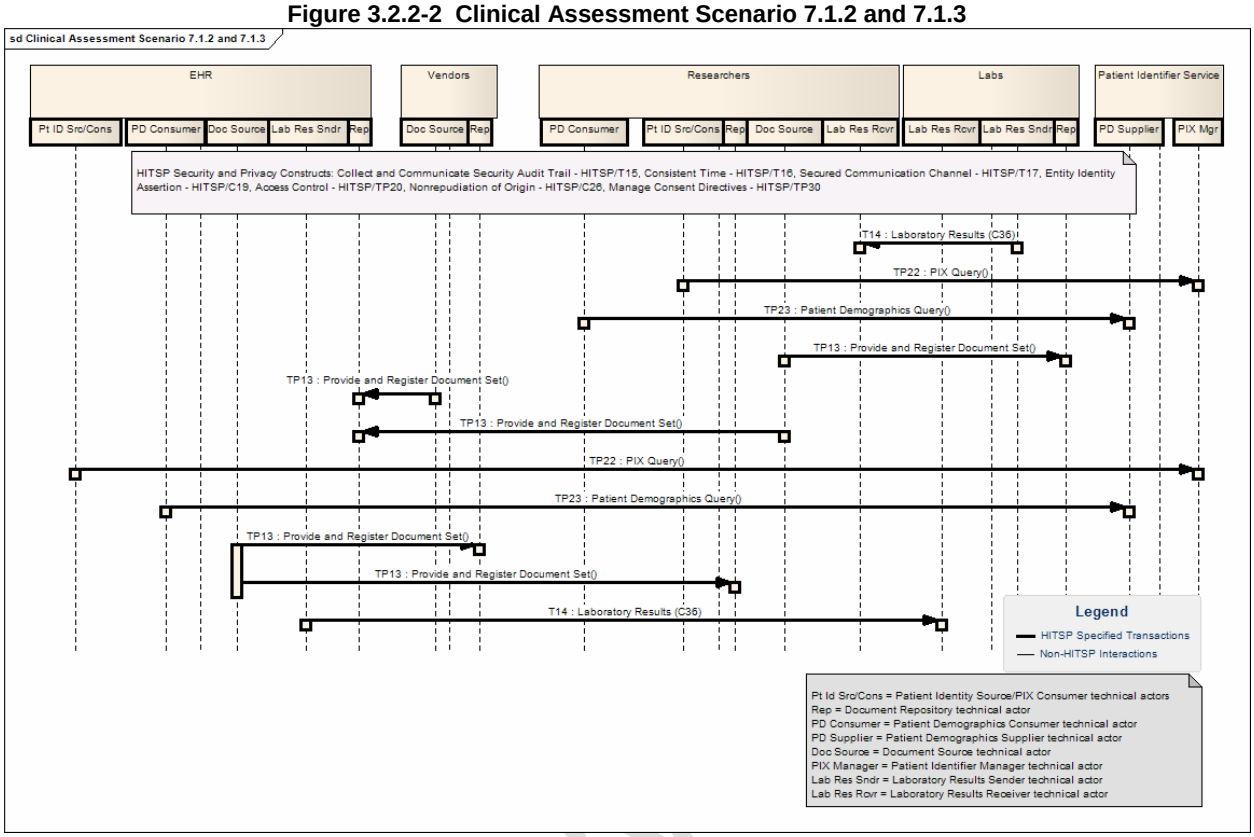

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Figure 3.2.2-3 Clinical Assessment Scenario 7.3.1 and 7.3.2

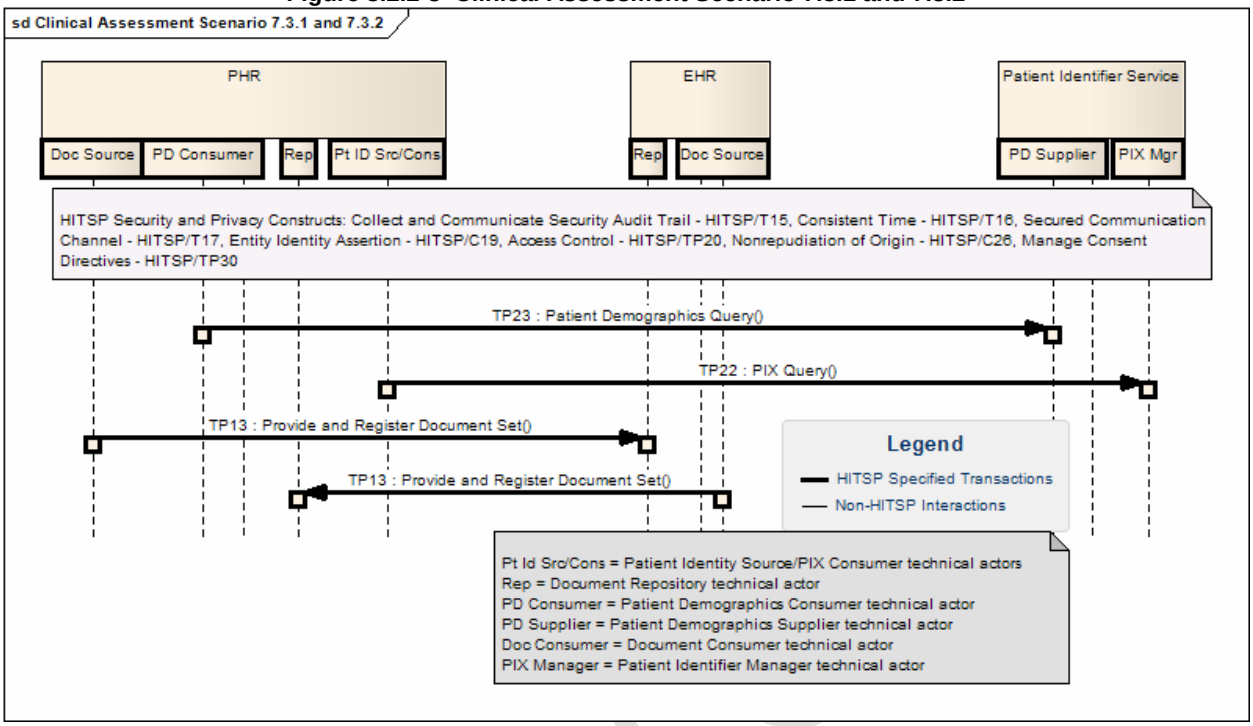

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Figure 3.2.2-4 Genetic Testing, Reporting, and Clinical Management Scenario 8.1.1

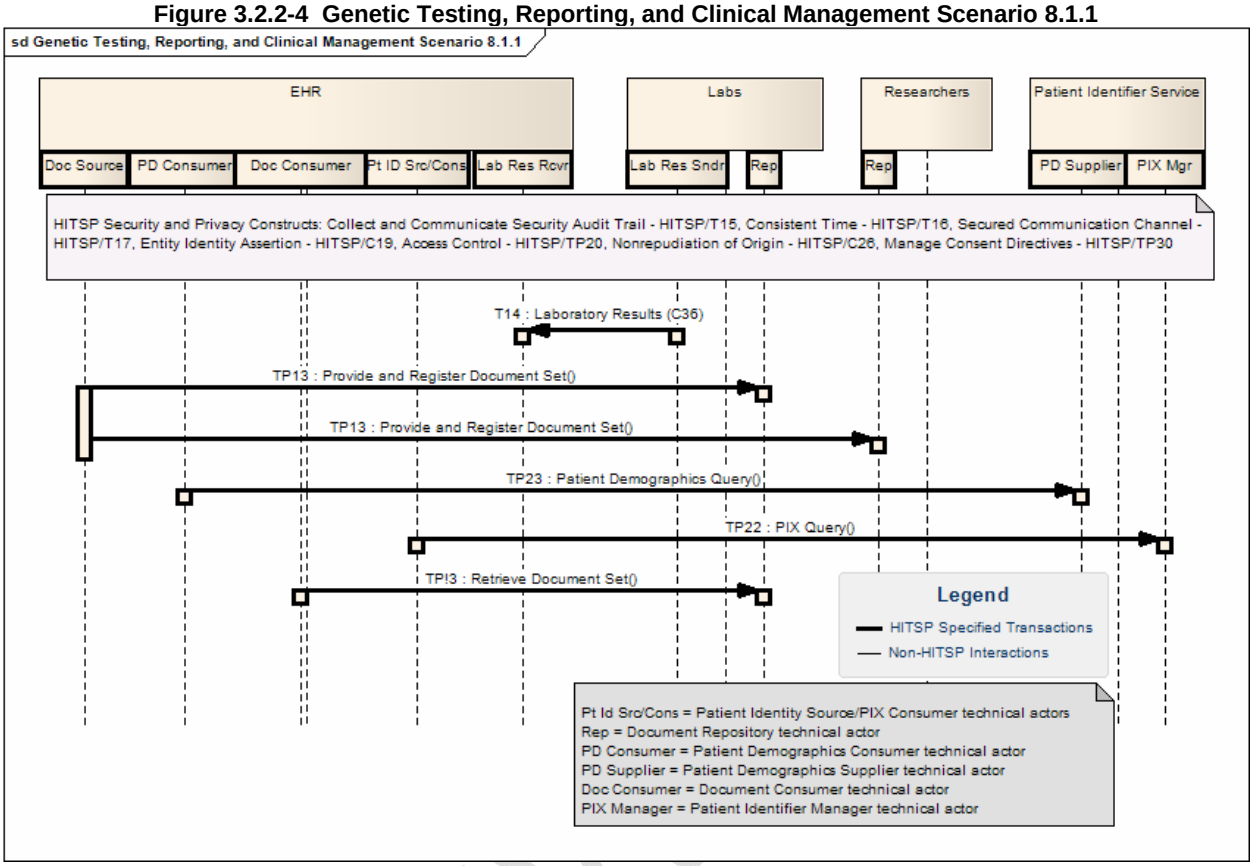

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Figure 3.2.2-5 Genetic Testing, Reporting, and Clinical Management Scenario 8.1.3

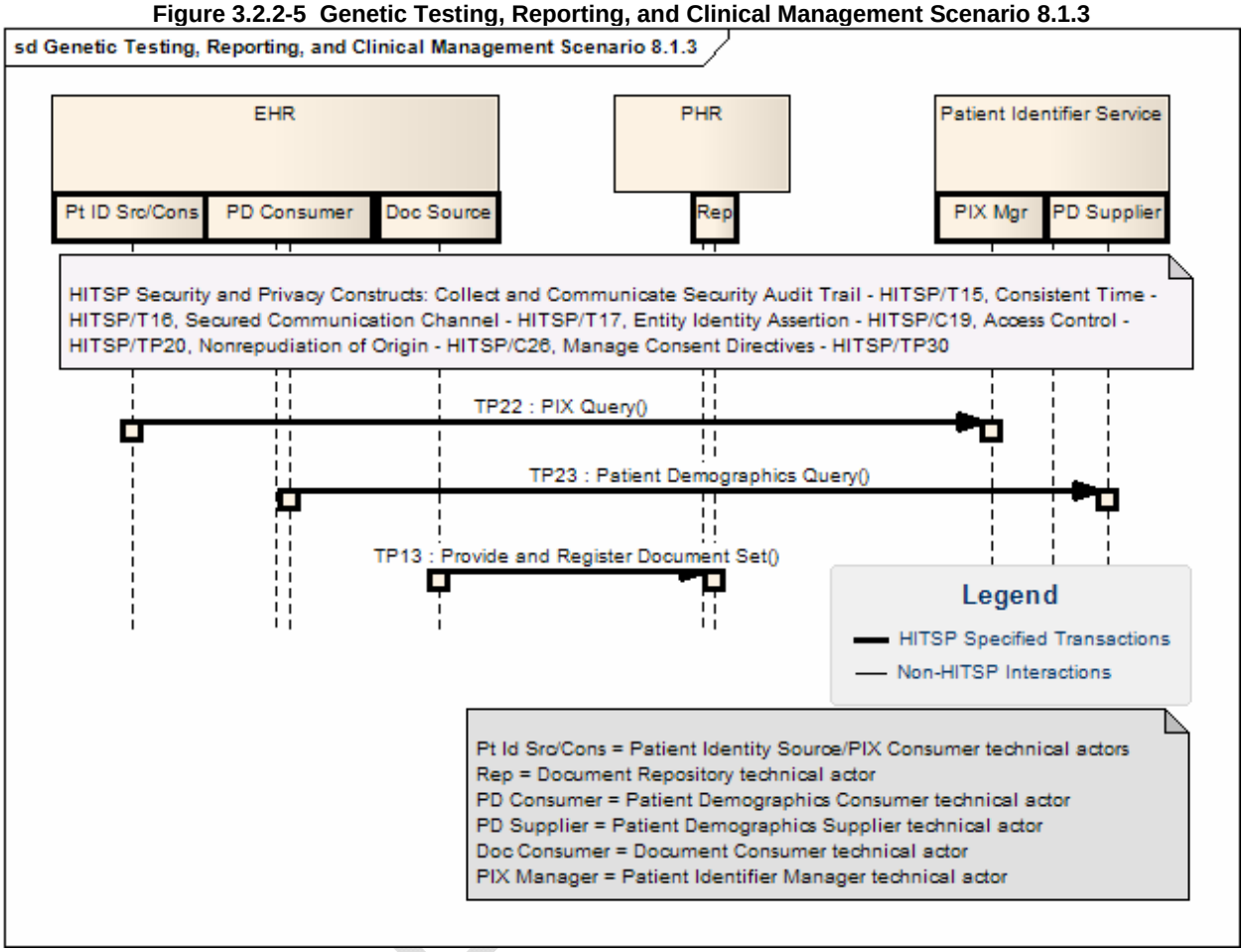

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Figure 3.2.2-6 Genetic Testing, Reporting, and Clinical Management Scenario 8.2.1 – 8.2.3

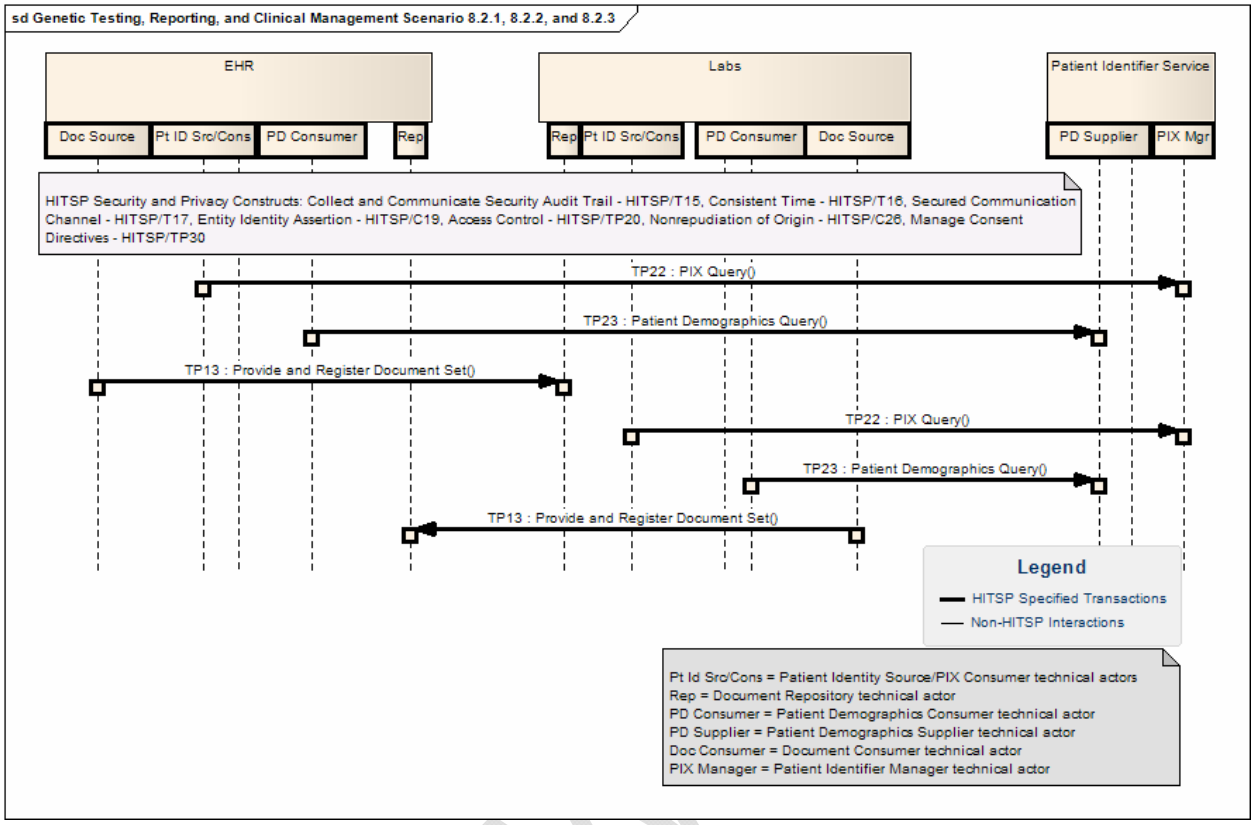

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Figure 3.2.2-7 Genetic Testing, Reporting, and Clinical Management Scenario 8.2.4 and 8.2.5

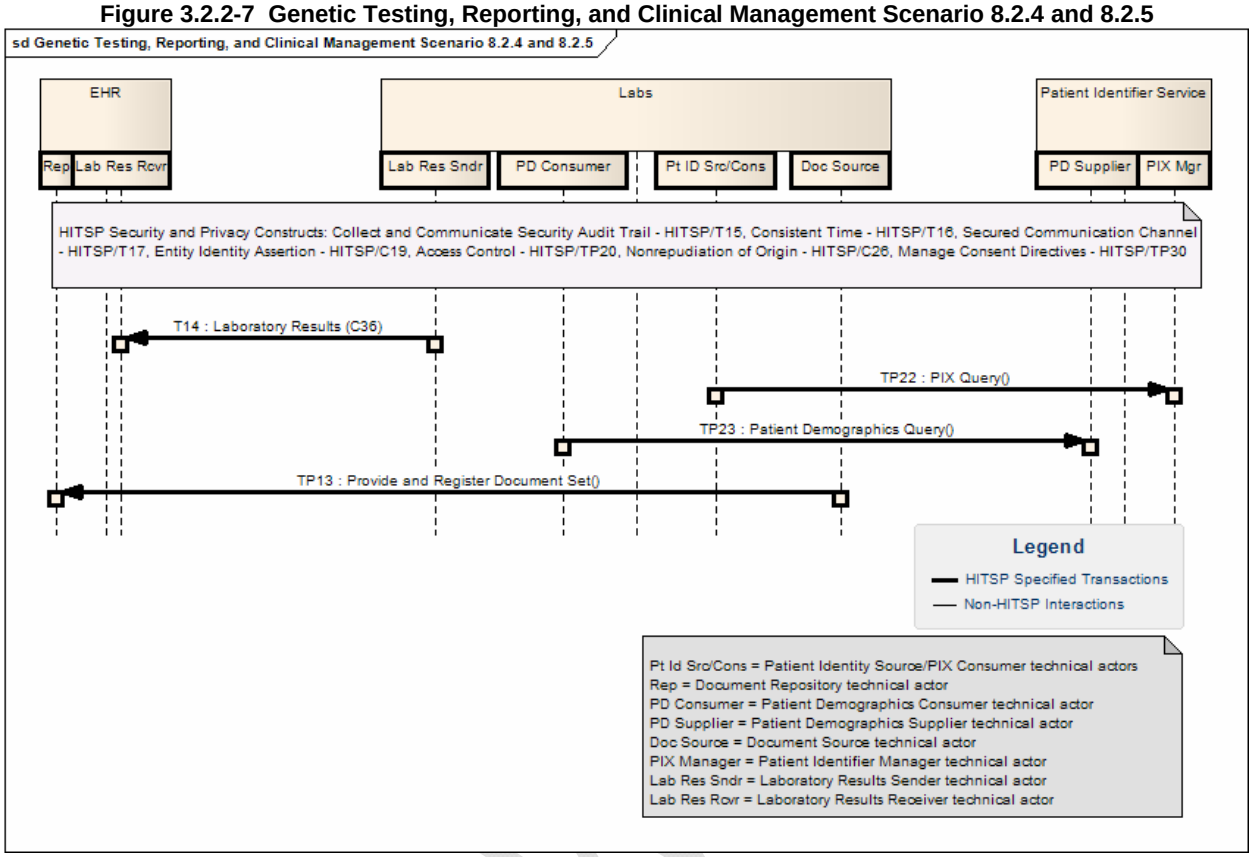

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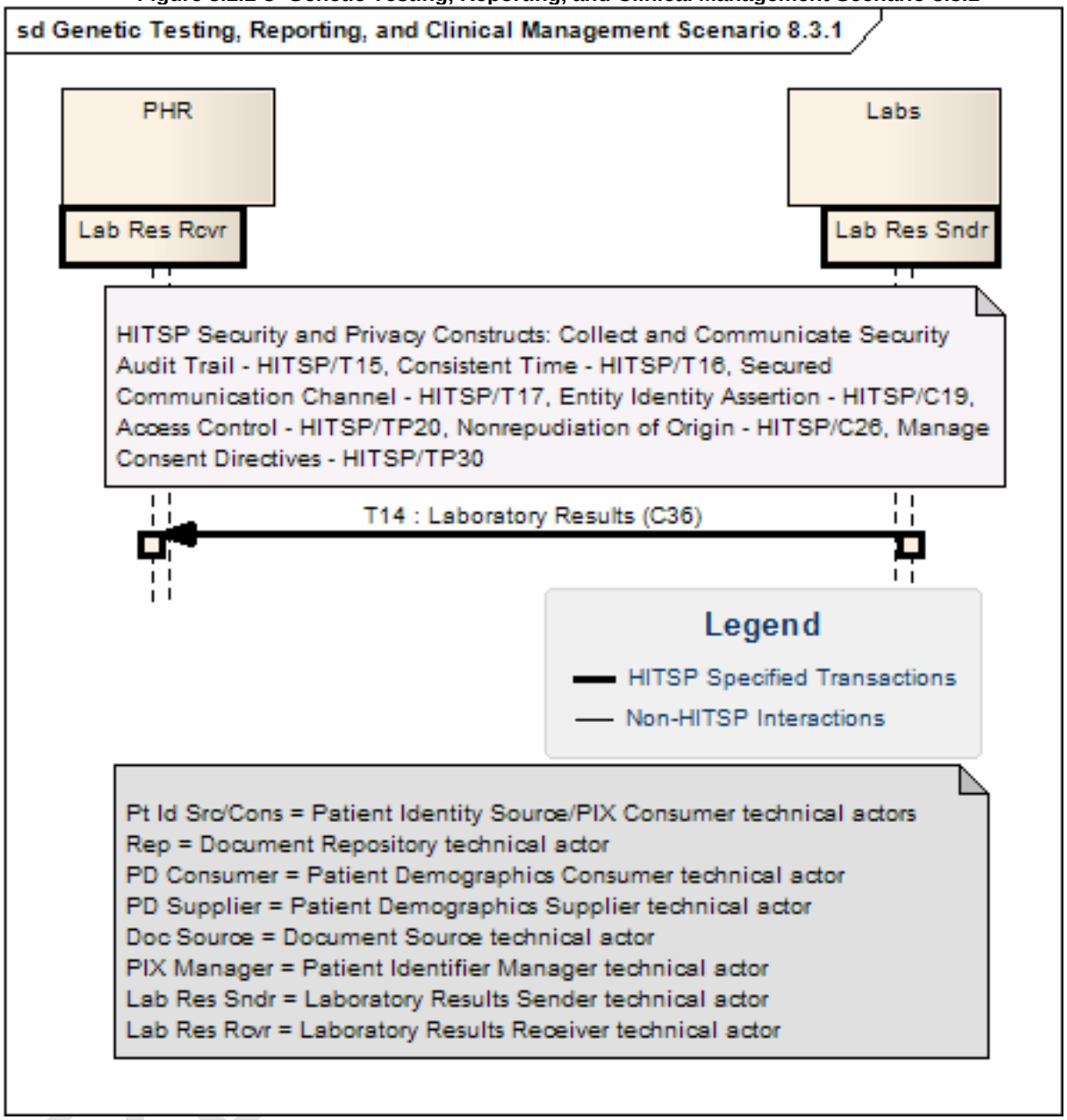
Figure 3.2.2-8 Genetic Testing, Reporting, and Clinical Management Scenario 8.3.1



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

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

a. The Required or Conditionally Required technical actors that shall be supported as specified in the associated construct

b. The Optional technical actors that may be supported as specified in the associated construct
c. All Required or Conditionally Required transactions and content subsets for each implemented technical actor assigned to the business actor that shall be supported as specified in the associated construct
d. The Optional transactions and content subsets for each implemented technical actor assigned to the business actor that 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.

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

Business Actor	Technical Actor(s)	Actor Optionality*	Construct	Transaction/Content (T/C)	T/C Optionality*
Electronic Health Record (EHR)	Service User	R	HITSP/C19	Convey Assertion	R
				Provide Assertion	O
			HITSP/TP20	Access Control Request	O
	Service Provider	R	HITSP/TP20	Access Control Request	O
	Identity Provider	O	HITSP/C19	Provide Assertion	R
				Verify Assertion	O
	Content Creator	R	HITSP/C32	Creator-Structured Family History (new subset)	R
			HITSP/TP30	Consent Document Component	R
			HITSP/C62	Unstructured Document	O
	Content Consumer	R	HITSP/C32	Creator-Structured Family History (new subset)	R
			HITSP/C37	Consumer-Genetic test results (new)	R
			HITSP/C36	Genetic test results message (new subset)	R
			HITSP/C35	Laboratory Vocabulary Terminology	R
			HITSP/TP30	Consent Document Component	R
			HITSP/C62	Unstructured Document	O
	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
	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
	Time Server	O	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
	Patient Identity Source	C [101]	HITSP/T23	Patient Demographics Query	R

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Business Actor	Technical Actor(s)	Actor Optionality*	Construct	Transaction/Content (T/C)	T/C Optionality*
				PIX Identity Feed	R
			HITSP/TP22	Patient Identity Feed	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
	Document Source	C [105]	HITSP/T31	Provide & Register Document Set.b	R
			HITSP/TP13	Provide & Register Document Set-b (XDS.b)	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
	Eligibility Information Receiver	R	HITSP/T40	Eligibility Information Request	R
	Eligibility Information Source	R	HITSP/T40	Eligibility Information Request	R
	Document Consumer	C [106], [110], [104]	HITSP/TP13	Registry Stored Query	R
				Retrieve Document Set	R
	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	R	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
PHR	Service User	R	HITSP/C19	Convey Assertion	R
				Provide Assertion	O
			HITSP/TP20	Access Control Request	O
	Service Provider	R	HITSP/TP20	Access Control Request	O
	Identity Provider	O	HITSP/C19	Provide Assertion	R
				Verify 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
	Time Server	O	HITSP/T16	Maintain Time	R
	Node	R [107]	HITSP/T17	Secured Communication Channel	R
	Access Control Service	R	HITSP/TP20	Access Control Request	O

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Business Actor	Technical Actor(s)	Actor Optionality*	Construct	Transaction/Content (T/C)	T/C Optionality*
	Content Creator	R	HITSP/TP30	Consent Document Component	R
			HITSP/C62	Unstructured Document	O
	Content Consumer	R	HITSP/TP30	Consent Document Component	R
			HITSP/C37	Genetic Test Results (new subset)	R
			HITSP/C32	Creator-Structured Family History (new subset)	R
			HITSP/C35	Laboratory Vocabulary Terminology	R
			HITSP/C62	Unstructured Document	O
	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
	Document Recipient	C [104]	HITSP/T31	Provide & Register Document Set.b (XDS.b)	R
	Document Consumer	C [106], [110], [104]	HITSP/TP13	Registry Stored Query	R
				Retrieve Document Set	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
	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
Laboratory Systems	Service User	R	HITSP/C19	Convey Assertion	R
				Provide Assertion	O
			HITSP/TP20	Access Control Request	O
	Service Provider	R	HITSP/TP20	Access Control Request	O
	Identity Provider	O	HITSP/C19	Provide Assertion	R
				Verify 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
	Time Server	O	HITSP/T16	Maintain Time	R
	Node	R [107]	HITSP/T17	Secured Communication Channel	R
	Access Control Service	R	HITSP/TP20	Access Control Request	O
	Content Creator	R	HITSP/TP30	Consent Document Component	R
			HITSP/C37	Creator-Genetic test results (new)	R

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Business Actor	Technical Actor(s)	Actor Optionality*	Construct	Transaction/Content (T/C)	T/C Optionality*
			HITSP/C36	Creator-Genetic test results message (new subset)	R
			HITSP/C35	Laboratory Vocabulary Terminology	R
	Content Consumer	R	HITSP/TP30	Consent Document Component	R
			HITSP/C32	Consumer-Structured Family History (new subset)	R
			HITSP/C37	Consumer-Genetic test results (new)	R
			HITSP/C36	Consumer-Genetic test results message (new subset)	R
			HITSP/C35	Laboratory Vocabulary Terminology	R
			HITSP/C62	Unstructured Document	O
	Consent Directive Requester	O [108]	HITSP/TP30	Stored Query	R
				Retrieve Document Set	R
	Access Control Service	R	HITSP/TP20	Access Control Request	O
	Document Repository	O [107]	HITSP/TP13	Provide & Register Document Set-b	R
				Register Document Set-b	R
				Retrieve Document	R
	Document Recipient	C [104]	HITSP/T31	Provide & Register Document Set.b (XDS.b)	R
	Document Consumer	C [106], [110], [104]	HITSP/TP13	Registry Stored Query	R
				Retrieve Document Set	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
	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
Payers	Service User	R	HITSP/C19	Convey Assertion	R
				Provide Assertion	O
			HITSP/TP20	Access Control Request	O
	Service Provider	R	HITSP/TP20	Access Control Request	O
	Identity Provider	O	HITSP/C19	Provide Assertion	R
				Verify 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
	Time Server	O	HITSP/T16	Maintain Time	R
	Node	R [107]	HITSP/T17	Secured Communication Channel	R
	Access Control Service	R	HITSP/TP20	Access Control Request	O

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Business Actor	Technical Actor(s)	Actor Optionality*	Construct	Transaction/Content (T/C)	T/C Optionality*
	Content Creator	R	HITSP/TP30	Consent Document Component	R
	Content Consumer	R	HITSP/TP30	Consent Document Component	R
	Consent Directive Requester	O [108]	HITSP/TP30	Stored Query	R
				Retrieve Document Set	R
	Eligibility Information Supplier	R	HITSP/T40	Eligibility Information Request	R
	Payor Authorization Information Source		HITSP/T68	Health Plan Authorization/Referral Request and Response	R
Researchers	Service User	R	HITSP/C19	Convey Assertion	R
				Provide Assertion	O
			HITSP/TP20	Access Control Request	O
	Service Provider	R	HITSP/TP20	Access Control Request	O
	Identity Provider	O	HITSP/C19	Provide Assertion	R
				Verify 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
	Time Server	O	HITSP/T16	Maintain Time	R
	Node	R [107]	HITSP/T17	Secured Communication Channel	R
	Access Control Service	R	HITSP/TP20	Access Control Request	O
	Content Creator	R	HITSP/TP30	Consent Document Component	R
			HITSP/C62	Unstructured Document	O
	Content Consumer	R	HITSP/TP30	Consent Document Component	R
			HITSP/C37	Genetic Test Results (new subset)	R
			HITSP/C32	Creator-Structured Family History (new subset)	R
			HITSP/C35	Laboratory Vocabulary Terminology	R
			HITSP/C62	Unstructured Document	O
	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
	Document Recipient	C [104]	HITSP/T31	Provide & Register Document Set.b (XDS.b)	R
	Document Consumer	C [106], [110], [104]	HITSP/TP13	Registry Stored Query	R
				Retrieve Document Set	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

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Business Actor	Technical Actor(s)	Actor Optionality*	Construct	Transaction/Content (T/C)	T/C Optionality*
	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
Locator Service Repository	Document Registry	R [110]	HITSP/TP13	Register Document Set-b (XDS.b)	R
				Registry Stored Query	R
Data Repository	Document Repository	R [107]	HITSP/TP13	Provide & Register Document Set-b (XDS.b)	R
				Retrieve Document Set	R
Patient Identifier Service	Patient Identifier Cross Reference Manager (PIX Manager)	R	HITSP/TP22	PIX Query	R
				Patient Identity Feed	R
				PIX Update Notification	R
	Patient Demographics Supplier	R	HITSP/T23	Patient Demographics Query	R
	Consent Repository	O	HITSP/TP30	Register Document Set	R
				Provide and Register Document Set	R
				Retrieve Document	R
	Consent Registry	O	HITSP/TP30	Registry Stored Query	R
				Register Document Set	R
	Consent Originator	O	HITSP/TP30	Provider and Register Document Set	R
	Identity Provider	O	HITSP/C19	Provide Assertion	R
				Verify Assertion	O
Provider Administrative and Financial Systems	Eligibility Information Receiver	R	HITSP/T40	Eligibility Information Request	R
	Payor Authorization Information Receiver	R	HITSP/T68	Health Plan Authorization/Referral Request and Response	R
	Payor Authorization Information Source	R	HITSP/T68	Health Plan Authorization/Referral Request and Response	R

***NOTE:** Optionality = "R" for Required, or "O" for Optional, or "C" for Conditional. Conditional footnotes are further described below.

Actor Optionality Conditions

- C [101] – Shall support (Patient Identity Source plus PIX Consumer) and/or Patient Demographics Consumer
- C [102] – Shall be supported if this Actor is a Document Repository
- C [103] – Shall be supported if this Actor is a Document Consumer
- C [104] – Business actor shall support at least one of these technical actors to receive or retrieve inbound content
- C [105] – Business actor shall support at least one of these technical actors to communicate outbound content

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- C [106] – Document Source or Consent Directive Consumer Technical Actors shall support either the XDS.b option or the XCA option or both options
- C [107] – Shall be grouped with Laboratory Results Receiver and Document Consumer when implemented
- C [108] – Shall be grouped with Document Consumer when implemented
- C [109] – Shall only be implemented when supporting a Document Consumer Technical Actor
- C [110] – Document Source, Document Consumer, Document Repository, and Document Registry shall support the XDS.b option

3.2.4 DATA DETAIL

This section details the data elements and related Transactions that were extracted from the selected standards and describes any corresponding HITSP imposed constraints (e.g., required or optional).

Table 3.2.4-1 Data Element Constraints

Data Element	Transaction	Constraint	Constraint Type (Pre-condition, post-condition, general)	Purpose (Reason for this constraint)
To be determined				

3.2.5 NEW HITSP CONSTRUCTS

This section describes the new HITSP constructs (including Interoperability Specifications, Transaction Packages, Transactions and Components) that are expected to be used for the Use Case. A current list of all existing HITSP constructs that are being used can be found in Section 3.2.6.

The table below provides a description of the new HITSP constructs that will be created for this Use Case.

Table 3.2.5-1 New HITSP Constructs

New Construct	Construct Description	Technical Actors	Interoperability or Data Requirement
HITSP/C62 Unstructured Document Component	Document that contains simple text such as a note to the patient or a note from the patient. This document could include an unstructured, presentation preserved format, such as pdf	Content Creator Content Consumer	IER 12, IER 13
HITSP/C69 - Generic Order Component	Genetic/genomic test order	Content Creator Content Consumer	IER 9, IER 10

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New Construct	Construct Description	Technical Actors	Interoperability or Data Requirement
HITSP/T68 - Health Plan Authorization/Referral Request and Response	System Inquiries to the Eligibility Information Source and Receiver about an individual's insurance eligibility, coverage and benefits. System Inquiries to the Authorization Information Source and Receiver about an individual's insurance requirements to obtain an authorization approval for purposes of benefit coverage determination and reimbursement in order to refer a patient for care or services to another clinician or providers of care.	Eligibility Information Receiver Eligibility Information Source Payer Authorization Information Receiver Payer Authorization Information Source	IER 8

3.2.6 MODIFICATIONS TO EXISTING HITSP CONSTRUCTS

The table below provides a description of the existing HITSP constructs that will be used for this Use Case. It also specifies whether the construct will require modification based on the new sets of requirements that are being satisfied by the construct.

Table 3.2.6-1 Existing HITSP Constructs

HITSP Construct	Construct Description	Technical Actors	Interoperability or Data Requirement Number	Modification Required
HITSP/C32 - Summary Documents Using HL7 Continuity of Care Document (CCD)	Describes the document content summarizing a consumer's registration, medication and health data information contained within a Personal Health Record (PHR) for the purpose of information exchange. This component only deals with the exchange of summary information to and from the PHR	Content Creator Content Consumer	2, 26, 27	Add structured family history
HITSP/C37 - Lab Report Document	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 an EHR system, or other clinical data system of designated providers of care, and * Transmission of laboratory result data from electronically enabled healthcare delivery and public health systems in standardized and anonymized format to authorized Public Health Agencies	Content Creator Content Consumer	5, 7, 17, 26, 27	Add ability to report genetic test results

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HITSP Construct	Construct Description	Technical Actors	Interoperability or Data Requirement Number	Modification Required
HITSP/C35 - Lab Result Terminology	Defines the vocabulary for either message-based or document-based laboratory results reporting	Content Creator Content Consumer	5, 7, 17, 26, 27	Component will be modified to a generic Clinical Vocabulary Terminology Guide
HITSP/T40 - Patient Generic Health Plan Eligibility Verification Transaction	Provides 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, professional physician office visit, pharmacy and vision services that are included in the patient's generic health plan benefit	Eligibility Information Receiver Eligibility Information Source	8, 9	T40 should be modified to support a more service specific inquiry based on the consultation requirements (specialist). More Domain TC discussion is needed about CORE Phase 1 rules with CORE Phase 2 rules – Generic versus Service/Procedure specific inquires
HITSP/C19 - Entity Identity Assertion	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	Service User Identity Provider Service Provider	1, 2, 4, 5, 9, 10, 11, 14, 16, 18, 19, 20	No
HITSP/T16 - Consistent Time	Provides a mechanism to ensure that all of the entities that are communicating within the network have synchronized system clocks	Time Server Time Client	1, 2, 4, 5, 9, 10, 11, 14, 16, 18, 19, 20	No
HITSP/T17 - Secured Communication Channel	Provides the mechanisms to ensure the authenticity, integrity, and confidentiality of Transactions, and the mutual trust between communicating parties. It supports both application and machine credentials, and user machines (user nodes)	Node	1, 2, 4, 5, 9, 10, 11, 14, 16, 18, 19, 20	No
HITSP/T15 - Collect and Communicate Security Audit Trail	Provides 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	Audit Record Source Audit Record Repository	1, 2, 4, 5, 9, 10, 11, 14, 16, 18, 19, 20	No

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HITSP Construct	Construct Description	Technical Actors	Interoperability or Data Requirement Number	Modification Required
HITSP/T23 - Patient Demographics Query	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	Patient Demographics Consumer Patient Demographics Supplier	1, 2, 4, 5, 9, 10, 11, 14, 16, 18, 19, 20	No
HITSP/T29 - Notification of Document Availability	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 Cross-Enterprise Document Sharing (XDS) Integration Profile"), eliminating the need for manual steps or polling mechanisms for a Document Consumer to be aware that documents of interest have been registered with an XDS Document Registry Actor	Notification Sender Notification Receiver	1, 2, 4, 5, 9, 10, 11, 14, 16, 18, 19, 20	No
HITSP/T31 - Document Reliable Interchange	Supports a healthcare delivery organization or clinician who may need to communicate a clinical document to a recipient through direct communication	Document Source Document Recipient	1, 2, 4, 5, 9, 10, 11, 14, 16, 18, 19, 20	No
HITSP/T33 - Transfer of Documents on Media	Transports the information from a source to a destination. An example might be to transport data from one healthcare provider to another healthcare provider. Based on the IHE Cross-Enterprise Document Media Interchange Integration Profile	Portable Media Creator Portable Media Importer	1, 2, 4, 5, 9, 10, 11, 14, 16, 18, 19, 20	No
HITSP/TP13 - Manage Sharing of Documents	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	Initiating Gateway Responding Gateway Document Source Document Consumer Document Registry Document Repository	1, 2, 4, 5, 9, 10, 11, 14, 16, 18, 19, 20	No
HITSP/TP20 - Access Control	Provides the mechanism to administer 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. In an emergency, this construct supports the capability to alter access privileges to the appropriate level (failsafe/emergency access), which may include override of non-emergency consents	Access Control Service Service Provider Service User	1, 2, 4, 5, 9, 10, 11, 14, 16, 18, 19, 20	No

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HITSP Construct	Construct Description	Technical Actors	Interoperability or Data Requirement Number	Modification Required
HITSP/TP22 - Patient ID Cross-Referencing	The two transactions within this package are: * The IHE Patient ID Cross-Referencing (PIX) transaction * The IHE Patient Identity Feed transaction	Patient Identifier Cross-Reference Consumer Patient Identifier Cross-Reference Manager Patient Identity Source	1, 2, 4, 5, 9, 10, 11, 14, 16, 18, 19, 20	No
HITSP/TP30 - Manage Consent Directives	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	Consent Originator Consent Repository Consent Registry Consent Directive Requestor	1, 2, 4, 5, 9, 10, 11, 14, 16, 18, 19, 20	No
HITSP/C36 - 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	Content Creator Content Consumer	2, 5, 14, 16, 20	Add ability to report genetic/genomic test results

3.2.7 DOCUMENT MAP

The document map summarizes the suite of constructs that are the detailed map to existing standards and specifications used to satisfy the requirements imposed by the Personalized Healthcare Use Case. The most effective way to see the construct breakdown is to begin with the document indicated at the top of the diagram.

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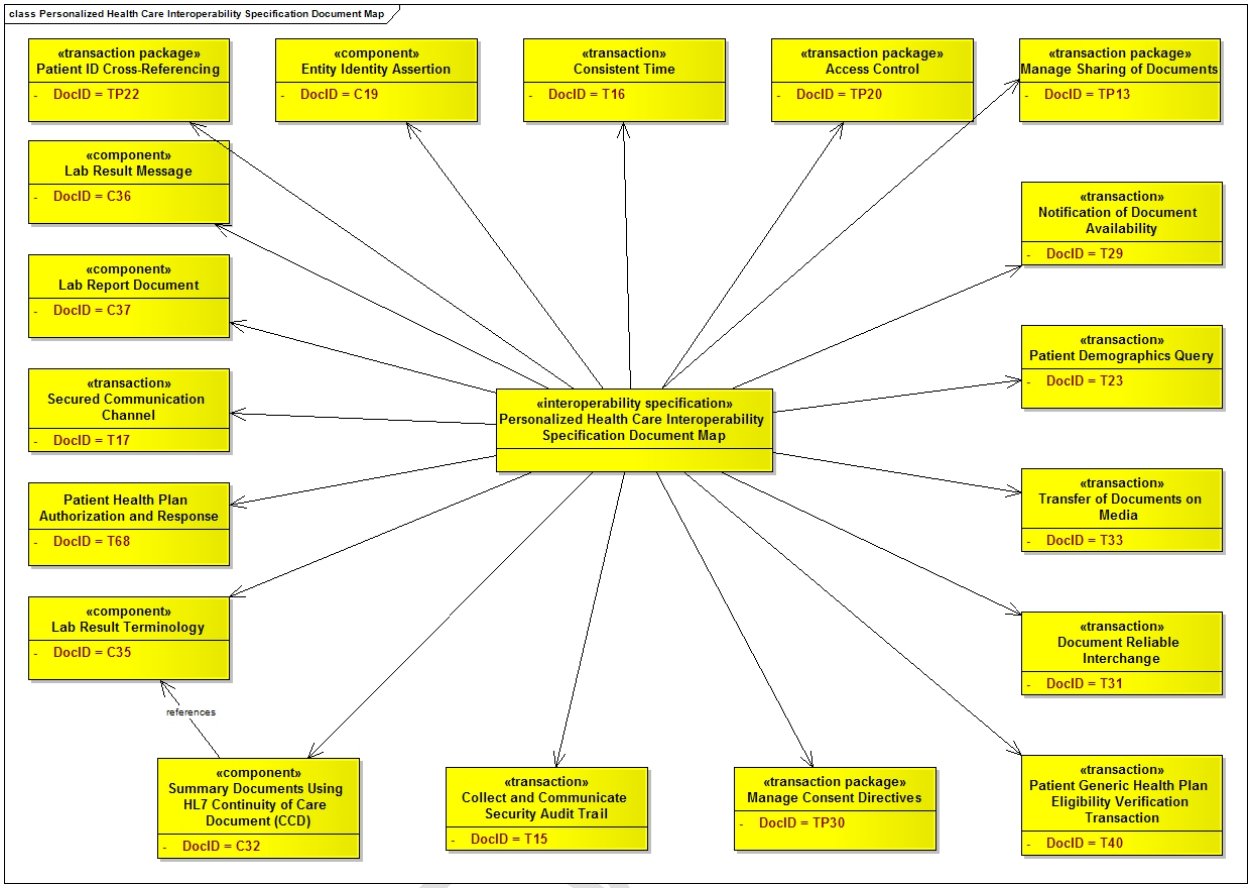
Figure 3.2.7-1 Requirements, Design and Standards Selection Document Map



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4.0 CANDIDATE STANDARDS

This section presents the candidate standards that may support the major Use Case events described in the requirements analysis. During Interoperability Specification development, standards selection will be based on the following process:

- Evaluation: The Technical Committee evaluates the standards using the Tier 2 Readiness Criteria. Standards considered for use may include provisional or to be named standards
- Selection: Based on the Tier 2 evaluations, named standards are selected and listed in Table 4.1.2-1. 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. During the actual construction of Interoperability Specifications, the Technical Committee may need to refine this listing based on detailed analysis
- Gap and Overlap Analysis and Recommendations: The Technical Committee also identifies, and analyzes gaps and overlaps within the standards industry as they related to the specific Use Case. The TC will provide a description of the gaps, including missing or incomplete standards, provide a description of all overlaps, or competition among standards for the relevant Use Cases, and recommendations for resolving these gaps and overlaps

Thus the following section lists a summary of the standards that will be further refined during the Interoperability Specification development phase.

4.1 LIST OF SELECTED AND CANDIDATE STANDARDS

This section presents the selected and candidate standards that may support the Use Case events described in the requirements analysis. As used by HITSP, the term “standard” refers, but is not limited to Specifications, Implementation Guides, Code Sets, Terminologies, and Integration Profiles. A standard should be produced through a well-defined approach that supports a business process and

1. has been agreed upon by a group of experts
2. has been publicly vetted
3. provides rules, guidelines, or characteristics
4. helps to ensure that materials, products, processes, and services are fit for their intended purpose
5. is available in an accessible format
6. is subject to an ongoing review and revision process

Candidate standards are then evaluated using the HITSP Tier 2 Readiness Criteria. Final selection does not occur until the Interoperability Specifications are completed. Thus there may be additions or deletions to this list.

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

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- Regulatory and guidance standards are legal or other authoritative declarations that HITSP must abide by. These may also be guidelines and recommendations that HITSP has adopted to aid in the selection of standards (see Section 4.1.1)
- Selected candidate standards are those candidate standards that are selected within the context of the specific Use Case requirements, and are evaluated for inclusion as part of the Interoperability Specification (see Section 4.1.2)

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 the Interoperability Specification.

Table 4.1.1-1 Regulatory and Guidance Standards

Standard	Description
For Regulatory and Guidance Standards relating to the Security and Privacy of Health Information, please see TN900	The HITSP/TN900 document is a reference document that provides the overall context for use of the HITSP Security and Privacy constructs. It also includes a set of overarching principles and concepts, derived from an analysis of major federal and common state laws and regulations

4.1.2 SELECTED AND CANDIDATE STANDARDS

The section provides a mapping of candidate standards that may be required to implement the requirements of the Interoperability Specification to the Use Case action codes which are supported.

Section 3.2 provides a description and listing of the new and existing constructs that are used by this Requirements, Design, and Standards Selection specification. Section 3.2.6 describes existing constructs that are expected to be used in this specification without changes (reused), or modified to include additional requirements (repurposed). Selected standards that are used by existing constructs are provided in the published construct specifications available from www.hitsp.org, and are not duplicated in this document. The following table only lists candidate standards that may be selected to meet use case requirements for new or repurposed constructs used in this specification. A detailed description of each standard is also provided in the appendix.

Table 4.1.2-1 Selected and Candidate Standards Linked to Requirements

SDO and Standard Name	Interoperability Requirement	Category	Remarks/ Minor Gaps
Accredited Standards Committee (ASC) X12N 275 Additional Information to Support a Health Care Claim or Encounter (005010X210)	9, 10	HITSP/C69 - Generic Order	

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SDO and Standard Name	Interoperability Requirement	Category	Remarks/ Minor Gaps
Accredited Standards Committee (ASC) X12N 278 - Health Care Services Review - Request for Review and Response, Version 4010, May 2000, and Addenda to Health Care Services Review - Request for Review and Response, Version 4010, October 2002	8 (for HITSP/T68) 9,10 (for HITSP/C69)	HITSP/T68 - Health Plan Authorization/Referral Request and Response HITSP/C69 - Generic Order	
Health Level Seven (HL7) Version 2.5.1	9, 10	HITSP/C69 - Generic Order	
Health Level Seven (HL7) Version 3.0	9, 10	HITSP/C69 - Generic Order	
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Supplement 2007 - 2008 Cross-Enterprise Sharing of Scanned Documents (XDS-SD)	12, 13	HITSP/C62 - Unstructured Document	

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 endorsement 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 Personalized Healthcare Use Case event. Recommended resolutions were developed through a series of steps including the committee's initial recommendations, cross team validation of the gap, provisional recommendations and peer review by the team.

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

Table 4.2-1 Use Case Events and Associated Gaps

Event Code	Event Description	Identified Gaps	Recommended Resolution
8.1.2	Perform interpretation and care planning activities	No way to receive a Risk Analysis report into an EHR/PHR	Care Management and Health Records Domain TC will investigate current standards

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4.3 STANDARD OVERLAPS

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

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

Table 4.3-1 Standard Overlaps

Event Code	Event Description	Standard Overlap	Recommended Resolution
To be determined			

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5.0 NEXT STEPS

The first step in the HITSP harmonization process is Requirements Analysis and Design. Upon completion of the Requirements, Design and Standards Selection for the Personalized Healthcare Use Case, the following steps will occur:

- This document will be submitted to the HITSP Panel and interested Public for comment
- After the comment period, the Technical Committee or Work Group will disposition the comments, maintaining a written log of all dispositions assigned to the TC/WG
- Persuasive comments will be used to inform the construction of the Interoperability Specification (IS)
- Non-persuasive comments or comments that are not applicable to the construction of the IS will be deferred with reason/explanation (e.g., need additional information or further analysis during construction)
- In parallel to the steps described above, the Technical Committee/Work Group will begin the construction of the Interoperability Specifications

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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 standards that are referenced by this Requirements, Design, and Standards Selection Specification:

Table 6.1-1 Description of Standards

Standard Name	Description
Accredited Standards Committee (ASC) X12N 275 Additional Information to Support a Health Care Claim or Encounter (005010X210)	The Additional Information to Support a Health Care Claim or Encounter Implementation Guide describes the use of the ASC X12 Patient Information (275) transaction set for the following business usage: To assist those who send additional supporting information or who receive additional supporting information to a health care claim or encounter. For more information, visit www.x12.org
Accredited Standards Committee (ASC) X12N 278 - Health Care Services Review - Request for Review and Response, Version 4010, May 2000, and Addenda to Health Care Services Review - Request for Review and Response, Version 4010, October 2002	This is the HIPAA standard for referral and authorization, as referenced in §162.1302 of the Regulation. This HIPAA transaction provides standardized data requirements and content for the exchange of information between providers and review entities. This transaction allows for the following business events and processes: admission certification review request and associated response referral review request and associated response health care services certification review request and associated response extend certification review request and associated response unsolicited notifications inquiries and responses. The HIPAA standard X12 278 is to be used when health care services reviews and requests and responses for review are made. For more information, visit www.x12.org
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	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.
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Supplement 2007 - 2008 Cross Enterprise Sharing of Scanned Documents (XDS-SD)	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. The latest version of the IHE Technical Framework is available at www.ihe.net

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6.2 PROTOTYPE BUSINESS PROCESS MODELING NOTATION MODEL

Figure 6.2-1 Scenario 1: Clinical Assessment

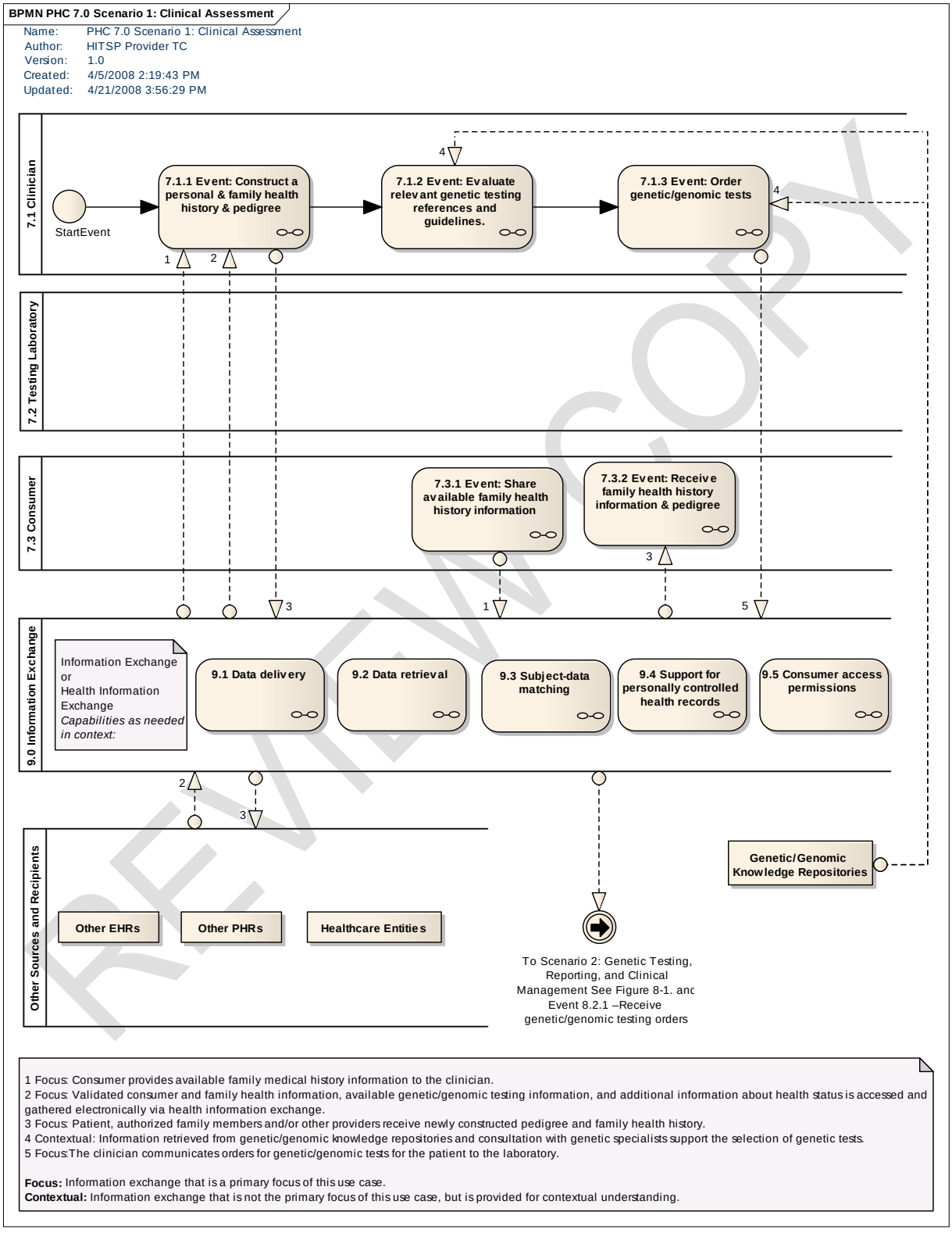

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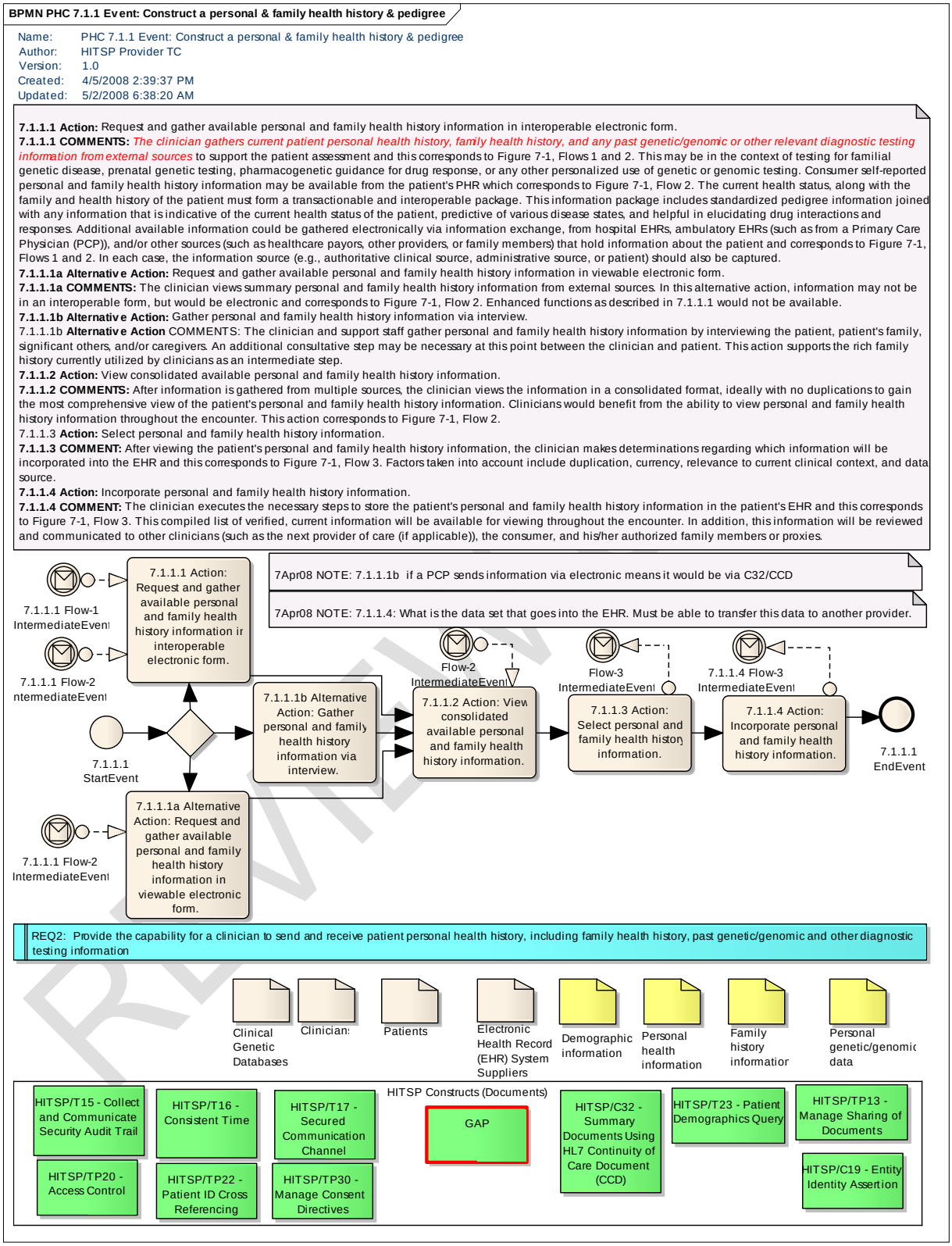
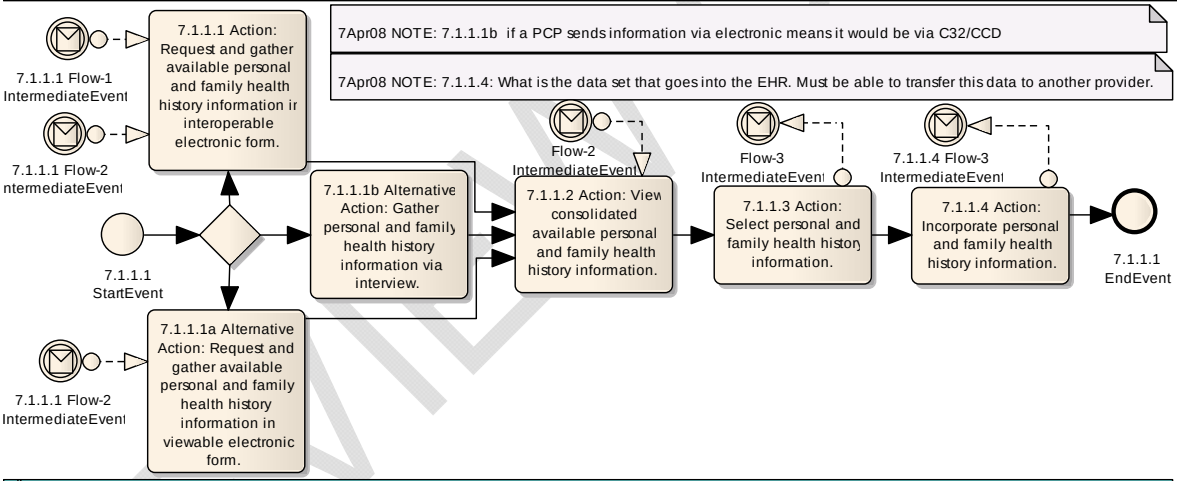
Figure 6.2-2 7.1.1 Construct a Personal & Family Health History & Pedigree

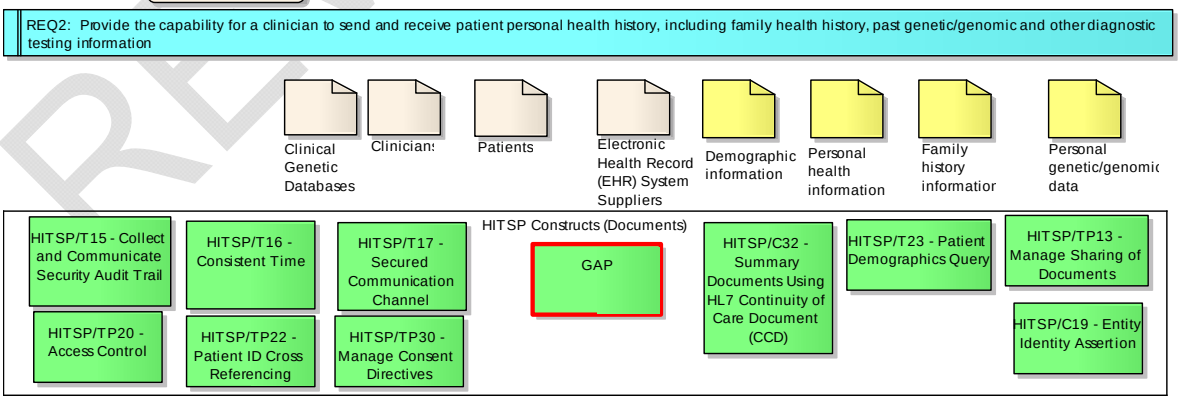


BPMN PHC 7.1.1 Event: Construct a personal & family health history & pedigree

Name: PHC 7.1.1 Event: Construct a personal & family health history & pedigree
Author: HITSP Provider TC
Version: 1.0
Created: 4/5/2008 2:39:37 PM
Updated: 5/2/2008 6:38:20 AM

7.1.1.1 Action: Request and gather available personal and family health history information in interoperable electronic form.
7.1.1.1 COMMENTS: *The clinician gathers current patient personal health history, family health history, and any past genetic/genomic or other relevant diagnostic testing information from external sources* to support the patient assessment and this corresponds to Figure 7-1, Flows 1 and 2. This may be in the context of testing for familial genetic disease, prenatal genetic testing, pharmacogenetic guidance for drug response, or any other personalized use of genetic or genomic testing. Consumer self-reported personal and family health history information may be available from the patient's PHR which corresponds to Figure 7-1, Flow 2. The current health status, along with the family and health history of the patient must form a transactionable and interoperable package. This information package includes standardized pedigree information joined with any information that is indicative of the current health status of the patient, predictive of various disease states, and helpful in elucidating drug interactions and responses. Additional available information could be gathered electronically via information exchange, from hospital EHRs, ambulatory EHRs (such as from a Primary Care Physician (PCP)), and/or other sources (such as healthcare payors, other providers, or family members) that hold information about the patient and corresponds to Figure 7-1, Flows 1 and 2. In each case, the information source (e.g., authoritative clinical source, administrative source, or patient) should also be captured.
7.1.1.1a Alternative Action: Request and gather available personal and family health history information in viewable electronic form.
7.1.1.1a COMMENTS: The clinician views summary personal and family health history information from external sources. In this alternative action, information may not be in an interoperable form, but would be electronic and corresponds to Figure 7-1, Flow 2. Enhanced functions as described in 7.1.1.1 would not be available.
7.1.1.1b Alternative Action: Gather personal and family health history information via interview.
7.1.1.1b **Alternative Action** COMMENTS: The clinician and support staff gather personal and family health history information by interviewing the patient, patient's family, significant others, and/or caregivers. An additional consultative step may be necessary at this point between the clinician and patient. This action supports the rich family history currently utilized by clinicians as an intermediate step.
7.1.1.2 Action: View consolidated available personal and family health history information.
7.1.1.2 COMMENTS: After information is gathered from multiple sources, the clinician views the information in a consolidated format, ideally with no duplications to gain the most comprehensive view of the patient's personal and family health history information. Clinicians would benefit from the ability to view personal and family health history information throughout the encounter. This action corresponds to Figure 7-1, Flow 2.
7.1.1.3 **Action:** Select personal and family health history information.
7.1.1.3 COMMENT: After viewing the patient's personal and family health history information, the clinician makes determinations regarding which information will be incorporated into the EHR and this corresponds to Figure 7-1, Flow 3. Factors taken into account include duplication, currency, relevance to current clinical context, and data source.
7.1.1.4 Action: Incorporate personal and family health history information.
7.1.1.4 COMMENT: The clinician executes the necessary steps to store the patient's personal and family health history information in the patient's EHR and this corresponds to Figure 7-1, Flow 3. This compiled list of verified, current information will be available for viewing throughout the encounter. In addition, this information will be reviewed and communicated to other clinicians (such as the next provider of care (if applicable)), the consumer, and his/her authorized family members or proxies.





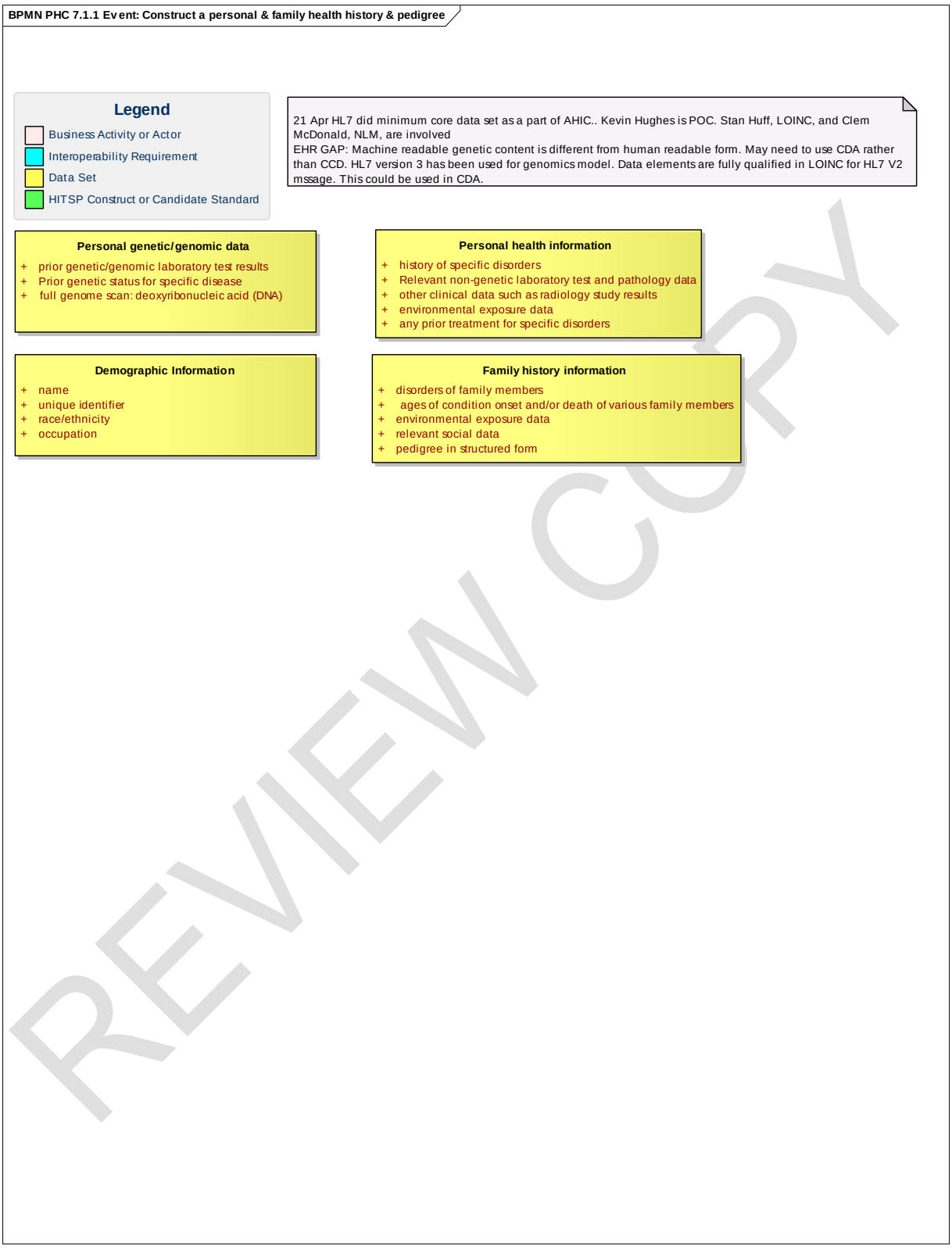

BPMN PHC 7.1.1 Event: Construct a personal & family health history & pedigree
Legend
Business Activity or Actor
Interoperability Requirement
Data Set
HITSP Construct or Candidate Standard
21 Apr HL7 did minimum core data set as a part of AHIC.. Kevin Hughes is POC. Stan Huff, LOINC, and Clem McDonald, NLM, are involved
EHR GAP: Machine readable genetic content is different from human readable form. May need to use CDA rather than CCD. HL7 version 3 has been used for genomics model. Data elements are fully qualified in LOINC for HL7 V2 mssage. This could be used in CDA.
Personal genetic/genomic data
+ prior genetic/genomic laboratory test results
+ Prior genetic status for specific disease
+ full genome scan: deoxyribonucleic acid (DNA)
Personal health information
+ history of specific disorders
+ Relevant non-genetic laboratory test and pathology data
+ other clinical data such as radiology study results
+ environmental exposure data
+ any prior treatment for specific disorders
Demographic Information
+ name
+ unique identifier
+ race/ethnicity
+ occupation
Family history information
+ disorders of family members
+ ages of condition onset and/or death of various family members
+ environmental exposure data
+ relevant social data
+ pedigree in structured form

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Figure 6.2-3 7.1.2 Evaluate Relevant Genetic Testing References and Guidelines

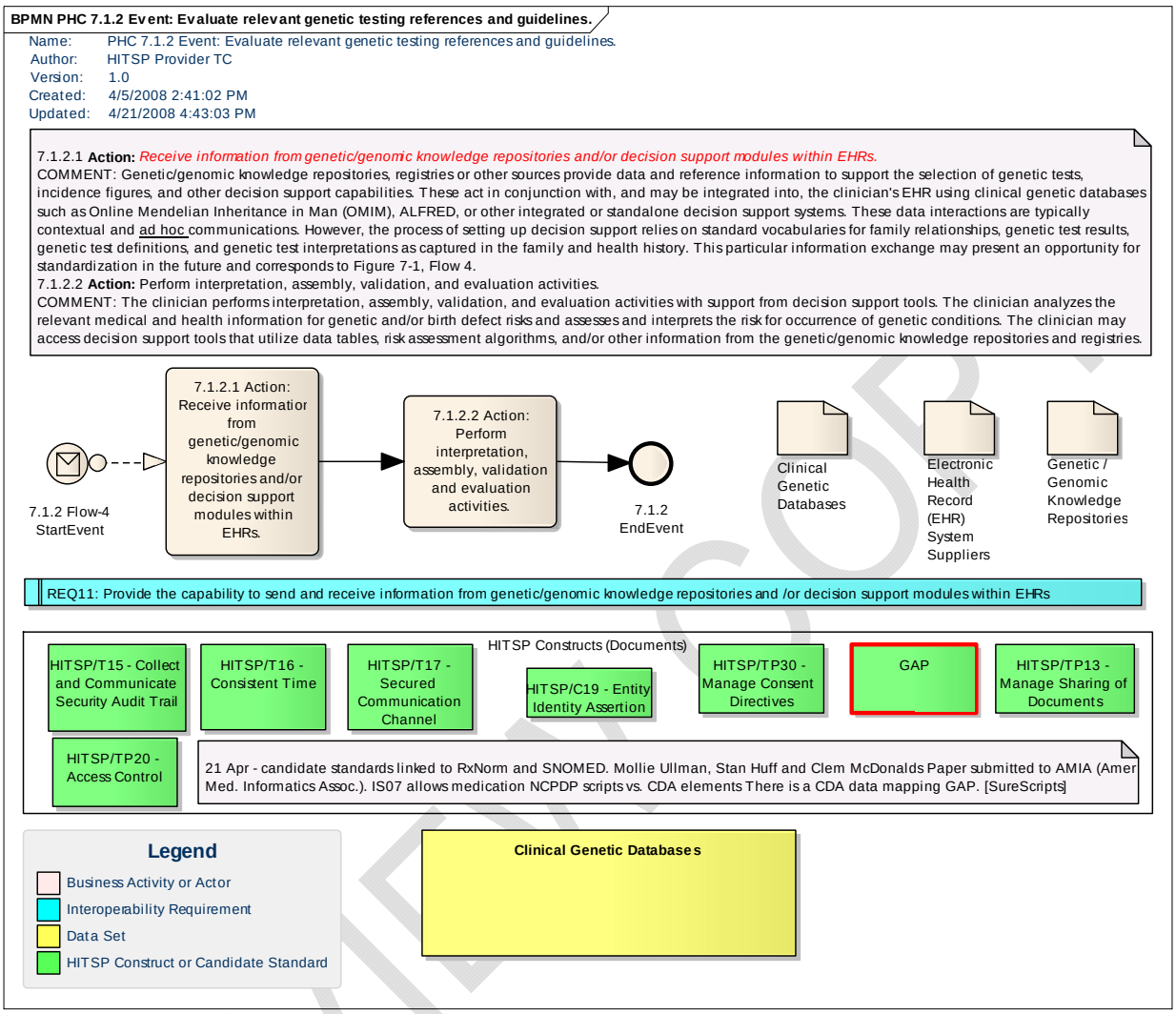

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Figure 6.2-4 7.1.3 Order Genetic/Genomic Tests

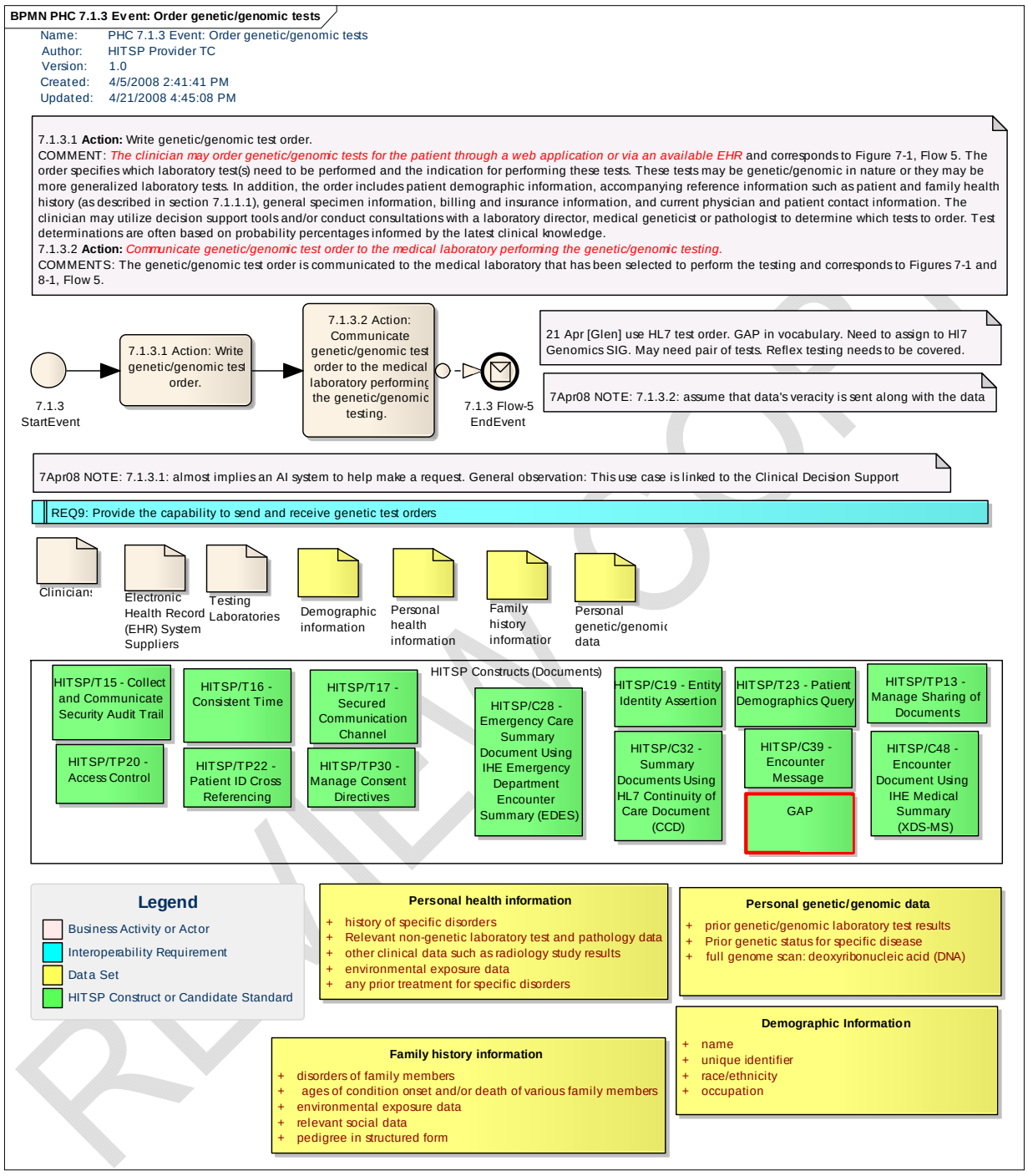

Figure 6.2-5 7.3.1 Share Available Family Health History Information

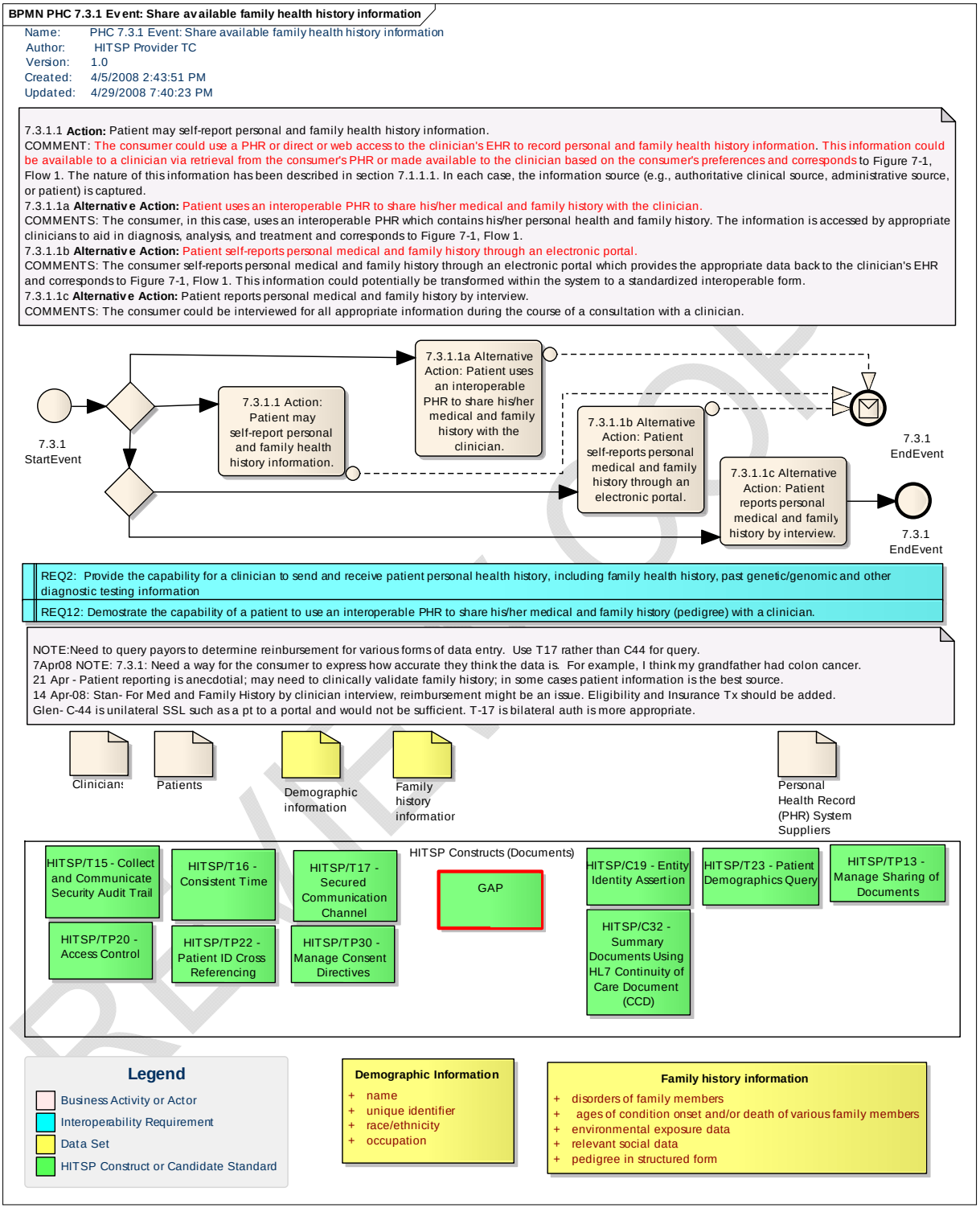

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Figure 6.2-6 7.3.2 Receive Family Health History Information & Pedigree

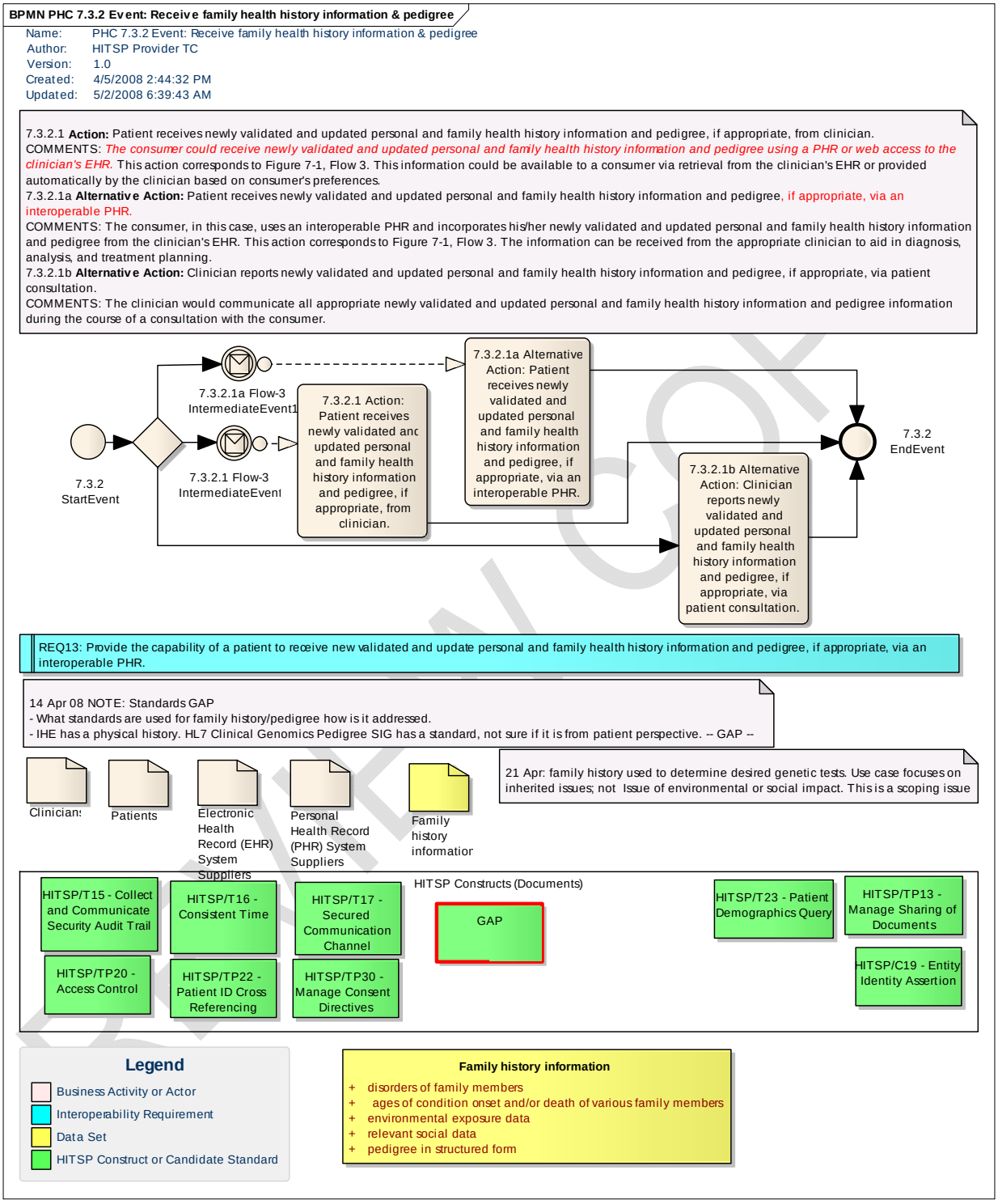

Figure 6.2-7 Scenario 2: Genetic Testing, Reporting, and Clinical Management

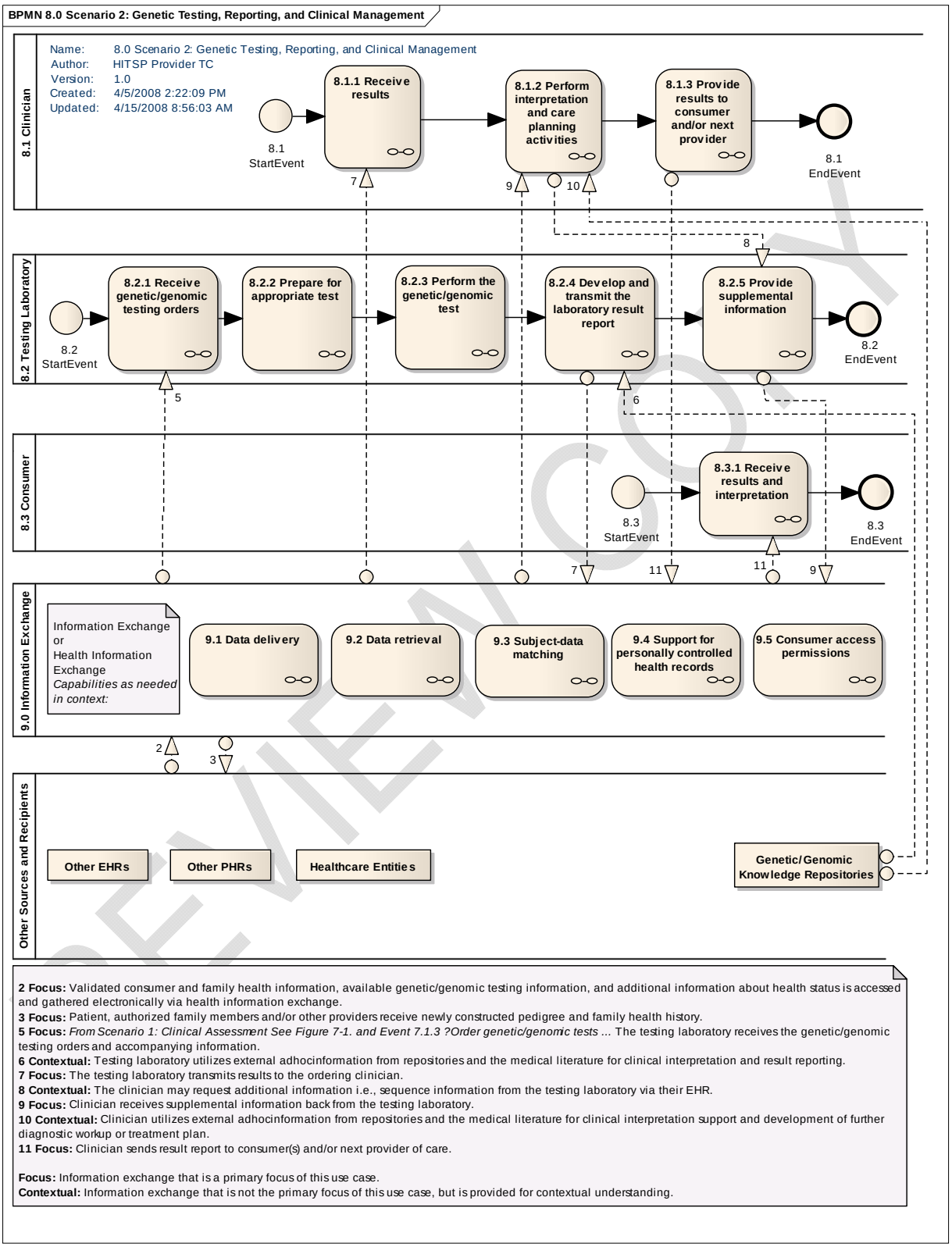

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Figure 6.2-8 8.1.1 Receive Results

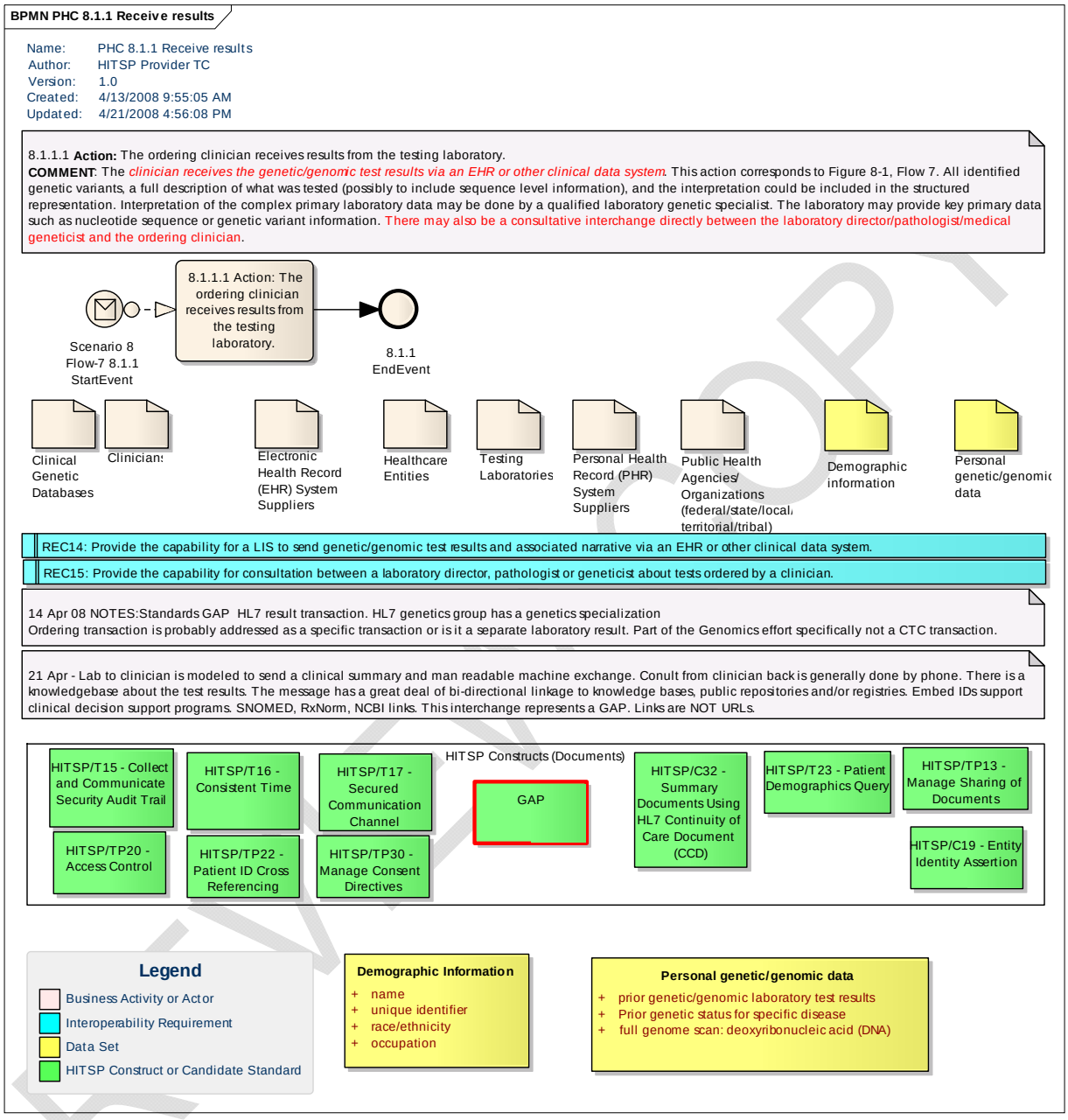

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Figure 6.2-9 8.1.2 Perform Interpretation and Care Planning Activities

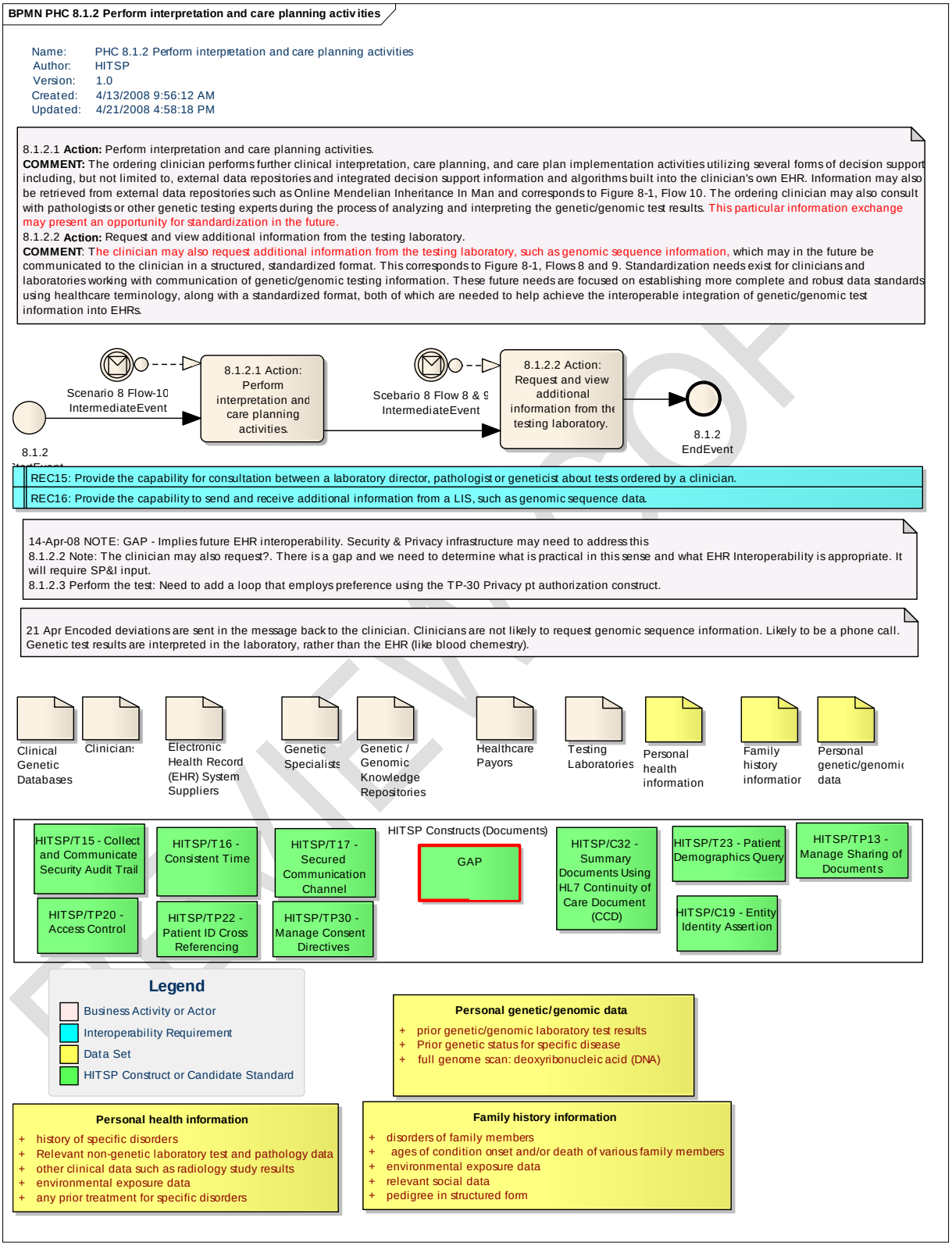

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Figure 6.2-10 8.1.3 Provide Results to Consumer and/or Next Provider

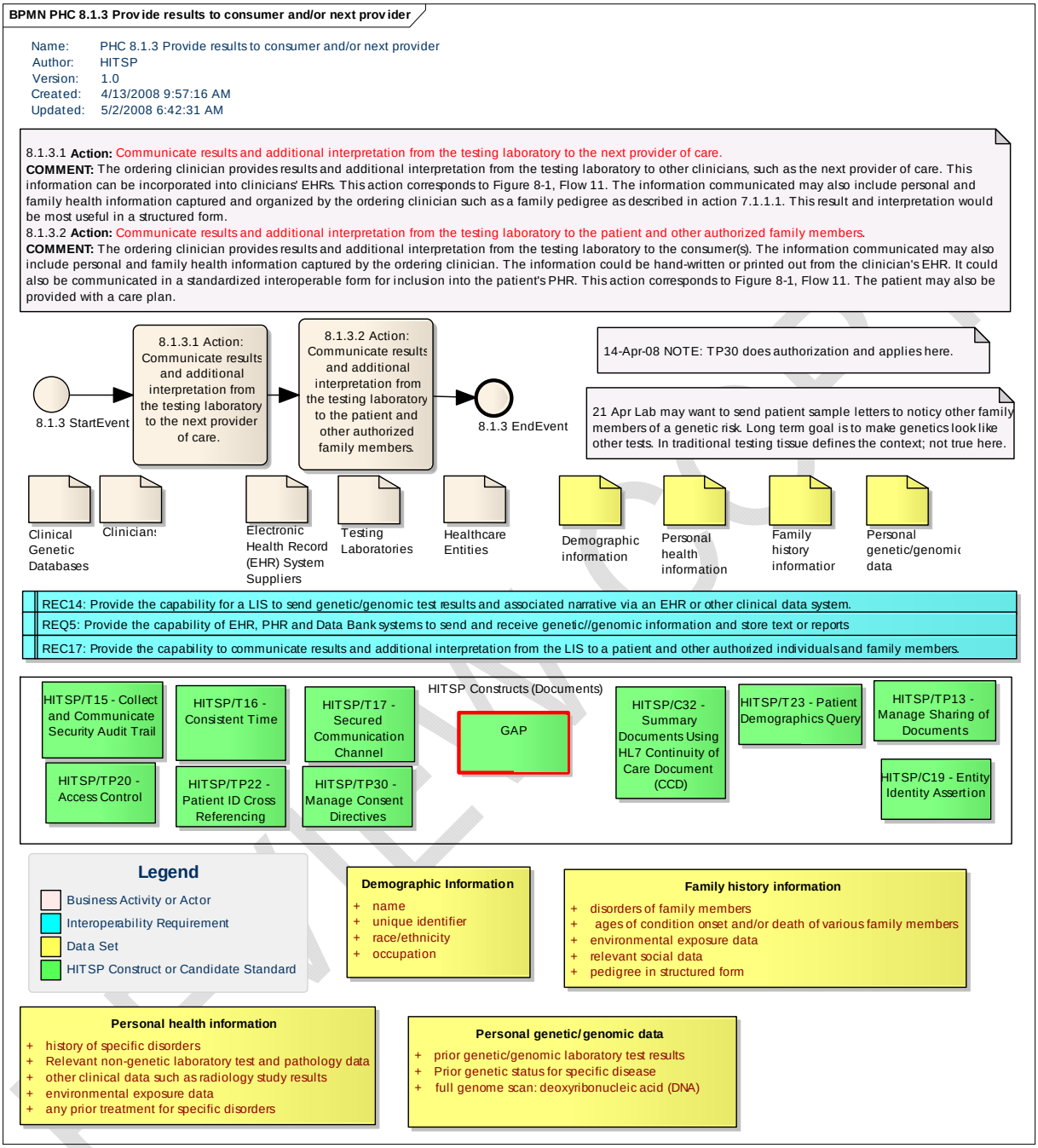

Figure 6.2-11 8.2.1 Receive Genetic/Genomic Testing Orders

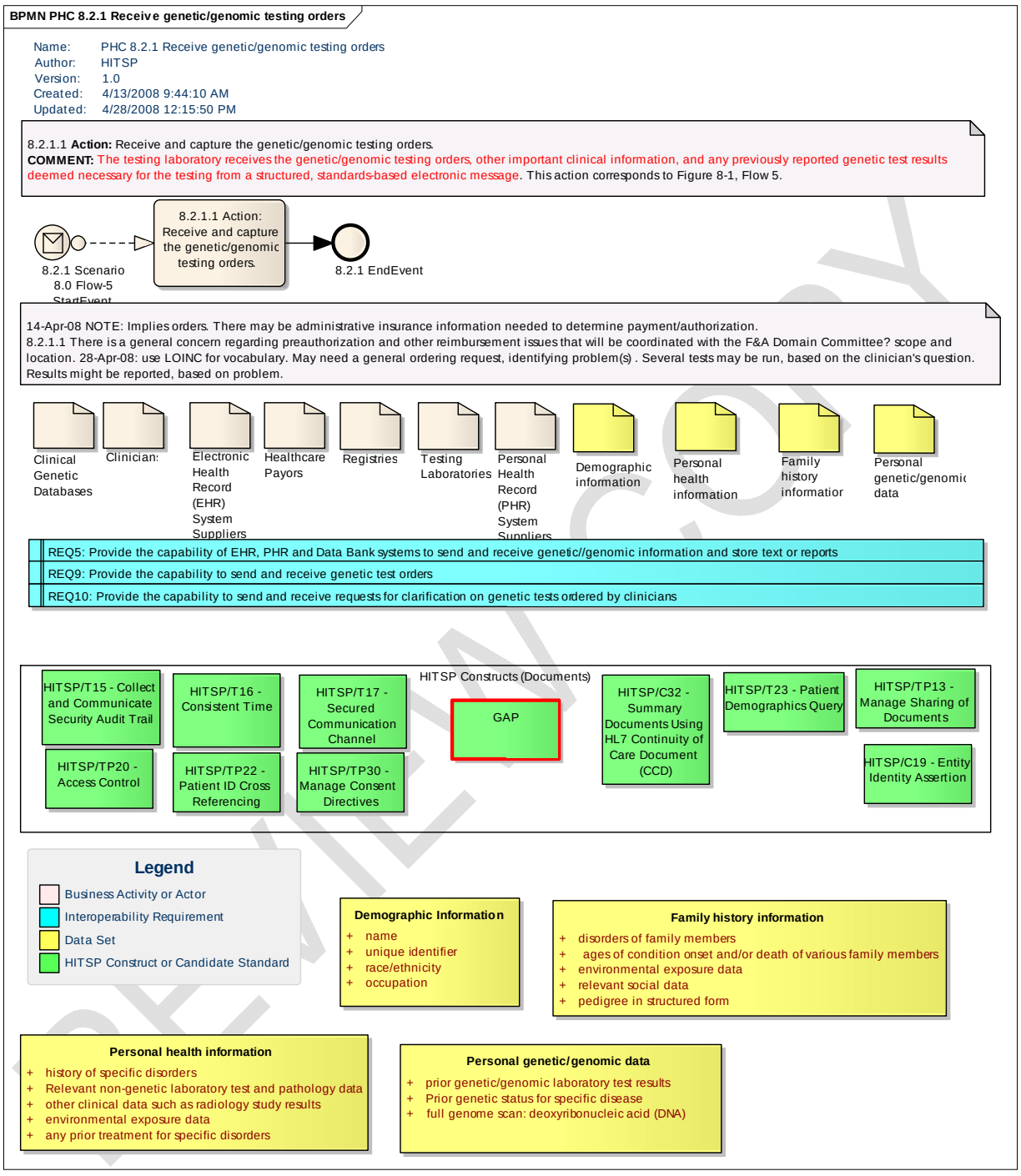

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Figure 6.2-12 8.2.2 Prepare for Appropriate Test

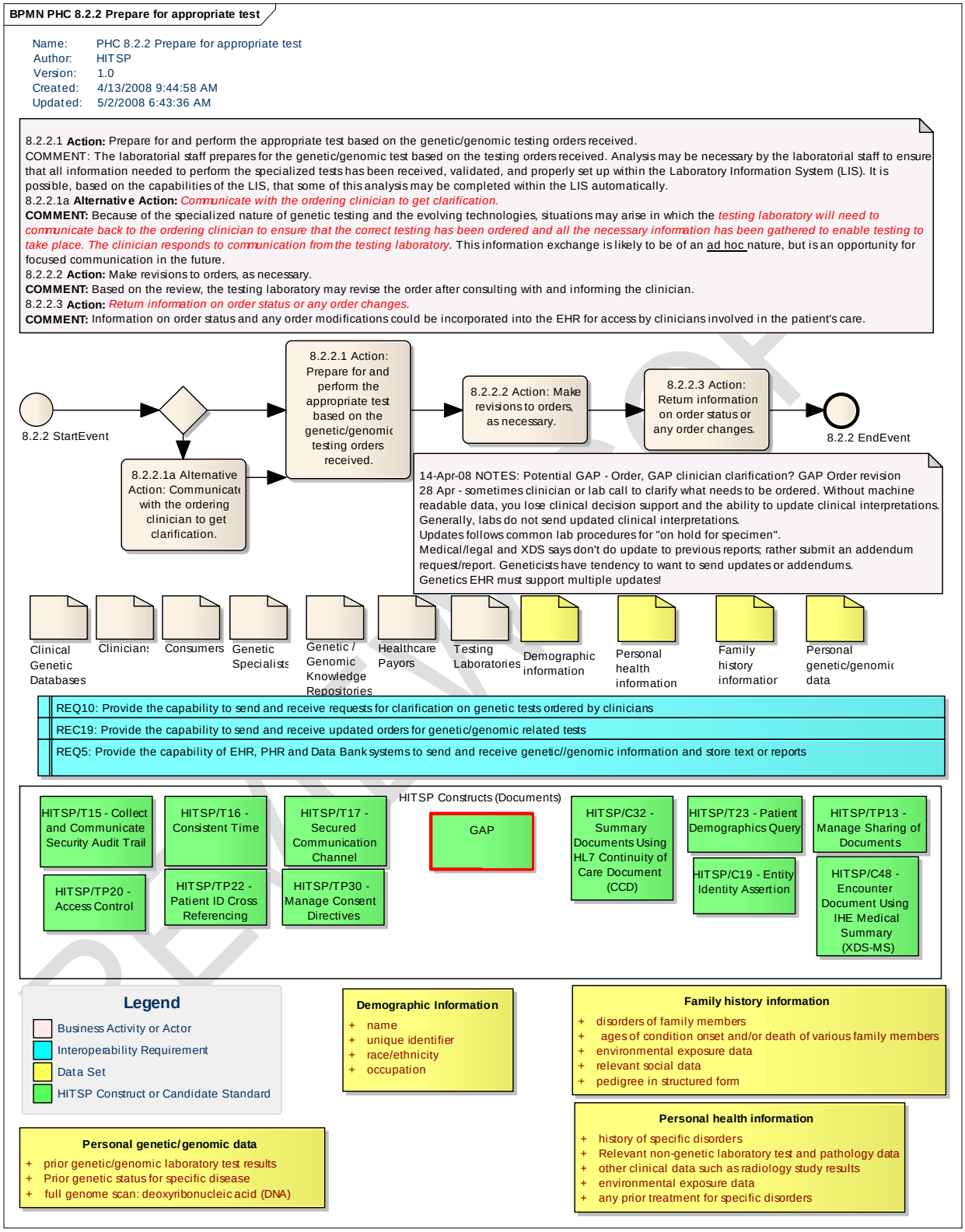

Figure 6.2-13 8.2.3 Perform the Genetic/Genomic Test

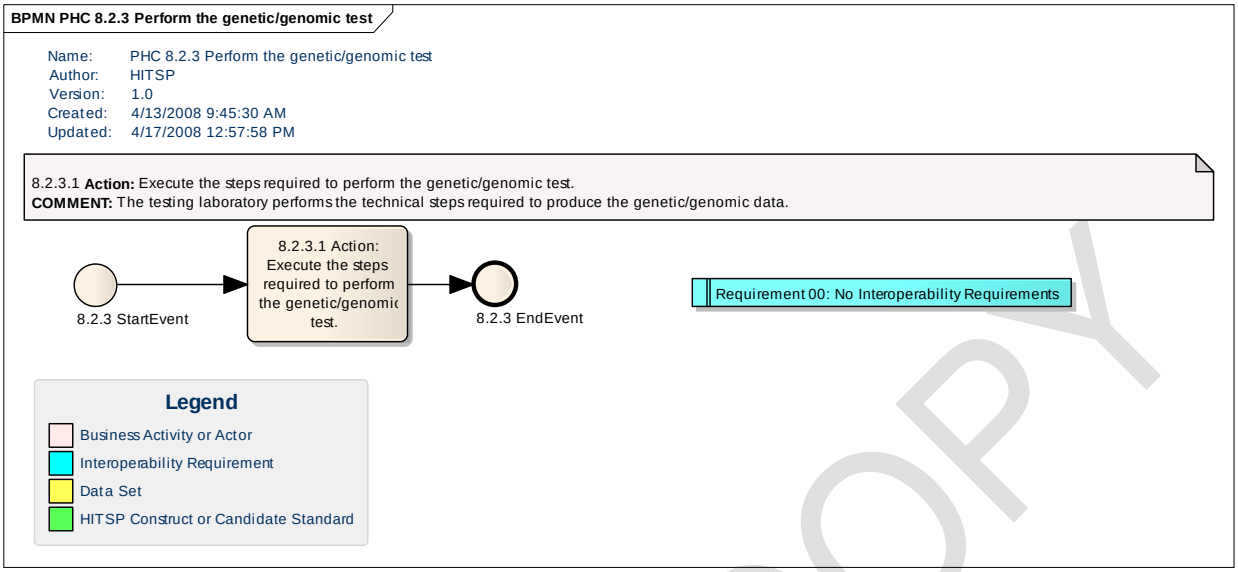

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Figure 6.2-14 8.2.4 Develop and Transmit the Laboratory Result Report

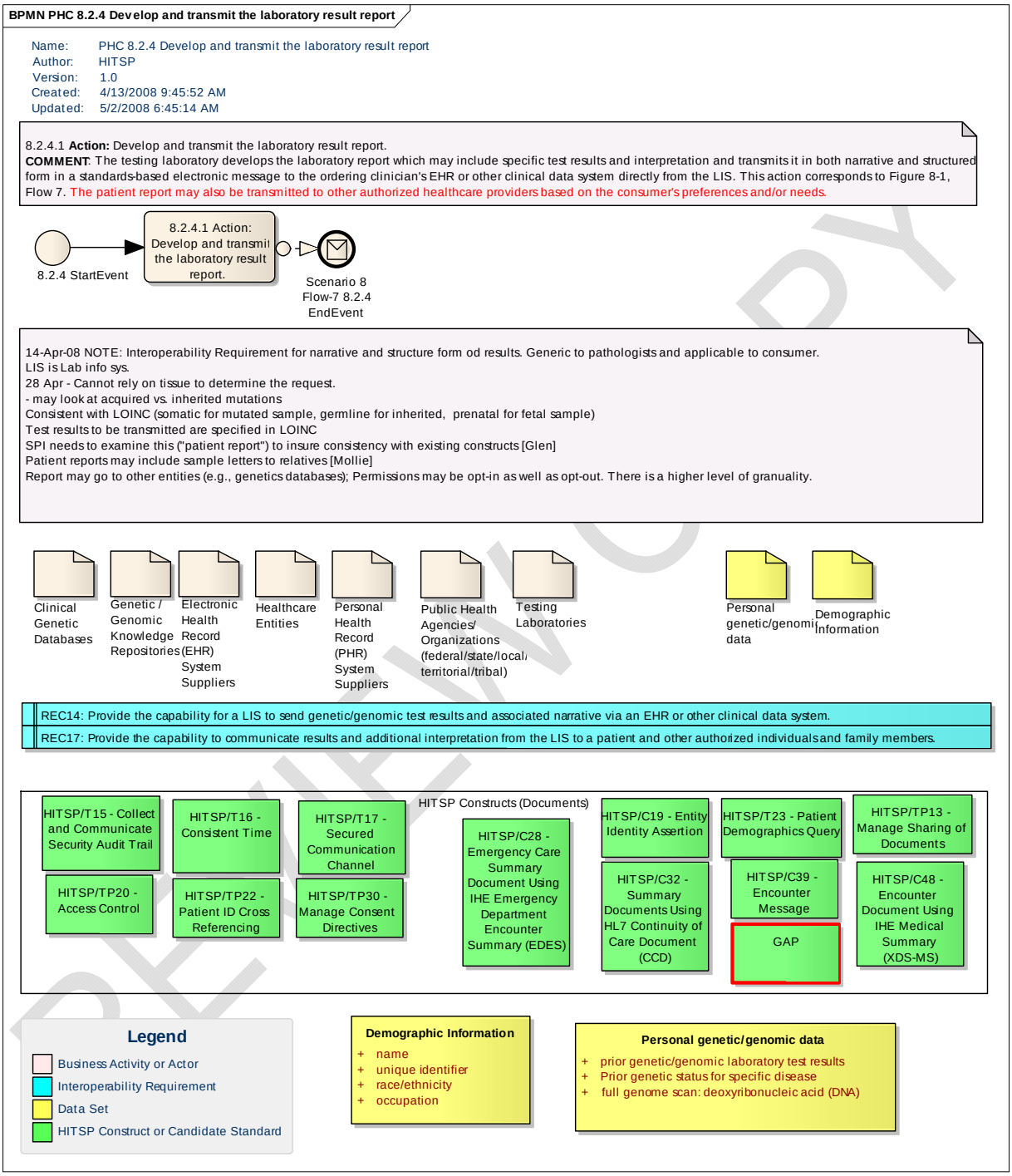

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Figure 6.2-15 8.2.5 Provide Supplemental Information

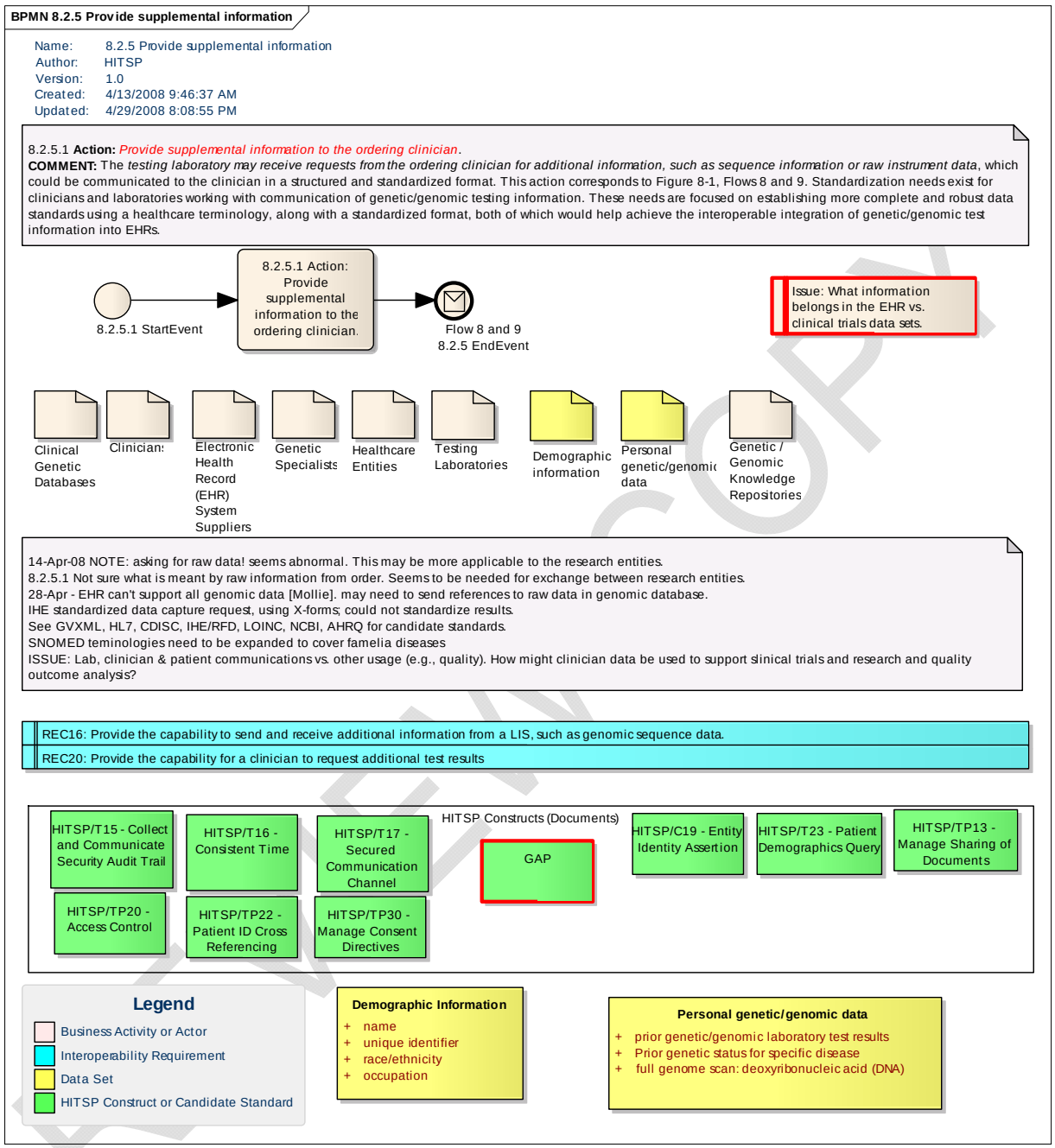

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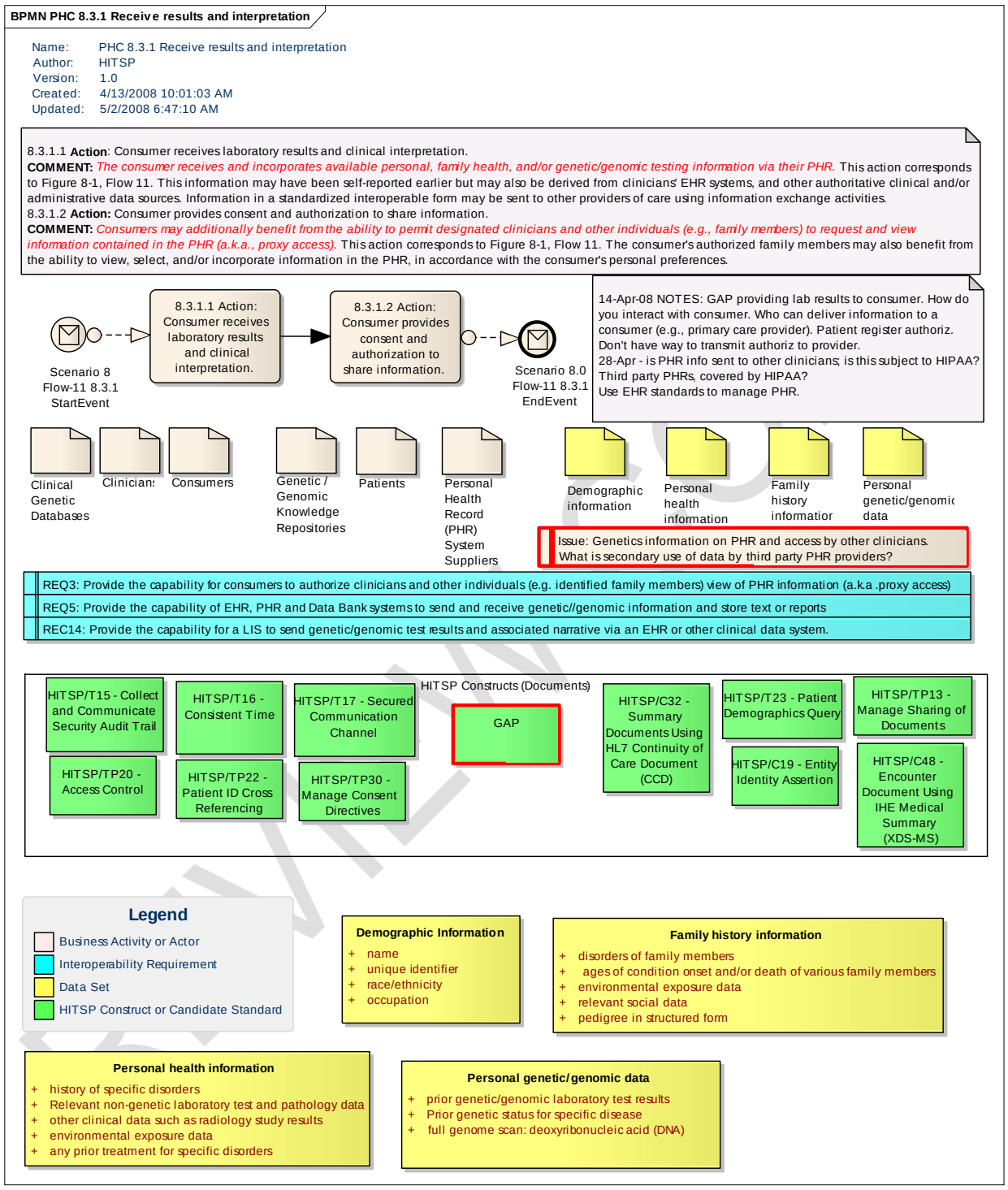
Figure 6.2-16 8.3.1 Receive Results and Interpretation



7.0 CHANGE HISTORY

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

No change at this time. This is the first published version.

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