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Ministry of Health

National eHealth Strategy and Change Management Office

(SCMO)

Enabling Standards-Based eHealth Interoperability

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Saudi eHealth Core Interoperability Specification for Clinical Notes and Summaries

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Document Revision History

Version	Date	Type of update	Prepared/Revised by
1.0	February 22, 2015	First Release	eHealth Strategy Management Office – eHealth Standards Department

PREFACE

DOCUMENT PURPOSE

The purpose of this document is to address the Saudi eHealth Core Interoperability Specification for the UC0007 *Saudi eHealth Interoperability Use Case for Clinical Notes and Summaries*. It forms a set of requirements that complements the set of Integrating the Healthcare Enterprise (IHE) Profiles, Health Level Seven (HL7) and Vocabulary Standards required by this specification with Saudi eHealth specific constraints. It also aligns with the Saudi e-Government Interoperability Standards (YEFI) to expedite national adoption.

This Interoperability Specification is applicable to existing and new information systems that will connect to exchange Health Information. In particular, this Interoperability Specification applies to the deployment of Health Information Exchange (HIE) Platforms such as the Saudi Health Exchange (SeHE).

HOW TO READ THIS DOCUMENT

This document contains four normative sections, as well as informative appendices for convenience. The document is structured as follows:

Section 1: Describes the Use Case, including design constraints and assumptions. Please refer to the UC0007 *Saudi eHealth Interoperability Use Case for Clinical Notes and Summaries* for workflows.

Section 2: Establishes the Core Interoperability Requirements for the Interoperability Specification.

Section 3: Establishes the Conformance Requirements for the Interoperability Specification.

Section 4: Establishes the conformance requirements for the Interoperability Specification to the Clinical Notes and Summaries Use Case

Section 5: Lists the Saudi eHealth reference documents, as well as the international standards which underpin the Interoperability Specification.

Appendix A: illustrates sample documents messages associated with Clinical Notes and Summaries.

REFERENCES

The Saudi eHealth Core Interoperability Specification (IS) is the sole entry point for the technology developers, the compliance assessor/testers and certifiers, and the purchaser of IT systems in terms of technical requirements.

It references a number of Supporting Interoperability Specifications:

- IS0001 *Saudi eHealth Core Interoperability Specification for KSA-Wide Patient Demographic Query*
- IS0002 *Saudi eHealth Core Interoperability Specification for KSA-Wide Healthcare Provider Directory Query*

- IS0003 *Saudi eHealth Core Interoperability Specification for Sharing Coded Laboratory Results*
- IS0005 *Saudi eHealth Core Interoperability Specification for Sharing Images and Imaging Reports*
- IS0008 *Saudi eHealth Core Interoperability Specification for ePrescriptions*
- IS0010 *Saudi eHealth Core Interoperability Specification for Immunization*
- IS0101 *Saudi eHealth Security and Privacy Interoperability Specification*
- IS0102 *Saudi eHealth Document Sharing Interoperability Specification*
- IS0106 *Saudi eHealth Clinical Documents Constrains Interoperability Specifications*
- IS0103 *Saudi eHealth Radiology Report Content Interoperability Specification*
- IS0105 *Saudi eHealth Laboratory Orders and Results Content Interoperability Specification*
- IS0200 *Saudi eHealth Terminology Repository*

The above Saudi eHealth Interoperability Specifications include precise references to internationally adopted profiles and standards as well as Saudi specific constraints.

This document fits into an overall specification framework described in Figure 0-1 Clinical Notes and Summaries Document Organization. Further descriptions and references for the documents identified below are provided in Section 5 Referenced Documents and Standards. This specification requires the ability to query and retrieve all of the types of clinical documentation in the HIE Document Repository. The Related Core Interoperability Specifications supporting the following document types and their related terminology Interoperability Specifications are not explicitly shown in this diagram:

- Laboratory Results
- Radiology Reports
- Electronic Prescriptions
- Immunization Documents

Implementations are required to conform to the requirements within this Interoperability Specification; all Saudi eHealth referenced Interoperability Specifications, and the standards and profiles they specify.

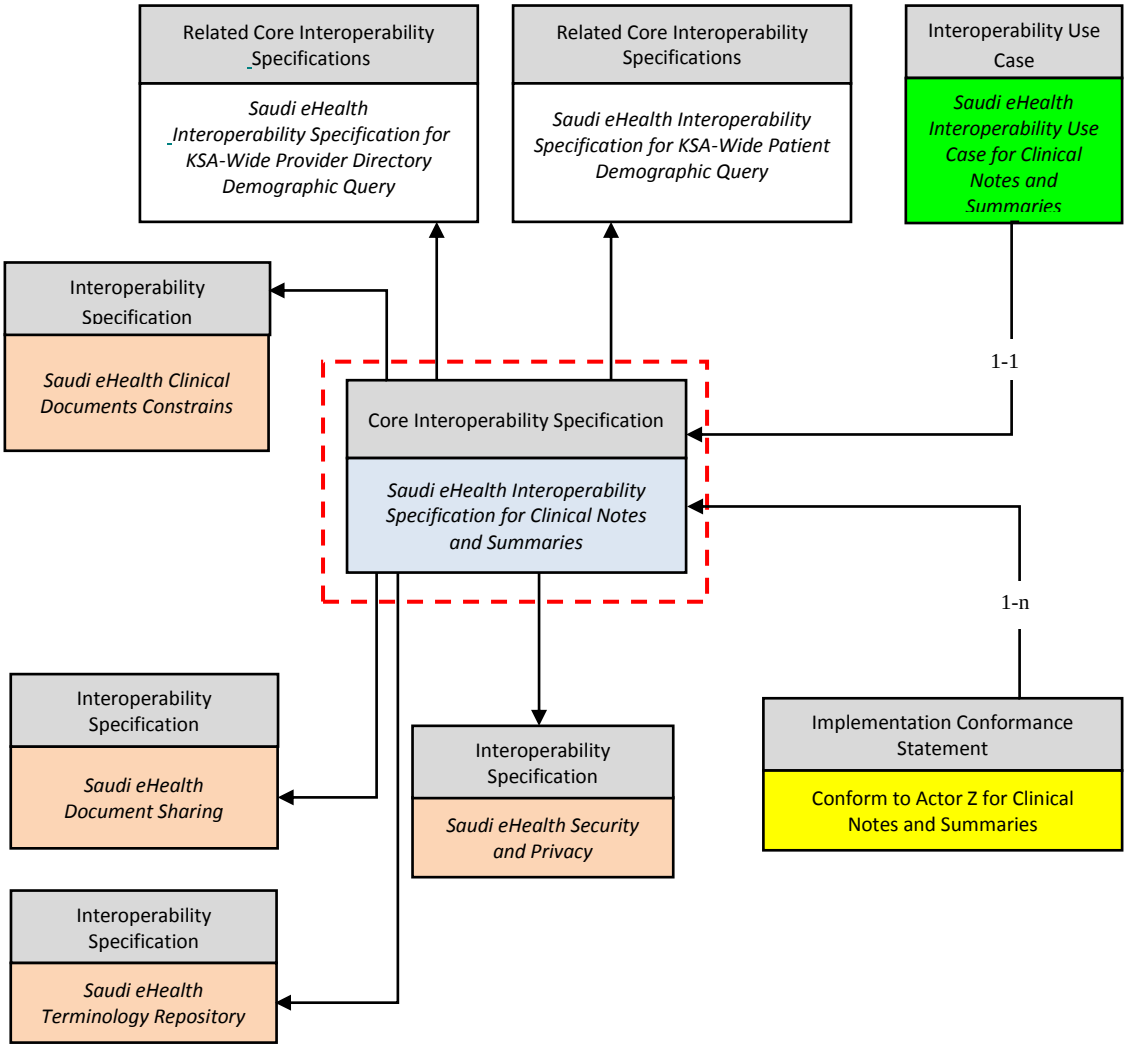


FIGURE 0-1 CLINICAL NOTES AND SUMMARIES DOCUMENT ORGANIZATION

This Core Interoperability Specification describes the technical interface requirements for sharing Clinical Notes and Summaries documents as well as access to clinical data through the Health Information Exchange (HIE). This capability is accessible to various "edge" applications including point of care systems and MOH business applications.

Clinical Summaries provide a synopsis of an encounter (i.e., an interaction between a patient and healthcare participant(s) for the purpose of providing patient service(s) or assessing the health status of a patient). Clinical Notes provide detailed information about a specific type of encounter (e.g., Operative Note) with a patient. The Clinical Notes and Summaries documentation includes information such as:

- General information about the patient,
- why the patient is being seen,
- relevant past medical history,
- what was done, and

- what should be done next.

The Clinical Notes and Summaries documents are created in a format that supports both human-readable rendering and machine processing (i.e., coded results data).

In addition to the Clinical documentation, the HIE Platform maintains pertinent clinical data which can be filtered and reported to point of care systems based upon the Healthcare Provider and/or Organization requirements.

DOCUMENT CONVENTIONS

Requirements Numbering Conventions:

All Saudi eHealth Interoperability Specifications contain numbered requirements that follow this format:

- [ABCD-###], where ABCD is a three or four letter acronym unique to that Interoperability Specification for convenient purposes, and ### is the unique number for that requirement within the Interoperability Specification.
- Where a specific value set or code is required to be used, it can be found in the "IS0200 Saudi eHealth Terminology Repository". The location and process to access the terminology repository will be specified in mechanisms external to this document.

Saudi eHealth numbered requirements are the elements of the Interoperability Specification that the system can claim conformance to. In other words, in order to implement a system that fully supports the Use Case and Interoperability Specification, the system shall be able to demonstrate that it conforms to every numbered requirement for the system actors to which it is claiming conformance.

Please note that all Saudi eHealth numbered requirements are numbered uniquely, however, numbered requirements may not always be sequential.

Requirements Language

Throughout this document the following conventions[1] are used to specify requirement levels:

SHALL: the definition is an absolute requirement of the specification. (Note: "SHALL …… IF KNOWN" means that the tag must be sent. However, if there were no information, then this tag should be sent with a <nullflavor>).

SHALL NOT: the definition is an absolute prohibition of the specification.

SHOULD: there may exist valid reasons in particular circumstances to ignore a particular item, but the full implications must be understood and carefully weighed before choosing a different course.

[1] Definitions based upon RFC 2119

SHOULD NOT: there may exist valid reasons in particular circumstances when the particular behavior is acceptable or even useful, but the full implications should be understood and the case carefully weighed before implementing any behavior described with this label.

MAY or **OPTIONAL**: means that an item is truly optional. One vendor may choose to include the item because a particular marketplace requires it or because the vendor feels that it enhances the product while another vendor may omit the same item.

METHODOLOGY

This Interoperability Specification has been developed with input from various Saudi stakeholders collected during several months through workshops and teleconferences. Stakeholders included Physicians from many different disciplines (e.g. Pediatricians, Surgeons, and Specialists) from all over the Kingdom.

The development of a Core Interoperability Specification relies on the high-level requirements set by the associated Use Case. These high-level requirements are not restated in this specification and readers may consider reviewing the related Use Case document.

1. USE CASE OVERVIEW

This section provides an overview of the Clinical Notes and Summaries Use case. For full details of the use case see the UC0007- *Saudi eHealth Interoperability Use Case for Clinical Notes and Summaries.*

This section describes the driving Use Case, including all design constraints and assumptions including the flows of information that will be specified in this Interoperability Specification. This section also introduces the scenarios that describe how the specified workflows may be used in the Saudi eHealth context.

1.1 SCOPE

In Scope:

The scope of this document is the specification of how various Health IT systems within the KSA can share and consume Clinical Notes and Summaries documents as well as clinical data for the purpose of transition of care.

Specification of the content of the Clinical Notes and Summaries is found in the supporting document: IS0106 *Saudi eHealth Clinical Documents Constraints Interoperability Specifications.*

The following topics are in scope for this Interoperability Specification:

- Shared clinical summaries to be used to support transitions of care (e.g., Outpatient Encounter Summary, Discharge Summary, Maternal Discharge Summary and Newborn Discharge Summary).
- Shared clinical summary to be used to provide clinical data (e.g. vital signs, medications, problem list) for any encounter (i.e., iEHR Summary) , and
- Shared clinical notes to be used to provide clinical details (e.g. operative note to provide the surgical details) for future reference.
- Review of any type of HIE historical medical document stored in the HIE Document Repository (as a consumer). This includes Laboratory Results Reports, Radiology Results Report, etc.

  Note: the scope is limited to the query/retrieve of historical medical documents from the document repository. All of the other interoperability requirements are documented in the respective Core Interoperability Specifications.
- Non-user interface functional requirements for the reconciliation of local clinical data and clinical data stored in the HIE Data Repository.

The scope of this document is further constrained as follows:

- Clinical Notes and Summaries may only be shared for patients with KSA-Wide Health IDs. Any person who is legally in Saudi Arabia may obtain a KSA-Wide Health ID. This includes newborns and foreign visitors who are assigned KSA-Wide Health IDs during the initial hospital encounter, and unidentified patients who are assigned temporary Health IDs which will later need to be reconciled with the patient's permanent KSA-Wide Health ID.

Out of Scope:

The following is a list of content and specifications that are specifically out of scope for this Interoperability Specification:

- The population of the Clinical Data from Clinical Documents or otherwise sourced to the Clinical Data Repository, or notification that new or updated clinical documents are available.
- The mechanism used to ensure that the patient identifiers are consistent between the Clinical Data Repository and the HIE System (which uses the KSA-Wide Health ID), since the sources of clinical data may include facilities that exist outside the HIE Platform.
- The reconciliation of temporary KSA-Wide Health IDs to a patient's permanent KSA-Wide Health ID.
- Requirements for the User Interface for querying and retrieving Clinical Notes and Summaries.
- Requirements for the User Interface for the visualization of the Clinical Notes and Summaries.
- Internal requirements for the documentation of clinical notes and summaries within a specific Healthcare Organization.
- The review and reconciliation of historical information for Immunizations and Prescriptions/Dispensations. Although the process for reconciliation is explained in general within this Interoperability Specification, the specific process details for the reconciliation of medications and immunizations are described in the IHE Reconciliation of Diagnoses Allergies and Medications (RECON) Profile.
- The review of radiology images. This Interoperability Specification covers only the review of clinical documents such a radiology Reports. The review of radiology images is covered in *IS0005 Saudi eHealth Core Interoperability Specification for Sharing Images and Imaging Reports*.
- User interface requirements for how Healthcare Providers or Organizations might reconcile local clinical data at the point-of-service with clinical data stored in the HIE Data Repository.
- Requirements for the consumption of HIE Document Repository documents other than Clinical Notes and Summaries (e.g. Laboratory Results Report, Imaging Results Report) are specified in other Core Interoperability Specifications. This specification is the umbrella specification for "reviewing medical documents", and only provides linkage to the specifications on how those medical documents are consumed.

1.2 USE CASE ACTORS AND SERVICES

The Use Case Actors and the Services that are used by this Interoperability Specification are described at a functional level in the UC0007 *Saudi eHealth Interoperability-Use Case for Clinical Notes and Summaries* document. Readers that wish to understand the mapping of Use Case Actors to real world products are recommended to read this Use Case document. A summary is provided in the following tables.

TABLE 1.2-1 USE CASE ACTORS

USE CASE ACTOR NAME	DESCRIPTION
Clinical Summary Content Creator	Responsible for the creation of care summary content (e.g. Discharge Summary, Outpatient Encounter Summary) of the electronic document and publishing the report to the HIE Document Repository. It is also responsible to manage the updates to summary documents, such as replace, amend and/or deprecate.
Clinical Note Content Creator	Responsible for the creation of clinical notes content (e.g. Operative Note) of the electronic document and publishing the report to the HIE Document Repository. It also is responsible to manage the updates to Clinical notes documents, such as replace, amend and/or deprecate.
Clinical Content Consumer	Responsible for querying and retrieving clinical notes and summaries for viewing, importing, or other processing of content from the HIE Document Repository.
HIE Document Repository	Stores the Documents and maintains metadata about each document. Also stores other shared historical medical documents (e.g. Laboratory Results Report, Images)
Clinical Data Repository	Maintains detailed demographic and clinical data for each patient. The Clinical Data Repository extends from the Clinical Content Consumer Actor to support extraction of data from clinical documents.
iEHR On-Demand Document Source	Creates iEHR Summary Documents on demand based upon the clinical data currently stored in the Clinical Data Repository.

How actual implementations support Use Case Actors may vary. For example, some implementations may support a Use Case Actor entirely by a single system design. While other implementations may support a Use Case Actor using a gateway system integrated with the point of service system.

The typical implementation architecture aligns the Use Case Actors capabilities as defined in this Core Interoperability Specification with a single system or integrated set of systems under the design and responsibility of one vendor.

In specific implementation situations, a single vendor's system might not align with the Use Case Actor. For example, a point of service system might be from one vendor, while a gateway system which converts the point of service system to the Use Case Actor might be from a different one. The interface between the two systems is not specified by this Core Interoperability Specification and is the responsibility of the implementation project.

TABLE 1.2-2 USE CASE SERVICES

SERVICE NAME	DESCRIPTION
Publish Document(s)	Used by the Clinical Content Summary Creator and the Clinical Content Note Creator to create and manage the clinical notes and summaries in the HIE Document Repository and to request that it stores these documents.
Query/Retrieve Document(s)	Queries the HIE Document Repository for information about stored clinical notes and summaries.

SERVICE NAME	DESCRIPTION
Notification of Document Availability	Provided by the HIE Document Repository for information about documents stored and indexed in a registry. This also includes the retrieval of one or more documents.
Reconciliation	Supports the synchronization of the clinical data between the HIE Platform and Clinical Content Consumer actors.
iEHR On-Demand Summary	Generates dynamic summaries of clinical data (iEHR Summaries) based upon the clinical documents in the HIE Document Repository.
Query Existing Data	Supports retrieval of detailed clinical data for a patient from the Clinical Data Repository.

1.3 DESIGN CONSTRAINTS AND ASSUMPTIONS

The following design principles underlie this interoperability specification:

- It is expected that all services initiated or provided by these Actors operate in accordance to IS0303 *Saudi Health Information Exchange Policies*
- Temporary KSA-Wide Health IDs can be created to enable the sharing of critical Clinical Notes and Summaries.
- A permanent KSA-Wide Health ID can be created for a newborn.
- It is the responsibility of the receiving system (Clinical Content Consumer) to reconcile their local patient IDs and any other coded data elements with the KSA-Wide Health ID, and nationally specified coded data as well as other coded information in the clinical note or summary.
- Configuration of the Document Metadata Subscription to enable receipt of notifications is expected to happen at installation/configuration time. This means that as Point Of Service Systems (e.g. new Hospital HIS, new PHC EMR) are added to the HIE, they need to be manually configured to be able to receive document notification. This simplifies implementation until specific need for dynamic subscription has been identified. For further details, see the IS0102 *Saudi eHealth Document Sharing Interoperability Specification*.
- Along with the Clinical Notes or Summaries document, a set of required metadata has to be created by the Clinical Note Content Creator or the Clinical Summary Content Creator and recorded in the Document Repository (Registry) in order to allow Clinical Content Consumer Actor to select relevant clinical documents.

2. CORE INTEROPERABILITY SPECIFICATION REQUIREMENTS

2.1 ACTOR MAPPING TO SAUDI EHEALTH INTEROPERABILITY SPECIFICATIONS

A system conforming to this Core Interoperability Specification shall claim conformance at the level of a Use Case Actor. A system may claim conformance to one or more Use Case Actors. Multiple systems may fulfill a Use Case Actor.

The Use Case Actors and the Services they support are described at a functional level in the UC0007 *Saudi eHealth Interoperability Use Case for Clinical Notes and Summaries*. Services may be required, conditional or optional. The Use Case Actors, Service(s) and Optionality are conveyed in the first three columns of Interoperability Conformance Requirement tables shown below.

The second part of the table (columns 4-7) provides the mapping for the Use Case Actor to the detailed specifications (such as IHE Profiles, Technical Actors, Optionality) that systems shall implement to exchange healthcare information in the context of this Use Case.

For a selected Use Case Actor (a single row in the table), all the requirements listed in the second part of the table (columns 4-7) shall be implemented. This includes the referenced profiles and the standards specified (terminology or other).For each Technical Actor (whether required or optional), the last column references the detailed specification that constrain and extend the implementation of this profile for KSA specific requirements (including information on where the requirements are specified). These specifications may be found in this core specification or in other referenced Saudi eHealth Interoperability Specifications (e.g. Saudi eHealth Security and Privacy Interoperability Specification, etc.).

TABLE 2.1-1 INTEROPERABILITY CONFORMANCE REQUIREMENTS FOR CLINICAL SUMMARY CONTENT CREATOR

CLINICAL NOTES AND SUMMARIES			MAPPING TO TECHNICAL CONSTRUCTS OF SAUDI EHEALTH INTEROPERABILITY SPECIFICATIONS			
USE CASE ACTOR	SERVICE SUPPORTED	OPT	TECHNICAL ACTOR	OPT	PROFILE/ STANDARD	REFERENCED SPECIFICATION AND COMMENTS
Clinical Summary Content Creator	Publish Document(s)	R	Content Creator	R	IHE - Cross-Enterprise Sharing of Medical Summaries (XDS-MS)	IS0106 Saudi eHealth Clinical Documents Constrains Interoperability Specifications - Section 5.2
			Content Creator	R	IHE – Cross-Enterprise Scanned Document (XDS-SD)	IS0106 Saudi eHealth Clinical Documents Constrains Interoperability Specifications - Section 5.11

CLINICAL NOTES AND SUMMARIES			MAPPING TO TECHNICAL CONSTRUCTS OF SAUDI EHEALTH INTEROPERABILITY SPECIFICATIONS			
USE CASE ACTOR	SERVICE SUPPORTED	OPT	TECHNICAL ACTOR	OPT	PROFILE/ STANDARD	REFERENCED SPECIFICATION AND COMMENTS
			Content Creator	R	IHE - Cross-Enterprise Sharing of Medical Summaries (XDS-MS) with the Discharge Summary Option	IS0106 Saudi eHealth Clinical Documents Constrains Interoperability Specifications - Section 5.3
			Content Creator	C (Note 1)	IHE – Newborn Discharge Summary (NBS)	IS0106 Saudi eHealth Clinical Documents Constrains Interoperability Specifications - Section 5.3
			Content Creator	C (Note 2)	IHE – Maternal Discharge Summary Content Profile (MDS)	IS0106 Saudi eHealth Clinical Documents Constrains Interoperability Specifications - Section 5.3
			Document Source	R	IHE – Cross-Enterprise Document Sharing (XDS.b)	IS0102 Saudi eHealth Document Sharing Interoperability Specification – Section 3.2
			Secure Node	R	IHE Audit Trail and Node Authentication (ATNA)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Sections 3.2 and 3.3.2
			Time Client	R	IHE Consistent Time (CT)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Section 3.1.2

R=Required, O = Optional, C= Conditional

Note 1: Systems supporting the creation of Newborn Discharge Summaries **SHALL** support this Option.

Note 2: Systems supporting the creation of Maternal Discharge Summaries **SHALL** support this Option.

TABLE 2.1-2 INTEROPERABILITY CONFORMANCE REQUIREMENTS FOR CLINICAL NOTE CONTENT CREATOR

CLINICAL NOTES AND SUMMARIES			MAPPING TO TECHNICAL CONSTRUCTS OF SAUDI EHEALTH INTEROPERABILITY SPECIFICATIONS			
USE CASE ACTOR	SERVICE SUPPORTED	OPT	TECHNICAL ACTOR	OPT	PROFILE/ STANDARD	REFERENCED SPECIFICATION AND COMMENTS
Clinical Note Content Creator	Publish Document(s)	R	Content Creator	R	HL7 CDA R2 IHE Health Story Consolidation Operative Note	IS0106 Saudi eHealth Clinical Documents Constrains Interoperability Specifications - Section 5.4
			Content Creator	R	IHE – Cross-Enterprise Scanned Document (XDS-SD)	IS0106 Saudi eHealth Clinical Documents Constrains Interoperability Specifications - Section 5.11
			Document Source	R	IHE – Cross-Enterprise Document Sharing (XDS.b)	IS0102 Saudi eHealth Document Sharing Interoperability Specification – Section 3.2
			Secure Node	R	IHE Audit Trail and Node Authentication (ATNA)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Sections 3.2 and 3.3.2
			Time Client	R	IHE Consistent Time (CT)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Section 3.1.2

R=Required, O = Optional, C= Conditional

The Clinical Content Consumer Actor must be able to query/retrieve any type of medical document stored in the HIE Document Repository, as it is required to support the review of all types of medical documentation. As the documents stored in the HIE Document Repository are based upon IHE Profiles and CDA Standards, the only thing necessary to consume the HIE documents are the rules specified in the Content IS Specifications. For this reason, Table 2.1-3 Interoperability Conformance Requirements for Clinical Content Consumer includes the content conformance requirements for all of the types of medical documents stored in the HIE Document Repository.

TABLE 2.1-3 INTEROPERABILITY CONFORMANCE REQUIREMENTS FOR CLINICAL CONTENT CONSUMER

CLINICAL NOTES AND SUMMARIES			MAPPING TO TECHNICAL DOCUMENTS OF SAUDI EHEALTH INTEROPERABILITY SPECIFICATIONS			
USE CASE ACTOR	SERVICE SUPPORTED	OPT	TECHNICAL ACTOR	OPT	PROFILE/ STANDARD	REFERENCED SPECIFICATION AND COMMENTS
Clinical Content Consumer	Query/Retrieve Documents(s)	R	Document Consumer	R	IHE – Cross-Enterprise Document Sharing (XDS.b)	IS0102 Saudi eHealth Document Sharing Interoperability Specification – Section 3.3
			Content Consumer	R	IHE - Cross-Enterprise Sharing of Medical Summaries (XDS-MS)	IS0106 Saudi eHealth Clinical Documents Constrains Interoperability Specifications - Section 5.2
			Content Consumer	R	IHE - Cross-Enterprise Sharing of Medical Summaries (XDS-MS)	IS0106 Saudi eHealth Clinical Documents Constrains Interoperability Specifications - Section 5.3
			Content Consumer	R	IHE – Newborn Discharge Summary (NBS)	IS0106 Saudi eHealth Clinical Documents Constrains Interoperability Specifications - Section 5.3
			Content Consumer	R	IHE – Maternal Discharge Summary Content Profile (MDS)	IS0106 Saudi eHealth Clinical Documents Constrains Interoperability Specifications - Section 5.3
			Content Consumer	R	HL7 – CDA R2 Health Story Consolidation - Operative Note	IS0106 Saudi eHealth Clinical Documents Constrains Interoperability Specifications - Section 5.4
			Content Consumer	R	IHE - Exchange of Personal Health Record (XPHR)	IS0106 Saudi eHealth Clinical Documents Constrains Interoperability Specifications - Section 5.5
			Content Consumer	R	IHE – Sharing Laboratory Reports (XD-LAB)	IS0105 Saudi eHealth Laboratory Results and Orders Content Interoperability Specification - Section 3.2

CLINICAL NOTES AND SUMMARIES			MAPPING TO TECHNICAL DOCUMENTS OF SAUDI EHEALTH INTEROPERABILITY SPECIFICATIONS			
USE CASE ACTOR	SERVICE SUPPORTED	OPT	TECHNICAL ACTOR	OPT	PROFILE/ STANDARD	REFERENCED SPECIFICATION AND COMMENTS
			Content Consumer	R	IHE – Cross-Enterprise Scanned Document (XDS-SD)	IS0106 Saudi eHealth Clinical Documents Constrains Interoperability Specifications - Section 5.11
			Content Consumer	R	IHE – Cross-Enterprise Scanned Document (XDS-SD) and HL7 – Clinical Document Architecture (CDA) Release 2	IS0103 Saudi eHealth Radiology Report Content Interoperability Specification- Sections 3.2 and 4.2
			X-Service User	R	IHE – Cross-Enterprise User Assertion (XUA)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Section 3.4.1
			Secure Node	R	IHE Audit Trail and Node Authentication (ATNA)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Sections 3.2 and 3.3.2
			Time Client	R	IHE Consistent Time (CT)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Section 3.1.2
	Notification of Document Availability	O	Document Metadata Notification Recipient	R	IHE - Document Metadata Subscription (DSUB)	IS0102 Saudi eHealth Document Sharing Interoperability Specification – Section 4.2
			Secure Node	R	IHE Audit Trail and Node Authentication (ATNA)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Sections 3.2 and 3.3.2
			Time Client	R	IHE Consistent Time (CT)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Section 3.1.2

CLINICAL NOTES AND SUMMARIES			MAPPING TO TECHNICAL DOCUMENTS OF SAUDI EHEALTH INTEROPERABILITY SPECIFICATIONS			
USE CASE ACTOR	SERVICE SUPPORTED	OPT	TECHNICAL ACTOR	OPT	PROFILE/ STANDARD	REFERENCED SPECIFICATION AND COMMENTS
	Reconciliation	R	Reconciliation Agent	R	IHE Reconciliation of Diagnoses, Allergies and Medications (RECON)	See Section 4.4
	iEHR On-Demand Summary	R	Document Consumer	R	IHE – Cross-Enterprise Document Sharing (XDS.b) IHE – On-Demand Documents	IS0102 Saudi eHealth Document Sharing Interoperability Specification – Section 3.3
			Content Consumer	R	IHE - Exchange of Personal Health Record (XPHR)	IS0106 Saudi eHealth Clinical Documents Constrains Interoperability Specifications - Section 5.5
			X-Service User	R	IHE – Cross-Enterprise User Assertion (XUA)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Section 3.4.1
			Secure Node	R	IHE Audit Trail and Node Authentication (ATNA)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Sections 3.2 and 3.3.2
			Time Client	R	IHE Consistent Time (CT)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Section 3.1.2

R=Required, O = Optional, C= Conditional

TABLE 2.1-4 INTEROPERABILITY CONFORMANCE REQUIREMENTS FOR IEHR ON-DEMAND DOCUMENT SOURCE

CLINICAL NOTES AND SUMMARIES			MAPPING TO TECHNICAL CONSTRUCTS OF SAUDI EHEALTH INTEROPERABILITY SPECIFICATIONS			
USE CASE ACTOR	SERVICE SUPPORTED	OPT	TECHNICAL ACTOR	OPT	PROFILE/ STANDARD	REFERENCED SPECIFICATION
iEHR On-Demand Document	Query Existing Data	R	Clinical Data Consumer	R	IHE –Query for Existing Data (QED)	See Section 4.3

CLINICAL NOTES AND SUMMARIES			MAPPING TO TECHNICAL CONSTRUCTS OF SAUDI EHEALTH INTEROPERABILITY SPECIFICATIONS			
USE CASE ACTOR	SERVICE SUPPORTED	OPT	TECHNICAL ACTOR	OPT	PROFILE/ STANDARD	REFERENCED SPECIFICATION
Source			Secure Node	R	IHE Audit Trail and Node Authentication (ATNA)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Sections 3.2 and 3.3.2
			Time Client	R	IHE Consistent Time (CT)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Section 3.1.2
	iEHR On-Demand Summary	R	On-Demand Document Source	R	IHE – Cross-Enterprise Document Sharing (XDS.b) IHE – On-Demand Documents	IS0102 Saudi eHealth Document Sharing Interoperability Specification – Section 3.6
		R	Content Creator	R	IHE - Exchange of Personal Health Record (XPHR)	IS0106 Saudi eHealth Clinical Documents Constrains Interoperability Specifications - Section 5.5
		R	Secure Node	R	IHE Audit Trail and Node Authentication (ATNA)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Sections 3.2 and 3.3.2
		R	Time Client	R	IHE Consistent Time (CT)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Section 3.1.2

R=Required, O = Optional, C= Conditional

TABLE 2.1-5 INTEROPERABILITY CONFORMANCE REQUIREMENTS FOR HIE DOCUMENT REPOSITORY

CLINICAL NOTES AND SUMMARIES			MAPPING TO TECHNICAL DOCUMENTS OF SAUDI EHEALTH INTEROPERABILITY SPECIFICATIONS			
USE CASE ACTOR	SERVICE SUPPORTED	OPT	TECHNICAL ACTOR	OPT	PROFILE/ STANDARD	REFERENCED SPECIFICATION AND COMMENTS
HIE Document Repository	Publish Document(s)	R	Document Repository	R	IHE – Cross-Enterprise Document Sharing (XDS.b)	IS0102 Saudi eHealth Document Sharing Interoperability Specification – Section 3.4

CLINICAL NOTES AND SUMMARIES			MAPPING TO TECHNICAL DOCUMENTS OF SAUDI EHEALTH INTEROPERABILITY SPECIFICATIONS			
USE CASE ACTOR	SERVICE SUPPORTED	OPT	TECHNICAL ACTOR	OPT	PROFILE/ STANDARD	REFERENCED SPECIFICATION AND COMMENTS
			Secure Node	R	IHE Audit Trail and Node Authentication (ATNA)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Sections 3.2 and 3.3.1
			Time Client	R	IHE Consistent Time (CT)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Section 3.1.2
	Query/Retrieve Document(s)	R	Document Registry and Document Repository	R	IHE – Cross-Enterprise Document Sharing (XDS.b)	IS0102 Saudi eHealth Document Sharing Interoperability Specification – Section 3.4
			X-Service Provider	R	IHE – Cross-Enterprise User Assertion (XUA)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Section 3.4.2
			Secure Node	R	IHE Audit Trail and Node Authentication (ATNA)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Sections 3.2 and 3.3.1
			Time Client	R	IHE Consistent Time (CT)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Section 3.1.2
	Notification of Document Availability	R	Document Metadata Notification Broker	R	IHE - Document Metadata Subscription (DSUB)	IS0102 Saudi eHealth Document Sharing Interoperability Specification – Section 4.1
			Secure Node	R	IHE Audit Trail and Node Authentication (ATNA)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Sections 3.2 and 3.3.1
			Time Client	R	IHE Consistent Time (CT)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Section 3.1.2

R=Required, O = Optional, C= Conditional

TABLE 2.1-6 INTEROPERABILITY CONFORMANCE REQUIREMENTS FOR CLINICAL DATA REPOSITORY

CLINICAL NOTES AND SUMMARIES			MAPPING TO TECHNICAL DOCUMENTS OF SAUDI EHEALTH INTEROPERABILITY SPECIFICATIONS			
USE CASE ACTOR	SERVICE SUPPORTED	OPT	TECHNICAL ACTOR	OPT	PROFILE/ STANDARD	REFERENCED SPECIFICATION AND COMMENTS
Clinical Data Repository	Query Existing Data	R	Clinical Data Source	R	IHE –Query for Existing Data (See Note 3)	See Section 4.6
			Secure Node	R	IHE Audit Trail and Node Authentication (ATNA)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Sections 3.2 and 3.3.1
			Time Client	R	IHE Consistent Time (CT)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Section 3.1.2

R=Required, O = Optional, C= Conditional

Note3: The Clinical Data Repository must support the following IHE-Query for Existing Data Options: Vital Signs, Problems and Allergies, Diagnostic Results, Medications, Immunizations and Professional Services.

2.2 INTEROPERABILITY SEQUENCE DIAGRAMS

The following Sequence diagrams provide an overview of the combined flow of transactions resulting from the above selected profiles and standards. The Main Flow Sequence Diagram illustrates a very common (i.e., typical) workflow and other sequence diagrams are shown to provide an alternative or exceptions to the main flow. Other sequence diagrams are possible but they cover the same key transactions with only slight variants of information exchange between the Use Case Actors, therefore, have been omitted.

The Clinical Notes and Summaries sequence diagrams provide a high level sequence of events for the exchange of information that culminate in the creation of Clinical Notes and Summaries documentation. It also illustrates typical security exchanges for authorized network communications and audit trail of patient information access.

There are three Main and three Alternate Flow Sequence Diagrams. In addition, number of pre-conditions must exist in order to enable the main and alternate sequence diagrams.

2.2.1 Sequence Diagram Pre-conditions

- First, prior to retrieving documents from the HIE Document Repository; the Healthcare Provider or Organization **SHALL** obtain the patient's KSA-Wide Health ID. The requirements on how to obtain a patient's KSA-Wide Health ID and key patient demographics are defined in IS0001 *Saudi eHealth Core Interoperability Specification for KSA-Wide Patient Demographic Query*. The Health ID and key patient demographics attributes are used to identify the patient for which the documents and reports are shared. This ensures KSA-Wide identification of the

patient in health records. This is not shown in any of the sequence diagrams, and the details to accomplish this are defined in IS0001 *Saudi eHealth Core Interoperability Specification for KSA-Wide Patient Demographic Query*.

- Second, the IHE XDS.b: [Register Document Set – b ITI-42] transaction is listed without first performing the authentication between the two systems [IHE ATNA Profile: Authenticate Node ITI-19]. This is because it is very common that the IHE Document Repository and Registry actors are implemented within the same system. If these Actors are implemented in separate systems the authentication transaction would be required.

The following transactions must occur prior to the start of the main or alternate Sequences:

1. Time synchronization **SHALL** occur at least once prior to communicating between the HIE System and the Edge Systems.
2. Before the information exchanges can take place, an authentication process takes place between the Edge System/Secure Node Actor and the HIE Document Repository System/Secure Node Actor occurs [IHE ATNA Profile: Authenticate Node ITI-19].

Note: It is assumed that once a secure connection has been established, it will be maintained. If this is not the case, then an additional authentication transaction will need to occur before continuing any exchange transactions.

Figure 2.2.1-1 Pre-condition Sequence Diagram depicts the pre-condition in the case that the Edge System is acting as a Document Source or as a Document Consumer.

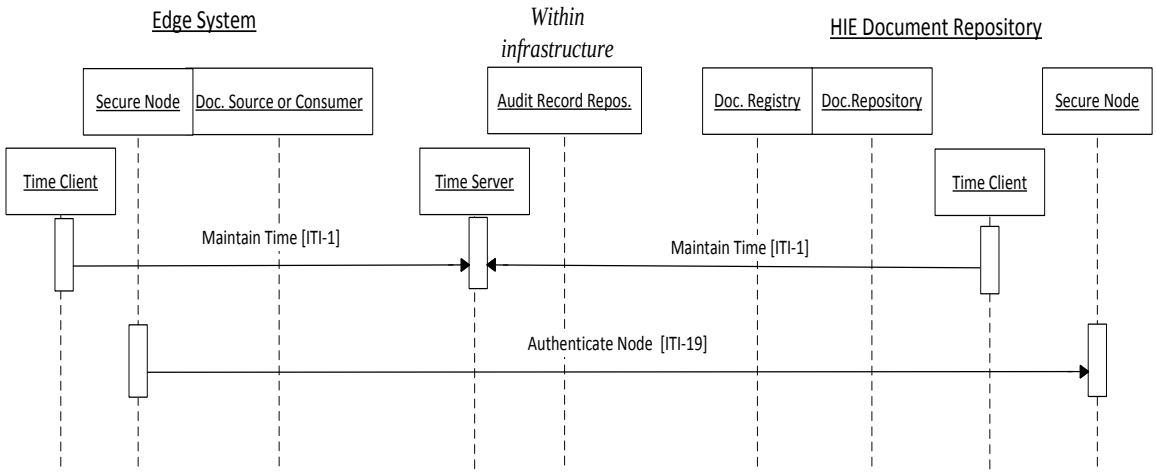


Figure 2.2.1-1 Pre-condition Sequence Diagram

2.2.2 Other Sequence Diagram Requirements

In order to simplify the sequence diagrams, the following transaction pairing should be taken into account.

2.2.2.1 Registry Stored Query to the HIE Document Repository

Figure 2.2.2-1 Transactions associated with a Registry Stored Query depicts the transactions associated with a Registry Stored Query. When a query is made from the Edge System to the HIE Document Repository, the following transactions **SHALL** all take place.

1. The Edge System/Document Consumer sends a query request. As part of the query request, a user assertion is conveyed to verify that the Healthcare Provider or Organization is an authorized user to obtain patient information [IHE XDS-b: Registry Stored Query ITI-18] and [IHE XUA: Provide X-User Assertion ITI-40].
2. The Edge System/Document Consumer/Secure Node generates a local audit record of the access to patient health information using the data content as defined by IHE ATNA Profile and the appropriate technical actor's ATNA conformance requirements in Section 3 Clinical Notes and Summaries Actor Conformance [IHE ATNA Profile: Record Audit Event ITI-20].

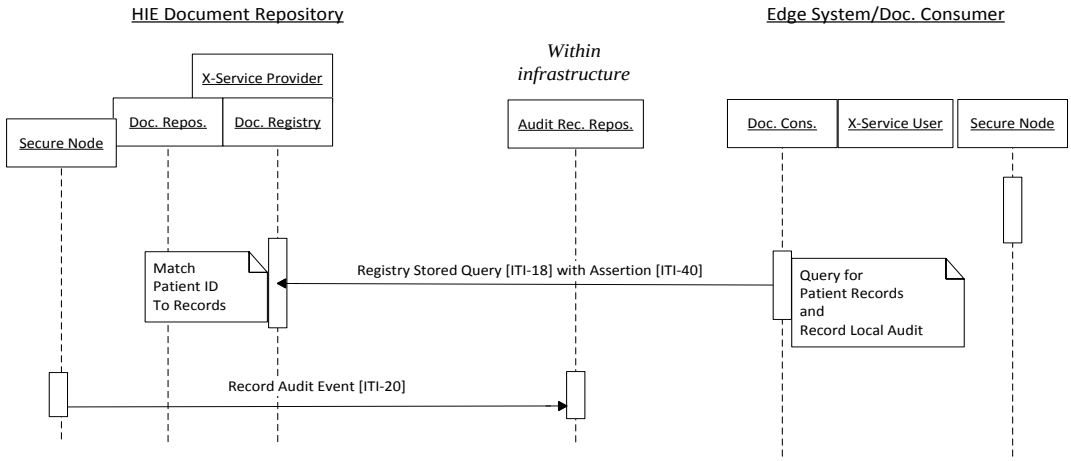


FIGURE 2.2.2-1 TRANSACTIONS ASSOCIATED WITH A REGISTRY STORED QUERY

2.2.2.2 Document Retrieval from the HIE Document Repository

Figure 2.2.2-2 Transactions Associated with a Document Retrieval depicts the transactions associated with document retrieval from the HIE Document Repository. When document(s) are retrieved from the HIE Document Repository, the following transactions must all take place.

1. The Edge System/Document Consumer/X-Service User retrieves the document(s). As part of the retrieve, a user assertion is conveyed to verify that the Healthcare Provider or Organization is an authorized user to obtain patient information [IHE XDS-b: Retrieve Document Set ITI-43] and [IHE XUA: Provide X-User Assertion ITI-40].
2. The Document Repository/Secure Node generates an audit record of the access to patient health information [IHE ATNA Profile: Record Audit Event ITI-20].

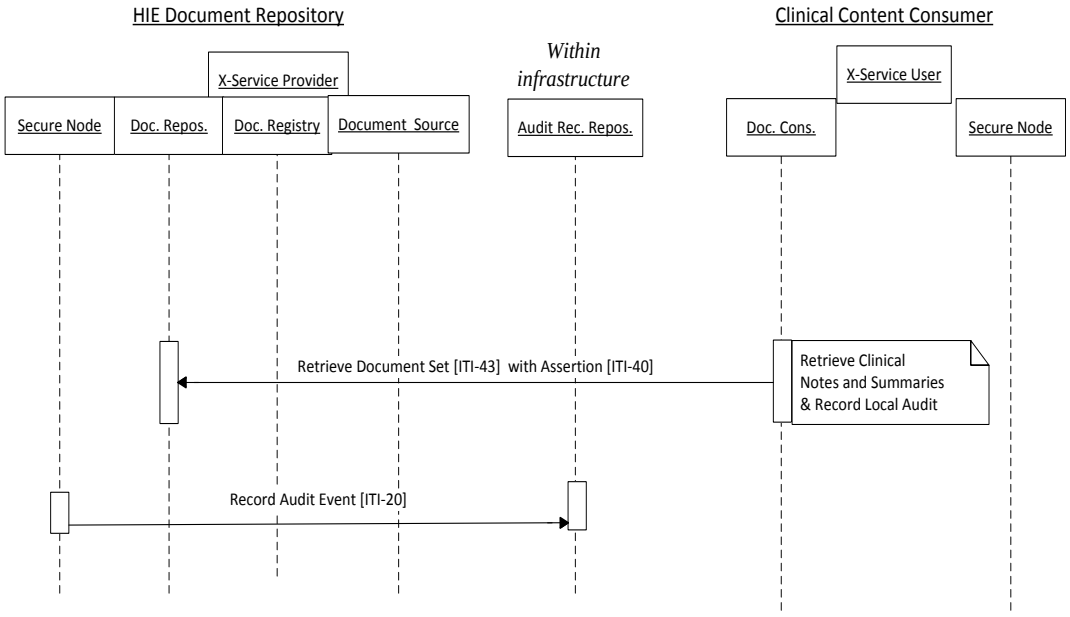


FIGURE 2.2.2-2 TRANSACTIONS ASSOCIATED WITH A DOCUMENT RETRIEVAL

2.2.2.3 Publish Document(s) to the HIE Document Repository

Figure 2.2.2-3 Transactions associated with Publish Document depicts the transactions associated with storage of document(s) to the HIE Document Repository. When document(s) are stored to the HIE Document Repository the following transactions must all take place:

1. The Document Source/Secure Node sends the document set to the Document Repository. [Provide & Register Document Set-b [ITI-41] with Clinical Document Type]
2. The IHE Document Repository registers the document with the IHE Document Registry [IHE XDS.b: Register Document Set – b ITI-42].
3. The Document Source/Secure Node generates a local audit record of the release of patient health information [using the data content as defined by IHE ATNA Profile and the appropriate technical actor's ATNA conformance requirements in Section 3 *Clinical Notes and* Summaries Actor Conformance] and the Document Repository/Secure Node generates an audit record of the receipt of patient health information [IHE ATNA Profile: Record Audit Event ITI-20].

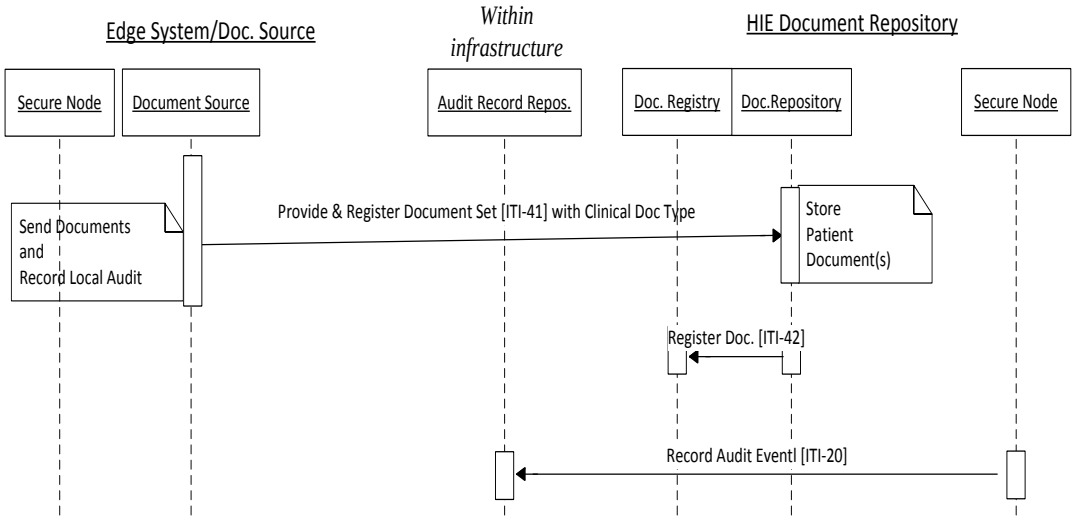


FIGURE 2.2.2-3 TRANSACTIONS ASSOCIATED WITH PUBLISH DOCUMENT

2.2.3 Main Flow Sequence Diagrams

These sequence diagrams depict Use Case Actors and a number of transactions between IHE Profile Actors specified in the tables in Section 2.1 Actor Mapping to Saudi eHealth Interoperability Specifications.

2.2.3.1 Main Flow Sequence Diagram-Retrieve and Reconcile Clinical Data

The main flow sequence starts with a scenario where a Healthcare Provider or Organization synchronize itself with Clinical Data maintained by the HIE System. This includes:

- All active Problems, Medications and Allergies
- Recent but no longer active Problems, Meds and Allergies.
- Recent laboratory results
- Recent immunizations
- Most recent vital signs
- Blood Type

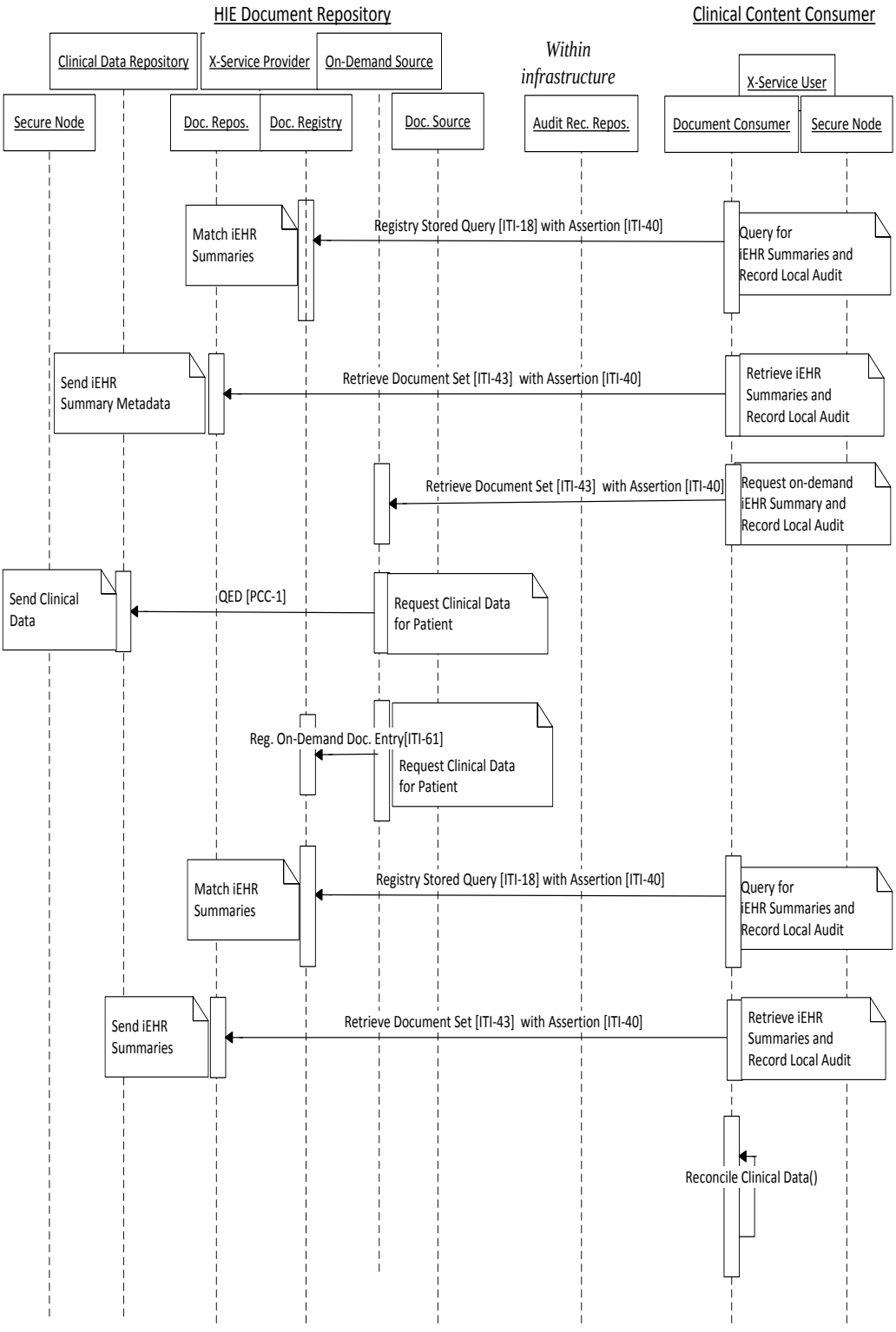
The purpose of clinical data reconciliation is to synchronize the information about the patient clinical data from the last time the Healthcare Provider or Organization saw the patient. If patient has been seen by another Healthcare Provider or Organization, it will be necessary to retrieve data from the HIE Repository. To accomplish this all of the relevant iEHR Summaries are retrieved from the HIE Document Repository based upon a pre-defined algorithms. A new iEHR Summary may need to be created with data from the Clinical Data Repository to include the changes from the last patient encounter. The local Clinical Content Consumer Actor can then assist the Healthcare Provider in the process of reconciling the local clinical data with the clinical data retrieved from the HIE System (See IHE Reconciliation of Diagnoses, Allergies and Medications (RECON) Profile). .

Steps 1 – 12 related to the retrieval and reconciliation of Clinical Data are shown in Figure 2.2.3-1 Retrieve and reconcile Clinical Data Sequence Diagram.

1. The patient visits a Healthcare Provider or Organization for care. As part of the encounter, it will be necessary for the Healthcare Provider or Organization to synchronize with clinical data from the HIE Document Repository. The Clinical Content Consumer/X-Service User queries the IHE Document Registry/X-Service Provider using the patient's KSA-Wide Health ID to locate iEHR Summaries available since the last synchronization performed. [IHE XDS-b: Registry Stored Query ITI-18] and [IHE XUA: Provide X-User Assertion ITI-40]. (See 2.2.2.1 Registry Stored Query to the HIE Document Repository for the full set of transactions).
2. The Document Registry processes the query and responds with the information needed to retrieve the iEHR Summaries metadata [IHE XDS-b: Registry Stored Query ITI-18].
3. The Healthcare Provider or Organization uses the Clinical Content Consumer to retrieve iEHR Summaries metadata. The Clinical Content Consumer/X-Service User retrieves the iEHR summaries. As part of the retrieve, a user assertion is conveyed to verify that the Healthcare Provider or Organization is an authorized user to obtain patient information [IHE XDS-b: Retrieve Document Set ITI-43] and [IHE XUA: Provide X-User Assertion ITI-40] (See 2.2.2.2 Document Retrieval from the HIE Document Repository for the full set of transactions).
4. The Healthcare Provider or Organization uses the Clinical Content Consumer/On-Demand Document Source to retrieve the discrete clinical data through a request to retrieve the dynamic iEHR On-Demand Summary. As part of the retrieve, a user assertion is conveyed to verify that the Healthcare Provider or Organization is an authorized user to obtain patient information [IHE XDS-b: Retrieve Document Set ITI-43] and [IHE XUA: Provide X-User Assertion ITI-40] (See 2.2.2.2 Document Retrieval from the HIE Document Repository for the full set of transactions).
5. The On-Demand Document Source queries the Clinical Data Repository using the patient's KSA-Wide Health ID to retrieve the clinical data [IHE PCC QED Profile: Query for Existing Data PCC-1].
6. The Clinical Data Repository processes the query and responds with the clinical data needed to create a new iEHR On-Demand Summary [IHE PCC QED Profile: Query for Existing Data PCC-1].
7. When there is new data the On-Demand Document Source creates a new iEHR Summary with the clinical data retrieved from the Clinical Data Repository and registers it with the Document Repository/Registry [IHE XDS-b/On Demand Documents Profile: Register On-Demand Document Entry [ITI-61].
8. iEHR Summaries are available for the Healthcare Provider or Organization to reconcile the HIE clinical data with the local clinical data using the Clinical Content Consumer. The Clinical Content Consumer/X-Service User queries the Document Registry/X-Service Provider using the patient's KSA-Wide Health ID to locate all of the iEHR Summaries [IHE XDS-b: Registry Stored Query ITI-18] and [IHE XUA: Provide X-User Assertion ITI-40]. (See 2.2.2.1 Registry Stored Query to the HIE Document Repository for the full set of transactions).

9. The Document Registry processes the query and responds with the information needed to retrieve the iEHR Summaries metadata [IHE XDS-b: Registry Stored Query ITI-18] (See Section 2.2.2.1 Registry Stored Query to the HIE Document Repository for the full set of transactions).
10. The Document Registry/Secure Node generates an audit record of the access to patient health information [IHE ATNA Profile: Record Audit Event ITI-20]. (See Section 2.2.2.1 Registry Stored Query to the HIE Document Repository for the full set of transactions).
11. The Healthcare Provider or Organization uses the Clinical Content Consumer to retrieve the iEHR Summaries metadata. The Clinical Content Consumer/X-Service User retrieves the iEHR summaries. As part of the retrieve, a user assertion is conveyed to verify that the Healthcare Provider or Organization is an authorized user to obtain patient information [IHE XDS-b: Retrieve Document Set ITI-43] and [IHE XUA: Provide X-User Assertion ITI-40] (See 2.2.2.2 Document Retrieval from the HIE Document Repository for the full set of transactions).
12. The Clinical Content Consumer then reconciles this with local clinical data. This is a local transaction. [See IHE Reconciliation of Diagnoses, Allergies and Medications (RECON)].

As a post-condition, the Healthcare Provider or Organization's clinical data has been synchronized between the local system and HIE.


HIE Document Repository
Clinical Content Consumer
Clinical Data Repository
X-Service Provider
On-Demand Source
Within infrastructure
X-Service User
Secure Node
Doc. Repos.
Doc. Registry
Doc. Source
Audit Rec. Repos.
Document Consumer
Secure Node
Match iEHR Summaries
Registry Stored Query [ITI-18] with Assertion [ITI-40]
Query for iEHR Summaries and Record Local Audit
Send iEHR Summary Metadata
Retrieve Document Set [ITI-43] with Assertion [ITI-40]
Retrieve iEHR Summaries and Record Local Audit
Retrieve Document Set [ITI-43] with Assertion [ITI-40]
Request on-demand iEHR Summary and Record Local Audit
Send Clinical Data
QED [PCC-1]
Request Clinical Data for Patient
Reg. On-Demand Doc. Entry[ITI-61]
Request Clinical Data for Patient
Match iEHR Summaries
Registry Stored Query [ITI-18] with Assertion [ITI-40]
Query for iEHR Summaries and Record Local Audit
Send iEHR Summaries
Retrieve Document Set [ITI-43] with Assertion [ITI-40]
Retrieve iEHR Summaries and Record Local Audit
Reconcile Clinical Data()

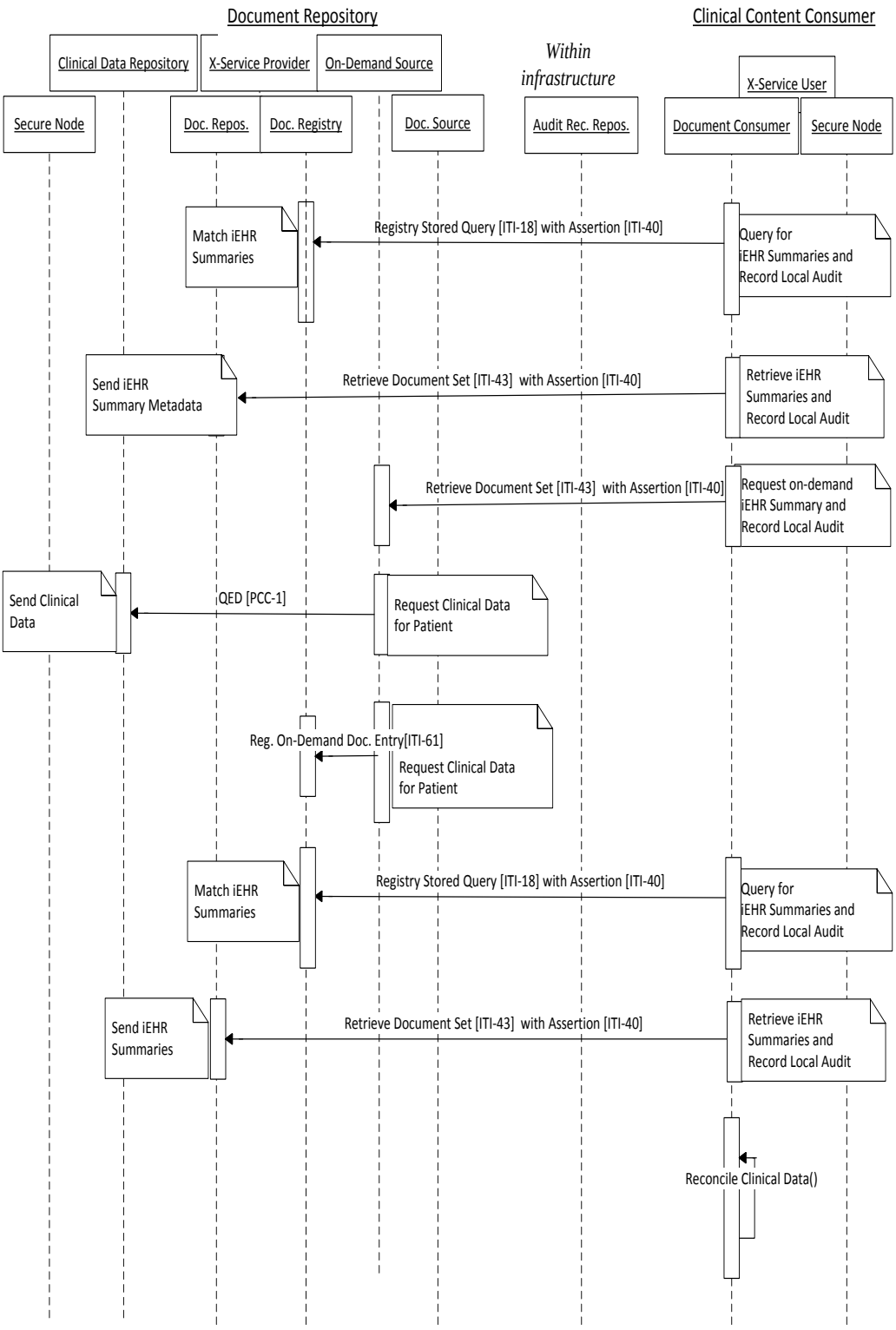


FIGURE 2.2.3-1 RETRIEVE AND RECONCILE CLINICAL DATA SEQUENCE DIAGRAM

2.2.3.2 Main Flow Sequence Diagram-Retrieve Historical Medical Documents

The main flow sequence typically continues with a scenario where a Healthcare Provider or Organization retrieves relevant historical medical documents about the patient. The Healthcare Provider can review a number of different documents from the HIE Document Repository as needed to provide appropriate patient care including:

- Laboratory results
- Imaging results
- Imaging studies
- Clinical notes and summaries
- Immunizations.

Steps 1 – 3 are shown in Figure 2.2.3-2 Retrieve Historical Medical Document Sequence Diagram

1. The patient visits a Healthcare Provider or Organization for care. As part of the encounter, it may be necessary for the Healthcare Provider or Organization to retrieve Clinical Notes and Summaries documentation from the HIE Document Repository. The Clinical Content Consumer/X-Service User queries the Document Registry/X-Service Provider using the patient's KSA-Wide Health ID to determine if the patient's medical documents are available. As part of the query request, a user assertion is conveyed to verify that the Healthcare Provider or Organization is an authorized user to obtain patient information [IHE XDS-b: Registry Stored Query ITI-18] and [IHE XUA: Provide X-User Assertion ITI-40] (See 2.2.2.1 Registry Stored Query to the HIE Document Repository for the full set of transactions).
2. The Document Registry processes the query and responds with the information needed to retrieve the Clinical Notes and Summaries [IHE XDS-b: Registry Stored Query ITI-18].
3. The Clinical Content Consumer/X-Service User retrieves the Clinical Notes and Summaries. As part of the retrieve, a user assertion is conveyed to verify that the Healthcare Provider or Organization is an authorized user to obtain patient information [IHE XDS-b: Retrieve Document Set ITI-43] and [IHE XUA: Provide X-User Assertion ITI-40] (See 2.2.2.2 Document Retrieval from the HIE Document Repository for the full set of transactions).

As a post-condition, the selected historical medical documentation (including Clinical Notes and Summaries) are now available for the Healthcare Provider or Organization for review.

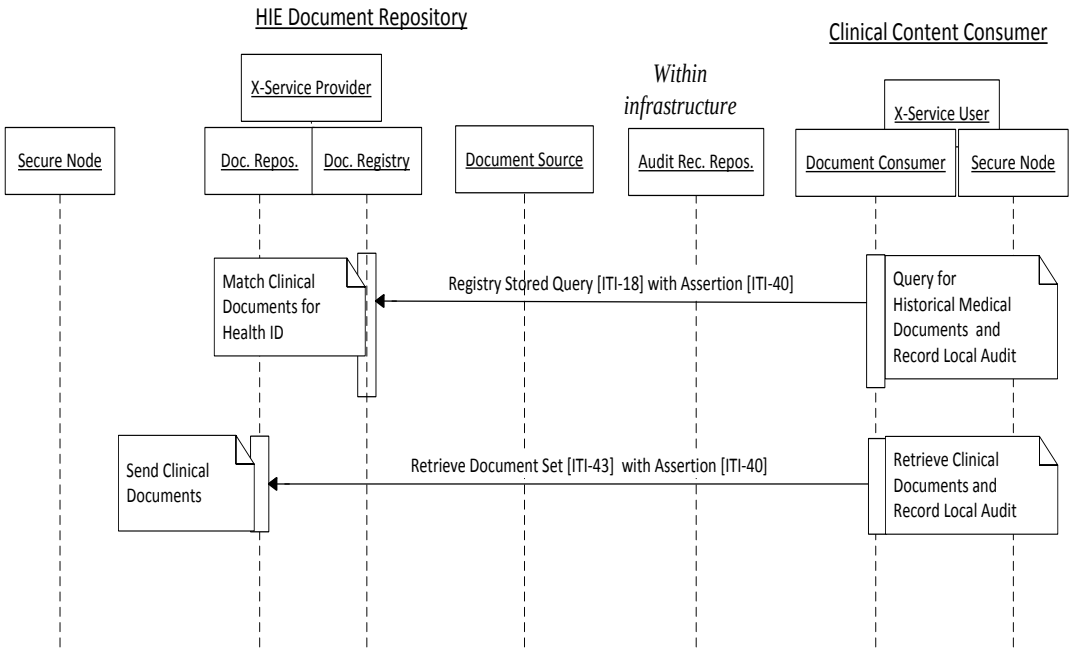


FIGURE 2.2.3-2 RETRIEVE HISTORICAL MEDICAL DOCUMENT SEQUENCE DIAGRAM

2.2.3.3 Main Flow Sequence Diagram-Publish Clinical Summaries

The main flow sequence ends with a scenario where a Healthcare Provider or Organization creates a clinical summary (Outpatient Encounter Summary, Discharge Summary, Maternal Discharge Summary or Newborn Discharge Summary) of the encounter (i.e., outpatient encounter or in-hospital stay):

> The Healthcare Provider or Organization completes the outpatient encounter or the in-hospital stay and creates the appropriate Clinical Summary (e.g. outpatient encounter summary, discharge summary, maternal discharge summary or newborn discharge summary) for the patient. The Clinical Summary Content Creator sends the clinical summary to the HIE Document Repository. See Section 2.2.2.3 Publish Document(s) to the HIE Document Repository for the sequence flow.

As a post-condition, the Clinical Summary document(s) have been stored and registered (i.e., published) to the HIE Document Repository. Clinical Summaries are now available for a Healthcare Provider or Organization for review.

2.2.4 Alternate Flow Sequence Diagrams

These sequence diagrams indicate additional transactions that may occurs between the Use Case Actors.

2.2.4.1 Publish Operative Note (after Surgery) Sequence Diagram

The Publish Operative Note (after Surgery) sequence diagram covers the scenario when a surgery is performed as part of an in-hospital or outpatient surgery. In this case, an Operative Note document is created in addition to the Discharge Summary document. The Clinical Note Content Creator sends the clinical note to the HIE Document Repository. See Section 2.2.2.3 Publish Document(s) to the HIE Document Repository for the sequence flow. It is assumed that an operative note lives within the context of an encounter, and therefore any required historical documents and clinical data are already available, and are not specified as part of the Operative Note Sequence Diagram

As a post-condition, the Clinical Notes document(s) have been stored and registered (i.e., published) to the HIE Document Repository. Clinical Note(s) are now available for a Healthcare Provider or Organization for review.

2.2.4.2 Amended Report (with optional Notification) Sequence Diagram

The amended clinical notes or summaries sequence diagram is for the scenario when a clinical note or summary has been updated via an amendment. It also includes the optional interaction to provide an automatic notification when the amended clinical note or summary is available for sharing. The main flow sequence diagram is a pre-condition to creating an amended clinical note or summary and is not repeated in this diagram.

Step 1 is shown in Figure 2.2.4-1 Amended Clinical Notes or Summary with Optional Notification Sequence Diagram (1)

1. The Healthcare Provider or Organization that created the original Clinical Note or Summary determines that the original Clinical Note or Summary needs an amendment (e.g. important information was left out of the document, information needs to be corrected). The Healthcare Provider or Organization creates an amended clinical document with the necessary changes. The exchange of the Clinical Note or Summary document is accomplished using the actors as described below. The amended Clinical Note or Summary is transmitted [IHE XDS.b: Profile: Provide and Register Document Set–b ITI-41]. The HIE Document Repository Use Case Actor stores the document and deprecates the old version.

Note: When the amended clinical document is published, the Clinical Content Summary or Note Creator Actor informs the Document Repository Actor that it is a replacement to the original, a previously shared document. This information is used by the Document Repository to manage the two versions (i.e., deprecate the original Clinical Note or Summary document and provide a link with the amended document).

As a post-condition, the Clinical Notes or Summary document(s) have been amended, and the new document stored and registered (published) to the HIE Document Repository is now available for review. The original Clinical Notes or Summary document(s) have been deprecated, but are still available for users who request all versions of a specific clinical document. When a document is amended, the Clinical Data Repository must deprecate any old clinical data entries which came only from that document. The mechanism by which this occurs is out of scope.

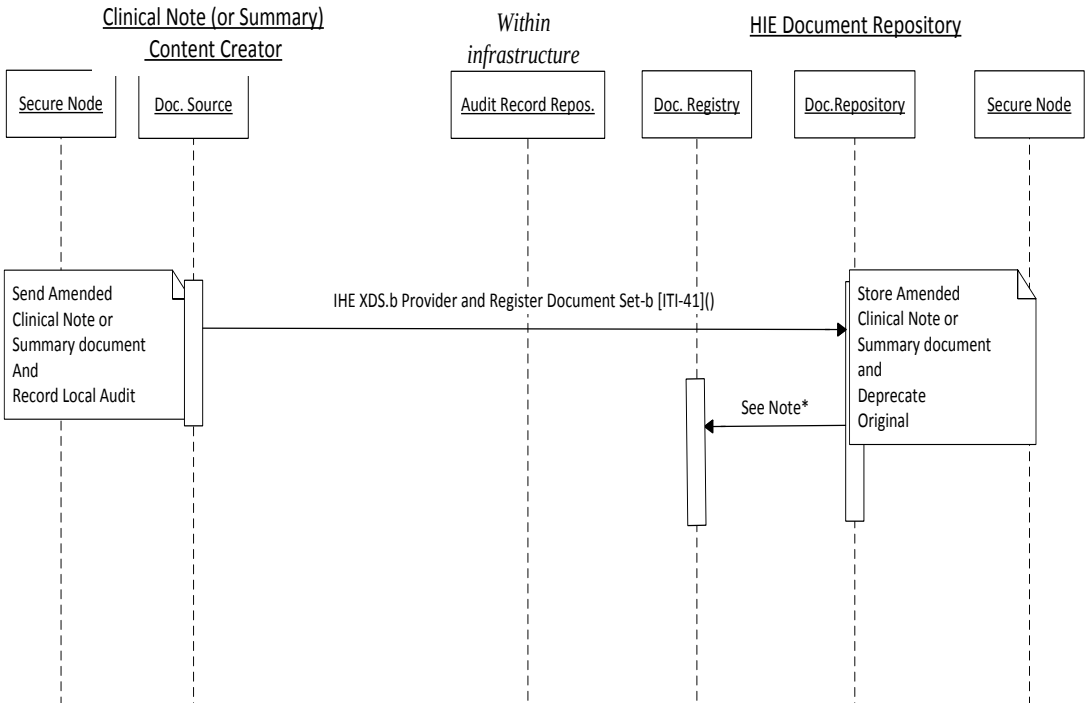


FIGURE 2.2.4-1 AMENDED CLINICAL NOTES OR SUMMARY WITH OPTIONAL NOTIFICATION SEQUENCE DIAGRAM (1)

Steps 2 – 4 are shown in Figure 2.2.4-2 Amended Document with Optional Notification Sequence Diagram (2) .

2. The Document Repository Actor notifies the Clinical Content Consumer that an amended clinical document was created. The Notification of Document Availability is transmitted [IHE DSUB Profile: Document Metadata Notify ITI-53]. The Clinical Content Consumer Actor has been notified that the amended clinical document is available.
3. Upon the successful transmission of the notification, the Clinical Content Consumer uses the Document Consumer Actor to retrieve the amended clinical document.
4. The Document Consumer/X-Service User retrieves the amended Clinical Note or Summary document. As part of the retrieve, an assertion process to verify that the Healthcare Provider or Organization is an authorized user to obtain patient information is performed [IHE XDS.b: Retrieve Document Set ITI-43] and [IHE XUA: Provide X-User Assertion ITI-40].

As a post-condition, the Healthcare Provider or Organization receives notification of an amended Clinical Notes or Summaries document and reviews the amended clinical document and provides follow up healthcare.

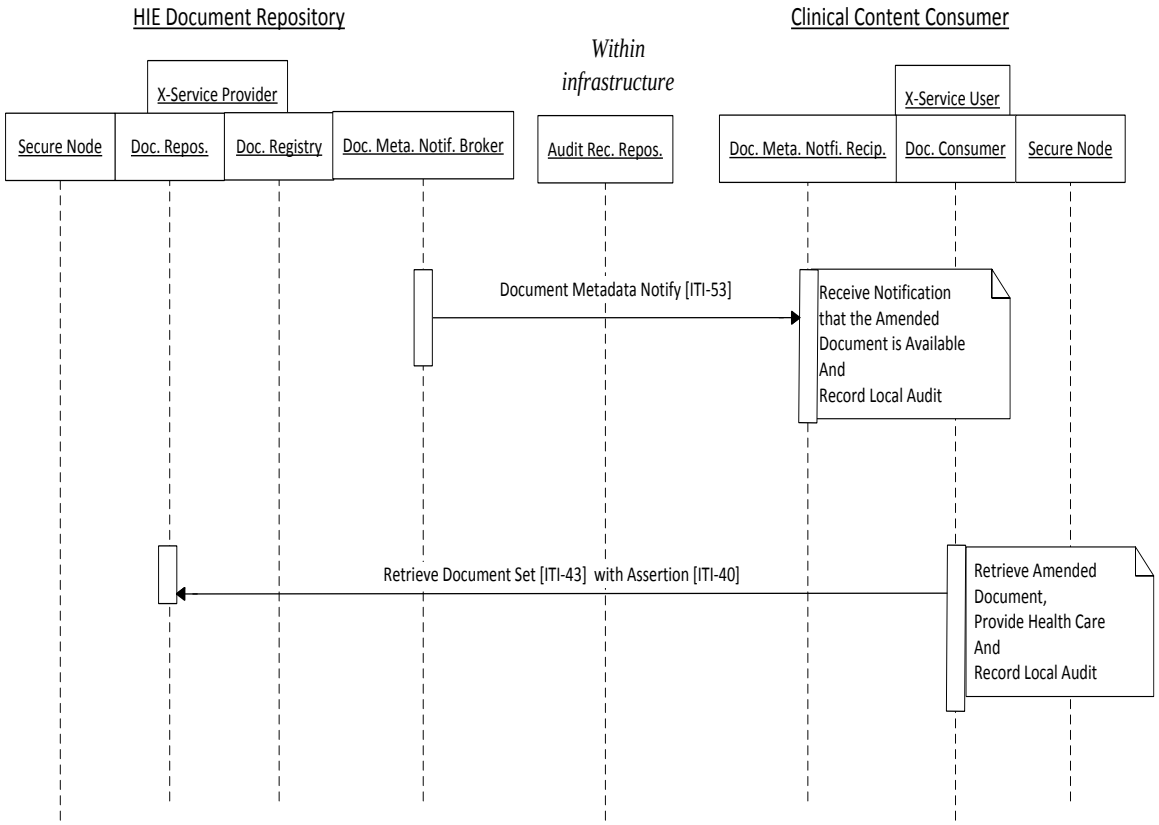


FIGURE 2.2.4-2 AMENDED DOCUMENT WITH OPTIONAL NOTIFICATION SEQUENCE DIAGRAM (2)

2.2.4.3 Cancel Clinical Note or Summary document (Amended Report) Sequence Diagram

The cancel Clinical Note or Summary document sequence diagram defines the scenario when a Healthcare Provider or Organization wishes to cancel a published clinical note or summary document that has already been sent to the HIE Document Repository. The main flow sequence diagram is a pre-condition to canceling a clinical note or summary and is not repeated in this diagram.

Step 1 is shown in Figure 2.2.4-3 Cancel Clinical Notes or Summary document Sequence Diagram

1. The Healthcare Provider or Organization that created the original Clinical Note or Summary determines that the Clinical Note or Summary document should not be used for clinical purposes. The Healthcare Provider or Organization creates a PDF document documenting the fact that the Clinical Note or Summary document should not be used for clinical purposes, and publishes the replacement Clinical Note or Summary document as an amendment to the original Clinical Note or Summary document. The exchange of the document is accomplished using the actors as described below. The replacement document indicating the cancellation of the original document is transmitted [IHE XDS.b: Profile: Provide and Register Document Set–b ITI-41]. The HIE Document Repository Use Case Actor stores the document and deprecates the old version.

Note: When the amended clinical document (indicating the cancellation of the original clinical document) is published, the Clinical Content Summary or Note Creator Actor informs the Document Repository Actor that it is a replacement to the original, a previously shared document. This information is used by the Document Repository to manage the two versions (i.e., deprecate the original Clinical Note or Summary document and provide a link with the amended document).

As a post-condition, the Clinical Notes or Summary document(s) indicating that the document is not to be used for clinical purposes is stored as a new document and registered (published) to the HIE Document Repository. The original Clinical Notes or Summary document(s) have been deprecated, but are still available for users who request all versions of a specific clinical document. When a document is amended, the Clinical Data Repository must deprecate any old clinical data entries which came only from that document. The mechanism by which this occurs is out of scope for this Implementation Specification.

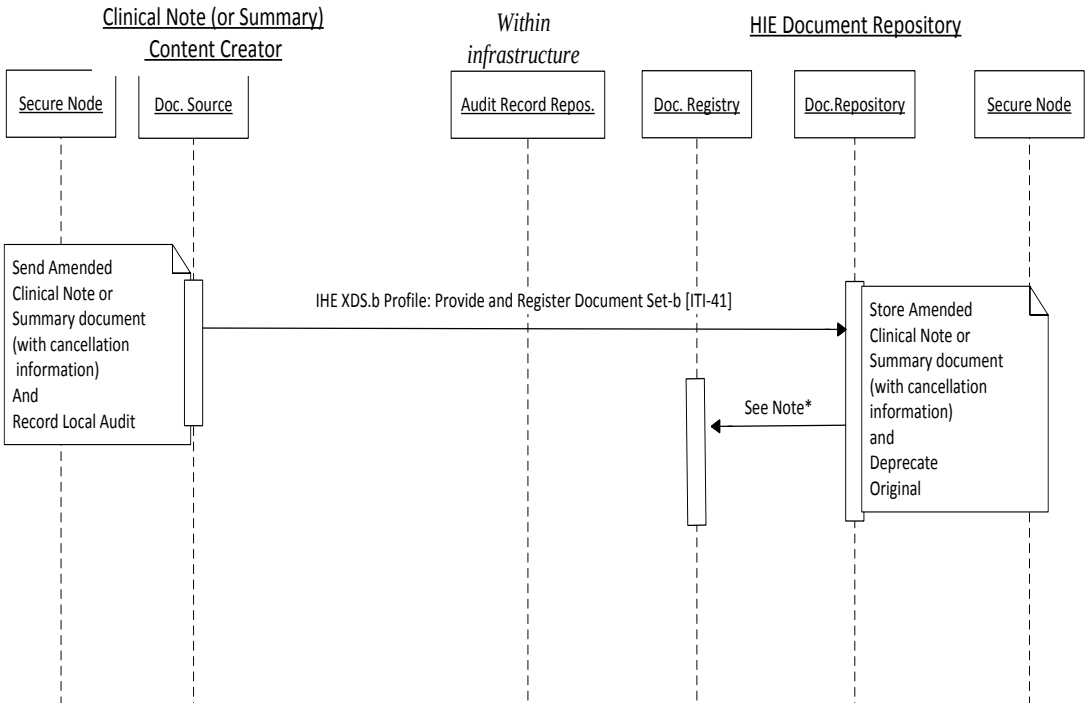


FIGURE 2.2.4-3 CANCEL CLINICAL NOTES OR SUMMARY DOCUMENT SEQUENCE DIAGRAM

To optionally setup document notification see Steps 2 – 4 of Section 2.2.4.2 Amended Report (with optional Notification) Sequence Diagram and Figure 2.2.4-2 Amended Document with Optional Notification Sequence Diagram (2).

3. CLINICAL NOTES AND SUMMARIES ACTOR CONFORMANCE

This section is designed to establish the Conformance Requirements for the Interoperability Specification. It maps one to one, with the tables in section 2.1.

3.1 CLINICAL SUMMARY CONTENT CREATOR CONFORMANCE

Systems may claim conformance to the IS0007 *Saudi eHealth Core Interoperability Specification for Clinical Notes and Summaries* as a Clinical Summary Content Creator as follows:

Clinical Summary Content Creator Actor

This requires:

- to support the Publish Document(s) Service by conforming to:

[CNS-002] - IHE – Cross-Enterprise Document Sharing (XDS.b) Integration Profile as a Document Source Actor with the additional constraints specified in:

- IS0102 *Saudi eHealth Document Sharing Interoperability Specification* – Section 3.2

[CNS-003] - IHE Audit Trail and Node Authentication (ATNA) Integration Profile as a Secure Node Actor with the additional constraints specified in:

- IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Sections 3.2 and 3.3.2

[CNS-004] – IHE Consistent Time (CT) Integration Profile as a Time Client Actor with the additional constraints specified in:

- IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Section 3.1.2

- to support the Outpatient Encounter Summary by conforming to:

[CNS-007] – IHE Cross-Enterprise Sharing of Medical Summaries (XDS-MS) Integration Profile as a Content Creator Actor with the additional constraints specified in:

- IS0106 *Saudi eHealth Clinical Documents Constrains Interoperability Specifications* - Section 5.2.

- to support the Discharge Summary by conforming to:

[CNS-001] – IHE Cross-Enterprise Sharing of Medical Summaries (XDS-MS) Integration Profile with the Discharge Summary Option as a Content Creator Actor with the additional constraints specified in:

- IS0106 *Saudi eHealth Clinical Documents Constrains Interoperability Specifications* - Section 5.3.

- To support the Newborn Discharge Summary by conforming to:

[CNS-005] – IHE Newborn Summary Discharge (NBS) Content Profile as a Content Creator Actor with the additional constraints specified in:

- IS0106 *Saudi eHealth Clinical Documents Constrains Interoperability Specifications* - Section 5.3.

Note: Healthcare Organizations responsible for Labor and Delivery **SHALL** support this option.

- To support the Maternal Discharge Summary by conforming to:

[CNS-006] – IHE Maternal Summary Discharge (MDS) Content Profile as a Content Creator Actor with the additional constraints specified in:

- IS0106 *Saudi eHealth Clinical Documents Constrains Interoperability Specifications* - Section 5.3.

Note: Healthcare Organizations responsible for Labor and Delivery **SHALL** support this option.

- To support the Scanned Clinical Summary Document by conforming to:

[CNS-008] IHE – Cross-Enterprise Scanned Document (XDS-SD) Content Profile as a Content Creator Actor with the additional constraints specified in:

- IS0106 *Saudi eHealth Clinical Documents Constrains Interoperability Specifications* - Section 5.11.

3.2 CLINICAL NOTE CONTENT CREATOR CONFORMANCE

Systems may claim conformance to the IS0007 *Saudi eHealth Core Interoperability Specification for Clinical Notes and Summaries* as a Clinical Note Content Creator as follows:

"Clinical Note Content Creator Actor"

This requires:

- to support the Publish Document(s) Service by conforming to:

[CNS-010] – HL7 CDA R2 IHE Health Story Consolidation Operative Note as a Content Creator Actor with the additional constraints specified in:

- IS0106 *Saudi eHealth Clinical Documents Constrains Interoperability Specifications* - Section 5.4.

[CNS-011] - IHE – Cross-Enterprise Document Sharing (XDS.b) Integration Profile as a Document Source Actor with the additional constraints specified in:

- IS0102 *Saudi eHealth Document Sharing Interoperability Specification* – Section 3.2

[CNS-012] - IHE Audit Trail and Node Authentication (ATNA) Integration Profile as a Secure Node Actor with the additional constraints specified in:

- IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Sections 3.2 and 3.3.2

[CNS-013] – IHE Consistent Time (CT) Integration Profile as a Time Client Actor with the additional constraints specified in:

- IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Section 3.1.2

➢ To support the Scanned Clinical Note Document by conforming to:

[CNS-014] – IHE – Cross-Enterprise Scanned Document (XDS-SD) Content Profile as a Content Creator Actor with the additional constraints specified in:

- IS0106 *Saudi eHealth Clinical Documents Constrains Interoperability Specifications* - Section 5.11.

3.3 CLINICAL CONTENT CONSUMER CONFORMANCE

Systems may claim conformance to the IS0007 *Saudi eHealth Core Interoperability Specification for Clinical Notes and Summaries* as a Clinical Content Consumer as follows:

"Clinical Content Consumer Actor"

This requires:

➢ To support the Query/Retrieve Document(s) Service by conforming to:

[CNS-020]- IHE Cross-Enterprise Document Sharing (XDS.b) Integration Profile as a Document Consumer Actor with the additional constraints specified in:

- IS0102 Saudi eHealth Document Sharing Interoperability Specification – Section 3.3

[CNS -031] - IHE Cross-Enterprise Sharing of Medical Summaries (XDS-MS) as an Document Consumer with the additional constraints specified in:

- IS0106 *Saudi eHealth Clinical Documents Constrains Interoperability Specifications* - Section 5.2.
- [CNS -021] - IHE Cross-Enterprise Sharing of Medical Summaries (XDS-MS) with the Discharge Summary Option as an Document Consumer with the additional constraints specified in:
- IS0106 *Saudi eHealth Clinical Documents Constrains Interoperability Specifications* - Section 5.3.

[CNS -022] - IHE Newborn Discharge Summary (NBS) as an Document Consumer with the additional constraints specified in:

- IS0106 *Saudi eHealth Clinical Documents Constrains Interoperability Specifications* - Section 5.3.

[CNS -023] - IHE Maternal Discharge Summary (MDS) as an Document Consumer with the additional constraints specified in:

- IS0106 *Saudi eHealth Clinical Documents Constrains Interoperability Specifications* - Section 5.3.

[CNS -024] – HL7 CDA R2 Health Story Consolidation – Operative Note as an Document Consumer with the additional constraints specified in:

- IS0106 *Saudi eHealth Clinical Documents Constrains Interoperability Specifications* - Section 5.4.

[CNS -025] – IHE Exchange of Personal Health Record (XPHR) as an Document Consumer with the additional constraints specified in:

- IS0106 *Saudi eHealth Clinical Documents Constrains Interoperability Specifications* - Section 5.5.

[CNS -032] - IHE – Cross-Enterprise Scanned Document (XDS-SD) as an Document Consumer with the additional constraints specified in:

- IS0106 *Saudi eHealth Clinical Documents Constrains Interoperability Specifications* - Section 5.11.

[CNS -026] - IHE Cross-Enterprise User Assertion (XUA) Integration Profile as a X-Service User Actor with the additional constraints specified in:

- IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Section 3.4.1

[CNS -027] - IHE Audit Trail and Node Authentication (ATNA) Integration Profile as a Secure Node Actor with the additional constraints specified in:

- IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Section 3.2 and 3.3.2

[CNS -028] – IHE Consistent Time (CT) Integration Profile as a Time Client Actor with the additional constraints specified in:

- IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Section 3.1.2

Specification of additional Clinical Documents to support:

[CNS-029] - IHE Sharing Laboratory Reports (XD-LAB) as an Document Consumer with the additional constraints specified in:

- IS0105 *Saudi eHealth Laboratory Results and Orders Content Interoperability Specification* - Section 3.2

[CNS-030] - IHE – Cross-Enterprise Scanned Document (XDS-SD) and HL7 Clinical Document Architecture (CDA) Release 2 Content Profiles as a Content Consumer Actor with the additional constraints specified in:

- IS0103 *Saudi eHealth Radiology Report Content Interoperability Specification*- Sections 3.2 and 4.2

- To optionally support the Notification of Document Availability Service by conforming to:

[CNS -050] – IHE Document Metadata Subscription (DSUB) Integration Profile as a Document Metadata Notification Recipient Actor with the additional constraints specified in:

- IS0102 *Saudi eHealth Document Sharing Interoperability Specification* - Section 4.2

[CNS -051] - IHE Audit Trail and Node Authentication (ATNA) Integration Profile as a Secure Node Actor with the additional constraints specified in:

- IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Sections 3.2 and 3.3.2

[CNS -052] – IHE Consistent Time (CT) Integration Profile as a Time Client Actor with the additional constraints specified in:

- IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Section 3.1.2

This requires:

- To support the Reconciliation Service by conforming to:

[CNS -060] – IHE Reconciliation of Diagnoses, Allergies and Medications (RECON) Integration Profile as a Reconciliation Agent Actor with the additional constraints specified in Section 4.4 Requirements for **Clinical Content Consumer**.

This requires:

- To support the iEHR On-Demand Summary Service by conforming to:

[CNS-070]- IHE Cross-Enterprise Document Sharing (XDS.b) Integration Profile with the On-Demand Option as a Document Consumer Actor with the additional constraints specified in:

- IS0102 *Saudi eHealth Document Sharing Interoperability Specification* – Section 3.3

[CNS -071] – IHE Exchange of Personal Health Record (XPHR) as an Content Consumer with the additional constraints specified in:

- IS0106 *Saudi eHealth Clinical Documents Constrains Interoperability Specifications* - Section 5.5.

[CNS -072] - IHE Cross-Enterprise User Assertion (XUA) Integration Profile as a X-Service User Actor with the additional constraints specified in:

- IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Section 3.4.1

[CNS -073] - IHE Audit Trail and Node Authentication (ATNA) Integration Profile as a Secure Node Actor with the additional constraints specified in:

- IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Sections 3.2 and 3.3.2

[CNS -074] – IHE Consistent Time (CT) Integration Profile as a Time Client Actor with the additional constraints specified in:

- IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Section 3.1.2

3.4 iEHR On-Demand Document Source Conformance

Systems may claim conformance to IS0007 *Saudi eHealth Core Interoperability Specification for Clinical Notes and Summaries* as an iEHR On-Demand Document Source as follows:

"iEHR On-Demand Document Source Actor"

This requires:

- To support the Query Existing Data Service by conforming to:

[CNS-090] – IHE-Query for Existing Data Profile as a Clinical Data Consumer with the additional constraints specified in Section 4.3 Requirements for **iEHR On-Demand Document Source**.

[CNS -091] - IHE Audit Trail and Node Authentication (ATNA) Integration Profile as a Secure Node Actor with the additional constraints specified in:

- IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Sections 3.2 and 3.3.2

[CNS -092] – IHE Consistent Time (CT) Integration Profile as a Time Client Actor with the additional constraints specified in:

- IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Section 3.1.2

This requires:

- To support the iEHR On-Demand Summary Service by conforming to:

[CNS -100] – IHE Exchange of Personal Health Record (XPHR) as an Content Creator with the additional constraints specified in:

- IS0106 *Saudi eHealth Clinical Documents Constrains Interoperability Specifications* - Section 5.5.

[CNS-101]- IHE Cross-Enterprise Document Sharing (XDS.b) Integration Profile with the On-Demand Documents Option as an On-Demand Document Source Actor with the additional constraints specified in:

- IS0102 *Saudi eHealth Document Sharing Interoperability Specification* – Section 3.6

[CNS -102] - IHE Audit Trail and Node Authentication (ATNA) Integration Profile as a Secure Node Actor with the additional constraints specified in:

- IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Sections 3.2 and 3.3.2

[CNS -103] – IHE Consistent Time (CT) Integration Profile as a Time Client Actor with the additional constraints specified in:

- IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Section 3.1.2

3.5 HIE DOCUMENT REPOSITORY CONFORMANCE

Systems may claim conformance to the IS0007 Saudi eHealth *Core Interoperability Specification* for Clinical Notes and Summaries as an HIE Document Repository as follows:

"Clinical Notes and Summaries as an HIE Document Repository Actor"

This requires:

- To support the Publish Document(s) Service by conforming to:

[CNS-110]- IHE Cross-Enterprise Document Sharing (XDS.b) Integration Profile as a Document Repository with the additional constraints specified in:

- IS0102 *Saudi eHealth Document Sharing Interoperability Specification* – Section 3.4

[CNS-111] - IHE Audit Trail and Node Authentication (ATNA) Integration Profile as a Secure Node Actor with the additional constraints specified in:

- IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Sections 3.2 and 3.3.1

[CNS-112] – IHE Consistent Time (CT) Integration Profile as a Time Client Actor with the additional constraints specified in:

- IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Section 3.1.2

- To support the Query/Retrieve Document(s) Service by conforming to:

[CNS-113]- IHE Cross-Enterprise Document Sharing (XDS.b) Integration Profile as a Document Registry and Document Repository Actor with the additional constraints specified in:

- IS0102 *Saudi eHealth Document Sharing Interoperability Specification* – Section 3.4

[CNS-114] - IHE Cross-Enterprise User Assertion (XUA) Integration Profile as a X-Service Provider Actor with the additional constraints specified in:

- IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Section 3.4.2

[CNS-115] - IHE Audit Trail and Node Authentication (ATNA) Integration Profile as a Secure Node Actor with the additional constraints specified in:

- IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Sections 3.2 and 3.3.1

[CNS-116] – IHE Consistent Time (CT) Integration Profile as a Time Client Actor with the additional constraints specified in:

- IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Section 3.1.2

➢ To support the Notification of Document Availability Service by conforming to::

[CNS-117] – IHE Document Metadata Subscription (DSUB) Integration Profile as a Document Metadata Notification Broker Actor with the additional constraints specified in:

- IS0102 *Saudi eHealth Document Sharing Interoperability Specification* - Section 4.1

[CNS-118] - IHE Audit Trail and Node Authentication (ATNA) Integration Profile as a Secure Node Actor with the additional constraints specified in:

- IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Sections 3.2 and 3.3.1

[CNS-119] – IHE Consistent Time (CT) Integration Profile as a Time Client Actor with the additional constraints specified in:

- IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Section 3.1.2

3.6 CLINICAL DATA REPOSITORY CONFORMANCE

Systems may claim conformance to the IS0007 *Saudi eHealth Core Interoperability Specification for Clinical Notes and Summaries* as a Clinical Data Repository as follows:

"Clinical Notes and Summaries as a Clinical Data Repository Actor"

This requires:

➢ To support the Query Existing Data Service by conforming to:

[CNS-130] - IHE Query for Existing Data Profile with the options listed below as a IHE Clinical Data Source Actor with the additional constraints specified in 4.6 Requirements for Clinical Data Repository:

The following Options must be supported by the Clinical Data Source:

- Vital Signs,
- Problems and Allergies,
- Diagnostic Results (i.e. Laboratory and Radiology Results),
- Medications,
- Immunizations and
- Professional Services.

[CNS-132] - IHE Audit Trail and Node Authentication (ATNA) Integration Profile as a Secure Node Actor with the additional constraints specified in:

- IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Sections 3.2 and 3.3.1

[CNS-133] – IHE Consistent Time (CT) Integration Profile as a Time Client Actor with the additional constraints specified in:

- IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Section 3.1.2

4. SAUDI EHEALTH CONSTRAINTS ON THE CLINICAL NOTES AND SUMMARIES

This section defines required behavior rules for Use Case Actors defined in this Core Interoperability Specification.

4.1 REQUIREMENTS FOR CLINICAL SUMMARY CONTENT CREATOR

The following rules shall be supported for the conformance to the Clinical Summary Content Creator.

[CNS-150] – The Clinical Summary Content Creator **SHALL** support the creation of Clinical Summary documents along with Document Sharing Metadata that shall include the following attributes:

[CNS-152] – A Title Attribute **SHALL** be present and **SHALL NOT** be null flavor.

[CNS-153] – A documentClass Attribute **SHALL** contain the coded value "SUMMARIES" as defined in the "KSA Class Code" value set.

[CNS-154] – A practiceSetting Attribute **SHALL** contain the practiceSetting coded value with one of the coded values defined in the "KSA Organization Provider Type" Value Set.

[CNS-155] – The typeCode Attribute **SHALL** contain one coded value which is identical to the Clinical Summary document code found in `/ClinicalDocument/code` and which is specified by IHE-PCC Document Exchange profile.

[CNS-156] – The mimeType attribute **SHALL** contain one coded value which **SHALL** be "text/xml" as described in the "MIME Type" value set.

[CNS-157] – The formatCode attribute **SHALL** contain one coded value which is identical to formatCode, which is specified by IHE-PCC Document Content Module.

[CNS-165] – When the Clinical Summary document is replaced by a PDF document, (to cancel a Clinical Summary document written in error), the formatCode attribute **SHALL** contain one coded value which shall be "urn:ihe:iti:xds-sd:pdf:2008" as described in the "KSA Format Code" value set.

[CNS-166] – When the Clinical Summary document is replaced by a scanned TEXT document, (to cancel a Clinical Summary document written in error), the formatCode attribute **SHALL** contain one coded value which shall be "urn:ihe:iti:xds-sd:text:2008" as described in the "KSA Format Code" value set.

[CNS-158] – All other Document Sharing Metadata Attributes **SHALL** contain values as specified in IS0102 *Saudi eHealth Document Sharing Interoperability Specification*.

[CNS-159] – All other Document Sharing Metadata Attributes with corresponding data elements in the Clinical Summary document **SHALL** be consistent with the values in the Clinical Summary document.

[CNS-160] – The Clinical Summary Content Creator **SHALL** support the update (i.e., replace) of a shared Clinical Summary document, by replacing a shared Clinical Summary document with an updated Clinical Summary document.

[CNS-161] – The associated Document Sharing Metadata in the updated document **SHALL** include the attributes specified in CNS-150 with identical values

[CNS-162] – If a Clinical Summary document has been published and assigned to an incorrect patient, the Clinical Summary Content Creator (the XDS document source actor is grouped with an XDS Document Administrator Actor-See [KXDS-072] **SHALL** correct the error by using the [IHE XDS.b Supplement – Metadata Update: Delete Document Set Request ITI-63] to deprecate the original Summary and a new Summary **SHALL** be published and assigned to the correct patient. (See IS0102 *Saudi eHealth Document Sharing Interoperability Specification Section 3.2*).

[CNS-164] – The Clinical Summary Content Creator **MAY** request that a notification be sent to a referred Clinical Content Consumer in order to provide timely notification. This notification request is performed by placing the address of the target Use Case Actor to be notified in the intendedRecipient XDS Metadata Attribute of the Provide and Register Document Set Transaction–b [IHE ITI-41] used to send the Clinical Summary document to the HIE Document Repository. The format of the address **SHALL** meet the specifications of IS0102 *Saudi eHealth Document Sharing Interoperability Specification* (See Section 4).

4.2 REQUIREMENTS FOR CLINICAL NOTES CONTENT CREATOR

The following rules **SHALL** be supported for the conformance to the Clinical Notes Content Creator:

[CNS-170] – The Clinical Notes Content Creator **SHALL** support the creation of Clinical Notes documents along with Document Sharing metadata that **SHALL** include the following attributes:

[CNS-172] – A Title Attribute **SHALL** be present and **SHALL NOT** be null flavor.

[CNS-173] – A documentClass Attribute **SHALL** contain the coded value “REPORT" as defined in the “KSA Class Code” value set.

[CNS-174] – A practiceSetting Attribute **SHALL** contain the “practiceSetting” coded value with one of the coded values defined in the “KSA Organization Provider Type”.

[CNS-175] – The typeCode Attribute **SHALL** contain one coded value which is identical to the Clinical Note document code found in `/ClinicalDocument/code` and, which is specified by HL7 – CDA R2 IHE Health Story Consolidation Operative Note.

[CNS-176] – The mimeType attribute **SHALL** contain one coded value which **SHALL** be “text/xml” as described in the “MIME Type” value set.

[CNS-177] – The formatCode attribute **SHALL** contain one coded value which is identical to the formatCode, which is specified by HL7 – CDA R2 IHE Health Story Consolidation Operative Note.

[CNS-184] When the Clinical Note document is replaced by a PDF document, (to cancel a Clinical Note document written in error), and the Clinical Note

document is a PDF document, the formatCode attribute **SHALL** contain one coded value which shall be "urn:ihe:iti:xds-sd:pdf:2008" as described in the "KSA Format Code" value set.

[CNS-185] – When the Clinical Note document is replaced by a scanned TEXT document, (to cancel a Clinical Note document written in error), the formatCode attribute **SHALL** contain one coded value which shall be "urn:ihe:iti:xds-sd:text:2008" as described in the "KSA Format Code" value set.

[CNS-178] – All other Document Sharing Metadata Attributes **SHALL** contain values as specified in IS0102 *Saudi eHealth Document Sharing Interoperability Specification*.

[CNS-179] – All other Document Sharing Metadata Attributes with corresponding data elements in the Clinical Note document **SHALL** be consistent with the values in the Clinical Note document.

[CNS-180] – The Clinical Note Content Creator **SHALL** support the update (i.e., replace) of a shared Clinical Note document, by replacing a shared Clinical Note document with an updated Clinical Note document.

[CNS-181] The associated Document Sharing Metadata in the updated document **SHALL** include the attributes specified in CNS-170 with identical values.

[CNS-182] – If a Clinical Note document has been published and assigned to an incorrect patient, the Clinical Note Content Creator (the XDS document source actor is grouped with an XDS Document Administrator Actor - See [KXDS-072] **SHALL** correct the error by using the [IHE XDS.b Supplement – Metadata Update: Delete Document Set Request ITI-62] to deprecate the original Clinical Note, and a new Clinical Note **SHALL** be published and assigned to the correct patient. (See IS0102 *Saudi eHealth Document Sharing Interoperability Specification* – Section 3.2).

[CNS-183] – The Clinical Note Content Creator **MAY** request that a notification be sent to a referred Clinical Content Consumer in order to provide timely notification. This notification request is performed by placing the address of the target Use Case Actor to be notified in the intendedRecipient Document Sharing Metadata Attribute of the Provide and Register Document Set Transaction–b [IHE ITI-41] used to send the Clinical Note document to the HIE Document Repository. The format of the address **SHALL** meet the specifications of IS0102 *Saudi eHealth Document Sharing Interoperability Specification* (See Section 4).

4.3 REQUIREMENTS FOR iEHR ON-DEMAND DOCUMENT SOURCE

The following rules shall be supported for the conformance to the iEHR On-Demand Document Source.

[CNS-190] – The iEHR On-Demand Document Source **SHALL** support the creation of iEHR Summary documents along with Document Sharing Metadata that **SHALL** include the following attributes:

[CNS-192] – A Title Attribute **SHALL** be created and contain the "iEHR Summary" display name.

[CNS-193] – A documentClass Attribute **SHALL** contain the coded value "SUMMARIES" as defined in the "KSA Class Code" value set.

[CNS-194] – A practiceSetting Attribute **SHALL** contain the "practiceSetting" coded value "394802001" (General Medicine) from the SNOMED CT Coding System (2.16.840.1.113883.6.96).

[CNS-195] – The typeCode Attribute **SHALL** contain one coded value which **SHALL** be "34133-9" (Summary of Episode Note) from LOINC as specified in PCC-TF-2:6.3.1.5.3

[CNS-196] – The mimeType attribute **SHALL** contain one coded value which **SHALL** be "text/xml" as described in the "MIME Type" value set.

[CNS-197] – The formatCode attribute **SHALL** contain one coded value which **SHALL** be "`urn:ihe:pcc:xphr:2007`" [IHE Exchange of Personal Health Records Profile] as described in the "KSA format Code" value set.

[CNS-198] – All other Document Sharing Metadata Attributes **SHALL** contain values as specified in IS0102 *Saudi eHealth Document Sharing Interoperability Specification*.

[CNS-199] – All other Document Sharing Metadata Attributes with corresponding data elements in the iEHR Summary document **SHALL** be consistent with the value in the iEHR Summary document.

4.4 REQUIREMENTS FOR CLINICAL CONTENT CONSUMER

The following rules **SHALL** be supported for the conformance to the Clinical Content Consumer:

[CNS-200] – When retrieving a patient's clinical document, it is the responsibility of the Clinical Content Consumer to rely on the metadata associated with the clinical document to reconcile the KSA-Wide information with its local information and conventions. At a minimum, it **SHALL** reconcile:

[CNS-201] – The KSA-Wide Health ID with the local Patient ID

[CNS-202] – Any KSA-Wide identifiers required by the individual Clinical Documents (e.g., Laboratory Results Report, Radiology Imaging Report) with the local identifiers.

[CNS-203] – When retrieving a patient's Clinical document, the Clinical Content Consumer **SHALL** be able to receive them in such a way that the user on the receiving system is able to display and process its content.

[CNS-204] – The Clinical Content Consumer **MAY** receive notifications (Notification of Availability Option) triggered by the Clinical Document Creator that created or updated the Clinical document. This notification is triggered by placing the address of the target system (i.e. the Clinical Document Consumer) in the intendedRecipient Document Sharing Metadata Attribute when sending a new or updated Clinical Document to the Document Repository [Provide and Register Document Set Transaction – b [IHE ITI-41]]. The format of the address **SHALL** meet the specifications in IS0102 *Saudi eHealth Document Sharing Interoperability Specification Section 3.2*.

Note: The list of types of Clinical Document Creators supported is specified in Section 3.3 Clinical Content Consumer Conformance.

[CNS-205] – At the beginning of the encounter, the Clinical Content Consumer **SHALL** be able to reconcile clinical data as follows:

[CNS-206] – It **SHALL** query for iEHR Summary Documents since the last reconciliation performed for the current patient.

[CNS-207] – It **SHALL** retrieve all iEHR Summary Documents returned from that query.

[CNS-208] – It **SHALL** reconcile all problems, medications and allergies with data currently in the local system.

[CNS-209] – It **SHALL** import all relevant laboratory results and immunizations into the local system.

4.5 REQUIREMENTS FOR HIE DOCUMENT REPOSITORY

The following rules **SHALL** be supported for the conformance to the HIE Document Repository Actor:

[CNS-210] – When responding to a query, a Document Registry **SHALL** be able to support the return of several Clinical documents for the same patient.

[CNS-211] – The following stored queries **SHALL** be supported by the XDS Document Registry:

FindDocuments

FindSubmissionSets

GetAll

GetDocuments

GetAssociations

GetDocumentsAndAssociations

GetSubmissionSets

GetSubmissionSetAndContents

GetRelatedDocuments

Folder related transaction may be optionally supported:

FindFolders

GetFolders

GetFolderAndContents

GetFoldersForDocument

Note: Information about the allowed query parameters and examples of how those parameters are used may be found in IHE IT Infrastructure Technical Framework Volume 2a describing transaction ITI-18 Registry Stored Query.

[CNS-212] – The Document Repository **SHALL** support the [IHE XDS.b Supplement – Metadata Update: Delete Document Set Request ITI-62] to deprecate an active or deprecated document. This is used to correct an error when a document has been published and assigned to an incorrect patient (See IS0102 *Saudi eHealth Document Sharing Interoperability Specification* – Section 4.2 for details).

4.6 REQUIREMENTS FOR CLINICAL DATA REPOSITORY

The following rules **SHALL** be supported for the conformance to the Clinical Data Repository Actor:

[CNS-220] – The Clinical Data Repository **SHALL** be populated by content provided to the HIE Repository.

[CNS-221] – When Clinical Data are returned by the Clinical Data Repository that originated in a clinical document, the Clinical Data Repository **SHALL** return a pointer to the document within the Document Repository from which that data originated.

[CNS-222] – The Clinical Data Repository **SHALL** support queries using the same vocabularies used for clinical documents to access data about Vital Signs, Problems and Allergies, Diagnostic Data, Medications, Immunizations and Professional Services with the additional constraints specified in:

IS0106 *Saudi eHealth Clinical Documents Constrains Interoperability Specifications* – Sections 6 and 7.

[CNS-223] – The values found in patientId **SHALL** contain a Health ID that has been verified with the KSA-Wide Health ID.

5. REFERENCED DOCUMENTS AND STANDARDS

The following Saudi eHealth documents are referenced by this interoperability specification.

TABLE 5-1 INTERNAL REFERENCES

MOH DOCUMENT	DESCRIPTION
IS0001 Saudi eHealth Core Interoperability Specification for KSA-Wide Patient Demographic Query	Documents the specifications required to obtain patient IDs and demographic information for the patient. It is used to ensure that the nationwide Health ID is used to register laboratory orders for the correct patient.
IS0002 Saudi eHealth Core Interoperability Specification for KSA-Wide Healthcare Provider Directory Query	Documents the specification of the content and structure of the Saudi eHealth Healthcare Provider Directory services in support of the Healthcare Provider Directory Query Use Case. This service supports searches for providers and organizations and conveys authoritative attributes related to them. This information describes organizations that provide patient care, such as public and private hospitals, primary care centers, laboratories, pharmacies, etc. It is used by these organizations and by the MOH business applications.
IS0003 Saudi eHealth Core Interoperability Specification for Sharing Coded Laboratory Results	Describes the technical requirements for the interface to share coded Laboratory Results Reports via the Saudi eHealth Information Exchange (HIE). These laboratory test results are generally used by primary and hospital care providers but may also be used by MOH Business Intelligence, including public health/MOH business intelligence organizations. Note that policies may require that patient information be pseudonymized for use in MOH business applications.
IS0005 Saudi eHealth Core Interoperability Specification for Sharing Images and Imaging Reports	Describes the technical requirements for the interface to share imaging reports and images via the Saudi eHealth Information Exchange (HIE). This includes reports and images acquired on a broad range of imaging modalities. Two common examples are to store images and reports about a patient's current imaging procedure and the ability to access images/reports from imaging studies previously performed for that patient.
IS0008 Saudi eHealth Core Interoperability Specification for ePrescriptions	Enables Healthcare Providers to record a prescription in an outpatient environment. The prescription conveys information necessary to ensure dispensers have the proper data to fulfill the dispensation including dosing information and additional clinical information to document the rationale behind the prescription as well as to support drug interaction checking.
IS0010 Saudi eHealth Core Interoperability Specification for Immunization	Enable Healthcare Providers to record a medication dispensation to a patient in an outpatient environment or at the time of an in-patient discharge
IS0101 Saudi eHealth Security and Privacy Interoperability Specification	Specifies the interoperability standards and profiles along with the Saudi specific constraints that are required to provide the technical security measures, data protection, and privacy management that will facilitate the implementation of the Saudi eHealth Policies for Health Information Exchange in the Kingdom of Saudi Arabia among communicating IT systems.
IS0102 Saudi eHealth Document Sharing Interoperability Specification	Forms a "container" for set of requirements that complements the IHE XDS Profile with Saudi eHealth specific constraints when it is called upon by any of the Core Interoperability Specifications.
IS0106 Saudi eHealth Clinical Documents Constrains Interoperability Specifications	Specifies common constraints for clinical documents such as data elements of document headers that are common across the Saudi eHealth Project.

MOH DOCUMENT	DESCRIPTION
IS0105 Saudi eHealth Laboratory Results and Orders Content Interoperability Specification	Specifies the clinical content for cross-enterprise sharing of laboratory orders and results reports using IHE Laboratory Technical Framework Volume 3 (LABTF-3) Content Section 2 (XD-LAB). IHE LABTF-3 Content supports the sharing of Laboratory Results Reports, and includes information on the original laboratory order. .
IS0200 Saudi eHealth Terminology Repository.	Specifies the terminology concepts and associated coded value sets for data elements used throughout the Saudi eHealth Interoperability Specifications.
IS0303 Saudi Health Information Exchange Policies	Contains the policies and supporting definitions that support the security and privacy aspects of the Saudi Health Information Exchange. The Saudi Health Information Exchange Policies apply to all individuals and organizations that have access to the Saudi Health Information Exchange managed health records, including those connected to the Saudi Health Information Exchange, their Business Associates, as well as any subcontractors of Business Associates. These policies apply to all information provided to or retrieved from the Saudi Health Information Exchange.
UC0007 Saudi eHealth *Interoperability Use Case* for Clinical Notes and Summaries	Specifies the Saudi eHealth Interoperability Use Cases applicable to existing and new information systems to be connected to the national Saudi eHealth Exchange (HIE) platform. Each Use Case provides one or more technical scenarios that convey how the system should interact with the end user, or another system, to achieve a specific business goal. The Use Case applicable to this document is Clinical Notes and Summaries. This Use Case describes the ability to create and share clinical notes and summaries for the purpose of transition of care via the HIE. This Use Case also describes the ability to retrieve clinical medical documentation and clinical data from the HIE for the purpose of patient care.

TABLE 5-2 EXTERNAL REFERENCES

STANDARD	DESCRIPTION
Health Level Seven (HL7) Clinical Document Architecture Release 2 (CDA R2)	An XML-based document markup standard that specifies the structure and semantics of clinical documents for the purpose of exchange. CDA R2 further builds upon the Version 3.0 Reference Information Model (RIM) Standard. For more information, see http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7
Health Level Seven (HL7) Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, Release 1.1 - US Realm	The Consolidated Templated implementation guide contains a library of CDA templates, incorporating and harmonizing previous efforts from Health Level Seven (HL7), Integrating the Healthcare Enterprise (IHE), and Health Information Technology Standards Panel (HITSP). It represents harmonization of the HL7 Health Story guides, HITSP C32, related components of IHE Patient Care Coordination (IHE PCC), and Continuity of Care (CCD), and it includes all required CDA templates in Final Rules for Stage 1 Meaningful Use and 45 CFR Part 170 – Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology; Final Rule. For more information, see http://www.hl7.org/implement/standards/product_brief.cfm?product_id=258

STANDARD	DESCRIPTION
IHE IT Infrastructure (ITI) Technical Framework – Volume 1 (ITI TF-1) Integrations Profiles, Section 10 Cross-Enterprise Document Sharing (XDS.b)	The Cross-Enterprise Document Sharing (XDS.b) IHE Integration Profile facilitates the registration, distribution and access across health enterprises of patient electronic health records. This profile is focused on providing a standards-based specification for managing the sharing of documents between healthcare enterprises, ranging from a private physician office to a clinic to an acute care in-patient facility. May be obtained at http://www.ihe.net/Technical_Frameworks/#iti
IHE IT Infrastructure Technical Framework Supplement – On Demand Documents	The IHE On-Demand Document supplement updates the XDS and XCA profiles to support the sharing of dynamically created document content by adding an option for On-Demand Documents. For more information See May be obtained at http://www.ihe.net/Technical_Frameworks/#IT
IHE IT Infrastructure (ITI) Technical Framework – Volume 1 (ITI TF-1) Integrations Profiles, Section 13 Cross-Enterprise User Attestation (XUA) profile	Cross-Enterprise User Assertion Profile (XUA) - provides a means to communicate claims about the identity of an authenticated principal (user, application, system...) in transactions that cross enterprise boundaries. To provide accountability in these cross-enterprise transactions there is a need to identify the requesting principal in a way that enables the receiver to make access decisions and generate the proper audit entries. The XUA Profile supports enterprises that have chosen to have their own user directory with their own unique method of authenticating the users, as well as others that may have chosen to use a third party to perform the authentication. May be obtained at http://www.ihe.net/Technical_Frameworks/#iti
IHE IT Infrastructure Technical Framework Volume 1 (ITI TF-1) Integration Profiles, Section 20 Cross-Enterprise Sharing of Scanned Documents	A variety of non-formatted healthcare reports, legacy paper, film, electronic and scanner outputted formats are used to store and exchange clinical documents. These formats do not have a uniform mechanism to store healthcare metadata associated with the documents, including patient identifiers, demographics, encounter, order, or service information. The association of structured, healthcare metadata with this kind of document is important to maintain the integrity of the patient health record as managed by the source system. It is necessary to provide a mechanism that allows such source metadata to be stored with the document. This profile defines how such information captured can be represented within a structured HL7 CDA R2 header, with a PDF or plaintext formatted document containing clinical information. Furthermore, this profile defines elements of the CDA R2 header necessary to minimally annotate these documents. Such header elements include information regarding patient identity, patient demographics, scanner operator identity, scanning technology, scan time as well as best available authoring information. Portions of CDA R2 header, along with supplemental document registration information, are then used to populate XDS Document Entry metadata. May be obtained at http://www.ihe.net/Technical_Frameworks/#iti.

STANDARD	DESCRIPTION
IHE IT Infrastructure (ITI) Technical Framework – Volume 3 (ITI TF-3) Integrations Profiles, Section 4 Metadata used in Document Sharing profiles	Describes the metadata that is used in IHE profiles designed for sharing documents (Document Sharing profiles). The Document Sharing profiles are implementing the Document Sharing concept outlined in the ITI whitepaper entitled Health Information Exchange: Enabling Document Sharing Using IHE Profiles May be obtained at http://www.ihe.net/Technical_Frameworks/#iti
IHE IT Infrastructure (ITI) Technical Framework – Volume 1 (ITI TF-1) Integration Profiles, Supplement -- XDS Metadata Update	This supplement updates the XDS and XDR profiles to add support for the updating and deleting of metadata. May be obtained at http://www.ihe.net/Technical_Frameworks/#iti
IHE Laboratory Technical Framework Volume 3 (LABTF-3) Content	This Content Integration Profile describes a clinical laboratory report as an electronic document to be published towards a document sharing resource such as an Electronic Health Record (EHR) or a Personal Health Record (PHR) shared by a community of care providers, using one of the document sharing profiles defined in ITI-TF. Such an electronic document contains the set of releasable results produced by a clinical laboratory in fulfillment of one or more test Orders for a patient. The report is both human-readable and importable in the consumer systems so as to consolidate their patient medical records. The scope of this profile covers all laboratory specialties except anatomic pathology. May be obtained at http://www.ihe.net/Technical_Frameworks/#laboratory.
International Health Terminology Standards Development Organization (IHTSDO) Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®)	SNOMED CT consists of a technical design, core content architecture, and Core content. SNOMED CT Core content includes the technical specification of SNOMED CT and fully integrated multi-specialty clinical content. The Core content also includes a concepts table, description table, relationships table, history table, ICD-9-CM mapping, and Technical Reference Guide. Additionally, SNOMED CT provides a framework to manage language dialects, clinically relevant subsets, qualifiers and extensions, as well as concepts and terms unique to particular organizations or localities. For more information visit *www.ihtsdo.com*
IHE Patient Care Coordination (PCC) Technical Framework Supplement – Query for Exiting Data (QED),	The IHE Query for Existing Data Profile (QED) Profile supports dynamic queries for clinical data including: vital signs, problems, medications, immunizations, diagnostic results, procedures and visit history. A wide variety of systems often need access to dynamic clinical information stored and maintained in an EMR system or other clinical data repository. This profile makes the information widely available to other systems within and across enterprises to support provision of better clinical care. May be obtained at http://www.ihe.net/Technical_Frameworks/#pcc
IHE Patient Care Coordination (PCC) Technical Framework Supplement – Reconciliation of Diagnoses, Allergies and Medications (RECON),	The IHE Reconciliation of Diagnoses, Allergies and Medications (RECON) Profile enables information contained in Health Information Systems and Exchanges to be used to support automation of these reconciliation tasks and clinical workflows. This profile explains what information can help reconciliation, and how it can be used to assist healthcare providers to automate this complex task. For more information See May be obtained at http://www.ihe.net/Technical_Frameworks/#pcc

STANDARD	DESCRIPTION
IHE Patient Care Coordination (PCC) Technical Framework – Volume 1 (IHE PCC TF-1) Integrations Profiles– Section 3 Cross-Enterprise Sharing of Medical Summaries (XDS-MS)	The IHE Cross-Enterprise Sharing of Medical Summaries (XDS-MS) Profile facilitates the identification of clinically relevant documents (and data elements those documents contain) that are used in typical "transfer of care" scenarios and then to provide interoperability standards to promote ease in transmission of those documents (and data elements). This is accomplished by defining the appropriate standards for document transmission and a minimum set of "record entries" that should be forwarded or made available to subsequent care provider(s) during specific transfer of care scenarios. In addition, this integration profile defines the utilization requirements/options for the receiving entity in order to ensure that the "care context" of the sending entity is appropriately maintained following the information transfer. For more information See May be obtained at http://www.ihe.net/Technical_Frameworks/#pcc
IHE Patient Care Coordination (PCC) Technical Framework – Volume 1 (IHE PCC TF-1) Integrations Profiles– Section 4 Exchange of Personal Health Record Content Integration Profile (XPHR)	The IHE Exchange of Personal Health Record Content (XPHR) Profile describes the content and format of summary information extracted from a PHR system used by a patient for import into healthcare provider information systems, and vice versa. The purpose of this profile is to support interoperability between PHR systems used by patients and the information systems used by healthcare providers. . For more information See May be obtained at http://www.ihe.net/Technical_Frameworks/#pcc
IHE Patient Care Coordination (PCC) Technical Framework Supplement - Section Z Labor and Delivery Profiles (LDHP, LDS and MDS)	Maternal Discharge Summary is a content profile that defines the structure of the data that is often collected from the time of delivery until discharge from the birthing facility. It includes, but is not limited to demographics, medications, laboratory results, newborn delivery information, patient education, and outcomes May be obtained at http://www.ihe.net/Technical_Frameworks/#pcc
IHE Patient Care Coordination (PCC) Technical Framework Supplement – Newborn Discharge Summary (NDS)	The Newborn Discharge Summary represents a summary of the most critical information to a newborn care provider after discharge from the birthing facility. The scope is constrained to newborn discharges cared for in a normal newborn nursery. May be obtained at http://www.ihe.net/Technical_Frameworks/#pcc
Logical Observation Identifiers Names and Codes (LOINC®)	A database of universal identifiers for laboratory and other clinical observations. The laboratory portion of the LOINC database contains the usual categories of chemistry, hematology, serology, microbiology (including parasitology and virology), and toxicology; as well as categories for drugs and the cell counts typically reported on a complete blood count or a cerebrospinal fluid cell count. Antibiotic susceptibilities are a separate category. The clinical portion of the LOINC database includes entries for vital signs, hemodynamics, intake/output, EKG, obstetric ultrasound, cardiac echo, urologic imaging, gastro endoscopic procedures, pulmonary ventilator management, selected survey instruments, and other clinical observations. For more information visit www.loinc.org.

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6. APPENDIX A: SAMPLE MESSAGES

EXAMPLES WILL BE PROVIDED AS PART OF THE IS SPECIFICATION VALIDATION PROCESS. UNTIL THEN THIS SECTION WILL REMAIN BLANK.