Integrating the Healthcare Enterprise

IHE PCC
Technical Framework Supplement

Query for Existing Data for Mobile (QEDm)

FHIR® STU3

Rev. 1.0 – Draft for Public Comment

Date: May 26, 2017

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Please verify you have the most recent version of this document. See here for Trial Implementation and Final Text versions and here for Public Comment versions.

Foreword

This is a supplement to the IHE Patient Care Coordination Technical Framework V11.0. Each supplement undergoes a process of public comment and trial implementation before being incorporated into the volumes of the Technical Frameworks.

This supplement is published on May 26, 2017 for public comment. Comments are invited and can be submitted at http://www.ihe.net/PCC_Public_Comments. In order to be considered in development of the trial implementation version of the supplement, comments must be received by June 25, 2017.

This supplement describes changes to the existing technical framework documents.

"Boxed" instructions like the sample below indicate to the Volume Editor how to integrate the relevant section(s) into the relevant Technical Framework volume.

Amend Section X.X by the following:

Where the amendment adds text, make the added text **bold underline**. Where the amendment removes text, make the removed text ~~**bold strikethrough**~~. When entire new sections are added, introduce with editor's instructions to "add new text" or similar, which for readability are not bolded or underlined.

General information about IHE can be found at http://ihe.net.

Information about the IHE Patient Care Coordination domain can be found at http://ihe.net/IHE_Domains.

Information about the organization of IHE Technical Frameworks and Supplements and the process used to create them can be found at http://ihe.net/IHE_Process and http://ihe.net/Profiles.

The current version of the IHE Patient Care Coordination Technical Framework can be found at http://ihe.net/Technical_Frameworks.

CONTENTS

Introduction to this Supplement

The Query for Existing Data for Mobile Profile (QEDm) supports dynamic queries for clinical data elements, including vital signs, allergy and intolerances, problems, diagnostic results, medications, immunizations, procedures, encounters and provenance by making the information widely available to other systems within and across enterprises to support provision of better clinical care. It defines a transaction used to query a list of specific data elements, persisted as FHIR®[1] resources.

It's functionally equivalent to QED Profile, but it's conceived to be implemented by application specific to mobile devices. The term "mobile" must be intended in a wider sense: it identifies not only mobile application, but the whole class of systems that are resource- and platform-constrained. (e.g.: tablets, smartphones, and embedded devices including home-health devices, but also larger systems where needs are simple, such as pulling the latest summary for display).

These constraints may drive the implementer to use simpler network interface technology for data elements sharing. The critical aspects of the 'mobile device' are that it is resource-constrained, has a simple programming environment (e.g., JSON, JavaScript), simple protocol stack (e.g., HTTP), and simple display functionality (e.g., HTML browser).

The goal is to limit required additional libraries to those that are necessary to process SOAP, WSSE, MIME-Multipart, MTOM/XOP, ebRIM, and multi-depth XML.

The Query for Existing Data for Mobile Profile (QEDm) Profile defines one standardized interface to health (HTTP-based RESTful APIs) for use by 'mobile devices' so that deployment of mobile applications is more consistent and reusable.

The Query for Existing Data for Mobile Profile (QEDm) Profile, by considering the already defined actors Clinical Data Consumer and Clinical Data Source, specifies options for them and a transaction to be used for querying a list of specific data elements, persisted as FHIR resources.

The current version of Supplement doesn't consider the reconciliation of the fine-grained data elements gathered by the Clinical Data Source and/or Clinical Data Consumer Actors. In order to perform reconciliation a grouping with RECON Reconciliation Agent should be considered, but the current version of RECON Profile Supplement needs be updated to make this actor properly work together with QEDm and PDLS Actors.

Open Issues and Questions

None

Closed Issues

QEDm_001: Agree on the list of requirements for QEDm by comparing with QED

[1] FHIR is the registered trademark of Health Level Seven International.

Resolution:

	Requirements	QED	QEDm
1	Support listing of Problems, Medications, Allergies, Med-Allergies	Yes	Yes
2	Supports listing of rest of DE (Data-element) per full QED List	Yes	Yes
3	Supports listing of additional DE per DAF resources	No	Yes, almost
4	Supports access to DE across DAF/US Core defined resources	No	Maybe
5	Identifies source documents from where DE was extracted, if any.	Yes (but not clearly)	Yes
6	Selects source documents for scope of query	No	Yes
7	Flag in response that auto de-duplication has happen by clinical DE source	No	No (Open Issue)
8	Shows specific DEs that have been auto de-duplicated	No? (not with RECON)	No, too complex

QEDm_002: Scope Listing of Data Elements

Which is the best approach in specifying the QEDm query transaction and complementary provenance information?

FHIR allows essentially two approaches (querying strategies in FHIR STU3):

- ⇨ *Querying 'named' Lists of resources ('Operations')*
- ⇨ *Querying directly the underlying resources*

Considerations:

- ⇨ *Only the support for listing Resources has sense from a clinical point of view (see Issue QEDm:001 - requirements 1,2,3)*
- ⇨ *FHIR List resource enumerates a flat collection of resources and provides features for managing the collection. While a particular List instance may represent a "snapshot", from a business process perspective the notion of "List" is dynamic – items are added and removed over time. The list resource references other resources. Lists may be curated and have specific business meaning (see here for more comments).*

Resolution:

- ⇨ *Basic remains the goal and Argonauts doesn't consider 'curated lists' (aka 'named' Lists of resources) as a basic function → start consider querying directly the underlying resources*

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Resolution:

- ⇨ *Basic remains the goal and Argonauts doesn't consider 'curated lists' (aka 'named' Lists of resources) as a basic function → start consider querying directly the underlying resources*

QEDm_003: which are the QEDm query parameters to consider for accessing Data Elements (Resources)?

Resolution:

- ⇨ *try to replicate QED functionalities according to the query strategy adopted.*

QEDm_004: To define the core set of FHIR resources that align with QED and related QEDm's options

Resolution strategy:

- ⇨ *consider a subset of FHIR Resources: the stable ones.*
  (keep in the Supplement the complete table to make evident all open issues about Resources until the final review: see "Classification of Information" section for more details)

⇨ *consider the STU3 version of Resources.*

Comments:

Here below a comparison table between the current clinical information classification/options from QED, QEDm and FHIR Resources.

Alternative classifications from Argonauts and US Core projects/initiatives have been considered and discussed.

QED Option	QEDm Option	FHIR Resource/Profile
Vital Signs	Simple Observations	Observation VitalSign (profile)
Diagnostic Results	Diagnostic Results Option	DiagnosticReport
Problems and Allergies	Allergy and Intolerances	AllergyIntolerance
	Conditions	Condition
Medications	Medications	Medication MedicationStatement MedicationRequest
Immunizations	Immunizations	Immunization
Professional Services	Procedures	Procedures
	Encounters	Encounter
	Provenance	
		Goals → not considered
		Assessment and Plan → not considered
		CareTeam → not considered
		Practitioner → not considered
		Organization → not considered
		Location → not considered

Resolution:

⇨ *Only a core-set of FHIR resources will be considered, consequently only a limited number of options are going to be specified. See the table above*

QEDm_005: Managing reconciliation of Data Elements

How to record reconciliation performed on the FHIR resources returned by the QEDm query transaction?

Considerations:

Reconciliation of clinical data without a manual intervention has no sense.
An automatic algorithm could work well if limited to the data deduplication.

Consequences:

- *a 'manual reconciliation' can be conceived at the Clinical Data Consumer side and it's necessary when this actor is going to perform multiple query for gathering and merging information from different sources → the reconciliation is obtained by considering a Reconciliation Agent grouped with it.*
- *an 'automatic deduplication' can be conceived as option for the Clinical Data Source*

Reconciliation/decuplication specific content is already defined by RECON. The results of reconciliation are noted in the FHIR List resource by using the FHIR Provenance resource. See the following two sections:

- *PCC Vol.3: 6.6.A - FHIR Reconciled List*
- *PCC Vol.3: 6.6.B - FHIR Provenance Constraints*

BUT:

⇨ *RECON specifications must be updated to FHIR STU3*

⇨ *See also considerations about multi-stage import/reconciliation supported by the Provenance Resource: http://hl7.org/fhir/2017Jan/provenance.html#6.2.4.6*

Resolution:

⇨ *too complex, no reconciliation and no deduplication will be considered by QEDm (no automatic operations specified by RECON Profile)*

QEDm_006: new name for the [PCC-Y] transaction: "Mobile Query Existing Data"?

In order to appear more generic it's proposed to use the name "Mobile Query Existing Data" for the transaction [PCC-Y] to be aligned with the QED [PCC-2] "Query Existing Data" transaction, just like done with PIX/PIXm and PDQ/PDQm

Resolution:

⇨ *ok to rename.*

QEDm_007: How to consider the "Multi-Patient Query Option" in the query transaction?

Resolution:

⇨ *ok to remove this option from this year scope*

QEDm_008: Consistency – How to identify Document Sources of Data Elements

Strategy:

Consider the FHIR Provenance resource as used in PCC-RECON: "When the Data Element comes from a Document, the ID of the document is used as the source. When the Data Element is the result of a query (such as QED), the query ID is the source.

When the data comes directly from a system, provenance may not exist because there is not a document source ID from the system. The solution is to start broad and add the "provenance" Option (source of the data). …"

Resolution:

- ⇨ *The original Document(s) reference(s) can be supported by the Provenance.entity: http://hl7.org/fhir/STU3/provenance.html*
  (in general each Provenance object can link N 'target' Resources to M 'entity' Documents)
- ⇨ *To consider also the available FHIR specifications on FHIR & XDS Documents https://www.hl7.org/FHIR/STU3/usecases.html#xds*
  - → *specifically the DocumentReference FHIR resource: https://www.hl7.org/FHIR/STU3/documentreference.html*
- ⇨ *Additional considerations on query for including Provenance:*
  - → *FHIR query on "resource" (e.g., medication), add "_revinclude" with "Provenance". GET [base]/MedicationRequest?_revinclude=Provenance:target&criteria...Always on the GET by client and server must support.*
  - → *For list FHIR is an "operation" (not RESTful GET). Is it worth exposing "list operations" because may be perfectly reconciled.*
  - → *Use Doc Resource versus and/or provenance resource*

QEDm_009: QED retirement

Resolution / comment:

- ⇨ *it may be considered, but the timing is independent of QEDm completion.*

QEDm_010: Which is the best FHIR Implementation Guide to refer?

- Should we move to US-Core? Are they other countries/international efforts?
- Alternative is Argonaut (modified, by removing a few US specific).

Considerations:

- ⇨ STU 3 'final' has been released and the US Core IG has been aligned to STU3

Resolution:

⇨ *No need to base the whole profile on US Core specific constrains. US Core resource specific profiling or other profiling can be referenced only if/when necessary*

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General Introduction

Update the following Appendices to the General Introduction as indicated below. Note that these are not appendices to Volume 1.

Appendix A – Actor Summary Definitions

Add the following actors to the IHE Technical Frameworks General Introduction list of actors:

Not applicable

Appendix B – Transaction Summary Definitions

Add the following transactions to the IHE Technical Frameworks General Introduction list of Transactions:

Mobile Query Existing Data [PCC-Y] – this transaction uses RESTful API to query clinical data elements and retrieve them as lists of FHIR resources.

Glossary

Add the following glossary terms to the IHE Technical Frameworks General Introduction Glossary:

No new terms added.

Volume 1 – Profiles

Copyright Licenses

Add the following to the IHE Technical Frameworks General Introduction Copyright section:

No new copyright licenses added.

Add new Section X

X Query for Existing Data for Mobile (QEDm) Profile

The Query for Existing Data for Mobile Profile (QEDm) supports queries for clinical data elements, including vital signs, allergy and intolerances, conditions, diagnostic results, medications, immunizations, procedures, encounters and provenance by making the information widely available to other systems within and across enterprises. It defines a transaction used to query a list of specific data elements, persisted as FHIR resources.

It's functionally equivalent to the QED Profile, but it's conceived to be implemented by applications specific to mobile devices. The term "mobile" should be considered in a wider sense: it identifies not only mobile applications, but the whole class of systems that are resource- and platform-constrained. (e.g., tablets, smartphones, and embedded devices including home-health devices, but also larger systems where needs are simple, such as pulling the latest summary for display).

These constraints may drive the implementer to use simpler network interface technology for data elements sharing.

The QEDm Profile defines one standardized interface to health (HTTP-based RESTful APIs) for use by 'mobile devices'. The QEDm actors can be implemented on a mobile application, and yet have sufficient functionality to support a wider range of applications and use cases.

The goal is also to make easier the configuration of mobile health application and mobile health application deployment, and to reduce the overall solution complexity.

X.1 QEDm Actors, Transactions and Content Modules

This section defines the actors, transactions, and/or content modules in this profile. General definitions of actors are given in the Technical Frameworks General Introduction Appendix A at http://www.ihe.net/Technical_Framework/index.cfm.

Figure X.1-1 shows the actors directly involved in the QEDm Profile and the relevant transaction between them.

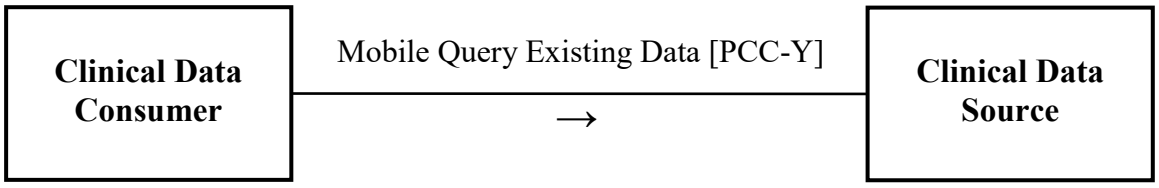

Figure X.1-1: QEDm Actor Diagram

Table X.1-1 lists the transactions for each actor directly involved in the QEDm Profile. To claim compliance with this profile, an actor shall support all required transactions (labeled "R") and may support the optional transactions (labeled "O").

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Table X.1-1: QEDm Integration Profile - Actors and Transactions

Actors	Transactions	Optionality	Reference
Clinical Data Source	Mobile Query Existing Data [PCC-Y]	R	PCC TF-2: 3.Y
Clinical Data Consumer	Mobile Query Existing Data [PCC-Y]	R	PCC TF-2: 3.Y

X.1.1 Actor Descriptions and Actor Profile Requirements

X.1.1.1 Clinical Data Source

370 The Clinical Data Source in this profile responds to FHIR-based queries for one or more fine-grained data elements (FHIR resources) defined by the options listed in Section X.2. The Clinical Data Source shall support at least one of those options and may support more than one option.

X.1.1.2 Clinical Data Consumer

The Clinical Data Consumer in this profile performs FHIR-based queries to the Clinical Data
375 Source for one or more fine-grained data elements (FHIR resources) defined by the options listed in Section X.2. Rendering or further processing of the data is not defined by this profile. The Clinical Data Consumer shall support querying for at least one of the data elements that are defined by this profile's options.

X.2 QEDm Actor Options

380 Options that may be selected for each actor in this profile, if any, are listed in the Table X.2-1. Dependencies between options when applicable are specified in notes.

Table X.2-1: QEDm - Actors and Options

Actor	Option Name	Reference
Clinical Data Consumer	Simple Observations Option (1)	PCC TF-X.2.1.1
	Allergies and Intolerances Option (1)	PCC TF-X.2.1.2
	Conditions Option (1)	PCC TF-X.2.1.3
	Diagnostic Results Option (1)	PCC TF-X.2.1.4
	Medications Option (1)	PCC TF-X.2.1.5
	Immunizations Option (1)	PCC TF-X.2.1.6
	Procedures Option (1)	PCC TF-X.2.1.7
	Encounters Option (1)	PCC TF-X.2.1.8

Actor	Option Name	Reference
	Provenance Option	PCC TF-X.2.1.9
Clinical Data Source	Simple Observations Option (1)	PCC TF-X.2.2.1
	Allergies and Intolerances Option (1)	PCC TF-X.2.2.2
	Conditions Option (1)	PCC TF-X.2.2.3
	Diagnostic Results Option (1)	PCC TF-X.2.2.4
	Medications Option (1)	PCC TF-X.2.2.5
	Immunizations Option (1)	PCC TF-X.2.2.6
	Procedures Option (1)	PCC TF-X.2.2.7
	Encounters Option (1)	PCC TF-X.2.2.8
	Provenance Option	PCC TF-X.2.2.9

Note: At least one of these options shall be supported by the related actor

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X.2.1 Clinical Data Consumer Options

X.2.1.1 Simple Observations Option

A Clinical Data Consumer that implements the Simple Observations Option performs the Mobile Query Existing Data transaction using the vocabulary specified for Simple Observations in PCC-
390 Y in PCC TF-2: 3.Y.4.1.2 “Message Semantics”.

X.2.1.2 Allergies and Intolerances Option

A Clinical Data Consumer that implements the Allergies and Intolerances Option performs the Mobile Query Existing Data transaction using the vocabulary specified for Allergies and Intolerances in PCC-Y in PCC TF-2: 3.Y.4.1.2 “Message Semantics”.

395 **X.2.1.3 Conditions Option**

A Clinical Data Consumer that implements the Conditions Option performs the Mobile Query Existing Data transaction using the vocabulary specified for Problems in PCC-Y in PCC TF-2: 3.Y.4.1.2 “Message Semantics”.

X.2.1.4 Diagnostic Results Option

400 A Clinical Data Consumer that implements the Diagnostic Results Option performs the Mobile Query Existing Data transaction using the vocabulary specified for Diagnostic Results in PCC-Y in PCC TF-2: 3.Y.4.1.2 “Message Semantics”.

X.2.1.5 Medications Option

A Clinical Data Consumer that implements the Medications Option performs the Mobile Query Existing Data transaction using the vocabulary specified for Medications in PCC-Y in PCC TF-2: 3.Y.4.1.2 “Message Semantics”.

X.2.1.6 Immunizations Option

A Clinical Data Consumer that implements the Immunizations Option performs the Mobile Query Existing Data transaction using the vocabulary specified for Immunizations in PCC-Y in PCC TF-2: 3.Y.4.1.2 “Message Semantics”.

X.2.1.7 Procedures Option

A Clinical Data Consumer that implements the Procedures Option performs the Mobile Query Existing Data transaction using the vocabulary specified for Procedures in PCC-Y in PCC TF-2: 3.Y.4.1.2 “Message Semantics”.

X.2.1.8 Encounters Option

A Clinical Data Consumer that implements the Encounters Option performs the Mobile Query Existing Data transaction using the vocabulary specified for Encounters in PCC-Y in PCC TF-2: 3.Y.4.1.2 “Message Semantics”.

X.2.1.9 Provenance Option

A Clinical Data Consumer that implements the Provenance Option performs the Mobile Query Existing Data transaction using the vocabulary specified for Provenance in PCC-Y in PCC TF-2: 3.Y.4.1.2 “Message Semantics”.

X.2.2 Clinical Data Source Options

X.2.2.1 Simple Observations Option

A Clinical Data Source that implements the Simple Observations Option responds to the message semantics specified for Simple Observations in PCC-Y in PCC TF-2: 3.Y.4.1.2 “Message Semantics”.

X.2.2.2 Allergies and Intolerances Option

A Clinical Data Source that implements the Allergies and Intolerances Option responds to the message semantics specified for Allergies and Intolerances in PCC-Y in PCC TF-2: 3.Y.4.1.2 “Message Semantics”.

X.2.2.3 Conditions Option

A Clinical Data Consumer that implements the Conditions Option responds to the message semantics specified for Problems in PCC-Y in PCC TF-2: 3.Y.4.1.2 “Message Semantics”.

X.2.2.4 Diagnostic Results Option

A Clinical Data Source that implements the Diagnostic Results Option responds to the message semantics specified for Diagnostic Results in PCC-Y in PCC TF-2: 3.Y.4.1.2 “Message Semantics”.

X.2.2.5 Medications Option

A Clinical Data Source that implements the Medications Option responds to the message semantics specified for Medications in PCC-Y in PCC TF-2: 3.Y.4.1.2 “Message Semantics”.

X.2.2.6 Immunizations Option

A Clinical Data Source that implements the Immunizations Option responds to the message semantics specified for Immunizations in PCC-Y in PCC TF-2: 3.Y.4.1.2 “Message Semantics”.

X.2.2.7 Procedures Option

A Clinical Data Source that implements the Procedures Option responds to the message semantics specified for Procedures in PCC-Y in PCC TF-2: 3.Y.4.1.2 “Message Semantics”.

X.2.2.8 Encounters Option

A Clinical Data Source that implements the Encounters Option responds to the message semantics specified for Encounters in PCC-Y in PCC TF-2: 3.Y.4.1.2 “Message Semantics”.

X.2.2.9 Provenance Option

A Clinical Data Source that implements the Provenance Option responds to the message semantics specified for Provenance in PCC-Y in PCC TF-2: 3.Y.4.1.2 “Message Semantics”.

X.3 QEDm Required Actor Groupings

Table X.3-1: QED for Mobile - Required Actor Groupings

QEDm Actor	Actor to be grouped with	Reference
Clinical Data Consumer	None	-
Clinical Data Source	None	-

Section X.5 describes some optional groupings that may be of interest for security considerations and Section X.6 describes some optional groupings in other related profiles.

X.4 QEDm Overview

X.4.1 Concepts

The QEDm Profile supports a broad set of the QED use cases and functionality while keeping the implementation as simple as possible, but it does not try to reproduce the full privacy, or security supported by QED infrastructure.

X.4.2 Use Cases

X.4.2.1 Use Case #1: Discovery and Retrieval of existing data elements

X.4.2.1.1 Use Case #1 Description

In this use case, the patient, by using his mobile device, needs access to existing data elements. For example, a mobile application involved in a workflow needs to discover all the current Vital Signs and Medications.

X.4.2.1.2 Use Case #1 Process Flow

The Mobile Query Existing Data transaction is used to provide parameterized queries that result in a list of returned data elements.

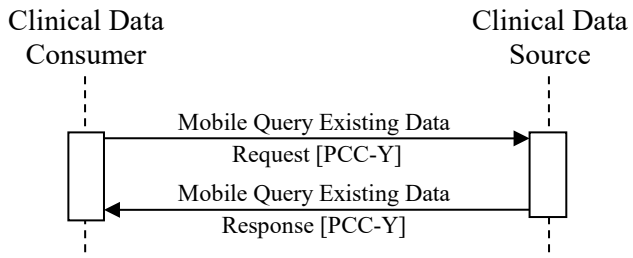


Figure X.4.2.1-1: Use Case #1 Process Flow in QEDm Profile

X.4.2.2 Use Case #2: Discovery and Retrieval of existing data elements with source document links

X.4.2.2.1 Use Case #2 Description

In this use case, the physician, by using his mobile device, needs to access all existing data elements and eventually to retrieve and consume the source documents if any.

For example, a mobile application involved in a workflow needs to discover all Encounters which the patient has participated in and, for those of interest, it needs to retrieve and show the related document where the Encounter was originally specified,

X.4.2.2.2 Use Case #2 Process Flow

The Query for Existing Data for Mobile transaction is used to provide parameterized queries that result in a list of returned data elements. One of the query options specifies that provenance information must be included in the result to obtain the links to source documents, if any.

The mobile application implements The Clinical Data Consumer to perform the query.

The mobile application also implements an MHD Document Consumer and retrieves the document from the MHD Document Responder by using the related returned document link.

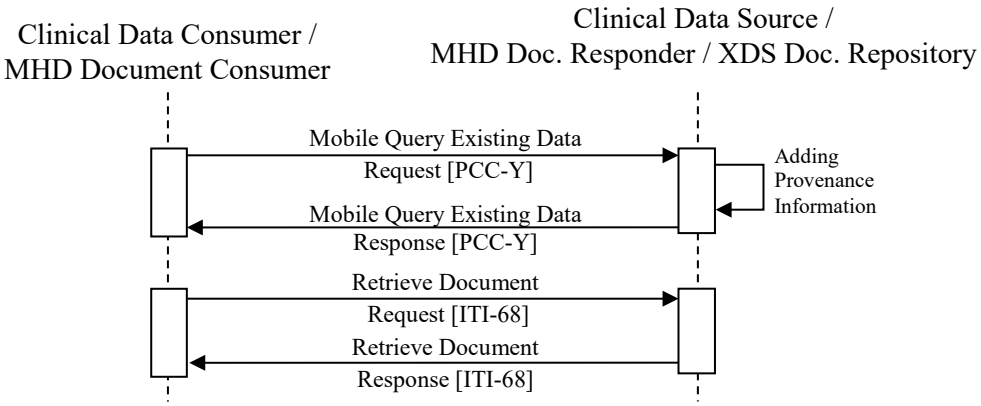


Figure X.4.2.2-1: Use Case #2 Process Flow in QEDm Profile

X.5 QEDm Security Considerations

See ITI TF-2.x Appendix Z.8 “Mobile Security Considerations”

NOTE (to be removed): this assumes the approval of the current ITI-CP1036 regarding the Appendix Z.8 “Mobile Security Considerations”

X.6 QEDm Cross Profile Considerations

This profile provides similar functionality to QED (Query for Existing Data), by using HTTP-based RESTful APIs instead of HL7®[2]v3 based transactions.

ITI PDLS – Consistency of Clinical Content

A Clinical Data Source may be grouped with a Data Element Extractor which requires the addition of necessary provenance information to ensure consistency within each returned data element.

This grouping allows the extraction of data elements and the addition of references to data origins (e.g., Documents) used in generating the result.

A Clinical Data Consumer may be grouped with a Data Element Provenance Consumer to extract the identifiers (provenance information) that consistently link the returned data elements to the related data origin.

ITI PIX - Patient Identity Cross Referencing and ITI PDQ - Patient Demographics Query

A Clinical Data Consumer may be grouped with a Patient Identifier Cross-reference Consumer or a Patient Demographics Consumer to resolve patient identifiers prior to submitting queries to a Repository.

Within an enterprise, the need to cross-reference patient identifiers may not be necessary. However, once enterprise boundaries are crossed, these identifiers will need to be resolved. In that case profiles such as PIX, PIXm, PDQ and/or PDQm may be used.

ITI XDS - Cross Enterprise Document Sharing

A Clinical Data Source may be grouped with an XDS Document Repository. Data gathered from clinical documents submitted to the Document Repository can be a source of information returned by the Clinical Data Source. Information returned by the Clinical Data Source may include references to all documents used in generating the results, by using the FHIR Provenance Resource.

Content Integration Profiles

A Content Creator may be grouped with a Clinical Data Consumer to obtain some or all of the information necessary to create a Medical Summary based on information found in a Clinical Data Source.

A Content Creator may be grouped with a Clinical Data Source. When grouped with a Content Creator, the Clinical Data Source shall respond to queries containing the relevant vocabulary codes used by the Content Creator.

[2] HL7 is the registered trademark of Health Level Seven International.

Volume 2 – Transactions

Add Section 3.Y

3.Y Mobile Query Existing Data [PCC-Y]

This section corresponds to Transaction PCC-Y of the IHE PCC Technical Framework. Transaction PCC-Y is used by the Clinical Data Consumer and Clinical Data Source Actors.

3.Y.1 Scope

The Mobile Query Existing Data transaction is used to query for clinical fine grained data elements that satisfy a set of parameters by using the FHIR framework. The result of the query is a FHIR Bundle containing FHIR clinical data Resources that match the query parameters.

3.Y.2 Actor Roles

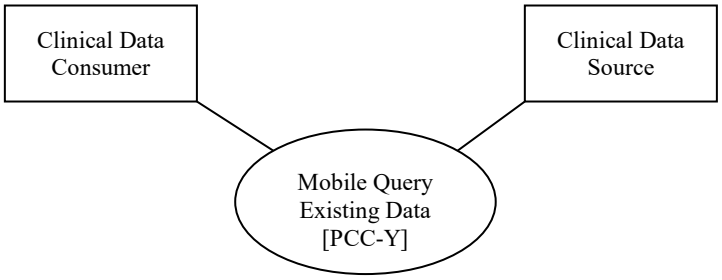


Figure 3.Y.2-1: Use Case Diagram

Table 3.Y.2-1: Actor Roles

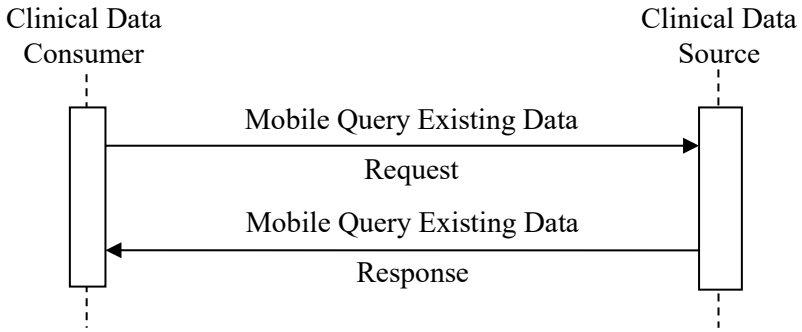
Actor:	Clinical Data Consumer
Role:	Queries for clinical data content, matching the supplied set of options, the Clinical Data Source.
Actor:	Clinical Data Source
Role:	Responds to query, supplying the FHIR Resources representing the clinical data content that match the search criteria provided by the Clinical Data Consumer.

3.Y.3 Referenced Standards

HL7 FHIR	HL7® FHIR® standard STU3: http://www.hl7.org/fhir/STU3/index.html
IETF RFC 2616	Hypertext Transfer Protocol – HTTP/1.1
IETF RFC 7540	Hypertext Transfer Protocol – HTTP/2

IETF RFC 3986	Uniform Resource Identifier (URI): Generic Syntax
IETF RFC 4627	The application/json Media Type for JavaScript Object Notation (JSON)
IETF RFC 6585	Additional HTTP Status Codes

3.Y.4 Interaction Diagram



3.Y.4.1 Mobile Query Existing Data Request message

This message uses the HTTP GET method parameterized query to obtain the FHIR Resources, representing the searched clinical data content, from the Clinical Data Source.

QEDm does not mandate any additional extended or custom method.

3.Y.4.1.1 Trigger Events

When the Clinical Data Consumer needs to discover clinical data Resources matching various search parameters it issues a Mobile Query Existing Data message.

3.Y.4.1.2 Message Semantics

The Clinical Data Consumer executes an HTTP GET against the proper Clinical Data Source's QEDm URL.

The search target follows the FHIR http specification (http://hl7.org/fhir/STU3/http.html), addressing the proper FHIR Resource type, according to the supported query options (see Section 3.Y.4.1.2.1). The syntax of the FHIR query is:

```
GET [base]/[Resource-type]{?[parameters]
```

The URL, that is the address where a certain resource defined by this interface is found, takes the form of:


```
[base]/[Resource-type]?<parameters>
```

The URL is relative to the server's [base] path, and always starts with a [Resource-type]. It is configurable by the Clinical Data Source and is subject to the following constraints.

- The [base] represents the Service Base URL
- The `[Resource-type]` represents the name of the FHIR Resource to consider (each option can involve one or more Resources), as specified in Section 3.Y.4.1.2.1
- The `<parameters>` represents a series of encoded name-value pairs representing the filter for the query, as specified in Section 3.Y.4.1.2.1, as well as control parameters to modify the behavior of the Clinical Data Source such as response format, or pagination.

3.Y.4.1.2.1 Query Search Parameters

All query parameter values shall be appropriately encoded per RFC 3986 “percent” encoding rules. Note that percent encoding does restrict the character set to a subset of ASCII characters which is used for encoding all other characters used in the URL.

The FHIR Resource type or types supported by the Clinical Data Consumer and Clinical Data Source are determined by a QEDm named option. An actor claiming a named option is required to support the FHIR Resource types listed below. According to the supported option, the Clinical Data Consumer may query and the Clinical Data Source shall be capable of responding on the Resources types specified in Table X.3-2 by processing all the search parameters defined in the following sections and by considering the related FHIR profiles, when available.

The Clinical Data Source may choose to support additional query parameters beyond the subset defined by the profiling listed below, if done according to the core FHIR specification. Such additional parameters are considered out of scope for this transaction. Any additional parameters not supported should be ignored by the Clinical Data Source. See http://hl7.org/fhir/STU3/search.html#errors.

Table 3.Y.4.1.2.1-1: QEDm Options, FHIR Resources and Query Search Parameters

QEDm Actor Option	FHIR Resource Type	Reference	Search Parameters
Simple Observations	**Observation**	http://hl7.org/fhir/STU3/observation.html For Vital Signs Observation, refer: https://www.hl7.org/fhir/vitalsigns.html	See Section 3.Y.4.1.2.1.1
Allergies and Intolerances	**AllergyIntolerance**	http://hl7.org/fhir/STU3/allergyintolerance.html	See Section 3.Y.4.1.2.1.2
Condition	**Condition (1)**	http://hl7.org/fhir/STU3/condition.html	See Section 3.Y.4.1.2.1.3

QEDm Actor Option	FHIR Resource Type	Reference	Search Parameters
Diagnostic Results Option	**DiagnosticReport**	http://hl7.org/fhir/STU3/diagnosticreport.html	See Section 3.Y.4.1.2.1.4
Medications	**Medication:**	http://hl7.org/fhir/STU3/medication.html	See Section 3.Y.4.1.2.1.5
	Medication Statement	http://hl7.org/fhir/STU3/medicationstatement.html	
	Medication Request	http://hl7.org/fhir/STU3/medicationrequest.html	
Immunizations	**Immunization**	http://hl7.org/fhir/STU3/immunization.html	See Section 3.Y.4.1.2.1.6
Procedures	**Procedure**	http://hl7.org/fhir/STU3/procedure.html	See Section 3.Y.4.1.2.1.7
Encounters	**Encounter**	http://hl7.org/fhir/STU3/encounter.html	See Section 3.Y.4.1.2.1.8
Provenance	**Provenance**	http://hl7.org/fhir/STU3/provenance.html	See Section 3.Y.4.1.2.1.9

Note 1: The intended use of FHIR Condition resource includes recording of detailed information about conditions, problems or diagnoses recognized by a clinician.

The following section details, for each option, the search parameters to be supported for each of FHIR Resource to consider.

See ITI TF-2.x Appendix Z.10 "Profiling conventions for constraints on FHIR" for a description of terms used in the Optionality columns.

3.Y.4.1.2.1.1 Simple Observation Option Search Parameters

When supporting the Simple Observations Option, the Clinical Data Consumer supplies and the Clinical Data Source shall be capable of processing the search parameters combinations as specified by the following table, according to the related optionality.

```
GET [base]/Observation?[parameters]
```

Parameters	Type	Modifiers	Optionality	
			Clinical Data Source	Clinical Data Consumer (1)
patient + category	reference + token		R	O
patient + category + code	reference + token		R	O
patient + category + date	reference + token +	date	R	O

Parameters	Type	Modifiers	Optionality	
			Clinical Data Source	Clinical Data Consumer (1)
	date	modifiers 'ge','le','gt','lt'		
patient + category + code + date	reference + token + date	date modifiers 'ge','le','gt','lt'	O	O

Note 1: The Clinical Data Consumer shall support at least one of the search parameters combinations

For Vital Signs Observations, it shall be considered the FHIR Vital Signs Profile defined at: https://www.hl7.org/fhir/vitalsigns.html.

3.Y.4.1.2.1.2 Allergies and Intolerances Option Search Parameters

When supporting the Allergies and Intolerances Option, the Clinical Data Consumer shall supply and the Clinical Data Source shall be capable of processing the search parameter as specified by the following table.

```
GET [base]/AllergyIntolerance?[parameters]
```

Parameters	Type	Optionality	
		Clinical Data Source	Clinical Data Consumer
patient	reference	R	R

3.Y.4.1.2.1.3 Conditions Option Search Parameters

When supporting the Problems Option, the Clinical Data Consumer supplies and the Clinical Data Source shall be capable of processing all the search parameters combinations as specified by the following table, according to the related optionality.

```
GET [base]/Condition?[parameters]
```

Parameters	Type	Optionality	
		Clinical Data Source	Clinical Data Consumer (1)
patient	reference	R	O
patient + category	reference + token	O	O
patient + clinicalstatus	reference + token	O	O

Note 1: The Clinical Data Consumer shall support at least one of the search parameters combinations

3.Y.4.1.2.1.4 Diagnostic Reports Option Search Parameters

When supporting the Diagnostic Reports Option, the Clinical Data Consumer supplies and the Clinical Data Source shall be capable of processing all the search parameters combinations as specified by the following table, according to the related optionality.

```
GET [base]/DiagnosticReport?[parameters]
```

Parameters	Type	Modifiers	Optionality	
			Clinical Data Source	Clinical Data Consumer (1)
patient + category	reference + token		R	O
patient + category + code	reference + token		R	O
patient + category + date	reference + token + date	date modifiers ‘ge’,‘le’,’gt’,’lt’	R	O
patient + category + code + date	reference + token + date	date modifiers ‘ge’,‘le’,’gt’,’lt’	O	O

Note 1: The Clinical Data Consumer shall support at least one of the search parameters combinations

3.Y.4.1.2.1.5 Medications Option Search Parameters

When supporting the Medications Option, the Clinical Data Consumer shall supply and the Clinical Data Source shall be capable of processing the search parameters as specified by the following tables.

The MedicationStatement and MedicationRequest resources can represent a medication, using an external reference to a Medication resource. If an external Medication Resource is used in a MedicationStatement or a MedicationRequest, it can be retrieved by using the _include search parameter.

For MedicationStatement:

```
GET [base]/MedicationStatement?[parameters]
```

Parameters	Type	_include	Optionality	
			Clinical Data Source	Clinical Data Consumer

Parameters	Type	_include	Optionality	
			Clinical Data Source	Clinical Data Consumer
patient	reference	MedicationStatement:medication	R	R

For MedicationRequest:

```
GET [base]/MedicationRequest?[parameters]
```

Parameters	Type	_include	Optionality	
			Clinical Data Source	Clinical Data Consumer
patient	reference	MedicationRequest:medication	R	R

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3.Y.4.1.2.1.6 Immunizations Option Search Parameters

When supporting the Immunizations Option, the Clinical Data Consumer may supply and the Clinical Data Source shall be capable of processing the search parameter as specified by the following table.

655 `GET [base]/Immunization?[parameters]`

Parameter	Type	Optionality	
		Clinical Data Source	Clinical Data Consumer
patient	reference	R	R

3.Y.4.1.2.1.7 Procedures Option Search Parameters

When supporting the Procedures Option, the Clinical Data Consumer supplies and the Clinical
660 Data Source shall be capable of processing all the search parameters as specified by the following table, according to the related optionality.

```
GET [base]/Procedure?[parameters]
```

Parameter	Type	Modifiers	Optionality

			Clinical Data Source	Clinical Data Consumer (1)
patient	reference		R	O
patient + date	reference + date	date modifiers ‘ge’,‘le’,’gt’,’lt’	R	O

Note 1: The Clinical Data Consumer shall support at least one of the search parameters combinations

3.Y.4.1.2.1.8 Encounters Option Search Parameters

When supporting the Encounters Option, the Clinical Data Consumer supplies and the Clinical Data Source shall be capable of processing all the search parameters as specified by the following table, according to the related optionality.

```
GET [base]/Encounter?[parameters]
```

Parameter	Type	Modifiers	Optionality	
			Clinical Data Source	Clinical Data Consumer (1)
patient	reference		R	O
patient + date	reference + date	date modifiers ‘ge’,‘le’,’gt’,’lt’	R	O

Note 1: The Clinical Data Consumer shall support at least one of the search parameters combinations

3.Y.4.1.2.1.9 Provenance Option Search Parameters

Clinical Data Consumer supporting this option is enabled to fetch a certain FHIR Resource(s) together with any reference to the original Document from which the Resource(s) has been derived. The FHIR Provenance Resource containing those references can be included by providing the _revinclude parameter in the query.

When supporting the Provenance Option, the Clinical Data Consumer shall supply and the Clinical Data Source shall be capable of processing the _revinclude parameter, as defined at: https://www.hl7.org/fhir/search.html#include

```
GET [base]/[Resource-type]?_revinclude=Provenance:target&criteria…
```

3.Y.4.1.2.2 Parameter Modifiers

The Clinical Data Source shall support the “`:exact`” parameter modifier on all query parameters of type string. When supplied by the Clinical Data Consumer, the “`:exact`” parameter modifier instructs the Clinical Data Source that exact matching should be performed.

The Clinical Data Consumer should not use and Clinical Data Source may ignore any additional parameter modifiers listed in the FHIR standard, which are considered out of scope in the context of this transaction.

3.Y.4.1.2.3 Populating Expected Response Format

The FHIR standard provides encodings for responses as either XML or JSON. The Document Responder shall support both message encodings, whilst the Document Consumer shall support one and may support both.

See ITI TF-2x: Appendix Z.6 for details.

3.Y.4.1.3 Expected Actions

The Clinical Data Source shall process the query to discover the clinical data FHIR Resource entries (the fine-grained data elements) that match the search parameters given in and shall use a FHIR Bundle resource to collect the matching entries to be returned.

The Clinical Data Source shall respond with a Mobile Query Existing Data Response synchronously (i.e., on the same connection as was used to initiate the request).

When the Provenance Option is specified, the response FHIR Bundle shall also contain FHIR Provenance Resource entries that provide consistency of the returned fine-grained data elements with the coarse-grained data origin (e.g.: Document). See Section 3.Y.4.2.2.1 for the specification about the Provenance content.

See ITI TF-2x: Appendix Z.6 for more details on response format handling. See ITI TF-2x: Appendix Z.7 for handling guidance for Access Denied.

3.Y.4.2 Mobile Query Existing Data Response message

The Clinical Data Source returns an HTTP Status code appropriate to the processing as well as a list of the matching clinical data FHIR Resources.

3.Y.4.2.1 Trigger Events

The Clinical Data Source completed processing of the Mobile Query Existing Data message.

3.Y.4.2.2 Message Semantics

Based on the query results, the Clinical Data Source will either return an error or success. The guidance on handling Access Denied related to use of 200, 403 and 404 can be found in ITI TF-2x: Appendix Z.7 (reproduced here for readability).

When the Clinical Data Source needs to report an error, it shall use HTTP error response codes and should include a FHIR OperationOutcome with more details on the failure. See FHIR http://hl7.org/fhir/STU3/http.html and http://hl7.org/fhir/STU3/operationoutcome.html.

If the Mobile Query Existing Data message is processed successfully, whether or not clinical data Resources are found, the HTTP status code shall be 200.

The Mobile Query Existing Data Response message shall be a FHIR Bundle Resource containing zero or more clinical data Resources plus eventual Provenance Resources. If the Clinical Data Source is sending warnings, the Bundle Resource shall also contain an OperationOutcome Resource that contains those warnings.

The response shall adhere to the FHIR Bundle constraints specified in ITI TF-2x: Appendix Z.1.

3.Y.4.2.2.1 Resource Specific Contents

FHIR Provenance Constrains (under the Provenance Option)

The FHIR Provenance Resource structure (defined at: http://hl7.org/fhir/STU3/provenance.html) shall allow the provenance of data elements (aka FHIR Resources) to be made available via QEDm queries when they are derived from documents.

The Clinical Data Source is responsible for creating this content. It is assumed this actor is part of a document sharing environment which enables it to access the data elements to be retuned and the references to original documents.
In this case the Clinical Data Source:

- shall create one FHIR Provenance resource for each source document (exactly one) from which data elements were extracted.

Each Provenance record:

- shall contain a pair of entities, for referencing a document and to enable its retrieval: one of the entities shall enable access via MHD (if any), the other entity shall enables access via XDS (if any).
- shall contain the Provenance.target to point at ALL of the resources (e.g., AllergyIntolerance, Condition, etc.) extracted from that document, providing an evidence for that resource.

In cases, the same resource may have been extracted from more than one document, then more Provenance Resources shall be created.

By using the Provenance.target in conjunction with the Provenance.entity information the Provenance Resource provides the ability for a XDS or MHD Document Consumer to access the zero or more documents from which a certain data element was extracted.

The following table shows the detailed constrains for the FHIR Provenance.

See ITI TF-2.x Appendix Z.10 “Profiling conventions for constraints on FHIR” for a description of terms used in the optionality column (Opt.).

Provenance					
Name	**Flags**	**Card.**	**Opt.**	**Type**	**Description & Constraints**
Provenance				DomainResource	Who, What, When for a set of resources Elements defined in Ancestors: id,

Provenance					
Name	**Flags**	**Card.**	**Opt.**	**Type**	**Description & Constraints**
					meta, implicitRules, language, text, contained, extension, modifierExtension
target	Σ	1..*	R	Reference(Any)	→ **Target Reference(s): it shall identify each of the resources extracted from the document associated with the provenance resource.**
period		0..1		Period	When the activity occurred
recorded	Σ	1..1	R	instant	**It shall specifies when the activity was recorded / updated**
policy		0..*		uri	Policy or plan the activity was defined by
location		0..1		Reference(Location)	Where the activity occurred, if relevant
reason		0..*		Coding	Reason the activity is occurring PurposeOfUse (Extensible)
activity		0..1		Coding	Activity that occurred ProvenanceActivityType (Extensible)
agent		1..*		BackboneElement	Actor involved
role	Σ	0..*	R	CodeableConcept	**It shall contain: REVIEWER**
who[x]	Σ	1..1	R		→ Who participated
whoUri			R	uri	It shall contain: **the URI of the device that performed the extraction of the data elements**
whoReference			R	Reference(Practitioner | RelatedPerson | Patient | Device | Organization)	**It shall contain: Device**
onBehalfOf[x]		0..1			Who the agent is representing
onBehalfOfUri				uri	
onBehalfOfReference				Reference(Practitioner | RelatedPerson | Patient | Device | Organization)	
relatedAgentType		0..1		CodeableConcept	Type of relationship between agents v3 Code System RoleLinkType (Example)
entity		0..2	R2	BackboneElement	→ *First entity of the pair that enables access via MHD.*
role	Σ	1..1	R	code	**The entity role shall be: derivation**
what[x]	Σ	1..1	R		*Identity of entity*

Provenance					
Name	**Flags**	**Card.**	**Opt.**	**Type**	**Description & Constraints**
whatUri			R	uri	**It shall be empty**
whatReference			R	Reference(Any)	**It shall contain the reference used to access documents in MHD Profile:** – **the pointer to the FHIR DocumentReference containing the reference metadata to the document from which the information was derived.**
whatIdentifier			R	Identifier	**It shall be empty**
entity		0..2	R2	BackboneElement	→ *Second entity of the pair that enables access via XDS.*
role	Σ	1..1	R	code	**It shall contain: "derivation"**
what[x]	Σ	1..1			Identity of entity
whatUri			R	uri	**It shall be empty**
whatReference			R	Reference(Any)	**It shall be empty**
whatIdentifier			R	Identifier	**It shall contain the reference used to access documents in XDS Profile:** – **the XDS RepositoryUniqueId and the DocumentUniqueId that may be used to query the metadata of the document from the XDS Registry. The DocumentUniqueId and the RepositoryUniqueId may be used to retrieve the document from the appropriate XDS Document Repository.**
agent		0..*		see agent	Entity is attributed to this agent
signature		0..*		Signature	Signature on target

3.Y.4.2.2.2 Resource Bundling

Resource Bundling shall comply with the guidelines in ITI TF-2x: Appendix Z.1.

The Clinical Data Source shall include all resources to be returned as a contained resource. This means that the query shall return resource data contained in the FHIR Bundle as entries.

3.Y.4.2.3 Expected Actions

The Clinical Data Consumer shall process the results according to application-defined rules. The Clinical Data Consumer grouped with the Document Consumer should be robust enough to manage error conditions due to uncompliant DocumentReference.

If a Clinical Data Consumer cannot automatically recover from an error condition, it should, at a minimum, display the error to the user.

3.Y.4.3 Conformance Resource

Clinical Data Sources implementing this transaction should provide a Conformance Resource as described in ITI TF-2x: Appendix Z.3 indicating the query operation for the Resources have been implemented and shall include all the supported query parameters.

3.Y.5 Security Considerations

The retrieved content contains PHI that SHALL be protected.

See the general Security Considerations in PCC TF-1: X.5.

3.Y.5.1 Security Audit Considerations

Grouping a Clinical Data Consumer or Clinical Data Source with an ATNA Secure Node or Secure Application is recommended, but not mandated. The Clinical Data Consumer may be considered overburdened to fully implement the requirements of a Secure Node or Secure Application. The Clinical Data Source is likely a more robust application and should generate audit messages.

Both actors should generate a ”Query” AuditEvent, which is consistent with ATNA, such that:

- All required AuditEvent content is provided
- AuditEvent.type = ”Query”
- AuditEvent.action = ”Execute”
- AuditEvent.object.query → contains the encoding of the query

3.Y.5.1.1 Clinical Data Consumer Specific Security Considerations

The Clinical Data Consumer SHALL create an additional “Import” AuditEvent when data are imported, such that:

- All required AuditEvent content is provided
- AuditEvent.type = “Import”
- AuditEvent.object.identifiers → contains the list of imported item identifiers

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Not applicable.

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