Integrating the Healthcare Enterprise

IHE Quality, Research and Public Health
Technical Framework Supplement

Data Element Exchange
(DEX)

Rev. 2.2 – Trial Implementation

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Foreword

This is a supplement to the IHE Quality, Research and Public Health (QRPH) Technical
Framework. 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 September 7, 2018 for trial implementation and may be
available for testing at subsequent IHE Connectathons. The supplement may be amended based
on the results of testing. Following successful testing it will be incorporated into the Quality,
Research and Public Health Technical Framework. Comments are invited and can be submitted
at http://www.ihe.net/QRPH_Public_Comments.

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 www.ihe.net.

Information about the IHE QRPH domain can be found at http://www.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://www.ihe.net/IHE_Process and
http://www.ihe.net/Profiles.

The current version of the IHE QRPH Technical Framework can be found at
http://www.ihe.net/Technical_Frameworks.

Introduction to this Supplement

160 This introduction defines the problem that the profile addresses. For exact constraints on how the profile works, see Section X.

To enable clinical research, public health, and quality assessment studies through secondary use of EHR data, a mechanism is needed to map EHR data to secondary domain meanings. This viewpoint of EHR data for secondary use will both benefit by the adoption of EHRs, and
165 encourages that adoption.

Re-use of EHR data has a number of potential uses in clinical research such as: lessening of the burden and optimization clinical trial data collection through the targeted re-purposing of EHR data during a trial's execution phase (Pre-population of a Research Case Report Form); leveraging routinely collected clinical data for adverse event detection and reporting (Screening
170 clinical data for ADE detection and notification and Pre-population of ICSRs); providing a better understanding of the available cohorts based on the trial's Inclusion and Exclusion criteria during trial design (Eligibility Determination); and use of routinely collected clinical data for conducting retrospective observational studies.

A major barrier to repurposing EHR data for clinical research studies (clinical trial design,
175 execution and observational studies) is that information systems in both domains – patient care and clinical research – use different schemas and terminology systems; meaning the data within each system is stand-alone and not interoperable. As stated by ISO[1], "One of the prerequisites for a correct and proper use and interpretation of data is that both users and owners of data have a common understanding of the meaning and descriptive characteristics (e.g., representation) of
180 that data. To guarantee this shared view, a number of basic attributes have to be defined".

In line with this vision, recent efforts in both patient care and clinical research consist of defining metadata and vocabulary standards for clinical information and thereby in building Common Data Elements (CDEs) (also called metadata repositories or item banks). HITSP has defined the C154: Data Dictionary Component as a library of data elements that are used to establish
185 common understanding of the meaning of the HL7[®2] Continuity of Care Document (CCD[®3]) elements in HITSP C32. Transitions of Care Initiative (ToC) maintains the S&I Clinical Element Data Dictionary (CEDD); CDISC provides common dataset definitions like SDTM and CDASH. There are other similar efforts to define CDEs and accompanying data models like MiniSentinel Common Data Model, NCI CaDSR data elements, GE/Intermountain Healthcare Clinical
190 Element Models (CEM), and I2B2 data model for clinical data warehouses. On top of these,

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[1] ISO/IEC. ISO/IEC 11179: Information Technology – Metadata Registries (MDR) Parts 1–6 (2nd Edition).

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

[3] CCD is the registered trademark of Health Level Seven International.

BRIDG and CDISC SHARE are efforts to bridge the gap between these different clinical care and research data elements.

Since broad-based, scalable computable semantic interoperability across multiple domains requires the integration of multiple standards, the international initiative **Integrating the Healthcare Enterprise (IHE)** plays a key role of "integration organization" involving multiple stakeholders (including both vendor and provider organizations).

Integrating patient care and clinical research domains requires a standard-based expressive and scalable semantic interoperability framework, allowing dynamic mappings between data elements and semantics of varying data sources. This can be achieved through a metadata registry architecture where machine processable definitions of data elements across domains can be shared, re-used, and semantically interlinked with each other to address this interoperability challenge to move towards EHR-enabled research. DEX enables retrieving "extraction specifications" for a data element defined in a selected domain (like SDTM data elements), from an implementation dependent information model in another domain (like HL7 CCD).

In the revision to DEX made during 2014/2015 cycle, three new options have been added: the Cross-enterprise Document Sharing (XDS) Document Type Binding Option, the Multi-Patient Queries (MPQ) Document Type Binding Option, and the Cross-Community Access (XCA) Document Type Binding Option.

These options extend the basic functionalities defined in DEX to address the general issue of making a Clinical Community interoperable with a Secondary Data Usage Community (meaning a Research Organization, a Public Health Organization, an Epidemiology Organization, a Quality Reporting Agency or any other organization which collects and uses patient's data for purposes different to the direct care of the patient). These options allows the Secondary Data Usage Community to know if and where the clinical data needed is available in the Clinical Community, when it is organized as a Document Sharing environment (a XDS or MPQ or XCA environment).

Many European and US Health Information Exchange (HIE) systems are implemented as a Document Sharing environment and can take advantage of these capabilities. Those systems are characterized by large amount of data stored in both structured and unstructured documents that need to be managed following a big data approach. Using the new options the data consumer can take advantage of a Metadata Source being able to identify what data is available, the meaning of the data, and the location of the data within documents, allowing the Metadata Source to get the data in a quick and reliable way. A deep understanding of XDS, MPQ and XCA is highly recommended to identify the value added by these options.

Referenced documents

ISO/IEC 11179: Information Technology – Metadata Registries (MDR) Parts 1–6 (2nd Edition).

Open Issues and Questions

None

Closed Issues

230   None

General Introduction

Appendix A – Actor Summary Definitions

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

Actor	Definition
Metadata Consumer	The Metadata Consumer is responsible for the importation of metadata created by the Metadata Source. The Metadata Consumer can optionally query the Metadata Source for a list of Data Elements matching selection criteria.
Metadata Source	The Metadata Source is responsible for creation of the Data Element list matching a selection criteria and the creation of metadata for a selected Data Element per request from the Metadata Consumer. The Metadata Source is associated with a metadata registry.

235 Appendix B – Transaction Summary Definitions

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

Transaction	Definition
Retrieve Data Element List [QRPH-43]	This transaction retrieves the list of data elements matching a selection criteria from a metadata registry
Retrieve Metadata [QRPH-44]	This transaction retrieves metadata for a specified data element from a metadata registry.

Glossary

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

Glossary Term	Definition
Electronic Health Record	An electronic record derived from a computerized system used primarily for delivering patient care in a clinical setting.
Data Element	A logical definition of data.
Data Field	A physical unit of storage in a record.
Data Item	An individual instance of a data element.
Case Report Form	A record of clinical study observations and other information that a study protocol designates must be completed for each subject.
Annotated Case Report Form	A case report form that includes the metadata associated with each data element on the form.

Glossary Term	Definition
Study Protocol	A document that describes the objective(s), design, methodology, statistical considerations, and organization of a trial.
Study Coordinator	Person who handles most of the administrative responsibilities of a clinical trial on behalf of a site investigator, acts as liaison between investigative site and sponsor, and reviews all data and records before a monitor's visit.
CDASH	A standard from CDISC which defines those data elements common to case report forms.
CDISC	A standards development organization which focuses on clinical research standards.
Extraction Specification	A detailed map of data locations within an EHR, an EHR export document, or similar source used as a guide to extract data for re-use by a research, quality reporting, or public health system.
eSource document	The electronic record used to keep together a collection of eSource data items for capture, transmission, storage, and/or display; and serving as a source document for a clinical investigation.
Electronic Data Capture (EDC)	The process of collecting clinical trial data into a permanent electronic form.
Metadata	Data that describe other data, particularly XML tags characterizing attributes of values in data fields, such as version, unique identifier, mappings.
ISO/IEC 11179 metadata registry	A metadata registry is defined as "an information system for registering metadata" by ISO/IEC 11179. In particular, ISO/IEC 11179 defines a metadata registry is a database that manages the semantics of Data Elements.
Research Eligibility Criteria	Defines the study population by specifying inclusion and exclusion criteria. Inclusion criteria must be met for prospective subjects to be eligible for participation in a study. Exclusion criteria are the characteristics in a protocol, any one of which may exclude a potential subject from participation in a study.
Cohort specification	Defines the public health cohort by specifying inclusion and exclusion criteria. Inclusion criteria must be met for cohorts. Exclusion criteria are the characteristics in a cohort specification, any one of which may exclude a potential subject from participation in a cohort.

Volume 1 – Profiles

Add Section X

245

X Data Element Exchange (DEX) Profile

This profile leverages the power of an ISO/IEC 11179 Metadata Registry (hereafter called "metadata registry") to add mapping metadata to an annotated data capture form at the point of form design. ISO/IEC 11179 is a family of specifications introducing a standard model for
250   metadata registries to increase the interoperability of applications.[4] The core object of ISO/IEC 11179 is the data element, which includes a data concept and data representation. The term "data element" in ISO/IEC 11179 refers to the *structure* of the data, and is distinct from a data instance. This profile describes the exchange of metadata, rather than the exchange of data instances.[5]

255   The Metadata Source in this profile serves as a metadata registry and defines and maintains correspondences between research and healthcare data elements. The Metadata Source provides an exact map by which an RFD Form Manager can extract data from the pre-population data set. It is important to note that these correspondences can indicate different semantics such as the level of the correspondence, i.e., exact or less exact (related). A precondition of use of DEX is
260   that its users understand their domain, and recognize the limitations of the correspondences between the data registry and the information model.

In some cases, researchers/ epidemiologists/ public health/ clinicians do not know a priori the types of document from which data of interest might be extracted, and they might need to identify the documents that contain the content they need in real time. The DEX Profile defines
265   the XDS Document Type Binding Option, the MPQ Document Type Binding Option and the XCA Document Type Binding Option to enable researchers, epidemiologists, public health officials, and clinicians to perform a search of a set of documents in a Document Sharing environment based on their content. It is intended to identify documents that may store data of interest. These options are applied to Document Sharing environments, so a good understanding
270   of concepts related to this kind of environment, as defined by XDS, MPQ and XCA profiles is highly recommended. In order to know which documents contain what types of clinical data, the

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[4] ISO/IEC. ISO/IEC 11179: Information Technology – Metadata Registries (MDR) Parts 1–6 (2nd Edition).

[5] "Technically, data elements describe the logical unit of data, fields are the actual storage units, and data items are the individual instances of the data elements as in this example. In practice, all three terms may be used interchangeably. However, technical documentation on database management should employ the terms properly." http://www.pcmag.com/encyclopedia/term/40771/data-element

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DEX Profile defines the functionality of a metadata registry, which both manages Document Sharing Metadata describing document content and also knows the Document Sharing Affinity Domain rules for document creation and metadata association.

275 Health Information Exchange (HIE) systems are a very common scenario where this profile can be applied. These systems are usually organized as Document Sharing environments where the number of documents created is large and the amount of clinical data is huge. This profile allows users both inside and outside the HIE systems to know what clinical data is available and how to get it. This functionality can be used by Clinical Research Organizations interested in performing

280 observational studies, or by Public Health or Epidemiological Institutions interested in performing analysis and assessing clinical outcomes at the population level. Moreover, users within the clinical community can exploit the functionalities defined in this profile: for example a clinician may need to know which types of documents may contain some clinical data about the patient he is assisting.

285 X.1 DEX 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://ihe.net/Technical_Frameworks/.

Figure X.1-1 shows the actors directly involved in the DEX Profile and the relevant transactions
290 between them. If needed for context, other actors that may be indirectly involved due to their participation in other related profiles are shown in dotted lines. Actors which have a mandatory grouping are shown in conjoined boxes.
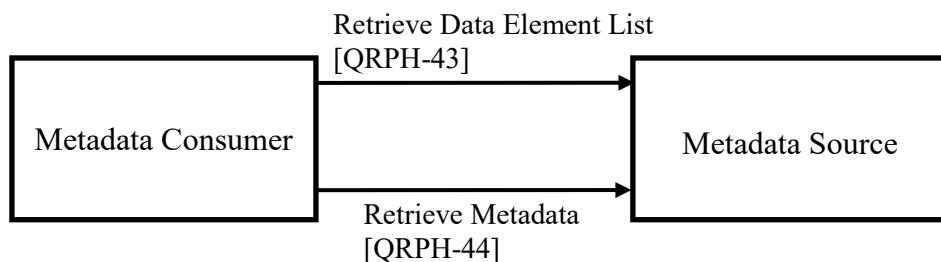
Figure X.1-1: DEX Actor Diagram

295 Table X.1-1 lists the transactions for each actor directly involved in the DEX 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: DEX Profile - Actors and Transactions

Actors	Transactions	Optionality	Reference
Metadata Source	Retrieve Data Element List [QRPH-43]	R	QRPH TF-2: 3.43
	Retrieve Metadata [QRPH- 44]	R	QRPH TF-2: 3.44
Metadata Consumer	Retrieve Data Element List [QRPH-43]	O	QRPH TF-2: 3.43
	Retrieve Metadata [QRPH- 44]	R	QRPH TF-2: 3.44

X.1.1 Actor Descriptions and Actor Profile Requirements

Most requirements are documented in Transactions (Volume 2) and Content Modules (Volume 3). This section documents any additional requirements on profile's actors.

305 ### X.1.1.1 Metadata Consumer

The Metadata Consumer is responsible for the importation of metadata created by the Metadata Source. The Metadata Consumer can optionally query the Metadata Source for a list of Data Elements matching selection criteria.

X.1.1.2 Metadata Source

310 The Metadata Source is responsible for creation of the Data Element list matching a selection criteria and the creation of metadata for a selected Data Element per request from the Metadata Consumer. The Metadata Source is associated with a metadata registry.

X.2 DEX Actor Options

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

Table X.2-1: Data Element Exchange - Actors and Options

Actor	Option Name	Reference
Metadata Consumer	XDS Document Type Binding Option	QRPH TF-1: X.2.1
	MPQ Document Type Binding Option	QRPH TF-1: X.2.2
	XCA Document Type Binding Option	QRPH TF-1: X.2.3
Metadata Source	XDS Document Type Binding Option	QRPH TF-1: X.2.1
	MPQ Document Type Binding Option	QRPH TF-1: X.2.2
	XCA Document Type Binding Option	QRPH TF-1: X.2.3

X.2.1 XDS Document Type Binding Option

The XDS Document Type Binding Option is applicable to Metadata Consumer and Metadata Source Actors that operate within a XDS Environment. To enable this option, the XDS Affinity domain practices must establish a tight relationship between Document Sharing metadata and document content model.

A Metadata Source that supports the XDS Document Type Binding Option SHALL provide to the Metadata Consumer information to enable the Metadata Consumer to retrieve documents that may contain data of interest. This information is conveyed in the response to the RetrieveMetadata [QRPH-44] transaction. See QRPH TF-2:3.44.

X.2.1.1 Metadata Source: XDS Document Type Binding Option

In order to claim conformance to this option:

- The Metadata Source SHALL adhere to XDS Affinity Domain rules for document creation and metadata association as a prerequisite;

- The Metadata Source SHALL manage Document Sharing Metadata that describe document content and format (see QRPH TF-2: 3.44.4.2.2.1). As an example, according to the required capabilities described above, a Metadata Source has to know that the "hemoglobin data element" is available in Hematological Laboratory Reports, identified by the following DocumentEntry metadata: classCode "11502-2" (LOINC code for Laboratory Report), typeCode "18723-7" (LOINC code for Hematological laboratory report), eventCodeList "Adult_lab_report" and formatCode "urn:ihe:lab:xd-lab:2008";

- The Metadata Source SHALL return to the Metadata Consumer the list of Document Sharing metadata for a selected Data Element request.

X.2.1.2 Metadata Consumer: XDS Document Type Binding Option

In order to claim conformance to this option:

- The Metadata Consumer SHALL be grouped with a XDS Document Consumer;

- The Metadata Consumer SHALL be able to use Document Sharing Metadata provided by the Metadata Source in order to perform the Registry Stored Query [ITI-18] transaction.
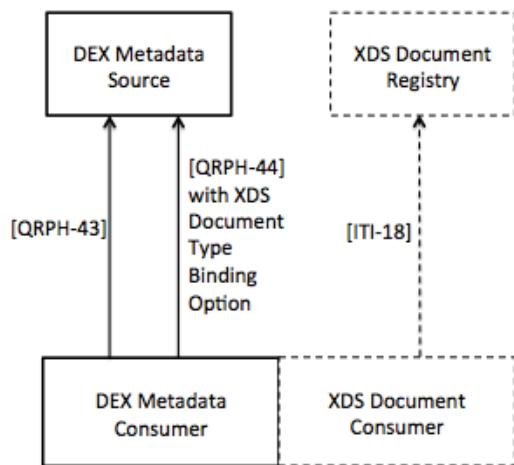
Figure X.2.1.2-1: Grouping Actors with XDS Document Type Binding Option

X.2.2 MPQ Document Type Binding Option

The MPQ Document Type Binding Option is applicable to Metadata Consumer and Metadata Source Actors that operate within a MPQ Environment. To enable this option, the MPQ Affinity domain practices must establish a tight relationship between Document Sharing metadata and document content model.

A Metadata Source that supports the MPQ Document Type Binding Option SHALL provide to the Metadata Consumer information to enable the Metadata Consumer to retrieve documents that may contain data of interest. This information is conveyed in the response to the RetrieveMetadata [QRPH-44] transaction. See QRPH TF-2:3.44.

X.2.2.1 Metadata Source: MPQ Document Type Binding Option

In order to claim conformance to this option:

- The Metadata Source SHALL adhere to MPQ Affinity Domain rules for document creation and metadata association as a prerequisite;

- The Metadata Source SHALL manage Document Sharing Metadata that describe document content and format (see QRPH TF-2: 3.44.4.2.2.1). As an example, according to the required capabilities described above, a Metadata Source has to know that the "hemoglobin data element" is available in Hematological Laboratory Reports, identified by the following DocumentEntry metadata: classCode "11502-2" (LOINC code for Laboratory Report), typeCode "18723-7" (LOINC code for Hematological laboratory report), eventCodeList "Adult_lab_report" and formatCode "urn:ihe:lab:xd-lab:2008";

- The Metadata Source SHALL return to the Metadata Consumer the list of Document Sharing metadata for a selected Data Element request.

X.2.2.2 Metadata Consumer: MPQ Document Type Binding Option

370   In order to claim conformance to this option:

- The Metadata Consumer SHALL be grouped with a MPQ Document Consumer;

- The Metadata Consumer SHALL be able to use Document Sharing Metadata provided by the Metadata Source in order to perform the Multi-Patient Stored Query [ITI-51] transaction.

375
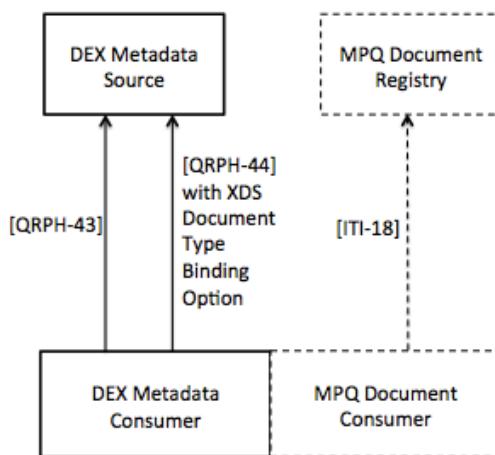
Figure X.2.2.2-1: Grouping Actors with MPQ Document Type Binding Option

X.2.3 XCA Document Type Binding Option

The XCA Document Type Binding Option is applicable to Metadata Consumer and Metadata
380   Source Actors that operate within a XCA Environment. To enable this option, each community involved in the XCA Environment must establish a tight relationship between Document Sharing metadata and document content model.

A Metadata Source that supports the XCA Document Type Binding Option SHALL provide to the Metadata Consumer information to enable the Metadata Consumer to retrieve documents that
385   may contain data of interest. This information is conveyed in the response to the RetrieveMetadata [QRPH-44] transaction. See QRPH TF-2:3.44. The Metadata Source may be set within a specific community and know and manage Document Sharing Metadata related to only that specific community or may be set in a Trusted Third Party and manage Document Sharing Metadata related to all communities involved in the XCA Environment.

390   ### X.2.3.1 Metadata Source: XCA Document Type Binding Option

In order to claim conformance to this option:

- The Metadata Source SHALL know the rules for document creation and metadata association for each community in the XCA Environment it relates to (as a prerequisite);

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- The Metadata Source SHALL manage Document Sharing Metadata that describe document content and format for each community in the XCA Environment it relates to (see QRPH TF-2: 3.44.4.2.2.1);

- The Metadata Source SHALL return to the Metadata Consumer the list of Document Sharing metadata for a selected Data Element request.

400 As an example, according to the required capabilities described above, a Metadata Source managing metadata related to multiple communities has to know that the "hemoglobin data element" is available:

- in "Community A" in Hematological Laboratory Reports, identified by the following Document Sharing metadata: classCode "11502-2" (LOINC code for Laboratory Report), typeCode "18723-7" (LOINC code for Hematological laboratory report), eventCodeList 405 "Adult_lab_report" and formatCode "urn:ihe:lab:xd-lab:2008";

- in "Community B" in Laboratory Reports, identified by the following Document Sharing metadata: classCode "Report", typeCode "Laboratory" and formatCode "2.16.840.1.113883.2.9.10.1.1".

X.2.3.2 Metadata Consumer: XCA Document Type Binding Option

410 In order to claim conformance to this option:

- The Metadata Consumer SHALL be grouped with a XCA Initiating Gateway;

- The Metadata Consumer SHALL be able to use Document Sharing Metadata provided by the Metadata Source in order to perform the Cross Gateway Query [ITI-38] transaction.
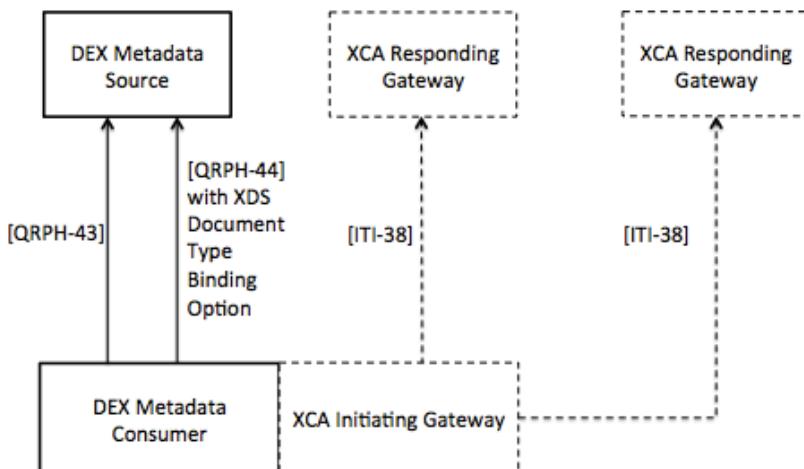

415 **Figure X.2.3.2-1: Grouping Actors with XCA Document Type Binding Option**

X.3 DEX Required Actor Groupings

An actor from this profile (Column 1) shall implement all of the required transactions and/or content modules in this profile *in addition to* all of the transactions required for the grouped actor (Column 2).

420 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.

Table X.3-1: DEX - Required Actor Groupings

DEX Actor (option)	Actor to be grouped with	Reference	Content Bindings Reference
Metadata Consumer (XDS Document Type Binding Option)	ITI XDS.b Document Consumer	X.2.1.2	--
Metadata Consumer (MPQ Document Type Binding Option)	ITI MPQ Document Consumer	X.2.2.2	--
Metadata Consumer (XCA Document Type Binding Option)	ITI XCA Initiating Gateway	X.2.3.2	--

X.4 DEX Overview

425 X.4.1 Concepts

The fundamental concept of DEX is the re-use of EHR data in support of a clinical research study. This support applies to clinical study feasibility, eligibility determination, subject recruiting, repurposing of EHR data for observational studies and data capture during clinical study execution. In the data capture use case, the EHR data is used to pre-populate, where 430 possible, the data elements of a case report form. This set of data elements is collectively called pre-population data.

X.4.2 Use Cases

Use Case #1 is patient-centric since it concerns a patient who has been recruited into a given clinical trial. The source is the EHR system. The patient gave his full informed consent for the 435 extraction of data from his EHR and for addition of new information into the patient record.

Use Case #2 and #3 are population-centric. For these use cases, usually, the EHR system may not be an ideal source since EHRs are typically built to look at data on single patients, not data across combinations of many patients. Unlike transaction systems that are optimized to show data regarding single patients, clinical data warehouses support queries that cut across multiple 440 patients. In clinical data warehouses, queries can be challenging to specify, and these queries have complex implications for the privacy of the patients. However, as described in Use Case

#3b, after the eligible patients are selected, EHRs can also provide the medical summaries of eligible patients through existing standard export documents such as CCD as a means to establish clinical data sets.

445   In most real world implementations a research system responsible for creating protocols would host the Metadata Consumer and a metadata registry served by organizations defining data dictionaries like NIH, CDC would host the Metadata Source.

X.4.2.1 Use Case #1: Pre-population of a Research Case Report Form

This use case describes how a researcher can create an extraction specification to extract specific
450   data elements from a standard electronic health record export document such as a CCD. The extraction specification is used to pre-populate a case report form for a research study. In this use case, the Metadata Consumer would likely be enacted by an electronic data capture system or research protocol design system. The Metadata Source would be provided by a metadata registry such as CDISC's SHARE.

455   ### X.4.2.1.1 Pre-population of a Research Case Report Form Use Case Description

A research forms designer is building a case report form for a particular research study. The designer refers to an on-line metadata registry of research data elements, e.g., SHARE, and selects the desired data elements from a set of research friendly elements such as CDASH. The forms designer uses unique identifiers for each data element, performs a series of metadata
460   retrievals into an annotated case report form. The metadata includes the exact specification, using XPath, to find the corresponding data element in the HL7 specification Continuity of Care Document (CCD) as extended in the IHE Clinical Research Document (CRD) Profile. Using the XPath statements, the research system creates an extraction specification for all elements to be extracted from the CCD. This extraction specification provides a map that enables re-use of the
465   proper data within a CCD with precision and without inappropriate access to extraneous information. The extraction specification could then be used with RFD to pre-populate the case report form.

X.4.2.1.2 Pre-population of a Research Case Report Form Process Flow
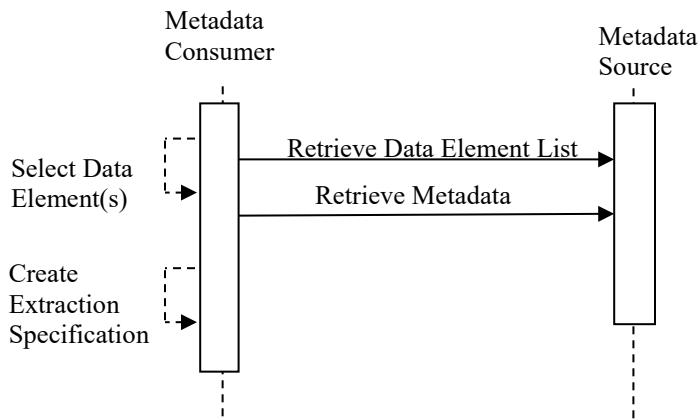
470   **Figure X.4.2.1.2-1: Basic Process Flow in DEX Profile**

Pre-conditions:

The research designer uses a blank template to design a case report form to meet the requirements of the study protocol.

Main Flow:

475   The research forms designer designs the case report form by selecting data elements from the metadata registry (like CDASH data elements) and retrieving the accompanying metadata. Not all elements of the form will be available in the EHR. These elements will be required to be input by the site research coordinator.

Post-conditions:

480   An annotated case report form is created that contains the exact location of each pre-population data element. This annotated case report form is then converted to an extraction specification to automatically populate the case report form from the EHR export.

X.4.2.2 Use Case #2: Eligibility Determination

This use case creates eligibility criteria that are intelligible to an EHR.

485   ### X.4.2.2.1 Research Eligibility Determination Description

Eligibility determination for feasibility studies

A research worker seeks to find eligible subjects for a research study by searching an EHR or a clinical data warehouse. The worker expresses eligibility criteria, as defined by the research protocol, as inclusion/exclusion criteria using a research standard such as CDISC's Study Design
490   Model (SDM). The eligibility criteria are drawn down from a metadata registry that includes the

exact mappings to corresponding data elements in the EHR or clinical data warehouse. Eligibility Determination is performed on anonymized clinical data warehouses or on EHRs. Using the exact mappings retrieved from the metadata registry (as XPath, as SQL or as SPARQL if the schema of clinical data warehouse is in RDF), the research system constructs the Eligibility
495   Determination Specification to be run on EHRs or clinical data warehouse.

The eligibility determination specification could be run against an EHR or a clinical data warehouse established for clinical research purposes (anonymized data) returning summary information only (e.g., counts and percentages) as a part of other profiles. Summary information might be cross-tabulated by a number of key inclusion/exclusion criteria. For instance, the
500   number of eligible participants might be returned for combinations of gender (male/female) and diabetes status (not diabetic/type I/type II). Data will be returned only if counts are sufficiently large to protect privacy.

Patient recruitment

Once a trial design has been finalized, all clinical trial approvals obtained and clinical
505   investigators recruited and contracts completed, there is the opportunity to use routinely collected patient data to facilitate the identification of potentially eligible recruits for the trial. The eligibility determination specification created as described above could be used in the subsequent workflow to create a list of eligible candidates using additional profiles such as Research Matching.

510   **X.4.2.2.2 Eligibility Determination Process Flow**
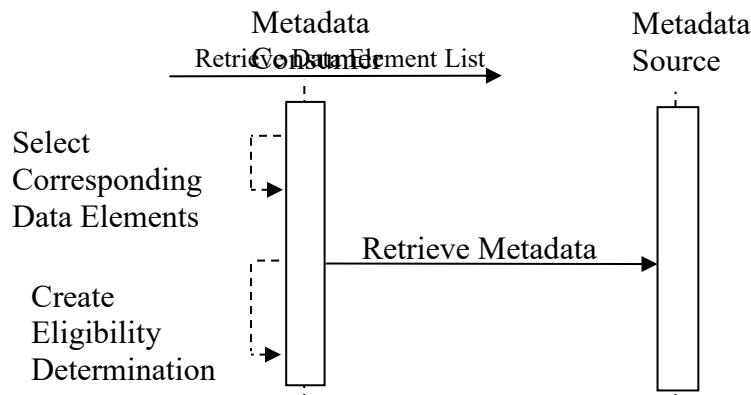
Figure X.4.2.2.2-1: Basic Process Flow in DEX Profile

Pre-conditions:

The research designer has defined the research eligibility criteria for a particular study in a
515   research protocol.

Main Flow:

The research designer selects the data elements representing the research eligibility criteria for a particular study.

520 The research designer retrieves the metadata of the selected data elements from the metadata registry.

Post-conditions:

The eligibility determination specification could be created to extract a list of candidates for inclusion in a study.

X.4.2.3 Use Case #3: Observational Study

525 This use of DEX enables direct extraction of data on patients for observational studies without the need for supplemental data entered by a human.

X.4.2.3.1 Observational Study Description

Alternative A

A research worker would like to collect a data collection set for an observational study in order 530 to create project-specific mini-databases ("data marts"). He selects research defined data elements that should be included in the data collection set from a metadata registry. He retrieves the exact mappings of the corresponding data elements to the data items in the clinical data warehouse from the metadata registry. Using the exact mappings retrieved from the metadata registry (as XPath, as SQL or as SPARQL if the schema of clinical data warehouse is in RDF), 535 the research system constructs the electronic query to be run on clinical data warehouse to collect the required data sets.

The electronic query would be run against a clinical data warehouse that would require the return of pseudonymized individual patient records containing patient level information on key inclusion/exclusion criteria and other variables of interest. The records would not contain any 540 patient identifiers (for example date of birth would be converted into age and recorded to nearest year).

The protocol of the observational study will be reviewed and restricted by the Institutional Review Board.

Alternative B

545 A research worker having identified eligible patients for a research study by searching an EHR or a clinical data warehouse (Use Case #2) selects research defined data elements from a metadata registry and creates the data collection set specification. The research system retrieves the metadata of the selected data elements that include the exact specifications, using XPath, to find the corresponding data element in a medical summary document expressed in HL7 550 specification Continuity of Care Document (CCD). Using the XPath statements, the research system creates an entire extraction specification for all elements to be extracted from the CCD.

This extraction specification provides a map that enables re-use of the proper data within a CCD with precision and without inappropriate access to extraneous information to retrieve highly detailed data available on these specific patients to the investigators for observational studies. The researcher then can collect the data sets in project-specific mini-databases ("data marts") to run safety analysis methods on top of it.

The protocol of the observational study will be reviewed and restricted by the Institutional Review Board. After the eligible patients are identified, the EHR system, that are already capable of producing medical summaries of patients in standard information models like IHE CCD templates, will share the pseudonymized medical summaries with the Research systems. As the data collection set is already annotated with extraction specifications to retrieve the data sets from medical summary documents, the research data collection of interest can easily be collected from these medical summaries and stored in the project specific databases to run the clinical research methods of interest.

X.4.2.3.2 Observational Study Process Flow
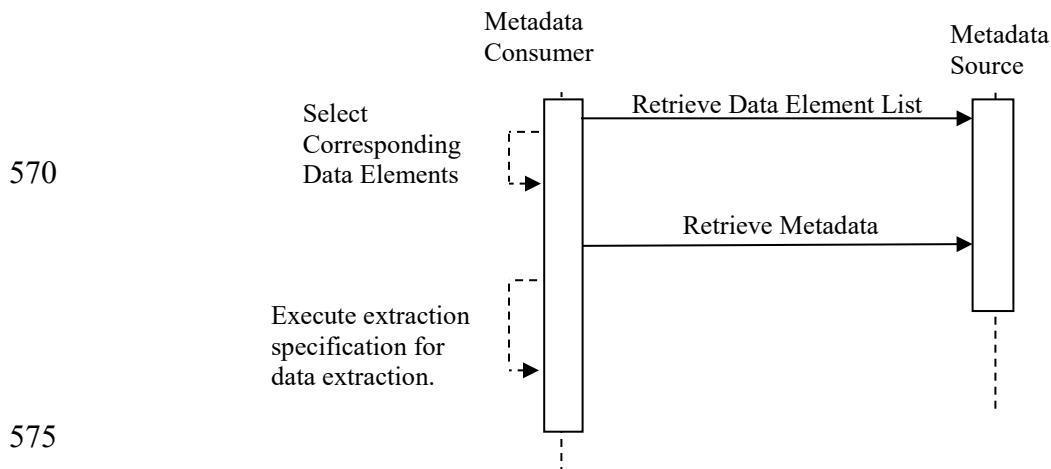
Figure X.4.2.3.2-1: Basic Process Flow in DEX Profile

Pre-conditions:

The research worker uses a blank template to design a data collection set to meet the requirements of the observational study protocol.

Main Flow:

The research worker designs the data collection set by selecting the data elements to be included.

585 The research worker retrieves the metadata of the data elements in the data collection set from the metadata registry (like CDASH data elements).

Post-conditions:

The data collection set is annotated with exact location of each research defined data element in a clinical data warehouse or in a pseudonymized medical summary. This annotated data collection set could either be used to query a clinical data warehouse, or converted to an extraction
590 specification to retrieve the data elements from medical summaries of eligible patients exported from an EHR.

X.4.2.4 Use Case #4: Public Health Case Reporting

X.4.2.4.1 Use Case Description

Current State

595 Patient Polly appears in Doctor Toci physician office, in the great state of Nirvana, with fever and a cough with an unusual whooping sound. Culture is taken and sent to the laboratory. Patient instructed to return in two days. Upon return, lab result shows positive for pertussis. Physician prescribes course of Erythromycin and instructs the patient to return in one week for follow up. The provider knows that pertussis is a reportable condition and knows to report the case to the
600 local, state and federal authorities.

Fortunately Dr. Toci's EHR has RFD capabilities that can access the pertussis case reporting form through the Form Manager hosted by the Bliss county health department. Fortunately, the Forms Manager supports the Public Health Reporting Initiative Content Profile, which enables pre-population of 30% of the form through a transform of CCD.

605 Dr. Andy Antiquated has an EHR that can only generate a CCR, which they provide for pre-pop. The Forms Manager is unable to do any pre-population with this non-compliant document.

Once the form is competed and submitted to the Forms Receiver. Randy, the software guy, has enabled the Bliss software to submit variants of the case reporting form to the Nirvana state health agency and to the Centers for Disease Control (CDC).

610 Desired State

Dave the forms designer has upgraded the Bliss county health department's pertussis form. He designed the form by drawing down data elements from a metadata registry that builds in the explicit path to the data elements in the CCD. Now the pre-population completes 60% of the form, using the same pre-population export document.

615 The Forms Manager must unscramble two different pre-population documents, and three different recipient documents.

A PhD epidemiologist at CDC has developed a case reporting form of 92 elements for pertussis reporting. A master's degree in public health employee at the state of Nirvana has defined a more concise form of 80 elements. A semi-retired physician, Dr. Quack, has a form that overlaps with

620 40 of the state's data elements, and insists on two elements for Bliss County that neither the state nor the federal jurisdiction specify, but which in HITSP data dictionary. The CDC data elements are contained in an agency metadata registry, which contains maps to corresponding elements in a CCD. The state uses a metadata registry from the Public Health Data Standards Consortium which maps to the CDC's metadata registry, and to the CCR, but not to the CCD. Dr. Quack uses
625 no metadata registry but his data elements are a subset of the state elements, except for two data elements are normally in a CCD.

X.4.2.4.2 Public Health Reporting Process Flow

Pre-conditions: There are three different Metadata Sources: as an interface to the metadata registry managed by CDC, as an interface to the metadata registry managed by Public Health
630 Data Standards Consortium (PHDSC) and as an interface to HITSP metadata registry. Form Designer selects the data elements to be included in the Form from the data elements maintained by these metadata registries. The metadata registries managed by CDC and PHDSC also maintain the exact paths of the data elements to the different Case Report Forms they are expecting to receive.

635 **Main Flow:**

- Form Designer queries the CDC metadata registry to retrieve metadata of the CDC data elements, and as a result, the mappings to CCD documents.

- Form Designer then queries the Public Health Data Standards Consortium metadata registry to retrieve the metadata of PHDSC data elements and as a result the mappings to
640 CCR. In this step we have the mappings of a subset of CDC data elements (80 of them) to CCR documents too.

- Form Designer then queries the HITSP metadata registry to retrieve the metadata of HITSP data elements and a result the mappings to CCD documents.

- As a result, the Form Designer annotates the Form, where 80 of the data elements have a
645 mapping to both CCD and CCR, 12 CDC data elements have a mapping to CCD, and 2 HITSP data elements have a mapping to CCD.

- While the Form Designer queries the CDC and PHDSC metadata registries, it also received the exact paths of the corresponding data elements in the Case Report Forms managed by CDC and PHDSC. These are also added to the annotated Form.

650 **Post-conditions:**

A Form Manager having the annotated Form, retrieves the prepop data in CCR and CCD format and by making use of the annotations (including the mappings to CCD and CCR documents), prepopulated the form with the data retrieved from EHRs.

A Form Receiver, receiving the annotated and filled Form, creates the different Case Report
655 Forms by making use of the annotations (i.e., the mappings of the data elements to different Case Report Forms).

X.4.2.5 Use Case #5: Public Health Case Reporting, USHIK

X.4.2.5.1 Use Case Description

A population health surveyor designed a new survey form to collect information for a national Emergency Department (ED) survey. The designer refers to the United States Health Information Knowledgebase (USHIK), an online metadata registry that may contain all of the survey data elements that are represented across the host of Centers for Disease Control and Prevention/National Center for Health Statistics (NCHS) surveys and the data elements that are included for several states/jurisdictions in the All Payers Claim Database (APCD). The APCD *are* large-scale databases that systematically collect health care claims data from a variety of payer sources which include claims from most health care providers. The survey designer selects the desired data elements that are needed for the new ED survey from the list of NCHS survey elements and the APCD elements using a unique identifier for each data element. The metadata defined by the metadata registry is retrieved into an annotated ED survey form. The metadata includes the exact specification, using XPath, to find the corresponding data element in the HL7 specification Continuity of Care Document (CCD). Using the XPath statements, an HL7 CDA®[6] compliant system that was utilized to develop the survey form may create an extraction specification for all elements to be extracted from the CCD. This extraction specification provides a map that enables re-use of the proper data within a CCD with precision and without inappropriate access to extraneous information.

X.4.2.6 Use Case #6: Epidemiological Study in a Document Sharing HIE Environment

This use case describes how a public health/epidemiology/research organization can obtain metadata related to data used to evaluate a specific clinical outcome (for example for epidemiological purposes). This use case is useful in a clinical community where an HIE system is established and it is organized as a Document Sharing environment, in particular an MPQ environment.

X.4.2.6.1 Epidemiological Study in a Document Sharing HIE Environment Use Case Description

An epidemiologist would like to study the disease burden of Diabetes in a Region where an HIE exists and different kinds of documents are produced: Discharge Summaries, ER Referrals, ePrescriptions, eReferrals, Laboratory Reports, Pathological Anatomy Reports, Vaccination reports, etc.

In the current state, it is not a trivial task for the epidemiologist to calculate the prevalence of a disease: usually an observational study is performed and cumbersome procedures have to be

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[6] CDA is the registered trademark of Health Level Seven International.

established, which takes a long time, includes a long follow-up, and involves a lot of people and resources.

In the desired future state, the epidemiologist asks the administrative authority of the Region to have access (in respect of legal and privacy issues) to the clinical data needed to answer the research question. Once the permission is obtained, the epidemiologist performs a search in the metadata registry implemented by the HIE system for the kind of documents where the diagnosis information is registered. The number of inhabitants in the Region (denominator) is known, so to calculate the prevalence only the number of cases of diabetes (numerator) is required. First of all, the epidemiologist queries the metadata registry for the list of data elements related to the "diagnosis" clinical concept according to a reference vocabulary (e.g., the HITEP II data dictionary). The epidemiologist chooses the "active diagnosis" as the data element most closely matching his needs. He queries the metadata registry for the documents where this element is potentially stored and the metadata registry provides the DocumentEntry metadata related to the Discharge Summary and to the ER Referral. The metadata registry provides the specifications (XPath) to extract the data from each type of document. The epidemiologist chooses both the document types since both of them actually allow identifying diabetic people.

Once this informative metadata is obtained, the epidemiologist's research system can initiate the process to retrieve documents using MPQ and XDS queries, extract the data and perform the analysis to calculate the prevalence of diabetes.

X.4.2.6.2 Epidemiological Study in a Document Sharing HIE Environment Process Flow
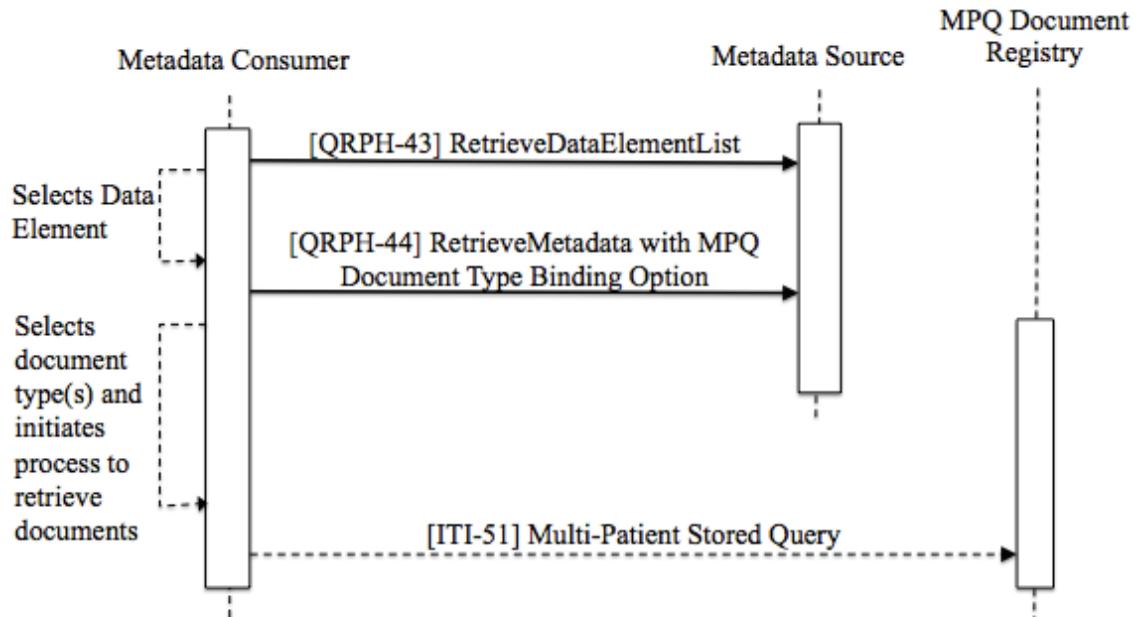
Figure X.4.2.6.2-1: Basic Process Flow in DEX Profile with MPQ Document Type Binding Option

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Pre-conditions:

The epidemiologist identifies the research question and a criterion to look for clinical data needed to answer the research question.

Main Flow:

720 The epidemiologist identifies the data element he needs, selecting from the list returned by the metadata registry. He then queries for the type of documents storing the data element and selects the type of documents in the Document Sharing HIE definitely matching his needs, choosing from the list returned by the metadata registry.

Post-conditions:

725 The epidemiologist's system performs XDS queries to get the documents of interest from the HIE, using the Document Sharing Metadata previously identified.

X.5 DEX Security Considerations

The DEX will not contain any patient health information (PHI) and as such will not require any of the methods that protect PHI.

730 Currently there are no use cases requiring authentication, authorization and auditing, but a risk analysis should be carried out per implementation and if needed.

X.6 DEX Cross Profile Considerations

Many profiles may use the eligibility determination specification based on the metadata returned by DEX to match eligible patients for a research study or a public health cohort.

735 Other cross-profile considerations are defined below.

X.6.1 SVS - Sharing Value Sets

If the Retrieve Metadata Response from the Metadata Source provides a reference to the value set from which the values of the data element can be selected, an SVS Value Set Repository might be grouped with the Metadata Source and an SVS Value Set Consumer with the Metadata
740 Consumer.

X.6.2 SDC - Structured Data Capture

A Form Manager in SDC might be grouped with the Metadata Consumer in order to use the metadata returned by DEX to create an annotated CRF for its automatic population by a Form Filler.

Appendices

745

None

Volume 2 – Transactions

Add Section 3.43

750 ## 3.43 Retrieve Data Element List [QRPH-43]

3.43.1 Scope

This transaction is used by the Metadata Consumer to retrieve a list of Data Elements from the Metadata Source matching the given selection criteria.

3.43.2 Actor Roles
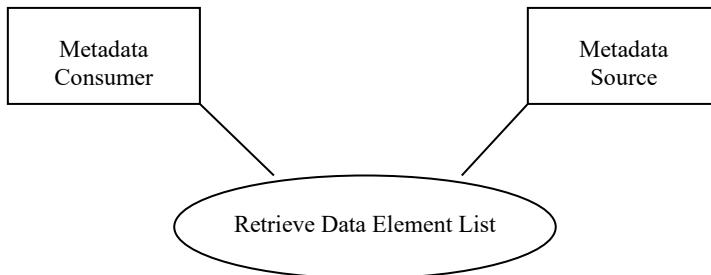
755

Figure 3.43.2-1: Use Case Diagram

The Roles in this transaction are defined in the following table and may be played by the actors shown here:

Table 3.43.2-1: Actor Roles

Actor:	Metadata Consumer
Role:	Obtain the list of Data Elements from the Metadata Source matching the given selection criteria
Actor:	Metadata Source
Role:	Maintain and provide the metadata definitions of Data Elements

760

3.43.3 Referenced Standards

- ISO/IEC 11179: Information Technology – Metadata Registries (MDR) Parts 1–6 (2nd Edition).

- IETF RFC2616 HyperText Transfer Protocol HTTP/1.1

765   •   Extensible Markup Language (XML) 1.0 (Second Edition). W3C Recommendation 6
October 2000. http://www.w3.org/TR/REC-xml.

       •   Web Services Description Language (WSDL) 1.1. W3C Note 15 March 2001.
http://www.w3.org/TR/wsdl.

       •   SOAP 1.2 Second Edition, W3C Recommendation 27 April 2007.
770   http://www.w3.org/TR/soap12-part1

IEEE Std 1003.2 IEEE Standard for Information Technology — Portable Operating
System Interface (POSIX®) — Part 2: Shell and Utilities — Amendment 1: Batch
Environment -Description

3.43.4 Interaction Diagram
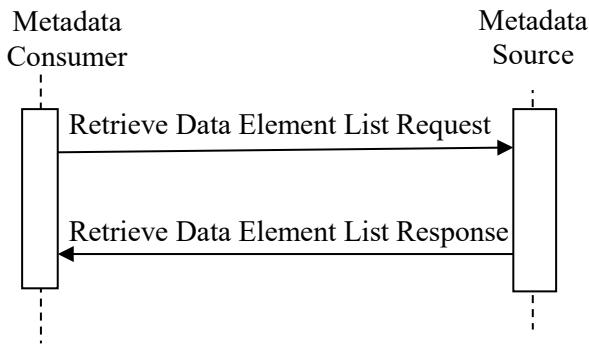
775

3.43.4.1 Retrieve Data Element List Request

3.43.4.1.1 Trigger Events

The Metadata Consumer wants to retrieve the list of Data Elements and has one or more
metadata element values to be matched in the metadata that describes Data Elements. The
780 Metadata Consumer sends a Retrieve Data Element List Request to the Metadata Source.

3.43.4.1.2 Message Semantics

The Metadata Source sends a Retrieve Data Element List Request message to specify request
parameters used by the Document Consumer to select and return a list of data elements that
match the parameters in Table 3.43.4.1.2-1. The Metadata Source shall send one or more
785 parameters in the Retrieve Data Element List Request. The Metadata Consumer shall be able to
perform matching on all parameters in Table 3.43.4.1.2-1. See Section 3.43.5 for the
requirements for the format of the Retrieve Data Element List.

The string data type corresponds to xsd:string and the date data type corresponds to xsd:date. The format for xsd:date is YYYY-MM-DD where Y is the year, M is the month, D is the day of month.

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Table 3.43.4.1.2-1: The Request Parameters in the Retrieve Data Element List Request

Parameter	Parameter Format	Metadata Element	Match Rules	Note
id	string	id	equals	Equality match
registrationAuthorityContains	string	registrationAuthority	Regex	POSIX rules
version	string	version	equals	Equality match
displayNameContains	string	displayName	Regex	POSIX rules
definitionContains	string	definition	Regex	POSIX rules
contextualDomainContains	string	contextualDomain	Regex	POSIX rules
creationDateBefore	date (YYYY-MM-DD)	creationDate	Before or equal	Date comparison to the day
creationDateAfter	date (YYYY-MM-DD)	creationDate	Equal or After	Date comparison to the day
effectiveDateBefore	date (YYYY-MM-DD)	effectiveDate	Before or equal	Date comparison to the day
effectiveDateAfter	date (YYYY-MM-DD)	effectiveDate	Equal or After	Date comparison to the day
expirationDateBefore	date (YYYY-MM-DD)	expirationDate	Before or equal	Date comparison to the day
expirationDateAfter	date (YYYY-MM-DD)	expirationDate	Equal or After	Date comparison to the day
revisionDateBefore	date (YYYY-MM-DD)	revisionDate	Before or equal	Date comparison to the day
revisionDateAfter	date (YYYY-MM-DD)	revisionDate	Equal or After	Date comparison to the day
decID	string	id	equals	Equality match
decDisplayNameContains	string	DataElementConcept.displayName	Regex	POSIX rules

Parameter	Parameter Format	Metadata Element	Match Rules	Note
decObjectClassContains	string	DataElementConcept.ObjectClass	Regex	POSIX rules
decPropertyContains	string	DataElementConcept.Property	Regex	POSIX rules
dataTypeContains	string	valueDomain	Regex	POSIX rules
valueSetID	string- should conform to this regular expression: [0-2](\.(0|[1-9][0-9]*))*	valueDomain	equals	Equality match

3.43.4.1.3 Expected Action

The Metadata Source shall perform matching in accordance with the rules in Table 3.43.4.1.2-1.

- Regex matches shall compare the contents of the referenced metadata field with the regex using the POSIX matching rules. If the regex matches the field, the Data Element matches.

- id, version and valueSetID matching compares only for equal values.

- Date comparisons convert the argument into a date, and compare it with the dates in the metadata using a date comparison. Equality means the same day.

Any Data Element, which has metadata that matches all of the provided request parameters at the same time, shall be included in the response (the parameters are mathematically ANDed).

3.43.4.2 Retrieve Data Element List Response

3.43.4.2.1 Trigger Events

This message will be triggered by a Retrieve Data Element List Request Message.

3.43.4.2.2 Message Semantics

The response shall be a Retrieve Data Element List Response Message which shall have one DataElementSummary element (presented in Table 3.43.4.2.2-1) for each matching Data Element found. If no matching Data Elements are found, Data Element List Response Message shall be empty.

The Optionality Field in Table 3.43.4.2.2-1, Table 3.43.4.2.2-2, Table 3.43.4.2.2-3, Table 3.43.4.2.2-4 and Table 3.43.4.2.2-5 can have the following values with their associated meanings:

Value	Meaning
R	Required
R2	Required if the information is available
O	Optional

Table 3.43.4.2.2-1: DataElementSummary in the Retrieve Data Element List Response Message

Element Name	Optionality	Is Repeatable	Type	Description
DataElementSummary	R2	Yes	See Table 3.43.4.2.2-2 for the details of DataElementSummaryType	The summary information about the Data Element.

The elements of the DataElementSummary elements is presented in Table 3.43.4.2.2-2. The string data type corresponds to xsd:string and the date data type corresponds to xsd:date. The format for xsd:date is YYYY-MM-DD where Y is the year, M is the month, D is the day of month.

Table 3.43.4.2.2-2: The elements of the DataElementSummary in the Retrieve Data Element List Response Message

Element Name	Optionality	Is Repeatable	Type	Description
id	R	No	string	Identifier of the Data Element.
registrationAuthority	R	No	string	The Authority who has defined and registered the Data Element to the Metadata Source (Examples: CDISC, HITSP, NCI).
version	R	No	string	Version of the Data Element.
displayName	R	No	string	A name that can be used for display purposes
definition	R	No	string	Definition that gives an unambiguous description of the Data Element and its use.
contextualDomain	R2	No	string	The specific domain that indicates the specific domain in which this Data Element is defined (Examples: CDASH, SDTM, HITSP C154). If such a contextualDomain is defined by the registrationAuthority for this Data Element in the metadata registry, then it shall be included in the message.

Element Name	Optionality	Is Repeatable	Type	Description
creationDate	R	No	date	The date that indicates the specific date when this Data Element is created.
effectiveDate	R2	No	date	The date that indicates the specific date when this Data Element becomes effective to be used. In the case that effectiveDate is not available, the creationDate is considered as the date at which the element is effective to be used.
expirationDate	R2	No	date	The date when the Data Element is no longer expected to be used.
revisionDate	R2	No	date	The date when the Data Element is revised.
revisionNote	R2	No	string	Note that indicates the revision reason, and the updates
dataElementConcept	R	No	See Table 3.43.4.2.2-3 for the details of dataElementConcept.	The data element concept which is the "concept" part of the data element definition. A Data Element is formed with an association of a dataElementConcept and a valueDomain.
valueDomain	R	No	See Table 3.43.4.2.2-4 for the details of valueDomain.	The description of the permissible set of values for the property of the data element definition. Each data element is composed of a dataElementConcept and a valueDomain. See Appendix A for the formal specification .

Table 3.43.4.2.2-3: The elements of dataElementConcept in the Retrieve Data Element List Response Message

Element Name	Optionality	Is Repeatable	Type	Description
id	R	No	string	The unique id that identifies a Data Element Concept
displayName	R	No	string	The textual representation of Data element Concept

Element Name	Optionality	Is Repeatable	Type	Description
objectClass	R2	No	string	Each data element concept is composed of an id, displayName, objectClass and a property term. An objectClass represents a set of ideas, abstractions, or things in the real world that are identified with explicit boundaries and meaning and whose properties and behavior follow the same rules. See Appendix B for further description.
property	R2	No	string	Each dataElementConcept is composed of an id, displayName, objectClass and a property term. See Appendix B for further description. A property is a characteristic common to all members of an object Class.

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Table 3.43.4.2.2-4: The elements of valueDomain in the Retrieve Data Element List Response Message

Element Name	Optionality	Is Repeatable	Type	Description
dataType	R	No	string	Data type which represents the characteristics of the permissible values for the data element property (Example: xsd:string)
unitOfMeasure	R2	No	string	Actual units in which the associated values of the property of the data element are measured.
valueSet	R2	No	See Table 3.43.4.2.2-5 for the details of valueSet.	A reference to the value set from which the values of this data element can be selected. The content of the value set can be further retrieved by IHE ITI SVS (Sharing Value Sets) Profile.

Table 3.43.4.2.2-5: The elements of valueSet in the Retrieve Data Element List Response Message

Element Name	Optionality	Is Repeatable	Type	Description
id	R	No	string - should conform to this regular expression: [0-2](\.(0|[1-9][0-9]*))*	Identifier of the valueSet. This is the OID of the valueSet as described in IHE ITI SVS.
version	R	No	string	The version of the valueSet in question.
displayName	O	No	string	The textual representation of the name of the valueSet.

3.43.4.2.3 Expected Actions

830   A Metadata Consumer processes the DataElementSummary elements according to its business process logic.

3.43.5 Protocol Requirements

The protocol for the Retrieve Data Element List transaction is based on SOAP 1.2. The relevant XML namespace definitions can be seen in Table 3.43.5-1 WSDL Namespace Definitions.

835   **Table 3.43.5-1: WSDL Namespace Definitions**

soap12	http://schemas.xmlsoap.org/wsdl/soap12/
wsdl	http://schemas.xmlsoap.org/wsdl/
xsd	http://www.w3.org/2001/XMLSchema
dex	urn:ihe:qrph:dex:2013

These are the requirements for the Retrieve Data Element List transaction presented in the order in which they would appear in the WSDL definition (see Appendix A for an informative WSDL):

840   The following types shall be included (xsd:include) in the /definitions/types section: namespace="urn:ihe:qrph:dex:2013", schema="DEX.xsd"

The /definitions/message/part/@element attribute of the Retrieve Data Element List Request message shall be defined as "dex:RetrieveDataElementListRequest"

The /definitions/message/part/@element attribute of the Retrieve Data Element List Response
845   message shall be defined as "dex:RetrieveDataElementListResponse"

The /definitions/portType/operation/input/@message attribute for the Retrieve Data Element List Operation shall be defined as "dex:RetrieveDataElementListRequestMessage"

The /definitions/portType/operation/output/@message attribute for the Retrieve Data Element List Operation shall be defined as "dex:RetrieveDataElementListResponseMessage"

850   The

/definitions/binding/operation/soap12:operation/@soapAction attribute shall be defined as "urn:ihe:qrph:dex:2013:RetrieveDataElementList"

These are the requirements that affect the wire format of the SOAP message. The other WSDL properties are only used within the WSDL definition and do not affect interoperability. Full
855   sample request and response messages are in QRPH: 3.43.5.1 and QRPH: 3.43.5.2.

A full XML Schema Document for the DEX types is available in Appendix A.

The protocol requirements for the request and response messages are given in the following subsections.

3.43.5.1 Retrieve Data Element List Request Message

860 Within the request message payload the <dex:RetrieveDataElementListRequest/> element is defined as:

- An optional /dex:RetrieveDataElementListRequest/dex:id element that contains the ID of the requested Data Element within the Metadata Source

865
- An optional /dex:RetrieveDataElementListRequest/dex:registrationAuthorityContains element with type "xsd:string"

- An optional /dex:RetrieveDataElementListRequest/dex:version element with type "xsd:string"

- An optional /dex:RetrieveDataElementListRequest/dex:displayNameContains element with type "xsd:string"

870
- An optional /dex:RetrieveDataElementListRequest/dex:definitionContains element with type "xsd:string"

- An optional /dex:RetrieveDataElementListRequest/dex:contextualDomainContains element with type "xsd:string"

875
- An optional /dex:RetrieveDataElementListRequest/dex:creationDateBefore element with type "xsd:date"

- An optional /dex:RetrieveDataElementListRequest/dex:creationDateAfter element with type "xsd:date"

- An optional /dex:RetrieveDataElementListRequest/dex:effectiveDateBefore element with type "xsd:date"

880
- An optional /dex:RetrieveDataElementListRequest/dex:effectiveDateAfter element with type "xsd:date"

- An optional /dex:RetrieveDataElementListRequest/dex:expirationDateBefore element with type "xsd:date"

885
- An optional /dex:RetrieveDataElementListRequest/dex:expirationDateAfter element with type "xsd:date"

- An optional /dex:RetrieveDataElementListRequest/dex:revisionDateBefore element with type "xsd:date"

- An optional /dex:RetrieveDataElementListRequest/dex:revisionDateAfter element with type "xsd:date"

890
- An optional /dex:RetrieveDataElementListRequest/dex:decID element that matches the ID of the Data Element Concept that is bound to the requested Data Element within the Metadata Source

___

- An optional /dex:RetrieveDataElementListRequest/dex:decDisplayNameContains element with type "xsd:string"

895
- An optional /dex:RetrieveDataElementListRequest/dex:decObjectClassContains element with type "xsd:string"

- An optional /dex:RetrieveDataElementListRequest/dex:decPropertyContains element with type "xsd:string"

- An optional /dex:RetrieveDataElementListRequest/dex:dataTypeContains element with type "xsd:string"
900

- An optional /dex:RetrieveDataElementListRequest/dex:valueSetID element with type "xsd:string". This string should conform to this regular expression: [0-2](\.(0|[1-9][0-9]*))*

A sample Retrieve Data Element List SOAP Request is given as follows:

905
```
<soap:Envelope xmlns:soap="http://schemas.xmlsoap.org/soap/envelope/"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xmlns:wsa=http://www.w3.org/2005/08/addressing

xmlns:xsd="http://www.w3.org/2001/XMLSchema">

  <soap:Header>

910       <wsa:MessageID>urn:uuid:f43f7bda-a5f9-42b1-b8dc-e78be1a2a180</wsa:MessageID>

        <wsa:Action>urn:ihe:qrph:dex:2013:RetrieveDataElementList</wsa:Action>

  </soap:Header>

  <soap:Body>

        <dex:RetrieveDataElementListRequest xmlns:dex="urn:ihe:qrph:dex:2013">

915           <dex:displayNameContains>ethnic</dex:displayNameContains>

        </dex:RetrieveDataElementListRequest>

  </soap:Body>

</soap:Envelope>
```

3.43.5.2 Retrieve Data Element List Response

920   Metadata Source shall include within the response message payload for the SOAP Binding Option the <dex:RetrieveDataElementListResponse/> element which contains:

- Zero or more /dex:RetrieveDataElementListResponse/dex:DataElementSummary element, containing

  o a required /dex:RetrieveDataElementListResponse/dex:DataElementSummary/dex:id
925   element with type "xsd:string"

  o a required /dex:RetrieveDataElementListResponse/dex:DataElementSummary/dex:registrationAuthority element with type "xsd:string"

___

930
- o a required /dex:RetrieveDataElementListResponse/dex:DataElementSummary/dex:version element with type "xsd:string"

- o a required /dex:RetrieveDataElementListResponse/dex:DataElementSummary/dex:displayName element with type "xsd:string"

935
- o a required /dex:RetrieveDataElementListResponse/dex:DataElementSummary/dex:definition element with type "xsd:string"

- o an optional /dex:RetrieveDataElementListResponse/dex:DataElementSummary/dex:contextualDo

940
  main element with type "xsd:string" (If such a contextualDomain is defined by the registrationAuthority for this Data Element in the metadata registry, then it shall be included in the message.)

- o a required /dex:RetrieveDataElementListResponse/dex:DataElementSummary/dex:creationDate

945
  element with type "xsd:date"

- o an optional /dex:RetrieveDataElementListResponse/dex:DataElementSummary/dex:effectiveDate element with type "xsd:date" (Required if available)

- o an optional

950
  /dex:RetrieveDataElementListResponse/dex:DataElementSummary/dex:expirationDa te element with type "xsd:date" (Required if available)

- o an optional /dex:RetrieveDataElementListResponse/dex:DataElementSummary/dex:revisionDate element with type "xsd:date" (Required if available)

955
- o an optional /dex:RetrieveDataElementListResponse/dex:DataElementSummary/dex:revisionNote element with type "xsd:string" a required (Required if available)

- o a required

  /dex:RetrieveDataElementListResponse/dex:DataElementSummary/dex:dataElement

960
  Concept element containing

  - ▪ a required /dex:RetrieveDataElementListResponse/dex:DataElementSummary/dex:dataElem entConcept/dex:id element with type "xsd:string"

  - ▪ a required

965
    /dex:RetrieveDataElementListResponse/dex:DataElementSummary/dex:dataElem entConcept/dex:displayName element with type "xsd:string"

- an optional /dex:RetrieveDataElementListResponse/dex:DataElementSummary/dex:dataElementConcept/dex:objectClass element with type "xsd:string"

970
- an optional /dex:RetrieveDataElementListResponse/dex:DataElementSummary/dex:dataElementConcept/dex:property element with type "xsd:string"

  o a required /dex:RetrieveDataElementListResponse/dex:DataElementSummary/dex:valueDomain
975 element containing

  - a required /dex:RetrieveDataElementListResponse/dex:DataElementSummary/dex:valueDomain/dex:dataType element with type "xsd:string"

  - an optional
980 /dex:RetrieveDataElementListResponse/dex:DataElementSummary/dex:valueDomain/dex:unitOfMeasure element with type "xsd:string" (Required if available)

  - an optional /dex:RetrieveDataElementListResponse/dex:DataElementSummary/dex:valueDomain/dex:valueSet element containing (Required if available)

985
    - a required /dex:RetrieveDataElementListResponse/dex:DataElementSummary/dex:valueDomain/dex:valueSet/dex:id element with type "xsd:string". This string should conform to this regular expression: [0-2](\.(0|[1-9][0-9]*))*

    - a required
990 /dex:RetrieveDataElementListResponse/dex:DataElementSummary/dex:valueDomain/dex:valueSet/dex:version element with type "xsd:string"

    - an optional /dex:RetrieveDataElementListResponse/dex:DataElementSummary/dex:valueDomain/dex:valueSet/dex:displayName element with type "xsd:string"

995 A sample Retrieve Data Element List SOAP Response is given as follows:

```
<soap:Envelope xmlns:soap="http://schemas.xmlsoap.org/soap/envelope/"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xmlns:wsa="http://www.w3.org/2005/08/addressing" xmlns:xsd="http://www.w3.org/2001/XMLSchema">

  <soap:Header>

      <wsa:Action>urn:ihe:qrph:dex:2013:RetrieveDataElementListResponse</wsa:Action>

      <wsa:RelatesTo>urn:uuid:f43f7bda-a5f9-42b1-b8dc-e78be1a2a180</wsa:RelatesTo>

  </soap:Header>

  <soap:Body>

      <dex:RetrieveDataElementListResponse xsi:schemaLocation="urn:ihe:qrph:dex:2013 dex.xsd"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns:dex="urn:ihe:qrph:dex:2013">

              <dex:DataElementSummary>

                      <dex:id>6fbbd463-7de1-4ebc-85f6-76b84bab678b</dex:uuid>

                      <dex:registrationAuthority>CDISC</dex:registrationAuthority>

                      <dex:version>0.1</dex:version>

                      <dex:displayName>DMETHNIC</dex:displayName>

                      <dex:definition>A social group characterized by a distinctive social and
cultural tradition maintained from generation to generation, a common history and origin and a
sense of identification with the group; members of the group have distinctive features in their
way of life, shared experiences and often a common genetic heritage; these features may be
reflected in their experience of health and disease</dex:definition>

                      <dex:contextualDomain>CDASH</dex:contextualDomain>

                      <dex:creationDate>2010-01-01</dex:creationDate>

                      <dex:effectiveDate>2010-02-01</dex:effectiveDate>

                      <dex:expirationDate>2020-01-01</dex:expirationDate>

                      <dex:dataElementConcept>

                              <dex:id>2145698</dex:id>

                              <dex:displayName>ETHNICITY</dex:displayName>
                              <dex:objectClass>DM</dex:objectClass>

                              <dex:property>ETHNIC</dex:property>

                      </dex:dataElementConcept>

                      <dex:valueDomain>

                              <dex:dataType>xsd:string</dex:dataType>

                              <dex:valueSet>

                                      <id>2.16.840.1.114222.4.11.837</id>

                                      <version>1</version>

                                      <displayName>Ethnicity group</displayName>

                              </dex:valueSet>

                      </dex:valueDomain>

              </dex:DataElementSummary>

</dex:RetrieveDataElementListResponse>

  </soap:Body>

</soap:Envelope>
```

Line numbers in left margin: 1000, 1005, 1010, 1015, 1020, 1025, 1030, 1035

3.43.6 Security Considerations

1040 The Retrieve Data Elements List [QRPH-43] transaction does not contain any patient health information (PHI) and does not require any of the methods that protect PHI, such as TLS or auditing required by the ITI ATNA Profile.

Currently there are no use cases requiring authentication, authorization and auditing, but a risk analysis should be carried out per implementation and if needed.

1045 | *Add Section 3.44* |

3.44 Retrieve Metadata [QRPH-44]

3.44.1 Scope

The Metadata Consumer uses the Retrieve Metadata transaction to retrieve the metadata of a selected Data Element from the Metadata Source.

1050 ### 3.44.2 Actor Roles
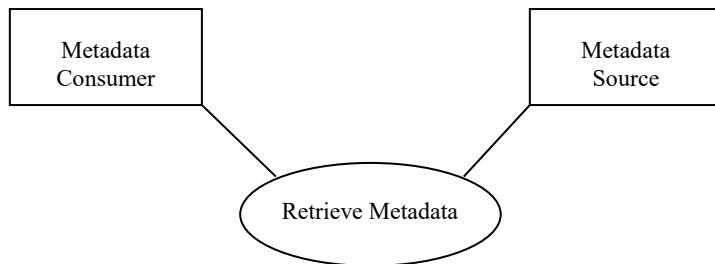
Figure 3.44.2-1: Use Case Diagram

The roles in this transaction are defined in the following table and may be played by the actors shown here:

1055 **Table 3.44.2-1: Actor Roles**

Actor:	Metadata Consumer
Role:	Obtain the metadata of a Data Element from the Metadata Source
Actor:	Metadata Source
Role:	Maintain and provide the metadata definitions of Data Elements

3.44.3 Referenced Standards

- ISO/IEC 11179: Information Technology – Metadata Registries (MDR) Parts 1–6 (2nd Edition).

1060
- IETF RFC2616 HyperText Transfer Protocol HTTP/1.1

- Extensible Markup Language (XML) 1.0 (Second Edition). W3C Recommendation 6 October 2000. http://www.w3.org/TR/REC-xml.

- Web Services Description Language (WSDL) 1.1. W3C Note 15 March 2001. http://www.w3.org/TR/wsdl.

1065
- SOAP 1.2 Second Edition, W3C Recommendation 27 April 2007. http://www.w3.org/TR/soap12-part1

3.44.4 Interaction Diagram
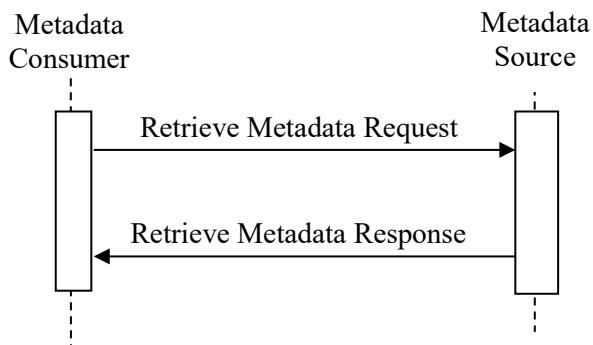
3.44.4.1 Retrieve Metadata Request

1070 #### 3.44.4.1.1 Trigger Events

The Metadata Consumer wants to retrieve a specific Data Element that may be included in study protocol (either as eligibility criteria, or a data element in case report form or in data collection set). The Metadata Consumer knows the ID of the Data Element, either by performing a Retrieve Data Element List [QRPH-43] transaction or by other means not defined by IHE.

1075 #### 3.44.4.1.2 Message Semantics

The Retrieve Metadata Request shall carry the following information presented in Table 3.44.4.1.2-1:

- A required ID that identifies the Data Element.

1080   • A required Registration Authority that indicates the authority who has defined and registered the Data Element to the Metadata Source.

   • An optional version that identifies a specific version of the Data Element. If no version is specified, the Metadata Consumer is requesting the most recent version of the Data Element.

The string data type corresponds to xsd:string.

1085   **Table 3.44.4.1.2-1: Summary of the elements in the Retrieve Metadata Request Message**

Element Name	Optionality	Type	Description
id	R	string	Identifier of the Data Element.
registrationAuthority	R	string	The Authority who has defined and registered the Data Element to the Metadata Source (Examples: CDISC, HITSP, NCI).
version	O	string	Version of the Data Element. If no version is specified, the Metadata Consumer is requesting the most recent version of the Data Element.

Section 3.44.5 describes the protocol requirements and the format of the message in full detail.

3.44.4.1.3 Expected Action

1090   When receiving a Retrieve Metadata Request, a Metadata Source shall generate a Retrieve Metadata Response containing the metadata of the Data Element that corresponds to the request parameters or an error code if the Data Element could not be retrieved. If no version is specified in the Request, then the most recent version shall be returned.

The following error responses may be returned:

1095   1. A SOAP fault, whose code value is NAV, with the reason being: "Unknown Data Element".

   2. A SOAP fault, whose code value is VERUNK, with the reason being: "Version unknown".

3.44.4.1.3.1 XDS or MPQ or XCA Document Type Binding Option

1100   If the Metadata Source claims the XDS Document Type Binding Option or the MPQ Document Type Binding Option or the XCA Document Type Binding Option, it SHALL provide also metadata related to DocumentEntry metadata describing documents storing the Data Element of interest.

If the Metadata Source claims at least one of the three options and the Metadata Consumer does not claim any options or claims an option different to that supported by the Metadata Source, the

1105 latter provides the metadata related to DocumentEntry metadata according to its own option and SHALL not generate any error condition.

Vice-versa if the Metadata Consumer claims at least one of the three options and the Metadata Source does not claim any option, the latter does not provide any metadata related to DocumentEntry metadata and SHALL not generate any error condition.

1110 **3.44.4.2 Retrieve Metadata Response**

3.44.4.2.1 Trigger Events

This message will be triggered by a Retrieve Metadata Request Message.

3.44.4.2.2 Message Semantics

The Retrieve Metadata Response Message shall carry the metadata of the Data Element
1115 presented in Table 3.44.4.2.2-1[7]:

The Optionality Field in Tables 3.44.4.2.2-1 through 3.44.4.2.2-5 can have the following values with their associated meanings:

Value	Meaning
R	Required
R2	Required if the information is available
O	Optional

The string data type corresponds to xsd:string and the date data type corresponds to xsd:date. The
1120 format for xsd:date is YYYY-MM-DD where Y is the year, M is the month, D is the day of month.

Table 3.44.4.2.2-1: Data Element Metadata Summary in the Retrieve Metadata Response Message

Element Name	Optionality	Is Repeatable	Type	Description
id	R	No	string	Identifier of the Data Element. This ID shall be the same as the Data Element ID in the received Retrieve Metadata Request Message.

---

[7] A flattened subset of the metadata element defined in ISO/IEC 11179: Information Technology – Metadata Registries (MDR) Parts 1–6 (2nd Edition). Each data element is composed of an ObjectClass, a property term and a valueDomain triple. See Appendix B for further description.

Element Name	Optionality	Is Repeatable	Type	Description
registrationAuthority	R	No	string	The Authority who has defined and registered the Data Element to the Metadata Source (Examples: CDISC, HITSP, NCI).
version	R	No	string	Version of the Data Element.
displayName	R	No	string	A name that can be used for display purposes
definition	R	No	string	Definition that gives an unambiguous description of the Data Element and its use.
contextualDomain	R2	No	string	The specific domain that indicates the specific domain in which this Data Element is defined (Examples: CDASH, SDTM, HITSP C154). If such a contextualDomain is defined by the registrationAuthority for this Data Element in the metadata registry, then it shall be included in the message.
creationDate	R	No	date	The date that indicates the specific date when this Data Element is created.
effectiveDate	R2	No	date	The date that indicates the specific date when this Data Element becomes effective to be used. In the case that effectiveDate is not available, the creationDate is considered as the date at which the element is effective to be used.
expirationDate	R2	No	date	The date when the Data Element is no longer expected to be used.
revisionDate	R2	No	date	The date when the Data Element is revised.
revisionNote	R2	No	string	Note that indicates the revision reason, and the updates
dataElementConcept	R	No	See Table 3.43.4.2.2-3 for the details of dataElementConcept	The data element concept which is the "concept" part of the data element definition. A Data Element is formed with an association of a dataElementConcept and a valueDomain.

Element Name	Optionality	Is Repeatable	Type	Description
valueDomain	R	No	See Table 3.43.4.2.2-4 for the details of valueDomain	The description of the permissible set of values for the property of the data element definition. Each data element is composed of a dataElementConcept and a valueDomain. See Appendix B for further description.
mappingSpecification	R	Yes	See description	The exact specification to locate the Data Element in a Content Model. If there are multiple mapping specifications, each specification is returned as a separate mappingSpecification. If the Metadata Source claims the XDS or the MPQ or the XCA Document Type Binding Option, the contentModel element shall provide also other metadata as described in Tables 3.44.2.2-7 and 3.44.2.2-8.

Table 3.44.4.2.2-2: mappingSpecification Summary in the Retrieve Metadata Response Message

1125

Element Name	Optionality	Is Repeatable	Type	Description
contentModel	R	No	See description	The Content Model that the Data Element is interrelated with. If the Metadata Source does not claim either the XDS or MPQ or XCA Document Type Binding Option, the contentModel element SHALL comply with the contentModel Summary as described in Tables 3.44.4.2.2-3. If the Metadata Source claims XDS or MPQ or XCA Document Type Binding Option, the contentModel element SHALL comply with the contentModel Summary as described in Tables 3.44.4.2.2-4 and 3.44.2.2-5. In this case the dex:contentModel/@DSoption attribute shall be valued as "true" and the dex:contentModel/@xsi:type attribute shall be "dex:ContentModelTypeDS".
type	R	No	string	Type of the mappingSpecification. The type shall be selected from Mapping Specification Type Value Set (1.3.6.1.4.1.19376.1.7.3.1.1.22.1).

Element Name	Optionality	Is Repeatable	Type	Description
mappingScript	R	No	string	The exact specification to locate the Data Element in a Content Model (Example: XPATH Scripts, SPARQL or SQL queries). The NULL value shall be used if the Metadata Source claims the XDS or MPQ or XCA Document Type Binding Option and the Content Model of clinical documents storing the Data Element is an unstructured document (e.g., for Data Elements available in the unstructured body of pdf documents with formatCode urn:ihe:iti:xds-sd:pdf:2008).

Table 3.44.4.2.2-3: contentModel Summary in the Retrieve Metadata Response Message

Element Name	Optionality	Is Repeatable	Type	Description
id	R	No	string	Identifier for the contentModel. This is the OID of the contentModel. (Example: 2.16.840.1.113883.10.20.1 for ASTM/HL7 CCD)
name	R	No	string	Name of the contentModel. (Example: ASTM/HL7 CCD)

Table 3.44.4.2.2-4: contentModel Summary in the Retrieve Metadata Response Message with XDS or MPQ or XCA Document Type Binding Option

Element Name	Optionality	Is Repeatable	Type	Description
id	R	No	string	Identifier for the contentModel. This is the OID of the contentModel. (Example: 2.16.840.1.113883.10.20.1 for ASTM/HL7 CCD) and it shall be coherent with the information provided by the "formatCode" and "typeCode" elements within the DSMetadata element.
name	R	No	string	Name of the contentModel. (Example: ASTM/HL7 CCD)
DSMetadata	R	No	See description	The DocumenEntry metadata describing the type of documents in the Document Sharing Affinity Domain where the Data Element is stored (see Table 3.44.4.2.2-5 for specifications about this data element).
minCardinality	R2	No	string	Value indicating the minimum number of times the Data Element

Element Name	Optionality	Is Repeatable	Type	Description
				can occur in the specific type of document described by the metadata within the DSMetadata Element. If no value is specified, the Metadata Consumer SHALL assume the value is "0".
maxCardinality	R2	No	string	Value indicating the maximum number of times the Data Element can occur in the specific type of document described by the metadata within the DSMetadata Element. If a Data Element may appear an unlimited number of times, the "unbounded" value shall be used. If no value is specified, the Metadata Consumer SHALL assume the value is "unbounded".

Table 3.44.4.2.2-5: DSMetadata Summary in the Retrieve Metadata Response Message with XDS or MPQ or XCA Document Type Binding Option

1130

Element Name	Optionality	Is Repeatable	Type	Description
homeCommunityID	C (required if the Metadata Source claims the XCA Document Type Binding Option)	No	string	It is the homeCommunityID DocumentEntry metadata describing the Document Sharing AffinityDomain where the type of document storing the Data Element is defined.
classCode	R	No	string	The classCode DocumentEntry metadata related to the type of documents storing the Data Element in the Document Sharing Affinity Domain.
classCodeDisplayName	R	No	string	The classCodeDisplayName DocumentEntry metadata related to the type of documents storing the Data Element in the Document Sharing Affinity Domain.
typeCode	R	No	string	The typeCode DocumentEntry metadata related to the type of documents storing the Data Element in the Document Sharing Affinity Domain.
typeCodeDisplayName	R	No	string	The typeCodeDisplayName DocumentEntry metadata related to the type of documents storing the Data Element in the Document Sharing Affinity Domain.

Element Name	Optionality	Is Repeatable	Type	Description
formatCode	R	No	string	The formatCode DocumentEntry metadata related to the type of documents storing the Data Element in the Document Sharing Affinity Domain.
formatCodeDisplayName	R	No	string	The formatCodeDisplayName DocumentEntry metadata related to the type of documents storing the Data Element in the Document Sharing Affinity Domain.
eventCodeList	R2	Yes	string	The eventCodeList DocumentEntry metadata related to the type of documents storing the Data Element in the Document Sharing Affinity Domain.
eventCodeListDisplayName	R2	Yes	string	The eventCodeListDisplayName DocumentEntry metadata related to the type of documents storing the Data Element in the Document Sharing Affinity Domain.

3.44.4.2.3 Expected Actions

The Metadata Consumer processes the Data Element definition according to its business process logic.

3.44.4.2.3.1 XDS/MPQ/XCA Document Type Binding Option

The Metadata Consumer processes the Data Element definition (with the Document Sharing metadata) according to its business process logic and to grouping functionalities specific for each option it claims.

If the Metadata Source claims the XDS Document Type Binding Option or the MPQ Document Type Binding Option or the XCA Document Type Binding Option and the Metadata Consumer does not claim any options or claims an option different to that supported by the Metadata Source, the latter provides also metadata related to DocumentEntry metadata according to its own option: the Metadata Consumer SHALL not generate any error condition and simply SHALL ignore the extra metadata that it does not know.

If the Metadata Consumer claims at least one of the three options and the Metadata Source does not claim any option, the latter does not provide any metadata related to DocumentEntry metadata: the Metadata Consumer SHALL not generate any error condition.

3.44.5 Protocol Requirements

The protocol for the Retrieve Metadata transaction is based on SOAP 1.2. The relevant XML namespace definitions can be seen in Table 3.44.5-1 WSDL Namespace Definitions.

1150

Table 3.44.5-1: WSDL Namespace Definitions.

soap12	http://schemas.xmlsoap.org/wsdl/soap12/
wsdl	http://schemas.xmlsoap.org/wsdl/
xsd	http://www.w3.org/2001/XMLSchema
dex	urn:ihe:qrph:dex:2013

These are the requirements for the Retrieve Metadata transaction presented in the order in which they would appear in the WSDL definition (see Appendix A for an informative WSDL):

The following types shall be included (xsd:include) in the /definitions/types section:

1155   namespace="urn:ihe:qrph:dex:2013", schema="DEX.xsd"

The /definitions/message/part/@element attribute of the Retrieve Metadata Request message shall be defined as "dex:RetrieveMetadataRequest"

The /definitions/message/part/@element attribute of the Retrieve Metadata Response message shall be defined as "dex:RetrieveMetadataResponse"

1160   The /definitions/portType/operation/input/@message attribute for the RetrieveMetadata Operation shall be defined as "dex:RetrieveMetadataRequestMessage"

The /definitions/portType/operation/output/@message attribute for the RetrieveMetadata Operation shall be defined as "dex:RetrieveMetadataResponseMessage"

The

1165   /definitions/binding/operation/soap12:operation/@soapAction attribute shall be defined as "urn:ihe:qrph:dex:2013:RetrieveMetadata"

These are the requirements that affect the wire format of the SOAP message. The other WSDL properties are only used within the WSDL definition and do not affect interoperability. Full sample request and response messages are in QRPH: 3.44.5.1 and QRPH: 3.44.5.2.

1170   A full XML Schema Document for the DEX types is available in Appendix A.

The protocol requirements for the request and response messages are given in the following subsections.

3.44.5.1 Retrieve Metadata Request

Within the request message payload the <dex:RetrieveMetadataRequest/> element is defined as:

1175   • A required /dex:RetrieveMetadataRequest/dex:id element that contains the ID of the requested Data Element within the Metadata Source

• A required /dex:RetrieveMetadataRequest/dex:registrationAuthority element with type "xsd:string"

• An optional /dex:RetrieveMetadataRequest/dex:version element with type "xsd:string"

A sample Retrieve Metadata SOAP Request is given as follows:

```
<soap:Envelope xmlns:soap="http://schemas.xmlsoap.org/soap/envelope/"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xmlns:wsa=http://www.w3.org/2005/08/addressing

 xmlns:xsd="http://www.w3.org/2001/XMLSchema">

  <soap:Header>

       <wsa:MessageID>urn:uuid:f43f7bda-a5f9-42b1-b8dc-e78be1a2a183</wsa:MessageID>

       <wsa:Action>urn:ihe:qrph:dex:2013:RetrieveMetadata</wsa:Action>

  </soap:Header>

  <soap:Body>

       <dex:RetrieveMetadataRequest xmlns:dex="urn:ihe:qrph:dex:2013">

            <dex:id>6fbbd463-7de1-4ebc-85f6-76b84bab678b</dex:id>

            <dex:registrationAuthority>CDISC</dex:registrationAuthority>

            <dex:version>0.1</dex:version>

</dex:RetrieveMetadataRequest>

  </soap:Body>

</soap:Envelope>
```

3.44.5.2 Retrieve Metadata Response

Metadata Source shall include within the response message payload for the SOAP Binding Option the <dex:RetrieveMetadataResponse/> element which contains:

- A required /dex:RetrieveMetadataResponse/dex:DataElement element, containing

  o a required /dex:RetrieveMetadataResponse/dex:DataElement/dex:id element with type "xsd:string"

  o a required /dex:RetrieveMetadataResponse/dex:DataElement/dex:registrationAuthority element with type "xsd:string"

  o a required /dex:RetrieveMetadataResponse/dex:DataElement/dex:version element with type "xsd:string"

  o a required /dex:RetrieveMetadataResponse/dex:DataElement/dex:displayName element with type "xsd:string"

  o a required /dex:RetrieveMetadataResponse/dex:DataElement/dex:definition element with type "xsd:string"

  o an optional /dex:RetrieveMetadataResponse/dex:DataElement/dex:contextualDomain element with type "xsd:string" (If such a contextualDomain is defined by the registrationAuthority for this Data Element in the metadata registry, then it shall be included in the message.)

- o a required /dex:RetrieveMetadataResponse/dex:DataElement/dex:creationDate element with type "xsd:date"

1220
- o an optional /dex:RetrieveMetadataResponse/dex:DataElement/dex:effectiveDate element with type "xsd:date" (Required if available)

- o an optional /dex:RetrieveMetadataResponse/dex:DataElement/dex:expirationDate element with type "xsd:date" (Required if available)

- o an optional /dex:RetrieveMetadataResponse/dex:DataElement/dex:revisionDate element with type "xsd:date" (Required if available)

1225
- o an optional /dex:RetrieveMetadataResponse/dex:DataElement/dex:revisionNote element with type "xsd:string" a required (Required if available)

- o a required /dex:RetrieveMetadataResponse/dex:DataElement/dex:dataElementConcept containing

1230
  - ▪ a required /dex:RetrieveMetadataResponse/dex:DataElement/dex:dataElementConcept/dex:id with type "xsd:string"

  - ▪ a required /dex:RetrieveMetadataResponse/dex:DataElement/dex:dataElementConcept/dex:displayName element with type "xsd:string"

1235
  - ▪ an optional /dex:RetrieveMetadataResponse/dex:DataElement/dex:dataElementConcept/dex:objectClass element with type "xsd:string"

1240
  - ▪ an optional /dex:RetrieveMetadataResponse/dex:DataElement/dex:dataElementConcept/dex:property element with type "xsd:string"

- o a required /dex:RetrieveMetadataResponse/dex:DataElement/dex:valueDomain element containing

1245
  - ▪ a required /dex:RetrieveMetadataResponse/dex:DataElement/dex:valueDomain/dex:dataType element with type "xsd:string"

  - ▪ an optional /dex:RetrieveMetadataResponse/dex:DataElement/dex:valueDomain/dex:unitOfMeasure element with type "xsd:string" (Required if available)

1250
  - ▪ an optional /dex:RetrieveMetadataResponse/dex:DataElement/dex:valueDomain/dex:valueSet element containing (Required if available)

- a required /dex:RetrieveMetadataResponse/dex:DataElement/dex:valueDomain/dex:valueSet/dex:id element with type "xsd:string"

- a required /dex:RetrieveMetadataResponse/dex:DataElement/dex:valueDomain/dex:valueSet/dex:version element with type "xsd:string"

- an optional /dex:RetrieveMetadataResponse/dex:DataElement/dex:valueDomain/dex:valueSet/dex:displayName element with type "xsd:string"

  o one or more /dex:RetrieveMetadataResponse/dex:DataElement/dex:MappingSpecification element containing

    ▪ a required /dex:RetrieveMetadataResponse/dex:DataElement/dex:MappingSpecification/dex:contentModel element containing

      - a required /dex:RetrieveMetadataResponse/dex:DataElement/dex:MappingSpecification/dex:contentModel/dex:id element with type "xsd:string"

      - a required /dex:RetrieveMetadataResponse/dex:DataElement/dex:MappingSpecification/dex:contentModel/dex:name element with type "xsd:string"

      If the Metadata Source claims the XDS Document Type Binding Option or the MPQ Document Type Binding Option or the XCA Document Type Binding Option, the dex:contentModel/@DSoption attribute shall be valued as "true" and the dex:contentModel/@xsi:type attribute shall be "dex:ContentModelTypeDS". In addition to that, the dex:contentModel element shall have the following child elements:

      - a required /dex:RetrieveMetadataResponse/dex:DataElement/dex:MappingSpecification/dex:contentModel/dex:DSMetadata containing:

        - a conditional /dex:RetrieveMetadataResponse/dex:DataElement/dex:MappingSpecification/dex:contentModel/ dex:DSMetadata/dex:homeCommunityID element with type "xsd:string" (required if the Metadata Source claims the XCA Document Type Binding Option)

        - a required /dex:RetrieveMetadataResponse/dex:DataElement/dex:MappingSpecificat

1290

ion/dex:contentModel/ dex:DSMetadata/dex:classCode element with type "xsd:string"

- a required /dex:RetrieveMetadataResponse/dex:DataElement/dex:MappingSpecificat ion/dex:contentModel/ dex:DSMetadata/dex:classCodeDisplayName element with type "xsd:string"

1295

- a required /dex:RetrieveMetadataResponse/dex:DataElement/dex:MappingSpecificat ion/dex:contentModel/ dex:DSMetadata/dex:typeCode element with type "xsd:string"

1300

- a required /dex:RetrieveMetadataResponse/dex:DataElement/dex:MappingSpecificat ion/dex:contentModel/ dex:DSMetadata/dex:typeCodeDisplayName element with type "xsd:string"

- a required /dex:RetrieveMetadataResponse/dex:DataElement/dex:MappingSpecificat ion/dex:contentModel/ dex:DSMetadata/dex:formatCode element with type "xsd:string"

1305

- a required /dex:RetrieveMetadataResponse/dex:DataElement/dex:MappingSpecificat ion/dex:contentModel/ dex:DSMetadata/dex:formatCodeDisplayName element with type "xsd:string"

1310

- an optional /dex:RetrieveMetadataResponse/dex:DataElement/dex:MappingSpecificat ion/dex:contentModel/ dex:DSMetadata/dex:eventCodeList element with type "xsd:string" (Required if in the Document Sharing Affinity Domain the eventCodeList DocumentEntry metadata has a value for this specific document type)

1315

- an optional /dex:RetrieveMetadataResponse/dex:DataElement/dex:MappingSpecificat ion/dex:contentModel/ dex:DSMetadata/dex:eventCodeListDisplayName element with type "xsd:string" (Required if in the Document Sharing Affinity Domain the eventCodeList DocumentEntry metadata has a value for this specific document type)

1320

- an optional /dex:RetrieveMetadataResponse/dex:DataElement/dex:MappingSpecification/ dex:contentModel/dex:minCardinality element with type "xsd:string" (Required if available)

1325

- an optional /dex:RetrieveMetadataResponse/dex:DataElement/dex:MappingSpecification/dex:contentModel/dex:maxCardinality element with type "xsd:string" (Required if available)

1330

  - a required /dex:RetrieveMetadataResponse/dex:DataElement/dex:MappingSpecification/dex:type element with type "xsd:string"

1335

  - a required /dex:RetrieveMetadataResponse/dex:DataElement/dex:MappingSpecification/dex:mappingScript element with type "xsd:string"

A sample Retrieve Metadata SOAP Response is given as follows:

```
1340   <soap:Envelope xmlns:soap="http://schemas.xmlsoap.org/soap/envelope/"
       xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
       xmlns:wsa="http://www.w3.org/2005/08/addressing" xmlns:xsd="http://www.w3.org/2001/XMLSchema">

         <soap:Header>

               <wsa:Action>urn:ihe:qrph:dex:2013:RetrieveMetadataResponse</wsa:Action>

1345          <wsa:RelatesTo>urn:uuid:f43f7bda-a5f9-42b1-b8dc-e78be1a2a183</wsa:RelatesTo>

         </soap:Header>

         <soap:Body>

               <dex:RetrieveMetadataResponse xsi:schemaLocation="urn:ihe:qrph:dex:2013 dex.xsd"
       xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns:dex="urn:ihe:qrph:dex:2013">

1350              <dex:DataElement>

                       <dex:id>6fbbd463-7de1-4ebc-85f6-76b84bab678b</dex:uuid>

                       <dex:registrationAuthority>CDISC</dex:registrationAuthority>

                       <dex:version>0.1</dex:version>

                       <dex:displayName>DMETHNIC</dex:displayName>

1355                  <dex:definition>A social group characterized by a distinctive social and
       cultural tradition maintained from generation to generation, a common history and origin and a
       sense of identification with the group; members of the group have distinctive features in their
       way of life, shared experiences and often a common genetic heritage; these features may be
       reflected in their experience of health and disease</dex:definition>

1360                  <dex:contextualDomain>CDASH</dex:contextualDomain>

                       <dex:creationDate>2010-01-01</dex:creationDate>

                       <dex:effectiveDate>2010-02-01</dex:effectiveDate>

                       <dex:expirationDate>2020-01-01</dex:expirationDate>

                       <dex:dataElementConcept>

1365                      <dex:id>2145698</dex:id>

                           <dex:displayName>ETHNICITY</dex:displayName>
                           <dex:objectClass>DM</dex:objectClass>

                           <dex:property>ETHNIC</dex:property>

                       </dex:dataElementConcept>

1370                  <dex:valueDomain>

                           <dex:dataType>xsd:string</dex:dataType>

                           <dex:valueSet>

                               <id>2.16.840.1.114222.4.11.837</id>

                               <version>1</version>

1375                          <displayName>Ethnicity group</displayName>

                           </dex:valueSet>

                       </dex:valueDomain>

                       <dex:mappingSpecification>

                           <dex:contentModel>

1380                          <dex:id>2.16.840.1.113883.10.20.1</dex:id>

                               <dex:name>HL7 CCD</dex:name>

                           </dex:contentModel>
```

```
                          <dex:type>XPATH</dex:type>

1385      <dex:mappingScript>./ClinicalDocument/recordTarget/patientRole/patient/ethnicGroupCode</dex:map
      pingScript>

                        </dex:mappingSpecification>

                </dex:DataElement>

</dex:RetrieveMetadataResponse>

1390    </soap:Body>

</soap:Envelope>
```

A sample Retrieve Metadata SOAP Response with XDS or MPQ or XCA Document Type Binding Option is given as follows:

1395

```
<soap:Envelope xmlns:soap="http://schemas.xmlsoap.org/soap/envelope/"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xmlns:wsa="http://www.w3.org/2005/08/addressing" xmlns:xsd="http://www.w3.org/2001/XMLSchema">
    <soap:Header>
        <wsa:Action>urn:ihe:qrph:dex:2013:RetrieveMetadataResponse</wsa:Action>
        <wsa:RelatesTo>urn:uuid:f43f7bda-a5f9-42b1-b8dc-e78be1a2a183</wsa:RelatesTo>
    </soap:Header>
    <soap:Body>
        <dex:RetrieveMetadataResponse xsi:schemaLocation="urn:ihe:qrph:dex:2013 dex.xsd"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns:dex="urn:ihe:qrph:dex:2013">
            <dex:DataElement>
                <dex:id>6fbbd463-7de1-4ebc-85f6-76b84bab678b</dex:id>
                    <dex:registrationAuthority>CDISC</dex:registrationAuthority>
                    <dex:version>0.1</dex:version>
                    <dex:displayName>DMETHNIC</dex:displayName>
                    <dex:definition>A social group characterized by a distinctive social and
cultural tradition maintained from generation to generation, a common history and origin and a
sense of identification with the group; members of the group have distinctive features in their
way of life, shared experiences and often a common genetic heritage; these features may be
reflected in their experience of health and disease</dex:definition>
                    <dex:contextualDomain>CDASH</dex:contextualDomain>
                    <dex:creationDate>2010-01-01</dex:creationDate>
                    <dex:effectiveDate>2010-02-01</dex:effectiveDate>
                    <dex:expirationDate>2020-01-01</dex:expirationDate>
                    <dex:dataElementConcept>
                        <dex:id>2145698</dex:id>
                        <dex:displayName>ETHNICITY</dex:displayName>
                        <dex:objectClass>DM</dex:objectClass>
                        <dex:property>ETHNIC</dex:property>
                    </dex:dataElementConcept>
                    <dex:valueDomain>
                        <dex:dataType>xsd:string</dex:dataType>
                        <dex:valueSet>
                            <dex:id>2.16.840.1.114222.4.11.837</dex:id>
                            <dex:version>1</dex:version>
                            <dex:displayName>Ethnicity group</dex:displayName>
                        </dex:valueSet>
                    </dex:valueDomain>
                    <dex:mappingSpecification>
                        <dex:contentModel DSoption="true" xsi:type="dex:ContentModelTypeDS">
                            <dex:id>1.3.6.1.4.1.19376.1.3.3</dex:id>
                            <dex:name>Laboratory Report</dex:name>
                            <dex:DSMetadata>

<dex:homeCommunityID>urn:oid:1.19.6.24.109.42.1.3</dex:homeCommunityID>
                                <dex:classCode>11502-2</dex:classCode>
                                <dex:classCodeDisplayName>Laboratory
Report</dex:classCodeDisplayName>
                                <dex:typeCode>18723-7</dex:typeCode>
                                <dex:typeCodeDisplayName>Hematological Laboratory
Report</dex:typeCodeDisplayName>
                                <dex:formatCode>urn:ihe:lab:xd-lab:2008</dex:formatCode>
                                <dex:formatCodeDisplayName>CDA Laboratory
Report</dex:formatCodeDisplayName>
                                <dex:eventCodeList>Adult_H_Lab_Report</dex:eventCodeList>
                                <dex:eventCodeListDisplayName>Adult Hematological Laboratory
Report</dex:eventCodeListDisplayName>
                            </dex:DSMetadata>
                            <dex:minCardinality>0</dex:minCardinality>
                            <dex:maxCardinality>1</dex:maxCardinality>
                        </dex:contentModel>
                        <dex:type>XPATH</dex:type>

<dex:mappingScript>./ClinicalDocument/recordTarget/patientRole/patient/ethnicGroupCode</dex:mappingScript>
```

```
                        </dex:mappingSpecification>
                    <dex:mappingSpecification>
                        <dex:contentModel DSoption="true" xsi:type="dex:ContentModelTypeDS">
                            <dex:id>1.3.6.1.4.1.19376.1.5.3.1.1.4</dex:id>
                            <dex:name>IHE PCC Discharge Summary</dex:name>
                            <dex:DSMetadata>

<dex:homeCommunityID>urn:oid:1.19.6.24.109.42.1.3</dex:homeCommunityID>
                                <dex:classCode>34105-7</dex:classCode>
                                <dex:classCodeDisplayName>Hospital Discharge
Summary</dex:classCodeDisplayName>
                                <dex:typeCode>34106-5</dex:typeCode>
                                <dex:typeCodeDisplayName>Physician Hospital Discharge
Summary</dex:typeCodeDisplayName>
                                <dex:formatCode>urn:ihe:pcc:xds-ms:2007</dex:formatCode>
                                <dex:formatCodeDisplayName>Discharge
Summary</dex:formatCodeDisplayName>
                            </dex:DSMetadata>
                            <dex:minCardinality>0</dex:minCardinality>
                            <dex:maxCardinality>1</dex:maxCardinality>
                        </dex:contentModel>
                        <dex:type>XPATH</dex:type>

<dex:mappingScript>./ClinicalDocument/recordTarget/patientRole/patient/ethnicGroupCode</dex:mappi
ngScript>
                    </dex:mappingSpecification>
                </dex:DataElement>
            </dex:RetrieveMetadataResponse>
        </soap:Body>
</soap:Envelope>
```

3.44.6 Security Considerations

The Retrieve Metadata [QRPH-44] transaction does not contain any patient health information
(PHI) and does not require any of the methods that protect PHI, such as TLS or auditing required
by the ITI ATNA Profile.

Currently there are no use cases requiring authentication, authorization and auditing, but a risk
analysis should be carried out per implementation and if needed.

Appendices

Appendix A – Schema and WSDL

```
<?xml version="1.0" encoding="UTF-8"?>
<!--
XML Schema for IHE Data Element Exchange Profile (DEX) with XDS/MPQ/XCA Document Type Binding
Option
for use in WSDL definitions.
-->
<xsd:schema xmlns="urn:ihe:qrph:dex:2013" xmlns:dex="urn:ihe:qrph:dex:2013"
xmlns:xsd="http://www.w3.org/2001/XMLSchema" xmlns:wsa="http://www.w3.org/2005/08/addressing"
targetNamespace="urn:ihe:qrph:dex:2013" elementFormDefault="qualified"
attributeFormDefault="unqualified">

  <xsd:element name="RetrieveMetadataRequest" type="dex:RetrieveMetadataRequestType"/>
  <xsd:element name="RetrieveMetadataResponse" type="dex:RetrieveMetadataResponseType"/>
  <xsd:element name="RetrieveDataElementListRequest"
type="dex:RetrieveDataElementListRequestType"/>
  <xsd:element name="RetrieveDataElementListResponse"
type="dex:RetrieveDataElementListResponseType"/>

  <xsd:complexType name="RetrieveMetadataRequestType">
    <xsd:sequence>
      <xsd:element name="id" type="xsd:string"/>
      <xsd:element name="registrationAuthority" type="xsd:string"/>
      <xsd:element name="version" type="xsd:string" minOccurs="0"/>
    </xsd:sequence>
  </xsd:complexType>

  <xsd:complexType name="RetrieveMetadataResponseType">
    <xsd:sequence>
      <xsd:element name="DataElement" type="dex:DataElementType"/>
    </xsd:sequence>
  </xsd:complexType>

  <xsd:complexType name="RetrieveDataElementListRequestType">
    <xsd:sequence>
      <xsd:element name="id" type="xsd:string" minOccurs="0"/>
      <xsd:element name="registrationAuthorityContains" type="xsd:string" minOccurs="0"/>
      <xsd:element name="version" type="xsd:string" minOccurs="0"/>
      <xsd:element name="displayNameContains" type="xsd:string" minOccurs="0"/>
      <xsd:element name="definitionContains" type="xsd:string" minOccurs="0"/>
      <xsd:element name="contextualDomainContains" type="xsd:string" minOccurs="0"/>
      <xsd:element name="creationDateBefore" type="xsd:date" minOccurs="0"/>
      <xsd:element name="creationDateAfter" type="xsd:date" minOccurs="0"/>
      <xsd:element name="effectiveDateBefore" type="xsd:date" minOccurs="0"/>
      <xsd:element name="effectiveDateAfter" type="xsd:date" minOccurs="0"/>
      <xsd:element name="expirationDateBefore" type="xsd:date" minOccurs="0"/>
      <xsd:element name="expirationDateAfter" type="xsd:date" minOccurs="0"/>
      <xsd:element name="revisionDateBefore" type="xsd:date" minOccurs="0"/>
      <xsd:element name="revisionDateAfter" type="xsd:date" minOccurs="0"/>
      <xsd:element name="decID" type="xsd:string" minOccurs="0"/>
      <xsd:element name="decDisplayNameContains" type="xsd:string" minOccurs="0"/>
      <xsd:element name="decObjectClassContains" type="xsd:string" minOccurs="0"/>
      <xsd:element name="decPropertyContains" type="xsd:string" minOccurs="0"/>
      <xsd:element name="dataTypeContains" type="xsd:string" minOccurs="0"/>
      <xsd:element name="valueSetID" type="dex:valueSetIdType" minOccurs="0"/>
    </xsd:sequence>
  </xsd:complexType>

  <xsd:complexType name="RetrieveDataElementListResponseType">
```

```
1560        <xsd:sequence>
              <xsd:element name="DataElementSummary" type="dex:DataElementSummaryType" minOccurs="0"
         maxOccurs="unbounded"/>
            </xsd:sequence>
          </xsd:complexType>
1565
          <xsd:complexType name="DataElementSummaryType">
            <xsd:sequence>
              <xsd:element name="id" type="xsd:string"/>
              <xsd:element name="registrationAuthority" type="xsd:string"/>
1570          <xsd:element name="version" type="xsd:string"/>
              <xsd:element name="displayName" type="xsd:string"/>
              <xsd:element name="definition" type="xsd:string"/>
              <xsd:element name="contextualDomain" type="xsd:string"/>
              <xsd:element name="creationDate" type="xsd:date"/>
1575          <xsd:element name="effectiveDate" type="xsd:date" minOccurs="0"/>
              <xsd:element name="expirationDate" type="xsd:date" minOccurs="0"/>
              <xsd:element name="revisionDate" type="xsd:date" minOccurs="0"/>
              <xsd:element name="revisionNote" type="xsd:string" minOccurs="0"/>
              <xsd:element name="dataElementConcept" type="dex:DataElementConceptType" />
1580          <xsd:element name="valueDomain" type="dex:ValueDomainType"/>
            </xsd:sequence>
          </xsd:complexType>

          <xsd:complexType name="DataElementType">
1585        <xsd:complexContent>
              <xsd:extension base="dex:DataElementSummaryType">
                <xsd:sequence>
                  <xsd:element name="mappingSpecification" type="dex:MappingSpecificationType"
         minOccurs="0" maxOccurs="unbounded"/>
1590            </xsd:sequence>
              </xsd:extension>
            </xsd:complexContent>
          </xsd:complexType>

1595      <xsd:complexType name="DataElementConceptType">
            <xsd:sequence>
              <xsd:element name="id" type="xsd:string"/>
              <xsd:element name="displayName" type="xsd:string"/>
              <xsd:element name="objectClass" type="xsd:string" minOccurs="0"/>
1600          <xsd:element name="property" type="xsd:string" minOccurs="0"/>
            </xsd:sequence>
          </xsd:complexType>

          <xsd:complexType name="ValueDomainType">
1605        <xsd:sequence>
              <xsd:element name="dataType" type="xsd:string"/>
              <xsd:element name="unitOfMeasure" type="xsd:string" minOccurs="0"/>
              <xsd:element name="valueSet" type="dex:ValueSetType" minOccurs="0"/>
            </xsd:sequence>
1610      </xsd:complexType>

          <xsd:complexType name="ValueSetType">
            <xsd:sequence>
              <xsd:element name="id" type="dex:valueSetIdType"/>
1615          <xsd:element name="version" type="xsd:string"/>
              <xsd:element name="displayName" type="xsd:string" minOccurs="0"/>
            </xsd:sequence>
          </xsd:complexType>

1620      <xsd:simpleType name="valueSetIdType">
            <xsd:restriction base="xsd:string">
              <xsd:pattern value="[0-2](\.(0|[1-9][0-9]*))*"/>
            </xsd:restriction>
          </xsd:simpleType>
```

```
1625      <xsd:complexType name="MappingSpecificationType">
            <xsd:sequence>
              <xsd:element name="contentModel" type="ContentModelType"/>
              <xsd:element name="type" type="xsd:string"/>
1630          <!-- This refers to a valueset identified by 1.3.6.1.4.1.19376.1.7.3.1.1.22.1 -->
              <xsd:element name="mappingScript" type="xsd:string"/>
            </xsd:sequence>
          </xsd:complexType>

1635      <xsd:complexType name="ContentModelType">
            <xsd:sequence>
              <xsd:element name="id" type="xsd:string"/>
              <xsd:element name="name" type="xsd:string"/>
            </xsd:sequence>
1640      </xsd:complexType>

          <xsd:complexType name="ContentModelTypeDS">
            <xsd:complexContent>
              <xsd:extension base="ContentModelType">
1645            <xsd:sequence>
                  <xsd:element name="DSMetadata" type="dex:DSMetadataType"/>
                  <xsd:element name="minCardinality" type="xsd:string" minOccurs="0"/>
                  <xsd:element name="maxCardinality" type="xsd:string" minOccurs="0"/>
                </xsd:sequence>
1650            <xsd:attribute name="DSoption" type="xsd:boolean" use="required" fixed="true"/>
              </xsd:extension>
            </xsd:complexContent>
          </xsd:complexType>

1655      <xsd:complexType name="DSMetadataType">
            <xsd:sequence>
              <xsd:element name="homeCommunityID" type="xsd:string" minOccurs="0"/>
              <!-- Required if the homeCommunityID DocumentEntry metadata is computed/assigned in the XDS
          Affinity Domain-->
1660          <xsd:element name="classCode" type="xsd:string"/>
              <xsd:element name="classCodeDisplayName" type="xsd:string"/>
              <xsd:element name="typeCode" type="xsd:string"/>
              <xsd:element name="typeCodeDisplayName" type="xsd:string"/>
              <xsd:element name="formatCode" type="xsd:string"/>
1665          <xsd:element name="formatCodeDisplayName" type="xsd:string"/>
              <xsd:element name="eventCodeList" type="xsd:string" minOccurs="0" maxOccurs="unbounded"/>
              <!-- Required if in the Affinity Domain the eventCodeList DocumentEntry metadata has a
          value for this specific document type -->
              <xsd:element name="eventCodeListDisplayName" type="xsd:string" minOccurs="0"
1670      maxOccurs="unbounded"/>
              <!-- Required if in the Affinity Domain the eventCodeList DocumentEntry metadata has a
          value for this specific document type -->
            </xsd:sequence>
          </xsd:complexType>
1675
      </xsd:schema>


      <?xml version="1.0" encoding="UTF-8"?>

      <!--
1680        IHE Data Element Exchange Profile (DEX) WSDL definition.

      -->

      <wsdl:definitions

            xmlns="urn:ihe:qrph:dex:2013"

            targetNamespace="urn:ihe:qrph:dex:2013"
```

```
1685        xmlns:dex="urn:ihe:qrph:dex:2013"
            xmlns:wsdl="http://schemas.xmlsoap.org/wsdl/"
            xmlns:soap12="http://schemas.xmlsoap.org/wsdl/soap12/"
            xmlns:http="http://schemas.xmlsoap.org/wsdl/http/"
            xmlns:xsd="http://www.w3.org/2001/XMLSchema"
1690        xmlns:wsa="http://www.w3.org/2005/08/addressing">


            <wsdl:types>
                    <xsd:schema targetNamespace="urn:ihe:qrph:dex:2013">
                            <xsd:include schemaLocation="DEX.xsd"/>
1695                </xsd:schema>
            </wsdl:types>


            <wsdl:message name="RetrieveMetadataRequestMessage">
                    <wsdl:part name="body" element="dex:RetrieveMetadataRequest"/>
1700        </wsdl:message>
            <wsdl:message name="RetrieveMetadataResponseMessage">
                    <wsdl:part name="body" element="dex:RetrieveMetadataResponse"/>
            </wsdl:message>
            <wsdl:message name="RetrieveDataElementListRequestMessage">
1705                <wsdl:part name="body" element="dex:RetrieveDataElementListRequest"/>
            </wsdl:message>
            <wsdl:message name="RetrieveDataElementListResponseMessage">
                    <wsdl:part name="body" element="dex:RetrieveDataElementListResponse"/>
            </wsdl:message>
1710


            <wsdl:portType name="DataElementExchangePortType">
                    <wsdl:operation name="RetrieveMetadata">
                            <wsdl:input message="dex:RetrieveMetadataRequestMessage"/>
1715                        <wsdl:output message="dex:RetrieveMetadataResponseMessage"/>
                    </wsdl:operation>
                    <wsdl:operation name="RetrieveDataElementList">
                            <wsdl:input message="dex:RetrieveDataElementListRequestMessage"/>
                            <wsdl:output message="dex:RetrieveDataElementListResponseMessage"/>
1720                </wsdl:operation>


            </wsdl:portType>


            <wsdl:binding name="DataElementExchangeBinding" type="dex:DataElementExchangePortType">
```

```
1725          <soap12:binding style="document"
transport="http://schemas.xmlsoap.org/soap/http"/>
              <wsdl:operation name="RetrieveMetadata">
                   <soap12:operation soapAction="urn:ihe:qrph:dex:2013:RetrieveMetadata"/>
                   <wsdl:input>
1730                    <soap12:body use="literal"/>
                   </wsdl:input>
                   <wsdl:output>
                        <soap12:body use="literal"/>
                   </wsdl:output>
1735          </wsdl:operation>
              <wsdl:operation name="RetrieveDataElementList">
                   <soap12:operation
soapAction="urn:ihe:qrph:dex:2013:RetrieveDataElementList"/>
                   <wsdl:input>
1740                    <soap12:body use="literal"/>
                   </wsdl:input>
                   <wsdl:output>
                        <soap12:body use="literal"/>
                   </wsdl:output>
1745          </wsdl:operation>


        </wsdl:binding>


        <wsdl:service name="DataElementExchangeService">
1750          <wsdl:documentation>SOAP Web Service for IHE Data Element Exchange
Profile</wsdl:documentation>
              <wsdl:port name="DataElementExchangePort"
binding="dex:DataElementExchangeBinding">
                   <soap12:address/>
1755          </wsdl:port>
        </wsdl:service>


</wsdl:definitions>
```

1760 ## Appendix B – Informative Appendix on ISO/IEC 11179 Data Element Definition

ISO/IEC 11179 (Part 3 of the standard) provides a generic metamodel that enables the definition of any data element model. In Figure B-1, decomposition of a data element is presented according to the metamodel of ISO/IEC 11179. Please note that this figure corresponds to a very

1765 small part of the metamodel exposed by the ISO standard. Apart from this decomposition, the metamodel includes the machinery to manage the administration and identification, different contexts, naming and definition, and classification of data elements.
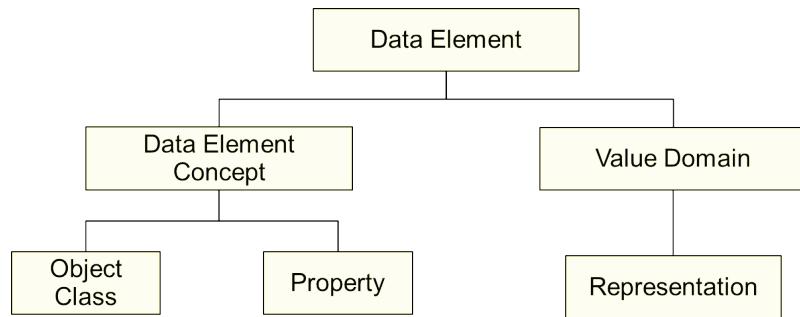
$$\left(\frac{Object}{Class} + Property = \frac{Data\ Element}{Concept}\right) + \frac{Value}{Domain} = \frac{Data}{Element}$$

1770 **Figure B-1: Decomposition of a data element according to ISO/IEC 11179**

Figure B-2 illustrates the decomposition of "Person.DateOfBirth.Date", which is a simple data element, according to the ISO/IEC 11179 metamodel.
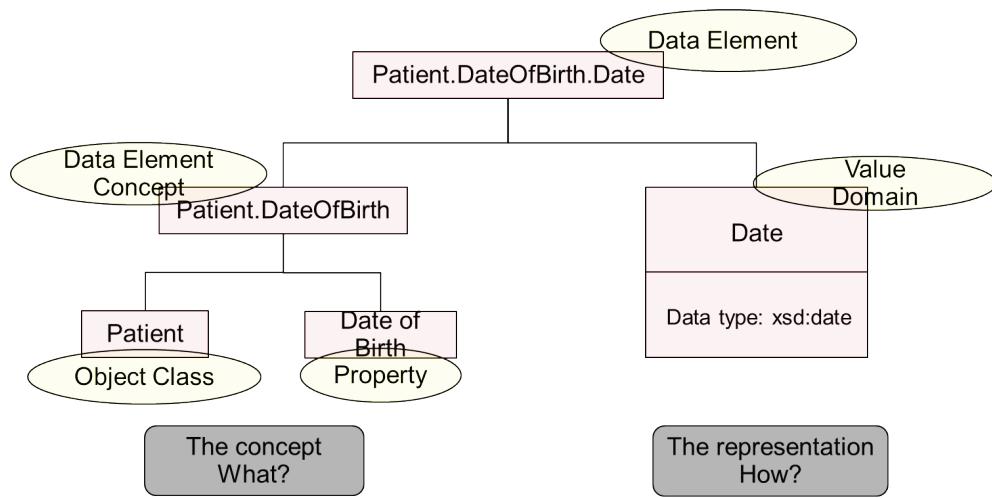
1775

Figure B-2: An example of decomposition of a Data Element: Patient.DateOfBirth.Date

As presented in Figure B-2, the concept of the data element and the representation are separate in the metamodel. These are modeled through Data Element Concepts and Value Domains respectively. A Data Element Concept is further decomposed into an Object Class and a
1780   Property. In the given example, "Patient" is the Object Class and "Date of Birth" is the property together which constitute the concept of "Patient.DateOfBirth". This is the concept of the data element regardless of its representation which can be dictated through a Value Domain. It is important to notice that the metamodel of ISO/IEC 11179 inherently supports the re-use of resources. For example, the "Patient" Object Class can be re-used while forming the
1785   "Patient.Address" data element concept with the use of "Address" property. Moreover, the "Address" property can be re-used in several other data elements such as "HealthcareProvider.Address.Address".

Appendix C – Specifications of the Value Sets used in the DEX Profile

C.1 Mapping Specification Type Codes

C.1.1 Metadata

1790

Metadata Element	Definition	Description
Identifier	This is the unique identifier of the value set	1.3.6.1.4.1.19376.1.7.3.1.1.22.1
Name	This is the name of the value set	Mapping Specification Type Value Set
Source	This is the source of the value set, identifying the originator or publisher of the information	IHE Quality Research and Public Health Domain
Purpose	Brief description about the general purpose of the value set	To reflect the type of the mapping script
Definition	A text definition describing how concepts in the value set were selected	Extensional definition: The value set was constructed by enumerating the possible mapping script types
Source URI	Most sources also have a URL or document URI that provides further details regarding the value set.	-None
Version	A string identifying the specific version of the value set.	Version 1.0
Status	Active (Current) or Inactive	Active
Effective Date	The date when the value set is expected to be effective	5/2/2013
Expiration Date	The date when the value set is no longer expected to be used	N/A
Creation Date	The date of creation of the value set	5/2/2013
Revision Date	The date of revision of the value set	N/A
Groups	The identifiers of the groups that include this value set. A group may also have an OID assigned.	IHE DEX

C.1.2 Mapping Specification Type Value Set Table

Value Set	1.3.6.1.4.1.19376.1.7.3.1.1.22.1	
Vocabulary	-	
Data Element	**Description**	
XPATH	XML Path Language. XPath is a language that describes a way to locate and process items in Extensible Markup Language (XML) documents by using an addressing syntax based on a path through the document's logical structure or hierarchy.	

SQL	Structured Query Language. An industry-standard language for creating, updating and, querying relational database management systems
SPARQL	Simple Protocol and RDF Query Language. SPARQL is a standard query language and data access protocol for use with the Resource Description Framework (RDF) data model.
FHIR Query	A FHIR®[8] Resource Query with a set of parameters (http://www.hl7.org/implement/standards/fhir/query.html)
NA	Not Applicable: Value to be used if the Metadata Source claims the XDS Document Type Binding Option or the MPQ Document Type Binding Option or the XCA Document Type Binding Option and the Content Model of clinical documents storing the Data Element is an unstructured document (e.g., for Data Elements available in the unstructured body of pdf documents with formatCode urn:ihe:iti:xds-sd:pdf:2008).

1795 Volume 2 Namespace Additions

Add the following terms to the IHE General Introduction Appendix G:

None

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

Volume 3 – Content Modules

1800   None

Volume 4 – National Extensions

Add appropriate Country section

None

1805