

Integrating the Healthcare Enterprise



5 **IHE Quality, Research and Public Health
Technical Framework Supplement**

10 **Data Element Exchange
(DEX)**

15 **Trial Implementation**

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25 **Please verify you have the most recent version of this document. See [here](#) for Trial Implementation and Final Text versions and [here](#) for Public Comment versions.**

Foreword

30 This is a supplement to the IHE Quality, Research and Public Health (QRPH) Technical Framework V0.1. Each supplement undergoes a process of public comment and trial implementation before being incorporated into the volumes of the Technical Frameworks.

35 This supplement is published on August 27, 2015 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.

40

<i>Amend Section X.X by the following:</i>
--

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.

45

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>.

50

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

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160 Introduction to this Supplement

Note: this introduction defines the problem that the profile addresses. For exact constraints on how the profile works, see Section X.

165 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 encourages that adoption.

170 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 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.

175 A major barrier to repurposing EHR data for clinical research studies (clinical trial design, 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 ISO¹, “One of the prerequisites for a correct and proper use and interpretation of data is that both users and owners of data have
180 a common understanding of the meaning and descriptive characteristics (e.g., representation) of 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
185 C154: Data Dictionary Component as a library of data elements that are used to establish common understanding of the meaning of the HL7® Continuity of Care Document® (CCD®) 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
190 Common Data Model, NCI CaDSR data elements, GE/Intermountain Healthcare Clinical Element Models (CEM), and I2B2 data model for clinical data warehouses. On top of these, BRIDG and CDISC SHARE are efforts to bridge the gap between these different clinical care and research data elements.

195 Since broad-based, scalable computable semantic interoperability across multiple domains requires the integration of multiple standards, the international initiative **Integrating the**

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

Healthcare Enterprise (IHE) plays a key role of “integration organization” involving multiple stakeholders (including both vendor and provider organizations).

200 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
205 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.

210 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
215 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).

220 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
225 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

230 Closed Issues

None

General Introduction

Appendix A - Actor Summary Definitions

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

235

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.

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.

240

Glossary

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.
Study Protocol	A document that describes the objective(s), design, methodology, statistical

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Glossary Term	Definition
	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

245 Add Section X

X Data Element Exchange (DEX) Profile

250 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
metadata registries to increase the interoperability of applications.² The core object of ISO/IEC
11179 is the data element, which includes a data concept and data representation. The term “data
255 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.³

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
260 level of the correspondence, i.e., exact or less exact (related). A precondition of use of DEX is
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
265 identify the documents that contain the content they need in real time. The DEX Profile defines
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
270 interest. These options are applied to Document Sharing environments, so a good understanding
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

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

³ “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>

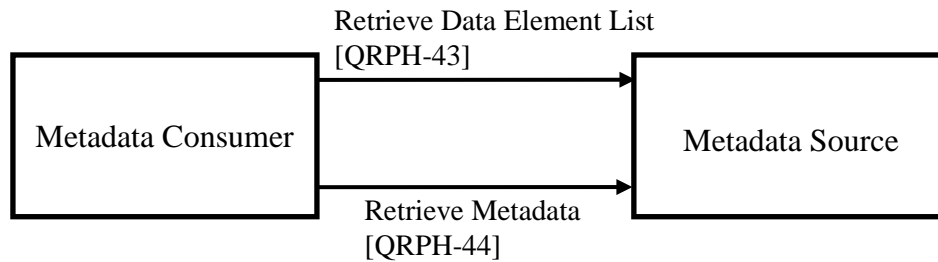
275 DEX Profile defines the functionality of a metadata registry, which both manages Document Sharing Metadata describing document content and also knows the Document Sharing Affinity Domain rules for document creation and metadata association.

280 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 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.

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/.

290 Figure X.1-1 shows the actors directly involved in the DEX Profile and the relevant transactions 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.



295 **Figure X.1-1: DEX Actor Diagram**

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”).

300

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

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

X.1.1.1 Metadata Consumer

310 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

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.

315 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. 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

320

X.2.1 XDS Document Type Binding Option

325 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.

330 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;
- 335 • 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”;
- 340 • 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:

- 345 • 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.

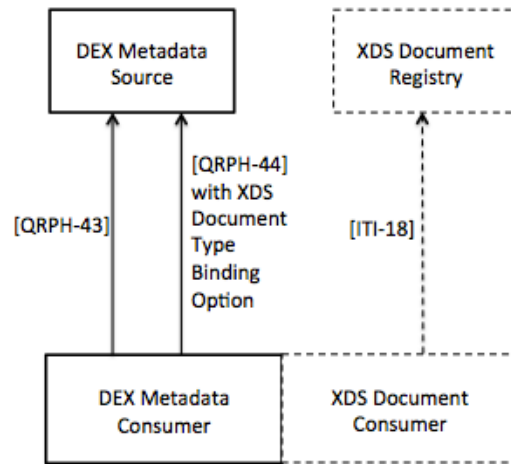


Figure X.2.1.2-1: Grouping Actors with XDS Document Type Binding Option

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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.

355

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.

360

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.

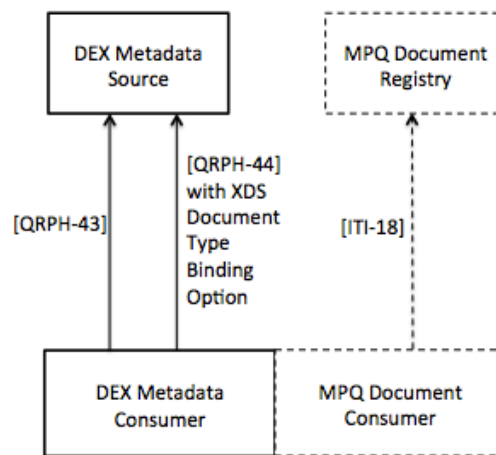
365

370

X.2.2.2 Metadata Consumer: MPQ Document Type Binding Option

In order to claim conformance to this option:

- 375
- 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.



380

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

X.2.3 XCA Document Type Binding Option

385 The XCA Document Type Binding Option is applicable to Metadata Consumer and Metadata 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.

390 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 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.

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);
- 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

405

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 “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”.

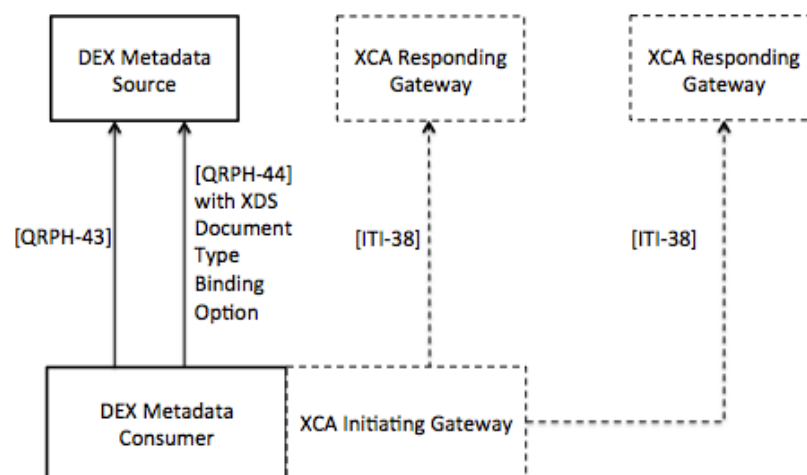
410

X.2.3.2 Metadata Consumer: XCA Document Type Binding Option

415

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.



420

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).

425 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	--

430 X.4 DEX Overview

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 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

440 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 extraction of data from his EHR and for addition of new information into the patient record.

445 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 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

450 #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.

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.

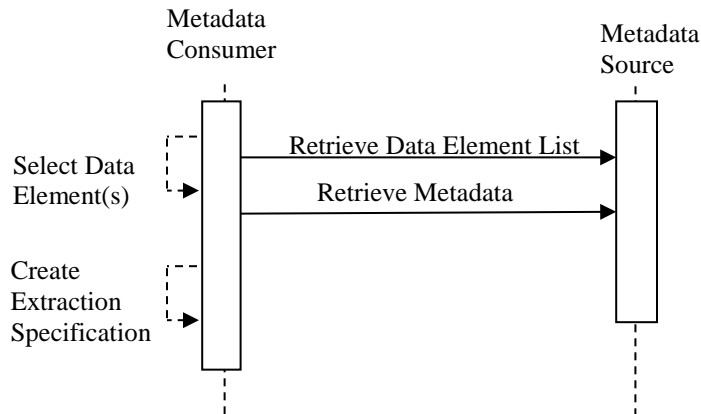
X.4.2.1 Use Case #1: Pre-population of a Research Case Report Form

455 This use case describes how a researcher can create an extraction specification to extract specific 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
460 such as CDISC's SHARE.

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
465 forms designer uses unique identifiers for each data element, performs a series of metadata 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
470 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. 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



475

Figure X.4.2.1.2-1: Basic Process Flow in DEX Profile

Pre-conditions:

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

Main Flow:

485 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:

490 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.

X.4.2.2.1 Research Eligibility Determination Description

495 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 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 Determination Specification to be run on EHRs or clinical data warehouse.

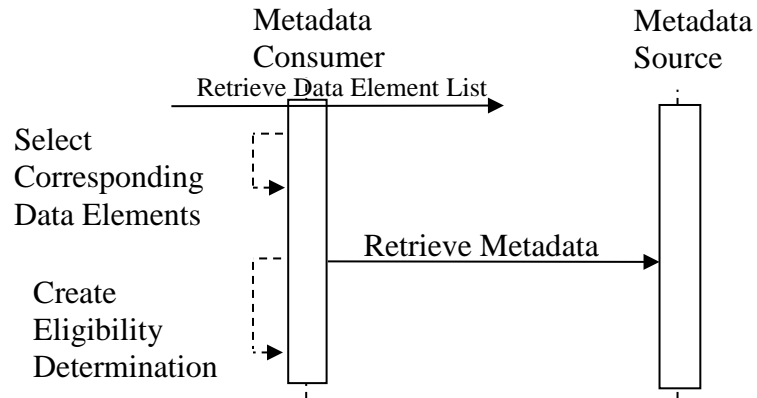
500
505 The eligibility determination specification could be run against an EHR or a clinical data warehouse established for clinical research purposes (anonymized data) returning summary information only (e.g., counts and percentages) as a part of other profiles. Summary information might be cross-tabulated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

Patient recruitment

515 Once a trial design has been finalized, all clinical trial approvals obtained and clinical 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.

520

X.4.2.2.2 Eligibility Determination Process Flow



525

Figure X.4.2.2.2-1: Basic Process Flow in DEX Profile

Pre-conditions:

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

Main Flow:

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

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

Post-conditions:

540 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

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

545 Alternative A

A research worker would like to collect a data collection set for an observational study in order 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), the research system constructs the electronic query to be run on clinical data warehouse to collect the required data sets.

555 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 patient identifiers (for example date of birth would be converted into age and recorded to nearest year).

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

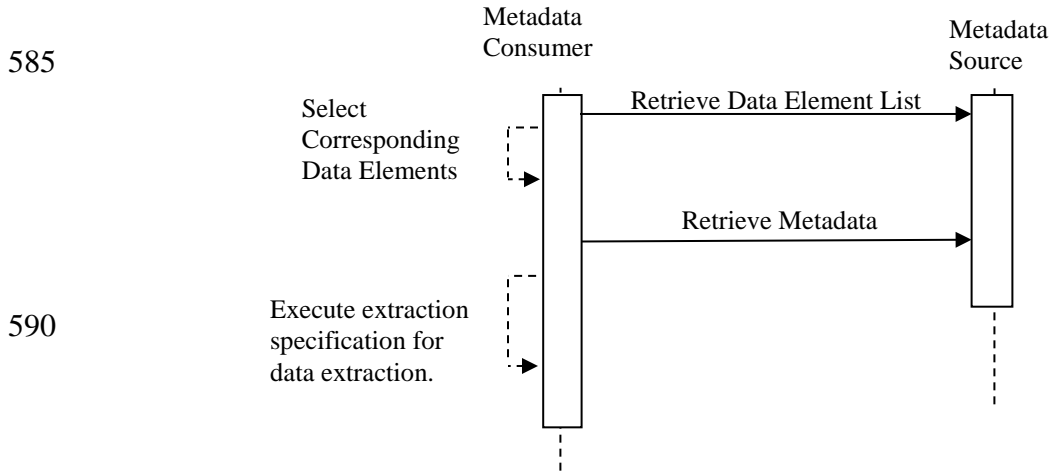
Alternative B

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® 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.

575 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.

580

X.4.2.3.2 Observational Study Process Flow



595 **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.

600

Main Flow:

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

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

605

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 specification to retrieve the data elements from medical summaries of eligible patients exported from an EHR.

610

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

X.4.2.4.1 Use Case Description

Current State

615 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 local, state and federal authorities.

620

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®.

625 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 completed 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).

630 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.

635 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 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 no metadata registry but his data elements are a subset of the state elements, except for two data elements are normally in a CCD®.

640

645

X.4.2.4.2 Public Health Reporting Process Flow

650 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 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.

655

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.
- 660 • 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 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.
- 665 • As a result, the Form Designer annotates the Form, where 80 of the data elements have a 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.
- 670

Post-conditions:

675 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 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

680 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
685 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
690 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® compliant system that was utilized to develop the survey form may create an
695 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

700 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.

705 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
710 reports, etc.

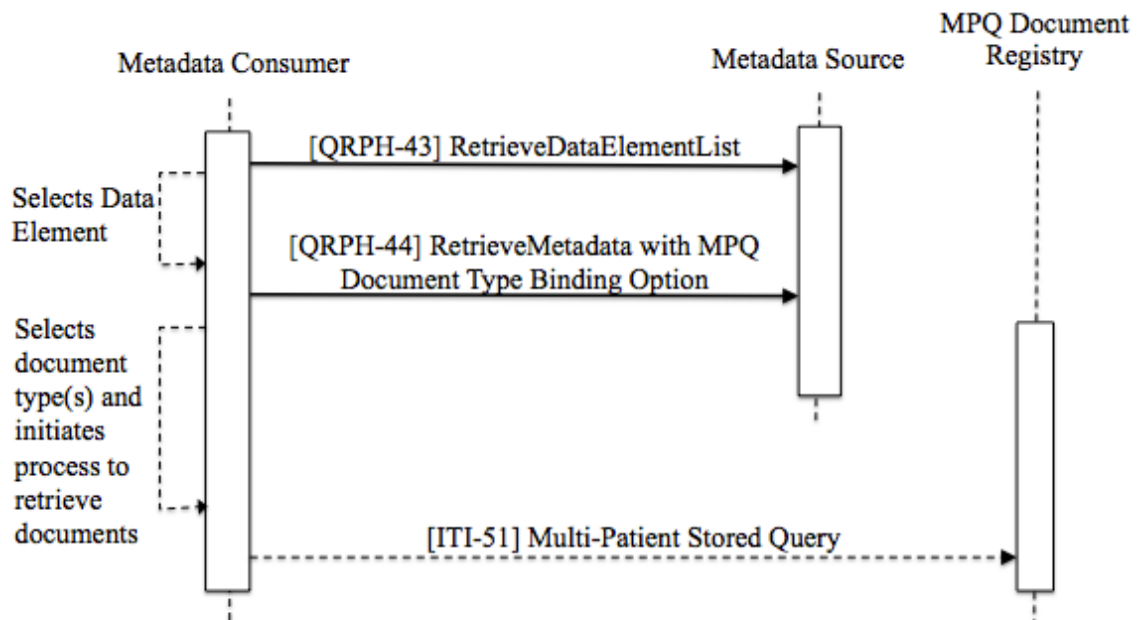
In the current state, it is not a trivial task for the epidemiologist to calculate the prevalence of a disease: usually an observational study is performed and cumbersome procedures have to be established, which takes a long time, includes a long follow-up, and involves a lot of people and resources.

715 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

720 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.

725
730 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



735

Figure X.4.2.6.2-1: Basic Process Flow in DEX Profile with MPQ Document Type Binding Option

Pre-conditions:

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

Main Flow:

- 745 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:

- 750 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.

- 755 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.

- 760 Other cross-profile considerations are defined below.

X.6.1 RSP – Redaction Services Profile

The Redaction Services Profile may make use of the extraction specification created by DEX to perform the duties of the Redactor in conjunction with RFD. This is not a grouping, per se, but rather a subsequent consumption of the output of this profile.

- 765 If the XDS Document Type Binding Option or the MPQ Document Type Binding Option or the XCA Document Type Binding Option is implemented, a Document Consumer in RSP might be grouped with the Metadata Consumer if documents need to be de-identified before their delivery to respectively the XDS or MPQ Document Consumer or XCA Initiating Gateway.

X.6.2 SVS - Sharing Value Sets

- 770 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 Consumer.

X.6.3 SDC - Structured Data Capture

775 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.

780

Appendices

None

Volume 2 – Transactions

785 *Add Section 3.43*

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.

790 **3.43.2 Actor Roles**

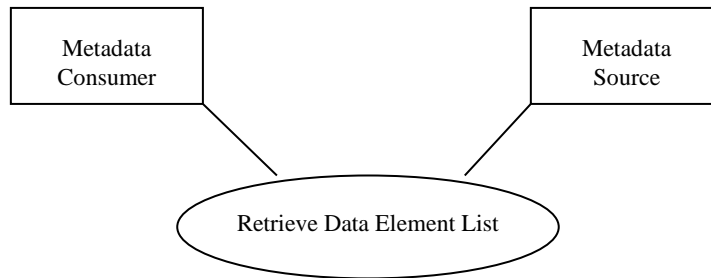


Figure 3.43.2-1: Use Case Diagram

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

795

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

3.43.3 Referenced Standards

800

- ISO/IEC 11179: Information Technology – Metadata Registries (MDR) Parts 1–6 (2nd Edition).
- IETF RFC2616 HyperText Transfer Protocol HTTP/1.1

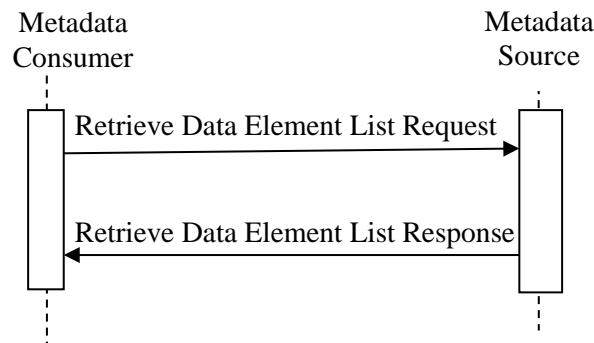
- Extensible Markup Language (XML) 1.0 (Second Edition). W3C Recommendation 6 October 2000. <http://www.w3.org/TR/REC-xml>.
- Web Services Description Language (WSDL) 1.1. W3C Note 15 March 2001. <http://www.w3.org/TR/wsdl>.
- SOAP 1.2 Second Edition, W3C Recommendation 27 April 2007. <http://www.w3.org/TR/soap12-part1>

805

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

810

3.43.4 Interaction Diagram



3.43.4.1 Retrieve Data Element List Request

3.43.4.1.1 Trigger Events

815 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 Metadata Consumer sends a Retrieve Data Element List Request to the Metadata Source.

3.43.4.1.2 Message Semantics

820 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 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.

825 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 3.43.4.1.2-1: 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

830 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.

835 • 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).

840 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

845 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.

850 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

855

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.

860

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.

865

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

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

870

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.

875

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
--------------	-------------	---------------	------	-------------

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

880 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.

885 **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):

890 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”

895 The /definitions/message/part/@element attribute of the Retrieve Data Element List Response 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”

900 The

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

905 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: 3.43.5.1 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

910 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
- 915 • 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”
- 920 • An optional /dex:RetrieveDataElementListRequest/dex:definitionContains element with type “xsd:string”
- An optional /dex:RetrieveDataElementListRequest/dex:contextualDomainContains element with type “xsd:string”
- 925 • 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”
- 930 • An optional /dex:RetrieveDataElementListRequest/dex:effectiveDateAfter element with type “xsd:date”
- An optional /dex:RetrieveDataElementListRequest/dex:expirationDateBefore element with type “xsd:date”

- 935
 - 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”
- 940
 - 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”
- 945
 - An optional /dex:RetrieveDataElementListRequest/dex:decObjectClassContains element with type “xsd:string”
 - An optional /dex:RetrieveDataElementListRequest/dex:decPropertyContains element with type “xsd:string”
- 950
 - An optional /dex:RetrieveDataElementListRequest/dex:dataTypeContains element with type “xsd:string”
 - 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:


```
955 <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>
960     <wsa:MessageID>urn:uuid:f43f7bda-a5f9-42b1-b8dc-e78bela2a180</wsa:MessageID>
     <wsa:Action>urn:ihe:qrph:dex:2013:RetrieveDataElementList</wsa:Action>
  </soap:Header>
  <soap:Body>
965     <dex:RetrieveDataElementListRequest xmlns:dex="urn:ihe:qrph:dex:2013">
        <dex:displayNameContains>ethnic</dex:displayNameContains>
     </dex:RetrieveDataElementListRequest>
  </soap:Body>
</soap:Envelope>
```

3.43.5.2 Retrieve Data Element List Response

970 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
 - a required /dex:RetrieveDataElementListResponse/dex:DataElementSummary/dex:id element with type “xsd:string”
 - a required /dex:RetrieveDataElementListResponse/dex:DataElementSummary/dex:registrationAuthority element with type “xsd:string”
 - a required /dex:RetrieveDataElementListResponse/dex:DataElementSummary/dex:version element with type “xsd:string”
 - a required /dex:RetrieveDataElementListResponse/dex:DataElementSummary/dex:displayName element with type “xsd:string”
 - a required /dex:RetrieveDataElementListResponse/dex:DataElementSummary/dex:definition element with type “xsd:string”
 - an optional /dex:RetrieveDataElementListResponse/dex:DataElementSummary/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.)

- 995
 - a required
/dex:RetrieveDataElementListResponse/dex:DataElementSummary/dex:creationDate element with type “xsd:date”
- 1000
 - an optional
/dex:RetrieveDataElementListResponse/dex:DataElementSummary/dex:effectiveDate element with type “xsd:date” (Required if available)
 - an optional
/dex:RetrieveDataElementListResponse/dex:DataElementSummary/dex:expirationDate element with type “xsd:date” (Required if available)
 - an optional
/dex:RetrieveDataElementListResponse/dex:DataElementSummary/dex:revisionDate element with type “xsd:date” (Required if available)
- 1005
 - an optional
/dex:RetrieveDataElementListResponse/dex:DataElementSummary/dex:revisionNote element with type “xsd:string” a required (Required if available)
 - a required
/dex:RetrieveDataElementListResponse/dex:DataElementSummary/dex:dataElement Concept element containing
- 1010
 - a required
/dex:RetrieveDataElementListResponse/dex:DataElementSummary/dex:dataElementConcept/dex:id element with type “xsd:string”
 - a required
/dex:RetrieveDataElementListResponse/dex:DataElementSummary/dex:dataElementConcept/dex:displayName element with type “xsd:string”
 - an optional
/dex:RetrieveDataElementListResponse/dex:DataElementSummary/dex:dataElementConcept/dex:objectClass element with type “xsd:string”
- 1015
 - an optional
/dex:RetrieveDataElementListResponse/dex:DataElementSummary/dex:dataElementConcept/dex:property element with type “xsd:string”
 - a required
/dex:RetrieveDataElementListResponse/dex:DataElementSummary/dex:valueDomain element containing
- 1020
 - a required
/dex:RetrieveDataElementListResponse/dex:DataElementSummary/dex:valueDomain element containing
- 1025
 - a required
/dex:RetrieveDataElementListResponse/dex:DataElementSummary/dex:valueDomain/dex:dataType element with type “xsd:string”

- 1030
 - an optional
/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)
- 1035
 - 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]*))*
- 1040
 - a required
/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”
- 1045 A sample Retrieve Data Element List SOAP Response is given as follows:

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```
1050 <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-e78bela2a180</wsa:RelatesTo>
  </soap:Header>
  <soap:Body>
1055   <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>
1060       <dex:version>0.1</dex:version>
       <dex:displayName>DMETHNIC</dex:displayName>
       <dex:definition>A social group characterized by a distinctive social and
1065       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>
1070       <dex:dataElementConcept>
         <dex:id>2145698</dex:id>
         <dex:displayName>ETHNICITY</dex:displayName>
         <dex:objectClass>DM</dex:objectClass>
         <dex:property>ETHNIC</dex:property>
1075       </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>
1080         </dex:valueSet>
         </dex:valueDomain>
       </dex:DataElementSummary>
1085 </dex:RetrieveDataElementListResponse>
    </soap:Body>
  </soap:Envelope>
```

3.43.6 Security Considerations

1090 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.

1095 *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.

1100 3.44.2 Actor Roles

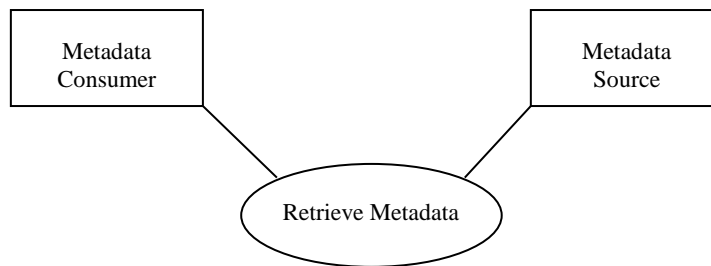


Figure 3.44.2-1: Use Case Diagram

1105 The Roles in this transaction are defined in the following table and may be played by the actors shown here:

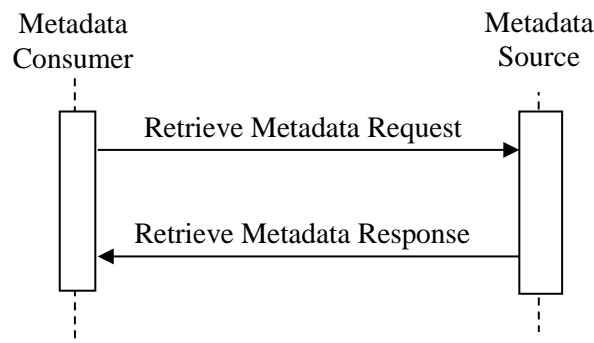
Table 3.44.2-1: Actor Roles

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

- 1110
- ISO/IEC 11179: Information Technology – Metadata Registries (MDR) Parts 1–6 (2nd Edition).
 - 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>.
- 1115
- 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. <http://www.w3.org/TR/soap12-part1>

3.44.4 Interaction Diagram



1120

3.44.4.1 Retrieve Metadata Request

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.

1125

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:

- 1130
- A required ID that identifies the Data Element.

- 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.

1135

The string data type corresponds to xsd:string.

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.

1140 **3.44.4.1.3 Expected Action**

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.

1145 The following error responses may be returned:

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”.

1150 **3.44.4.1.3.1 XDS or MPQ or XCA Document Type Binding Option**

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.

1155 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

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

1160 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.

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.

1165 3.44.4.2.2 Message Semantics

The Retrieve Metadata Response Message shall carry the metadata of the Data Element presented in Table 3.44.4.2.2-1⁴:

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:

1170

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 format for xsd:date is YYYY-MM-DD where Y is the year, M is the month, D is the day of month.

1175 **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.
registrationAuthority	R	No	string	The Authority who has defined and registered the Data Element to the Metadata Source (Examples:

⁴ 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.

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Element Name	Optionality	Is Repeatable	Type	Description
				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.
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

Element Name	Optionality	Is Repeatable	Type	Description
				<p>specifications, each specification is returned as a separate mappingSpecification.</p> <p>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.</p>

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

Element Name	Optionality	Is Repeatable	Type	Description
contentModel	R	No	See description	<p>The Content Model that the Data Element is interrelated with.</p> <p>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.</p> <p>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".</p>
type	R	No	string	<p>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).</p>
mappingScript	R	No	string	<p>The exact specification to locate the Data Element in a Content Model (Example: XPATH Scripts, SPARQL or SQL queries).</p> <p>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).</p>

1180

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 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,

Element Name	Optionality	Is Repeatable	Type	Description
				the Metadata Consumer SHALL assume the value is “unbounded”.

1185

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

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.
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

Element Name	Optionality	Is Repeatable	Type	Description
				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

1190 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.

1195 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.

1200

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

1205 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.

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

1210 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: 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”

1215 The /definitions/message/part/@element attribute of the Retrieve Metadata Response message shall be defined as “dex:RetrieveMetadataResponse”

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

1220 The /definitions/portType/operation/output/@message attribute for the RetrieveMetadata Operation shall be defined as “dex:RetrieveMetadataResponseMessage”

The

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

1225 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.

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.

1230 **3.44.5.1 Retrieve Metadata Request**

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

- 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:

1240

```
<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-e78bela2a183</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>
```

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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:

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1265

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- A required /dex:RetrieveMetadataResponse/dex:DataElement element, containing
 - a required /dex:RetrieveMetadataResponse/dex:DataElement/dex:id element with type “xsd:string”
 - a required /dex:RetrieveMetadataResponse/dex:DataElement/dex:registrationAuthority element with type “xsd:string”
 - a required /dex:RetrieveMetadataResponse/dex:DataElement/dex:version element with type “xsd:string”
 - a required /dex:RetrieveMetadataResponse/dex:DataElement/dex:displayName element with type “xsd:string”
 - a required /dex:RetrieveMetadataResponse/dex:DataElement/dex:definition element with type “xsd:string”
 - 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.)

- 1275
 - a required /dex:RetrieveMetadataResponse/dex:DataElement/dex:creationDate element with type “xsd:date”
 - an optional /dex:RetrieveMetadataResponse/dex:DataElement/dex:effectiveDate element with type “xsd:date” (Required if available)
- 1280
 - an optional /dex:RetrieveMetadataResponse/dex:DataElement/dex:expirationDate element with type “xsd:date” (Required if available)
 - an optional /dex:RetrieveMetadataResponse/dex:DataElement/dex:revisionDate element with type “xsd:date” (Required if available)
 - an optional /dex:RetrieveMetadataResponse/dex:DataElement/dex:revisionNote element with type “xsd:string” a required (Required if available)
- 1285
 - a required /dex:RetrieveMetadataResponse/dex:DataElement/dex:dataElementConcept containing
 - 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”
 - an optional /dex:RetrieveMetadataResponse/dex:DataElement/dex:dataElementConcept/dex:objectClass element with type “xsd:string”
 - an optional /dex:RetrieveMetadataResponse/dex:DataElement/dex:dataElementConcept/dex:property element with type “xsd:string”
- 1290
- 1295
- 1300
 - a required /dex:RetrieveMetadataResponse/dex:DataElement/dex:valueDomain element containing
 - a required /dex:RetrieveMetadataResponse/dex:DataElement/dex:valueDomain/dex:dataType element with type “xsd:string”
- 1305
 - an optional /dex:RetrieveMetadataResponse/dex:DataElement/dex:valueDomain/dex:unitOfMeasure element with type “xsd:string” (Required if available)
 - an optional /dex:RetrieveMetadataResponse/dex:DataElement/dex:valueDomain/dex:valueSet element containing (Required if available)
- 1310

- a required
/dex:RetrieveMetadataResponse/dex:DataElement/dex:valueDomain/dex:valu
eSet/dex:id element with type “xsd:string”
- 1315 • a required
/dex:RetrieveMetadataResponse/dex:DataElement/dex:valueDomain/dex:valu
eSet/dex:version element with type “xsd:string”
- an optional
/dex:RetrieveMetadataResponse/dex:DataElement/dex:valueDomain/dex:valu
eSet/dex:displayName element with type “xsd:string”
- 1320 • one or more
/dex:RetrieveMetadataResponse/dex:DataElement/dex:MappingSpecification element
containing
- 1325 • 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”
- 1330 • a required
/dex:RetrieveMetadataResponse/dex:DataElement/dex:MappingSpecification/
dex:contentModel/dex:name element with type “xsd:string”
- 1335 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:
- 1340 • a required
/dex:RetrieveMetadataResponse/dex:DataElement/dex:MappingSpecification/
dex:contentModel/dex:DSMetadata containing:
- a conditional
/dex:RetrieveMetadataResponse/dex:DataElement/dex:MappingSpecificat
ion/dex:contentModel/ dex:DSMetadata/dex:homeCommunityID element
with type “xsd:string” (required if the Metadata Source claims the XCA
Document Type Binding Option)
- 1345 • a required
/dex:RetrieveMetadataResponse/dex:DataElement/dex:MappingSpecificat

- ion/dex:contentModel/ dex:DSMetadata/dex:classCode element with type “xsd:string”
- 1350
 - a required /dex:RetrieveMetadataResponse/dex:DataElement/dex:MappingSpecification/dex:contentModel/ dex:DSMetadata/dex:classCodeDisplayName element with type “xsd:string”
- 1355
 - a required /dex:RetrieveMetadataResponse/dex:DataElement/dex:MappingSpecification/dex:contentModel/ dex:DSMetadata/dex:typeCode element with type “xsd:string”
- 1360
 - a required /dex:RetrieveMetadataResponse/dex:DataElement/dex:MappingSpecification/dex:contentModel/ dex:DSMetadata/dex:typeCodeDisplayName element with type “xsd:string”
- 1365
 - a required /dex:RetrieveMetadataResponse/dex:DataElement/dex:MappingSpecification/dex:contentModel/ dex:DSMetadata/dex:formatCode element with type “xsd:string”
- 1370
 - a required /dex:RetrieveMetadataResponse/dex:DataElement/dex:MappingSpecification/dex:contentModel/ dex:DSMetadata/dex:formatCodeDisplayName element with type “xsd:string”
- 1375
 - an optional /dex:RetrieveMetadataResponse/dex:DataElement/dex:MappingSpecification/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)
- 1380
 - an optional /dex:RetrieveMetadataResponse/dex:DataElement/dex:MappingSpecification/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)
- 1385
 - an optional /dex:RetrieveMetadataResponse/dex:DataElement/dex:MappingSpecification/dex:contentModel/dex:minCardinality element with type “xsd:string” (Required if available)

- an optional
/dex:RetrieveMetadataResponse/dex:DataElement/dex:MappingSpecification/
dex:contentModel/dex:maxCardinality element with type “xsd:string”
(Required if available)
- 1390 • a required
/dex:RetrieveMetadataResponse/dex:DataElement/dex:MappingSpecification/dex
:type element with type “xsd:string”
- a required
/dex:RetrieveMetadataResponse/dex:DataElement/dex:MappingSpecification/dex
1395 :mappingScript element with type “xsd:string”

A sample Retrieve Metadata SOAP Response is given as follows:

IHE Quality, Research and Public Health Technical Framework Supplement – Data Element Exchange (DEX)

1400

```
<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-e78bela2a183</wsa:RelatesTo>
```

1405

```
  </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>
```

1410

```
        <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>
```

1415

```
        <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>
```

1420

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

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

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

```
        <dex:dataElementConcept>
```

1425

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

```
          <dex:displayName>ETHNICITY</dex:displayName>
```

```
          <dex:objectClass>DM</dex:objectClass>
```

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

```
        </dex:dataElementConcept>
```

```
        <dex:valueDomain>
```

1430

```
          <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>
```

1435

```
          </dex:valueSet>
```

```
        </dex:valueDomain>
```

```
        <dex:mappingSpecification>
```

```
          <dex:contentModel>
```

1440

```
            <dex:id>2.16.840.1.113883.10.20.1</dex:id>
```

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

```
          </dex:contentModel>
```

```
1445     <dex:type>XPATH</dex:type>
    <dex:mappingScript>./ClinicalDocument/recordTarget/patientRole/patient/ethnicGroupCode</dex:map
pingScript>
        </dex:mappingSpecification>
    </dex:DataElement>
</dex:RetrieveMetadataResponse>
1450 </soap:Body>
</soap:Envelope>
```

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

IHE Quality, Research and Public Health Technical Framework Supplement – Data Element Exchange (DEX)

```

1455 <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>
1460     <wsa:Action>urn:ihe:qrph:dex:2013:RetrieveMetadataResponse</wsa:Action>
     <wsa:RelatesTo>urn:uuid:f43f7bda-a5f9-42b1-b8dc-e78bela2a183</wsa:RelatesTo>
  </soap:Header>
  <soap:Body>
1465     <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>
1470         <dex:id>6fbbd463-7de1-4ebc-85f6-76b84bab678b</dex:id>
         <dex:registrationAuthority>CDISC</dex:registrationAuthority>
         <dex:version>0.1</dex:version>
1475         <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>
1480         <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>
1485             <dex:id>2145698</dex:id>
             <dex:displayName>ETHNICITY</dex:displayName>
             <dex:objectClass>DM</dex:objectClass>
             <dex:property>ETHNIC</dex:property>
         </dex:dataElementConcept>
1490         <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>
1495             <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>
1500                     <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
1505 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
1510 Report</dex:eventCodeListDisplayName>
                     </dex:DSMetadata>
                     <dex:minCardinality>0</dex:minCardinality>
                     <dex:maxCardinality>1</dex:maxCardinality>
                 </dex:contentModel>
                 <dex:type>XPATHT</dex:type>
1515
             </dex:mappingSpecification>
         </dex:DataElement>
     </dex:RetrieveMetadataResponse>
  </soap:Body>
</soap:Envelope>
<dex:mappingScript>./ClinicalDocument/recordTarget/patientRole/patient/ethnicGroupCode</dex:mappi
ngScript>

```

```

1520         </dex:mappingSpecification>
           <dex:mappingSpecification>
             <dex:contentModel DSoption="true" xsi:type="dex:ContentModelTypeDS">
1525               <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>
1530 <dex:homeCommunityID>urn:oid:1.19.6.24.109.42.1.3</dex:homeCommunityID>
                 <dex:classCode>34105-7</dex:classCode>
                 <dex:classCodeDisplayName>Hospital Discharge
1535 Summary</dex:classCodeDisplayName>
                 <dex:typeCode>34106-5</dex:typeCode>
                 <dex:typeCodeDisplayName>Physician Hospital Discharge
1540 Summary</dex:typeCodeDisplayName>
                 <dex:formatCode>urn:ihe:pcc:xds-ms:2007</dex:formatCode>
                 <dex:formatCodeDisplayName>Discharge
1545 Summary</dex:formatCodeDisplayName>
                 </dex:DSMetadata>
                 <dex:minCardinality>0</dex:minCardinality>
                 <dex:maxCardinality>1</dex:maxCardinality>
1550 </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.

1555 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

```
1560 <?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.
1565 -->
      <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"
1570 attributeFormDefault="unqualified">
          <xsd:element name="RetrieveMetadataRequest" type="dex:RetrieveMetadataRequestType"/>
          <xsd:element name="RetrieveMetadataResponse" type="dex:RetrieveMetadataResponseType"/>
          <xsd:element name="RetrieveDataElementListRequest"
1575 type="dex:RetrieveDataElementListRequestType"/>
          <xsd:element name="RetrieveDataElementListResponse"
          type="dex:RetrieveDataElementListResponseType"/>

          <xsd:complexType name="RetrieveMetadataRequestType">
1580     <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>

1585 <xsd:complexType name="RetrieveMetadataResponseType">
          <xsd:sequence>
          <xsd:element name="DataElement" type="dex:DataElementType"/>
          </xsd:sequence>
1590 </xsd:complexType>

          <xsd:complexType name="RetrieveDataElementListRequestType">
          <xsd:sequence>
1595     <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"/>
1600     <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"/>
1605     <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"/>
1610     <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>
1615 </xsd:complexType>

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


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```
1620     <xsd:sequence>
        <xsd:element name="DataElementSummary" type="dex:DataElementSummaryType" minOccurs="0"
maxOccurs="unbounded" />
    </xsd:sequence>
</xsd:complexType>

1625 <xsd:complexType name="DataElementSummaryType">
    <xsd:sequence>
        <xsd:element name="id" type="xsd:string" />
        <xsd:element name="registrationAuthority" type="xsd:string" />
        <xsd:element name="version" type="xsd:string" />
1630 <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" />
        <xsd:element name="effectiveDate" type="xsd:date" minOccurs="0" />
        <xsd:element name="expirationDate" type="xsd:date" minOccurs="0" />
1635 <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" />
        <xsd:element name="valueDomain" type="dex:ValueDomainType" />
    </xsd:sequence>
1640 </xsd:complexType>

    <xsd:complexType name="DataElementType">
        <xsd:complexContent>
            <xsd:extension base="dex:DataElementSummaryType">
1645 <xsd:sequence>
                <xsd:element name="mappingSpecification" type="dex:MappingSpecificationType"
minOccurs="0" maxOccurs="unbounded" />
            </xsd:sequence>
        </xsd:extension>
1650 </xsd:complexContent>
    </xsd:complexType>

    <xsd:complexType name="DataElementConceptType">
1655 <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" />
        <xsd:element name="property" type="xsd:string" minOccurs="0" />
    </xsd:sequence>
1660 </xsd:complexType>

    <xsd:complexType name="ValueDomainType">
        <xsd:sequence>
1665 <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>
    </xsd:complexType>

1670 <xsd:complexType name="ValueSetType">
    <xsd:sequence>
        <xsd:element name="id" type="dex:valueSetIdType" />
        <xsd:element name="version" type="xsd:string" />
        <xsd:element name="displayName" type="xsd:string" minOccurs="0" />
1675 </xsd:sequence>
    </xsd:complexType>

    <xsd:simpleType name="valueSetIdType">
        <xsd:restriction base="xsd:string">
1680 <xsd:pattern value="[0-2](\.(0|[1-9][0-9]*)*)*" />
        </xsd:restriction>
    </xsd:simpleType>
```

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```
1685 <xsd:complexType name="MappingSpecificationType">
  <xsd:sequence>
    <xsd:element name="contentModel" type="ContentModelType"/>
    <xsd:element name="type" type="xsd:string"/>
    <!-- This refers to a valueset identified by 1.3.6.1.4.1.19376.1.7.3.1.1.22.1 -->
1690 <xsd:element name="mappingScript" type="xsd:string"/>
  </xsd:sequence>
</xsd:complexType>

1695 <xsd:complexType name="ContentModelType">
  <xsd:sequence>
    <xsd:element name="id" type="xsd:string"/>
    <xsd:element name="name" type="xsd:string"/>
  </xsd:sequence>
</xsd:complexType>

1700 <xsd:complexType name="ContentModelTypeDS">
  <xsd:complexContent>
    <xsd:extension base="ContentModelType">
      <xsd:sequence>
1705 <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>
      <xsd:attribute name="DSOption" type="xsd:boolean" use="required" fixed="true"/>
    </xsd:extension>
  </xsd:complexContent>
1710 </xsd:complexType>

1715 <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-->
    <xsd:element name="classCode" type="xsd:string"/>
    <xsd:element name="classCodeDisplayName" type="xsd:string"/>
1720 <xsd:element name="typeCode" type="xsd:string"/>
    <xsd:element name="typeCodeDisplayName" type="xsd:string"/>
    <xsd:element name="formatCode" type="xsd:string"/>
    <xsd:element name="formatCodeDisplayName" type="xsd:string"/>
    <xsd:element name="eventCodeList" type="xsd:string" minOccurs="0" maxOccurs="unbounded"/>
1725 <!-- 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"
maxOccurs="unbounded"/>
    <!-- Required if in the Affinity Domain the eventCodeList DocumentEntry metadata has a
value for this specific document type -->
1730 </xsd:sequence>
  </xsd:complexType>

1735 </xsd:schema>

<?xml version="1.0" encoding="UTF-8"?>
<!--
  IHE Data Element Exchange Profile (DEX) WSDL definition.
-->
1740 <wsdl:definitions
  xmlns="urn:ihe:qrph:dex:2013"
  targetNamespace="urn:ihe:qrph:dex:2013"
```

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```
1745   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"
        xmlns:wsa="http://www.w3.org/2005/08/addressing">

1750   <wSDL:types>
           <xsd:schema targetNamespace="urn:ihe:qrph:dex:2013">
               <xsd:include schemaLocation="DEX.xsd"/>
           </xsd:schema>
   </wSDL:types>

1755   <wSDL:message name="RetrieveMetadataRequestMessage">
           <wSDL:part name="body" element="dex:RetrieveMetadataRequest"/>
   </wSDL:message>

1760   <wSDL:message name="RetrieveMetadataResponseMessage">
           <wSDL:part name="body" element="dex:RetrieveMetadataResponse"/>
   </wSDL:message>

   <wSDL:message name="RetrieveDataElementListRequestMessage">
           <wSDL:part name="body" element="dex:RetrieveDataElementListRequest"/>
   </wSDL:message>

1765   <wSDL:message name="RetrieveDataElementListResponseMessage">
           <wSDL:part name="body" element="dex:RetrieveDataElementListResponse"/>
   </wSDL:message>

1770   <wSDL:portType name="DataExchangePortType">
           <wSDL:operation name="RetrieveMetadata">
               <wSDL:input message="dex:RetrieveMetadataRequestMessage"/>
               <wSDL:output message="dex:RetrieveMetadataResponseMessage"/>
           </wSDL:operation>

1775   <wSDL:operation name="RetrieveDataElementList">
           <wSDL:input message="dex:RetrieveDataElementListRequestMessage"/>
           <wSDL:output message="dex:RetrieveDataElementListResponseMessage"/>
   </wSDL:operation>

1780   </wSDL:portType>

   <wSDL:binding name="DataExchangeBinding" type="dex:DataExchangePortType">
```

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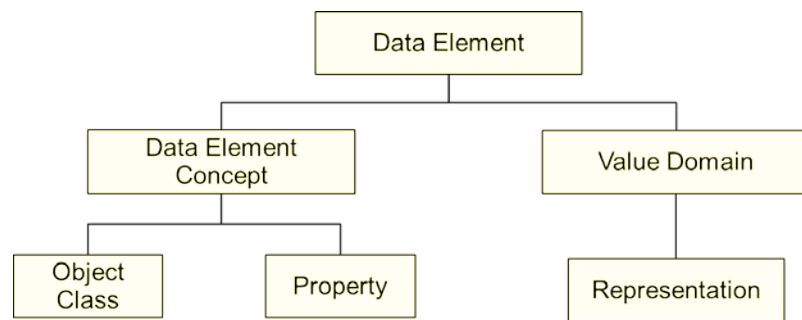
```
1785         <soap12:binding style="document"
transport="http://schemas.xmlsoap.org/soap/http"/>
        <wsdl:operation name="RetrieveMetadata">
            <soap12:operation soapAction="urn:ihe:qrph:dex:2013:RetrieveMetadata"/>
            <wsdl:input>
                <soap12:body use="literal"/>
            </wsdl:input>
            <wsdl:output>
                <soap12:body use="literal"/>
            </wsdl:output>
        </wsdl:operation>
        <wsdl:operation name="RetrieveDataElementList">
1795         <soap12:operation
soapAction="urn:ihe:qrph:dex:2013:RetrieveDataElementList"/>
            <wsdl:input>
                <soap12:body use="literal"/>
            </wsdl:input>
1800         <wsdl:output>
                <soap12:body use="literal"/>
            </wsdl:output>
        </wsdl:operation>
1805     </wsdl:binding>

        <wsdl:service name="DataElementExchangeService">
            <wsdl:documentation>SOAP Web Service for IHE Data Element Exchange
Profile</wsdl:documentation>
1810         <wsdl:port name="DataElementExchangePort"
binding="dex:DataElementExchangeBinding">
            <soap12:address/>
        </wsdl:port>
        </wsdl:service>
1815 </wsdl:definitions>
```

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

1820 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 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.

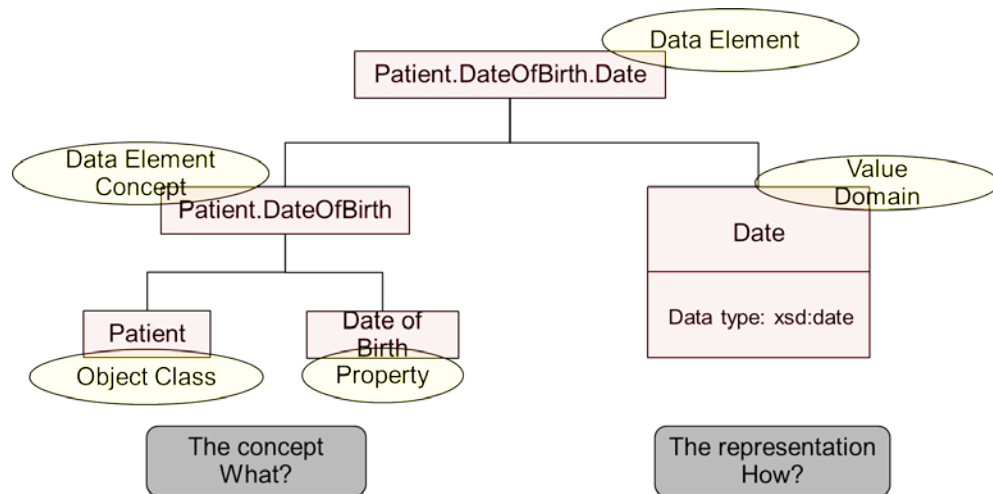
1825



$$\left(\begin{matrix} \text{Object} \\ \text{Class} \end{matrix} + \text{Property} = \begin{matrix} \text{Data Element} \\ \text{Concept} \end{matrix} \right) + \begin{matrix} \text{Value} \\ \text{Domain} \end{matrix} = \begin{matrix} \text{Data} \\ \text{Element} \end{matrix}$$

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

1830 Figure B-2 illustrates the decomposition of “Person.DateOfBirth.Date”, which is a simple data element, according to the ISO/IEC 11179 metamodel.



1835 **Figure B-2: An example of decomposition of a Data Element: Patient.DateOfBirth.Date**

1840 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 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 “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”.

1845

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

C.1 Mapping Specification Type Codes

1850

C.1.1 Metadata

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 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).

1855 Volume 2 Namespace Additions

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

None

Volume 3 – Content Modules

1860 None

Volume 4 – National Extensions

Add appropriate Country section

None

1865