Integrating the Healthcare Enterprise

IHE Quality, Research and Public Health Technical Framework Supplement

Data Element Exchange (DEX)

Trial Implementation

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Foreword

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.

This supplement is published on September 13, 2013 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 may be submitted at http://www.ihe.net/QRPH_Public_Comments/. This supplement describes changes to the existing technical framework documents.

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

Amend section X.X by the following:

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

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

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

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

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

CONTENTS

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.

To enable clinical research, public health, and quality assessment studies through secondary use of EHR, 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.

Re-use of EHRs 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.

A major barrier to repurposing clinical data of EHRs 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 ISO[1], "One of the prerequisites for a correct and proper use and interpretation of data is that both users and owners of data have a common understanding of the meaning and descriptive characteristics (e.g., representation) of 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 in defining metadata and vocabulary standards for clinical information and thereby in building Common Data Elements (CDEs) (also called metadata repositories or item banks). HITSP has defined the C154: Data Dictionary Component as a library of data elements that are used to establish 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 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.

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

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

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

Referenced documents

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

Open Issues and Questions

None

Closed Issues

None

General Introduction

Appendix A - Actor Summary Definitions

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

Actor	Definition
Metadata Consumer	The Metadata Consumer is responsible for the importation of metadata created by the Metadata Source. The Metadata Consumer can optionally query the Metadata Source for a list of Data Elements matching a 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
RetrieveDataElementList [QRPH-43]	This transaction retrieves the list of data elements matching a selection criteria from a metadata registry
RetrieveMetadata [QRPH-44]	This transaction retrieves metadata for a specified data element from a metadata registry.

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.

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

200

Volume 1 – Profiles

Add section X

X Data Element Exchange (DEX) Profile

This profile leverages the power of an ISO/IEC 11179 Metadata Registry (here after called "metadata registry") to add mapping metadata to an annotated data capture form at the point of form design. ISO/IEC 11179 is a "standard for metadata-driven exchange of data in a heterogeneous environment" (http://en.wikipedia.org/wiki/ISO_11179). The core object of ISO/IEC 11179 is the data element, which includes a data concept and data representation. The term "data element" in ISO/IEC 11179 refers to the *structure* of the data, and is distinct from a data instance. This profile describes the exchange of metadata, rather than the exchange of data instances.[2]

The metadata registry which serves as the Metadata Source in this profile will define and maintain correspondences between research and healthcare data elements, and will provide 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 should always be useful, but may be more or less exact 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 content model.

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://www.ihe.net/Technical_Framework/index.cfm.

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.

[2] "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

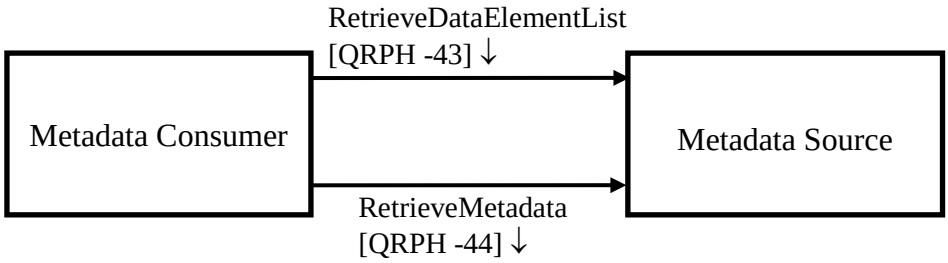


Figure X.1-1: DEX Actor Diagram

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").

Table X.1-1: DEX Profile - Actors and Transactions

Actors	Transactions	Optionality	Reference
Metadata Source	RetrieveDataElementList [QRPH-43]	R	QRPH TF-2: 3.44
	RetrieveMetadata [QRPH- 44]	R	QRPH TF-2: 3.44
Metadata Consumer	RetrieveDataElementList [QRPH-43]	O	QRPH TF-2: 3.43
	RetrieveMetadata [QRPH- 44]	R	QRPH TF-2: 3.43

X.1.1 Actor Descriptions and Actor Profile Requirements

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

X.1.1.1 Metadata Consumer

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

X.2 DEX Actor Options

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

Actor	Option Name	Reference
Metadata Consumer	No options defined	
Metadata Source	No options defined	

X.3 DEX Required Actor Groupings

Not applicable.

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

Use Case #1 is patient-centric since it concerns a patient who has been recruited into a given clinical trial. The source system is the EHR. 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.

Use Case #2 and #3 are population-centric. For these use cases, usually, the EHR may not be an ideal source system 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 #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 actor, and a metadata registry served by organizations defining data dictionaries like NIH, CDC would host the Metadata Source actor.

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

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

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

A research forms designer is building a case report form for a particular research study. The designer refers to an on-line metadata registry of research data elements, e.g., SHARE, and selects the desired data elements from a set of research friendly elements such as CDASH. The forms designer uses unique identifiers for each data element, performs a series of metadata retrievals into an annotated case report form. The metadata includes the exact specification, using XPath, to find the corresponding data element in the HL7 specification Continuity of Care Document (CCD) as extended in the IHE Clinical Research Document (CRD) profile. Using the XPath statements, the research system creates an extraction specification for all elements to be extracted from the CCD. This extraction specification provides a map that enables re-use of the 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

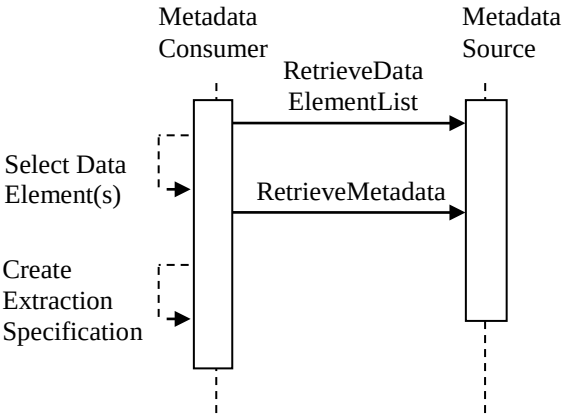


Figure X.4.2.1.2-1: Basic Process Flow in DEX Profile

Pre-conditions:

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

Main Flow:

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:

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

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.

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 diabetes status (not diabetic/type I/type II). Data will be returned only if counts are sufficiently large to protect privacy.

Patient recruitment

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

X.4.2.2.2 Eligibility Determination Process Flow

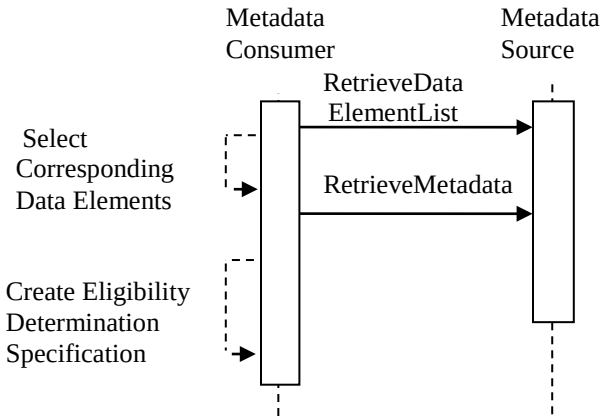


Figure X.4.2.2.2-1: Basic Process Flow in DEX Profile

Pre-conditions:

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

Main Flow:

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

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

Post-conditions:

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

X.4.2.3 Use Case #3: Observational Study

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

X.4.2.3.1 Observational Study Description

Alternative A

A research worker would like to collect a data collection set for an observational study in order 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.

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).

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.

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 content models like IHE CCD templates, will share the pseudonymized medical summaries with the Research systems. As the data collection set is already annotated with extraction specifications to retrieve the data sets from medical summary documents, the research data collection of interest can easily be collected from these medical summaries and stored in the project specific databases to run the clinical research methods of interest.

X.4.2.3.2 Observational Study Process Flow

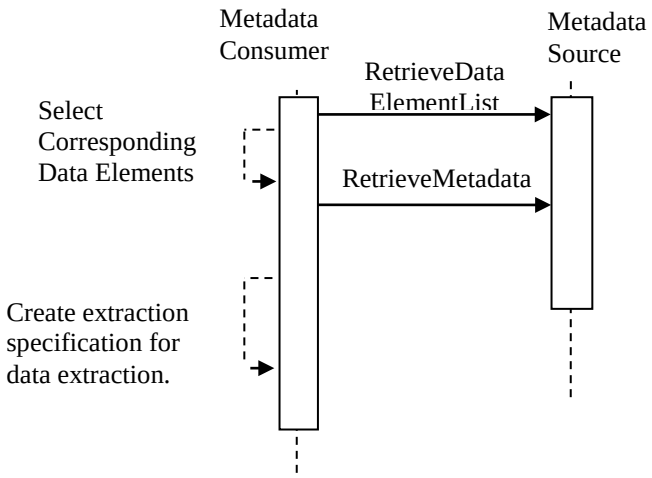


Figure X.4.2.3.2-1: Basic Process Flow in DEX Profile

Pre-conditions:

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

Main Flow:

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

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

Post-conditions:

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

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

X.4.2.4.1 Use Case Description

Current State

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.

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.

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

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

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.

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.

X.4.2.4.2 Public Health Reporting Process Flow

Pre-conditions: There are three different Metadata Sources: as an interface to the metadata registry managed by CDC, as an interface to the metadata registry managed by Public Health 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.

Main Flow:

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

Post-conditions:

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

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

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

X.4.2.5.1 Use Case Description

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

X.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.

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

RSP – 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.

Other 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.

Appendices

None

Volume 2 – Transactions

Add section 3.43

3.43 RetrieveDataElementList [QRPH-43]

3.43.1 Scope

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

3.43.2 Actor Roles

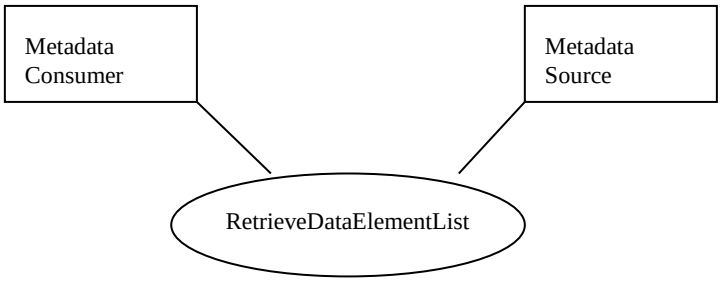


Figure 3.43.2-1: Use Case Diagram

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

Table 3.43.2-1: Actor Roles

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

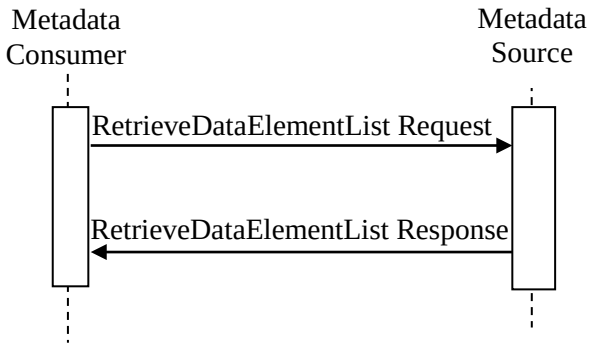
3.43.3 Referenced Standards

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

- 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

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

3.43.4 Interaction Diagram



3.43.4.1 RetrieveDataElementList Request

3.43.4.1.1 Trigger Events

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

3.43.4.1.2 Message Semantics

The RetrieveDataElementList Request shall specify retrieval selection parameters as shown in the Table 3.43.4.1.2-1. It requests retrieval of a list of all Data Elements that have metadata matching the parameters used. At least one request parameter shall be provided.

Table 3.43.4.1.2-1: The Request Parameters in the RetrieveDataElementList 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	creationDate	Before or equal	Date comparison to the day
creationDateAfter	date	creationDate	Equal or After	Date comparison to the day
effectiveDateBefore	date	effectiveDate	Before or equal	Date comparison to the day
effectiveDateAfter	date	effectiveDate	Equal or After	Date comparison to the day
expirationDateBefore	date	expirationDate	Before or equal	Date comparison to the day
expirationDateAfter	date	expirationDate	Equal or After	Date comparison to the day
revisionDateBefore	date	revisionDate	Before or equal	Date comparison to the day
revisionDateAfter	date	revisionDate	Equal or After	Date comparison to the day
objectClassContains	string	objectClass	Regex	POSIX rules
propertyContains	string	property	Regex	POSIX rules
dataTypeContains	string	valueDomain	Regex	POSIX rules
valueSetID	string	valueDomain	equals	Equality match

Section 3.43.5 describes the protocol requirements and the format of the message in full detail.

3.43.4.1.3 Expected Action

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

- Regex matches shall compare the contents of the referenced metadata field with the regex using the POSIX matching rules. If the regex matches the field, the Data Element matches.
- id, version and valueSetID matching compares only for equal values.
- Date comparisons convert the argument into a date, and compare it with the dates in the metadata using a date comparison. Equality means the same day.

Any Data Element, which has metadata that matches all of the request parameters, shall be included in the response.

The Metadata Source and Metadata Consumer shall support the SOAP binding for this transaction.

3.43.4.2 RetrieveDataElementList Response

3.43.4.2.1 Trigger Events

This message will be triggered by a RetrieveDataElementList Request Message.

3.43.4.2.2 Message Semantics

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

Table 3.43.4.2.2-1: Data Element Summary in the RetrieveDataElementList Response Message

Element Name	Optionality	Is Repeatable	Description
Id	R	No	Identifier of the Data Element.
registrationAuthority	R	No	The Authority who has defined and registered the Data Element to the Metadata Source (Examples: CDISC, HITSP, NCI).
Version	R	No	Version of the Data Element.
displayName	R	No	A name that can be used for display purposes
Definition	R	No	Definition that gives an unambiguous description of the Data Element and its use.
contextualDomain	R2	No	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

Element Name	Optionality	Is Repeatable	Description
			defined by the registrationAuthority for this Data Element in the Metadata Registry, then it shall be included in the message.
creationDate	R	No	The date that indicates the specific date when this Data Element is created.
effectiveDate	R2	No	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	The date when the Data Element is no longer expected to be used.
revisionDate	R2	No	The date when the Data Element is revised.
revisionNote	R2	No	Note that indicates the revision reason, and the updates
objectClass	R	No	The object that is a part of this data element definition. Definition from ISO/IEC 11179: "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". Each data element is composed of an objectClass, a property term and a valueDomain triple. See informative appendix for further description.
Property	R	No	The name of the property term which is a part of this data element definition. Definition from ISO/IEC 11179: "A property is a characteristic common to all members of an object Class". Each data element is composed of an objectClass, a property term and a valueDomain triple. See informative appendix for further description.
valueDomain	R	No	The description of the permissible set of values for the property of the data element definition. Each data element is composed of an objectClass, a property term and a valueDomain triple. See informative appendix for further description. A valueDomain description is composed (See Table 3.43.4.2.2-2): • A required dataType, representing the characteristics of the permissible values for the data element property (Examples: xsd:string) • A required (if available) unitOfMeasure which indicates the actual units in which the associated values of the property of the data element are measured. • A required (if available) valueSet which gives reference to the value set from which the values of this data element can be selected. The content of the valueSet can be further retrieved by IHE ITI SVS (Sharing Value Sets) profile. A valueSet description is composed (See Table 3.43.4.2.2-3): • A required id, representing the unique identifier

Element Name	Optionality	Is Repeatable	Description
			for the valueSet. • A required version, representing the version of the valueSet in question. • An optional displayName, presenting the textual representation of the name of the valueSet.

Table 3.43.4.2.2-2: valueDomain Summary in the RetrieveDataElementList Response Message

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

Table 3.43.4.2.2-3: valueSet Summary in the RetrieveDataElementList Response Message

Element Name	Optionality	Is Repeatable	Description
id	R	No	Identifier of the valueSet. This is the OID of the valueSet as described in IHE ITI SVS.
version	R	No	The version of the valueSet in question.
displayName	O	No	The textual representation of the name of the valueSet.

3.43.4.2.3 Expected Actions

A Metadata Source shall return a summary of the metadata of the Data Elements matching the selection criteria. If no matching Data Elements are found, RetrieveDataElementList Response Message shall be empty.

3.43.5 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.

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

3.43.6 Protocol Requirements

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

Table 3.43.6-1: 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 RetrieveDataElementList 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 RetrieveDataElementList Request message shall be defined as “dex:RetrieveDataElementListRequest”

The /definitions/message/part/@element attribute of the RetrieveDataElementList Response message shall be defined as “dex:RetrieveDataElementListResponse”

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

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

The

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

These are the requirements that affect the wire format of the SOAP message. The other WSDL properties are only used within the WSDL definition and do not affect interoperability. Full sample request and response messages are in ITI QRPH: 3.43.5.3 Sample SOAP Message.

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
- 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"
- An optional /dex:RetrieveDataElementListRequest/dex:definitionContains element with type "xsd:string"
- An optional /dex:RetrieveDataElementListRequest/dex:contextualDomainContains element with type "xsd:string"
- 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"
- An optional /dex:RetrieveDataElementListRequest/dex:effectiveDateAfter element with type "xsd:date"
- An optional /dex:RetrieveDataElementListRequest/dex:expirationDateBefore element with type "xsd:date"
- 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"
- An optional /dex:RetrieveDataElementListRequest/dex:objectClassContains element with type "xsd:string"
- An optional /dex:RetrieveDataElementListRequest/dex:propertyContains element with type "xsd:string"
- An optional /dex:RetrieveDataElementListRequest/dex:dataTypeContains element with type "xsd:string"
- An optional /dex:RetrieveDataElementListRequest/dex:valueSetID element with type "xsd:string"

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.)
  - a required /dex:RetrieveDataElementListResponse/dex:DataElementSummary/dex:creationDate element with type “xsd:date”
  - 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)

- 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:objectClass element with type “xsd:string”
- a required /dex:RetrieveDataElementListResponse/dex:DataElementSummary/dex:property element with type “xsd:string”
- a required /dex:RetrieveDataElementListResponse/dex:DataElementSummary/dex:valueDomain element containing
  - a required /dex:RetrieveDataElementListResponse/dex:DataElementSummary/dex:valueDomain/dex:dataType element with type “xsd:string”
  - 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)
    - a required /dex:RetrieveDataElementListResponse/dex:DataElementSummary/dex:valueDomain/dex:valueSet/dex:id element with type “xsd:string”
    - 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”

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

3.43.6.1 Sample RetrieveDataElementList SOAP Request

```
<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-e78be1a2a180</wsa:MessageID>
        <wsa:Action>urn:ihe:qrph:dex:2013:RetrieveDataElementList</wsa:Action>
  </soap:Header>
  <soap:Body>
        <dex:RetrieveDataElementListRequest xmlns:dex="urn:ihe:qrph:dex:2013">
                <dex:displayNameContains>ethnic</dex:displayNameContains>
        </dex:RetrieveDataElementListRequest>
  </soap:Body>
</soap:Envelope>
```

3.43.6.2 Sample RetrieveDataElementList SOAP Response

```
<soap:Envelope xmlns:soap="http://schemas.xmlsoap.org/soap/envelope/"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xmlns:wsa="http://www.w3.org/2005/08/addressing" xmlns:xsd="http://www.w3.org/2001/XMLSchema">
  <soap:Header>
        <wsa:Action>urn:ihe:qrph:dex:2013:RetrieveDataElementListResponse</wsa:Action>
        <wsa:RelatesTo>urn:uuid:f43f7bda-a5f9-42b1-b8dc-e78be1a2a180</wsa:RelatesTo>
  </soap:Header>
  <soap:Body>
        <dex:RetrieveDataElementListResponse xsi:schemaLocation="urn:ihe:qrph:dex:2013 dex.xsd"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns:dex="urn:ihe:qrph:dex:2013">
                <dex:DataElementSummary>
                        <dex:id>6fbbd463-7de1-4ebc-85f6-76b84bab678b</dex:uuid>
                        <dex:registrationAuthority>CDISC</dex:registrationAuthority>
                        <dex:version>0.1</dex:version>
                        <dex:displayName>DMETHNIC</dex:displayName>
                        <dex:definition>A social group characterized by a distinctive social and
cultural tradition maintained from generation to generation, a common history and origin and a
sense of identification with the group; members of the group have distinctive features in their
way of life, shared experiences and often a common genetic heritage; these features may be
reflected in their experience of health and disease</dex:definition>
                        <dex:contextualDomain>CDASH</dex:contextualDomain>
                        <dex:creationDate>2010-01-01</dex:creationDate>
                        <dex:effectiveDate>2010-02-01</dex:effectiveDate>
                        <dex:expirationDate>2020-01-01</dex:expirationDate>
                        <dex:objectClass>DM</dex:objectClass>
                        <dex:property>ETHNIC</dex:property>
```



```
                        <dex:valueDomain>
                                <dex:dataType>xsd:string</dex:dataType>
                                <dex:valueSet>
                                        <id>2.16.840.1.114222.4.11.837</id>
                                        <version>1</version>
                                        <displayName>Ethnicity group</displayName>
                                </dex:valueSet>
                        </dex:valueDomain>
                </dex:DataElementSummary>
</dex:RetrieveDataElementListResponse>
  </soap:Body>
</soap:Envelope>
```

Add section 3.44

3.44 RetrieveMetadata [QRPH-44]

3.44.1 Scope

This transaction is used by the Metadata Consumer to retrieve the metadata of a selected Data Element from the Metadata Registry. The Metadata Consumer has previously obtained the ID of the Data Element he is looking. He may have used the RetrieveDataElementList [QRPH-43] transaction to obtain the ID of the Data Element he is looking for.

3.44.2 Actor Roles

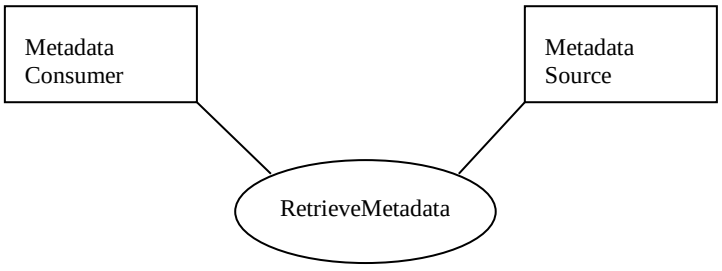


Figure 3.44.2-1: Use Case Diagram

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

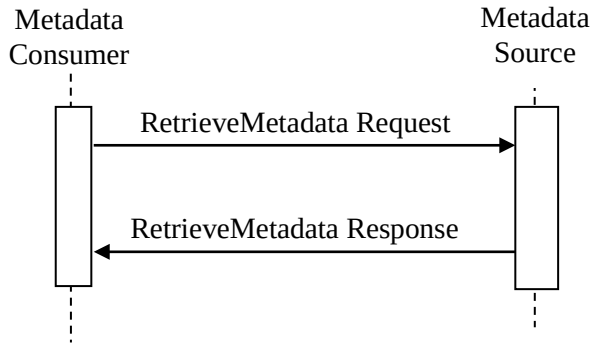
Table 3.44.2-1: Actor Roles

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

3.44.3 Referenced Standards

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

3.44.4 Interaction Diagram



3.44.4.1 RetrieveMetadata Request

3.44.4.1.1 Trigger Events

Having obtained the registration authority and the ID (and the version if requested) of the Data Element to 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 will send the RetrieveMetadata Request to the Metadata Source. The request is composed of the ID, registrationAuthority and the version of the data element that is altogether uniquely identifies the Data Element.

3.44.4.1.2 Message Semantics

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

- 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.

Table 3.44.4.1.2-1: Summary of the elements in the RetrieveMetadata Request Message

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

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

3.44.4.1.3 Expected Action

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

The Metadata Source and Metadata Consumer shall support the SOAP binding for this transaction.

3.44.4.2 RetrieveMetadata Response

3.44.4.2.1 Trigger Events

This message will be triggered by a RetrieveMetadata Request Message.

3.44.4.2.2 Message Semantics

The RetrieveMetadata Response Message shall carry the metadata of the Data Element presented in Table 3.44.4.2.2-1[3]:

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

Element Name	Optionality	Is Repeatable	Description
id	R	No	Identifier of the Data Element. This ID shall be the same as the Data Element ID in the received RetrieveMetadata Request Message.
registrationAuthority	R	No	The Authority who has defined and registered the Data Element to the Metadata Source (Examples: CDISC, HITSP, NCI).
version	R	No	Version of the Data Element.
displayName	R	No	A name that can be used for display purposes
definition	R	No	Definition that gives an unambiguous description of the Data Element and its use.
contextualDomain	R2	No	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	The date that indicates the specific date when this Data Element is created.
effectiveDate	R2	No	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	The date when the Data Element is no longer expected to be used.
revisionDate	R2	No	The date when the Data Element is revised.

[3] 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 informative appendix for further description.

Element Name	Optionality	Is Repeatable	Description
revisionNote	R2	No	Note that indicates the revision reason, and the updates
objectClass	R	No	The object that is a part of this data element definition. Definition from ISO/IEC 11179: "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". Each data element is composed of an objectClass, a property term and a valueDomain triple. See informative appendix for further description.
property	R	No	The name of the property term which is a part of this data element definition. Definition from ISO/IEC 11179: "A property is a characteristic common to all members of an object Class". Each data element is composed of an objectClass, a property term and a valueDomain triple. See informative appendix for further description.
valueDomain	R	No	The description of the permissible set of values for the property of the data element definition. Each data element is composed of an objectClass, a property term and a valueDomain triple. See informative appendix for further description. A valueDomain description is composed (See Table 3.44.4.2.2-2): • A required dataType, representing the characteristics of the permissible values for the data element property (Examples: xsd:string) • A required (if available) unitOfMeasure which indicates the actual units in which the associated values of the property of the data element are measured. • A required (if available) valueSet which gives reference to the value set from which the values of this data element can be selected. The content of the valueSet can be further retrieved by IHE ITI SVS (Sharing Value Sets) profile. A valueSet description is composed (See Table 3.44.4.2.2-3): • A required id, representing the unique identifier for the valueSet. • A required version, representing the version of the valueSet in question. • An optional displayName, presenting the textual representation of the name of the valueSet.
mappingSpecification	R	Yes	The exact specification to locate the Data Element in a Content Model. If there are multiple mapping specifications, each specification is returned as a separate mappingSpecification. mappingSpecification description is composed: • A required contentModel element which uniquely indicates the Content Model that the Data

Element Name	Optionality	Is Repeatable	Description
			Element is interrelated with. • A required type that indicates the 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). • A required mappingScript that actually gives the exact specification to locate the Data Element in a Content Model (Examples: XPATH Scripts, SPARQL or SQL queries). contentModel description is composed: • A required id that identifies contentModel uniquely. This is the OID of the contentModel. (Example: 2.16.840.1.113883.10.20.1 for ASTM/HL7 CCD) • A required name of the contentModel. (Example: ASTM/HL7 CCD)

Table 3.44.4.2.2-2: valueDomain Summary in the RetrieveMetadata Response Message

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

Table 3.44.4.2.2-3: valueSet Summary in the RetrieveMetadata Response Message

Element Name	Optionality	Is Repeatable	Description
id	R	No	Identifier of the valueSet. This is the OID of the valueSet as described in IHE ITI SVS.
version	R	No	The version of the valueSet in question.
displayName	O	No	The textual representation of the name of the valueSet.

Table 3.44.4.2.2-4: mappingSpecification Summary in the RetrieveMetadata Response Message

Element Name	Optionality	Is Repeatable	Description

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

Table 3.44.4.2.2-5: contentModel Summary in the RetrieveMetadata Response Message

Element Name	Optionality	Is Repeatable	Description
id	R	No	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	Name of the contentModel. (Example: ASTM/HL7 CCD)

3.44.4.2.3 Expected Actions

A Metadata Source shall return the metadata of the Data Element indicated in the request.

The Metadata Source shall return the metadata of the Data Element or an error code in case the Data Element could not be located in the Metadata Source. 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”.

3.44.5 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.

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

3.44.6 Protocol Requirements

The protocol for the RetrieveMetadata 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 3.44.6-1: 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 RetrieveMetadata 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 RetrieveMetadata Request message shall be defined as “dex:RetrieveMetadataRequest”

The /definitions/message/part/@element attribute of the RetrieveMetadata 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”

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”

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 ITI QRPH: 3.44.5.3 Sample SOAP Message.

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”

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

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

- 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.)
- 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)
- 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)
- a required /dex:RetrieveMetadataResponse/dex:DataElement/dex:objectClass element with type “xsd:string”
- a required /dex:RetrieveMetadataResponse/dex:DataElement/dex:property element with type “xsd:string”
- 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”

- 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)
  - a required /dex:RetrieveMetadataResponse/dex:DataElement/dex:valueDomain/dex:valueSet/dex:id element with type “xsd:string”
  - a required /dex:RetrieveMetadataResponse/dex:DataElement/dex:valueDomain/dex:valueSet/dex:version element with type “xsd:string”
  - an optional /dex:RetrieveMetadataResponse/dex:DataElement/dex:valueDomain/dex:valueSet/dex:displayName element with type “xsd:string”

- one or more /dex:RetrieveMetadataResponse/dex:DataElement/dex:MappingSpecification element containing
  - a required /dex:RetrieveMetadataResponse/dex:DataElement/dex:MappingSpecification/dex:contentModel element containing
    - a required /dex:RetrieveMetadataResponse/dex:DataElement/dex:MappingSpecification/dex:contentModel/dex:id element with type “xsd:string”
    - a required /dex:RetrieveMetadataResponse/dex:DataElement/dex:MappingSpecification/dex:contentModel/dex:name element with type “xsd:string”
  - a required /dex:RetrieveMetadataResponse/dex:DataElement/dex:MappingSpecification/dex:type element with type “xsd:string”
  - a required /dex:RetrieveMetadataResponse/dex:DataElement/dex:MappingSpecification/dex:mappingScript element with type “xsd:string”

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

3.44.6.1 Sample RetrieveMetadata SOAP Request

```
<soap:Envelope xmlns:soap="http://schemas.xmlsoap.org/soap/envelope/"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xmlns:wsa=http://www.w3.org/2005/08/addressing
 xmlns:xsd="http://www.w3.org/2001/XMLSchema">
  <soap:Header>
        <wsa:MessageID>urn:uuid:f43f7bda-a5f9-42b1-b8dc-e78be1a2a183</wsa:MessageID>
        <wsa:Action>urn:ihe:qrph:dex:2013:RetrieveMetadata</wsa:Action>
  </soap:Header>
  <soap:Body>
        <dex:RetrieveMetadataRequest xmlns:dex="urn:ihe:qrph:dex:2013">
                <dex:id>6fbbd463-7de1-4ebc-85f6-76b84bab678b</dex:id>
                <dex:registrationAuthority>CDISC</dex:registrationAuthority>
                <dex:version>0.1</dex:version>
</dex:RetrieveMetadataRequest>
  </soap:Body>
</soap:Envelope>
```

3.44.6.2 Sample RetrieveMetadata SOAP Response

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



```
                        <dex:objectClass>DM</dex:objectClass>
                        <dex:property>ETHNIC</dex:property>
                        <dex:valueDomain>
                                <dex:dataType>xsd:string</dex:dataType>
                                <dex:valueSet>
                                        <id>2.16.840.1.114222.4.11.837</id>
                                        <version>1</version>
                                        <displayName>Ethnicity group</displayName>
                                </dex:valueSet>
                        </dex:valueDomain>
                        <dex:mappingSpecification>
                                <dex:contentModel>
                                        <dex:id>2.16.840.1.113883.10.20.1</dex:id>
                                        <dex:name>HL7 CCD</dex:name>
                                </dex:contentModel>
                                <dex:type>XPATH</dex:type>

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


Appendices

Appendix A – Schema and WSDL

```
<?xml version="1.0" encoding="UTF-8"?>
<!--
	IHE Data Element Exchange Profile (DEX) XML Schema
	for use in WSDL definitions.
-->
<xsd:schema
	xmlns="urn:ihe:qrph:dex:2013"
	targetNamespace="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"
	elementFormDefault="qualified"
	attributeFormDefault="unqualified">

	<xsd:element name="RetrieveMetadataRequest" type="dex:RetrieveMetadataRequestType"/>
	<xsd:element name="RetrieveMetadataResponse" type="dex:RetrieveMetadataResponseType"/>

	<xsd:complexType name="RetrieveMetadataRequestType">
		<xsd:sequence>
			<xsd:element name="id" type="xsd:string" minOccurs="1" maxOccurs="1"/>
			<xsd:element name="registrationAuthority" type="xsd:string" minOccurs="1"
maxOccurs="1"/>
			<xsd:element name="version" type="xsd:string" minOccurs="0"
maxOccurs="1"/>
		</xsd:sequence>
	</xsd:complexType>

	<xsd:complexType name="RetrieveMetadataResponseType">
		<xsd:sequence>
			<xsd:element name="DataElement" type="dex:DataElementType" minOccurs="1"
maxOccurs="1"/>
		</xsd:sequence>
	</xsd:complexType>
	<xsd:element name="RetrieveDataElementListRequest"
type="dex:RetrieveDataElementListRequestType"/>
	<xsd:element name="RetrieveDataElementListResponse"
type="dex:RetrieveDataElementListResponseType"/>
```



```
        <xsd:complexType name="RetrieveDataElementListRequestType">
                <xsd:sequence>
                        <xsd:element name="id" type="xsd:string" minOccurs="0" maxOccurs="1"/>
                        <xsd:element name="registrationAuthorityContains" type="xsd:string"
minOccurs="0" maxOccurs="1"/>
                        <xsd:element name="version" type="xsd:string" minOccurs="0"
maxOccurs="1"/>
                        <xsd:element name="displayNameContains" type="xsd:string" minOccurs="0"
maxOccurs="1"/>
                        <xsd:element name="definitionContains" type="xsd:string" minOccurs="0"
maxOccurs="1"/>
                        <xsd:element name="contextualDomainContains" type="xsd:string"
minOccurs="0" maxOccurs="1"/>
                        <xsd:element name="creationDateBefore" type="xsd:date" minOccurs="0"
maxOccurs="1"/>
                        <xsd:element name="creationDateAfter" type="xsd:date" minOccurs="0"
maxOccurs="1"/>
                        <xsd:element name="effectiveDateBefore" type="xsd:date" minOccurs="0"
maxOccurs="1"/>
                        <xsd:element name="effectiveDateAfter" type="xsd:date" minOccurs="0"
maxOccurs="1"/>
                        <xsd:element name="expirationDateBefore" type="xsd:date" minOccurs="0"
maxOccurs="1"/>
                        <xsd:element name="expirationDateAfter" type="xsd:date" minOccurs="0"
maxOccurs="1"/>
                        <xsd:element name="revisionDateBefore" type="xsd:date" minOccurs="0"
maxOccurs="1"/>
                        <xsd:element name="revisionDateAfter" type="xsd:date" minOccurs="0"
maxOccurs="1"/>
                        <xsd:element name="objectClassContains" type="xsd:string" minOccurs="0"
maxOccurs="1"/>
                        <xsd:element name="propertyContains" type="xsd:string" minOccurs="0"
maxOccurs="1"/>
                        <xsd:element name="dataTypeContains" type="xsd:string" minOccurs="0"
maxOccurs="1"/>
                        <xsd:element name="valueSetID" type="xsd:string" minOccurs="0"
maxOccurs="1"/>

                </xsd:sequence>
        </xsd:complexType>

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



```
        </xsd:complexType>


        <xsd:complexType name="DataElementType">
                <xsd:sequence>
                        <xsd:element name="id" type="xsd:string" minOccurs="1" maxOccurs="1"/>
                        <xsd:element name="registrationAuthority" type="xsd:string" minOccurs="1"
maxOccurs="1"/>
                        <xsd:element name="version" type="xsd:string" minOccurs="1"
maxOccurs="1"/>
                        <xsd:element name="displayName" type="xsd:string" minOccurs="1"
maxOccurs="1"/>
                        <xsd:element name="definition" type="xsd:string" minOccurs="1"
maxOccurs="1"/>
                        <xsd:element name="contextualDomain" type="xsd:string" minOccurs="1"
maxOccurs="1"/>
                        <xsd:element name="creationDate" type="xsd:date" minOccurs="1"
maxOccurs="1"/>
                        <xsd:element name="effectiveDate" type="xsd:date" minOccurs="0"
maxOccurs="1"/>
                        <xsd:element name="expirationDate" type="xsd:date" minOccurs="0"
maxOccurs="1"/>
                        <xsd:element name="revisionDate" type="xsd:date" minOccurs="0"
maxOccurs="1"/>
                        <xsd:element name="revisionNote" type="xsd:string" minOccurs="0"
maxOccurs="1"/>
                        <xsd:element name="objectClass" type="xsd:string" minOccurs="1"
maxOccurs="1"/>
                        <xsd:element name="property" type="xsd:string" minOccurs="1"
maxOccurs="1"/>
                        <xsd:element name="valueDomain" type="dex:ValueDomainType" minOccurs="1"
maxOccurs="1"/>
                        <xsd:element name="mappingSpecification"
type="dex:MappingSpecificationType" minOccurs="0" maxOccurs="unbounded"/>
                </xsd:sequence>
        </xsd:complexType>

        <xsd:complexType name="ValueDomainType">
                <xsd:sequence>
                        <xsd:element name="dataType" type="xsd:string" minOccurs="1"
maxOccurs="1"/>
                        <xsd:element name="unitOfMeasure" type="xsd:string" minOccurs="0"
maxOccurs="1"/>
                        <xsd:element name="valueSet" type="dex:ValueSetType" minOccurs="0"
maxOccurs="1"/>
                </xsd:sequence>
```



```
        </xsd:complexType>

        <xsd:complexType name="ValueSetType">
                <xsd:sequence>
                        <xsd:element name="id" type="xsd:string" minOccurs="1" maxOccurs="1"/>
                        <xsd:element name="version" type="xsd:string" minOccurs="1"
maxOccurs="1"/>
                        <xsd:element name="displayName" type="xsd:string" minOccurs="0"
maxOccurs="1"/>
                </xsd:sequence>
        </xsd:complexType>

        <xsd:complexType name="MappingSpecificationType">
                <xsd:sequence>
                        <xsd:element name="contentModel" type="dex:ContentModelType" minOccurs="1"
maxOccurs="1"/>
                        <xsd:element name="type" type="xsd:string" minOccurs="1" maxOccurs="1"/>
                        <xsd:element name="mappingScript" type="xsd:string" minOccurs="1"
maxOccurs="1"/>
                </xsd:sequence>
        </xsd:complexType>

        <xsd:complexType name="ContentModelType">
                <xsd:sequence>
                        <xsd:element name="id" type="xsd:string" minOccurs="1" maxOccurs="1"/>
                        <xsd:element name="name" type="xsd:string" minOccurs="1" maxOccurs="1"/>
                </xsd:sequence>
        </xsd:complexType>
<xsd:complexType name="DataElementSummaryType">
                <xsd:sequence>
                        <xsd:element name="id" type="xsd:string" minOccurs="1" maxOccurs="1"/>
                        <xsd:element name="registrationAuthority" type="xsd:string" minOccurs="1"
maxOccurs="1"/>
                        <xsd:element name="version" type="xsd:string" minOccurs="1"
maxOccurs="1"/>
                        <xsd:element name="displayName" type="xsd:string" minOccurs="1"
maxOccurs="1"/>
                        <xsd:element name="definition" type="xsd:string" minOccurs="1"
maxOccurs="1"/>
                        <xsd:element name="contextualDomain" type="xsd:string" minOccurs="1"
maxOccurs="1"/>
                        <xsd:element name="creationDate" type="xsd:date" minOccurs="1"
maxOccurs="1"/>
```



```
                        <xsd:element name="effectiveDate" type="xsd:date" minOccurs="0"
maxOccurs="1"/>
                        <xsd:element name="expirationDate" type="xsd:date" minOccurs="0"
maxOccurs="1"/>
                        <xsd:element name="revisionDate" type="xsd:date" minOccurs="0"
maxOccurs="1"/>
                        <xsd:element name="revisionNote" type="xsd:string" minOccurs="0"
maxOccurs="1"/>
                        <xsd:element name="objectClass" type="xsd:string" minOccurs="1"
maxOccurs="1"/>
                        <xsd:element name="property" type="xsd:string" minOccurs="1"
maxOccurs="1"/>
                        <xsd:element name="valueDomain" type="dex:ValueDomainType" minOccurs="1"
maxOccurs="1"/>
                </xsd:sequence>
        </xsd:complexType>

</xsd:schema>

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

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

        <wsdl:message name="RetrieveMetadataRequestMessage">
                <wsdl:part name="body" element="dex:RetrieveMetadataRequest"/>
        </wsdl:message>
```



```
        <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>
        <wsdl:message name="RetrieveDataElementListResponseMessage">
                <wsdl:part name="body" element="dex:RetrieveDataElementListResponse"/>
        </wsdl:message>


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

        </wsdl:portType>

        <wsdl:binding name="DataElementExchangeBinding" type="dex:DataElementExchangePortType">
                <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">
                        <soap12:operation
soapAction="urn:ihe:qrph:dex:2013:RetrieveDataElementList"/>
                        <wsdl:input>
                                <soap12:body use="literal"/>
```



```
                        </wsdl:input>
                        <wsdl:output>
                                <soap12:body use="literal"/>
                        </wsdl:output>
                </wsdl:operation>

        </wsdl:binding>

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

</wsdl:definitions>
```

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

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

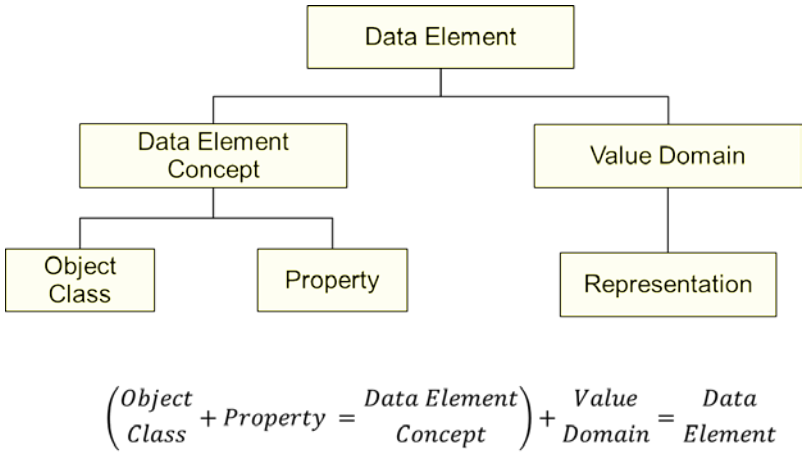


Figure B-1: Decomposition of a data element according to ISO/IEC 11179

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

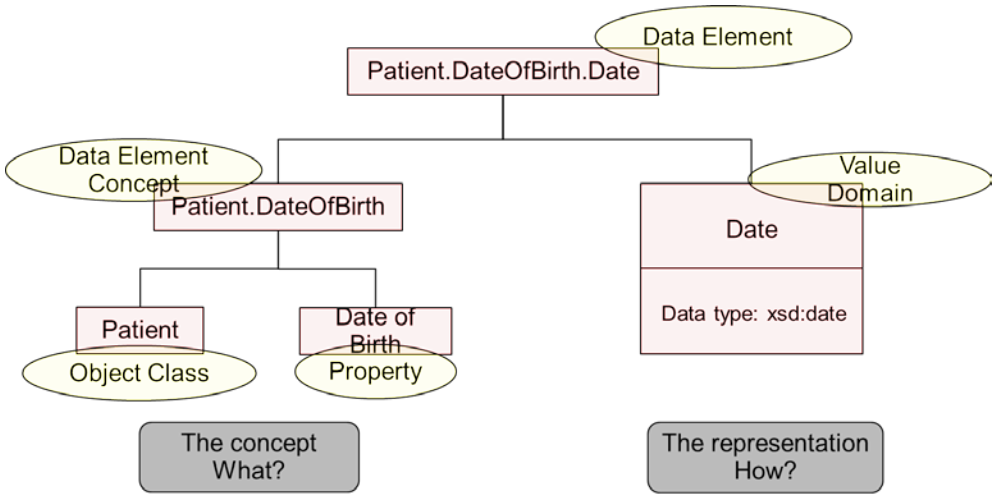


Figure B-2: An example of decomposition of a Data Element: Patient.DateOfBirth.Date

As presented in figure B-2, the concept of the data element and the representation are separate in the metamodel. These are modeled through Data Element Concepts and Value Domains respectively. A Data Element Concept is further decomposed into an Object Class and a 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
1370 “HealthcareProvider.Address.Address”.

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

C.1 Mapping Specification Type Codes

C.1.1 Metadata

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

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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.

Volume 2 Namespace Additions

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

None

Volume 3 – Content Modules

None

Volume 4 – National Extensions

Add appropriate Country section

None