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Information technology — Concepts and usage of metadata —

Part 23: Data element exchange (DEX) for a subset of ISO/IEC 11179-3

PROOF/ÉPREUVE

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Foreword

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This document was prepared by Joint Technical Committee ISO/IEC JTC 1, *Information technology*, Subcommittee SC 32, *Data management and interchange*.

A list of all parts in the ISO/IEC 19583 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

The ISO/IEC 11179 series addresses the semantics of data, the representation of data, and the registration of the descriptions of that data, i.e. metadata. While ISO/IEC 11179-3 provides the basic conceptual model for a metadata registry (MDR) in which information about metadata can be recorded and maintained, implementers and users of the registries described in the ISO/IEC 11179 series require further guidance to exchange data element definitions with each other via a standard-based protocol. It is necessary to have a common protocol and message semantics to be able to communicate with an MDR to locate the data elements given the search criteria and exchange metadata of data elements by addressing the technical and semantic interoperability challenges.

This document was developed to describe a message exchange framework specification for communicating a subset of data element metadata with an ISO/IEC 11179-3 MDR.

Information technology — Concepts and usage of metadata —

Part 23: Data element exchange (DEX) for a subset of ISO/IEC 11179-3

1 Scope

This document specifies the message exchange framework for communicating data element definitions with an ISO/IEC 11179-3 metadata registry (MDR). It defines message semantics, protocols and bindings for a set of transactions allowing the exchange of a commonly used subset of data element metadata with an ISO/IEC 11179-3 MDR.

This document establishes the following data element message exchange interoperability specifications:

— retrieving data element list from an ISO/IEC 11179-3 MDR matching the selection criteria;

— retrieving metadata of a selected data element from an ISO/IEC 11179-3 MDR.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO/IEC 11179-3, *Information technology — Metadata registries (MDR) — Part 3: Registry metamodel and basic attributes*

3 Terms, definitions and abbreviated terms

3.1 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/IEC 11179-3 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at https://www.iso.org/obp

3.1.1
target data model
information view of an application schema

Note 1 to entry: Implementation-dependent realizations of logical information models such as XML serializations, RDF serializations, JSON serializations and relational database schemas.

[SOURCE: ISO/TS 19129:2009, 4.1.2, modified — Note 1 to entry has been added.]

3.1.2
mapping specification
procedural functions to locate the data element in a given *target data model* (3.1.1)

Note 1 to entry: A mapping specification includes a *mapping script* (3.1.3), the type of the script (e.g. XPATH) and the target data model on which the mapping script can be executed.

3.1.3
mapping script
executable script on a given *target data model* (3.1.1)

Note 1 to entry: A mapping script can be an XPATH expression to be executed on XML documents[1].

3.1.4
metadata consumer
actor that retrieves the metadata created by the *metadata source* (3.1.5)

Note 1 to entry: A metadata consumer can optionally query the *metadata source* (3.1.5) for a list of data elements matching the *selection criteria* (3.1.6).

3.1.5
metadata source
actor responsible for creation of the data element list matching the *selection criteria* (3.1.6) and the creation of metadata for a selected data element per request from the *metadata consumer* (3.1.4)

Note 1 to entry: A metadata source is associated with an ISO/IEC 11179-3 metadata registry.

3.1.6
selection criteria
logical expression, the criteria being satisfied only if the expression evaluates to the value TRUE

[SOURCE: ISO 10303-14:2005, 3.3.9]

3.1.7
value set
finite set in a specific correspondence with the index-set of the list

Note 1 to entry: A value set is identified with a unique ID and version.

[SOURCE: ISO 8485:1989, 5.3.1.4, modified — Note 1 to entry has been added.]

3.2 Abbreviated terms

CDASH	Clinical Data Acquisition Standards Harmonization
CDISC	Clinical Data Interchange Standards Consortium
DEX	data element exchange
FHIR	fast healthcare interoperability resources
HITSP	Healthcare Information Technology Standards Panel
JSON	JavaScript object notation
MDR	metadata registry
NAV	navigation error (due to unknown data element)
NCI	National Cancer Institute

POSIX	portable operating system interface
RDF	resource description framework
regex	regular expressions
REST	representational state transfer
SDTM	study data tabulation model
SPARQL	simple protocol and RDF query language
SQL	structured query language
XML	eXtensible Markup Language
XPATH	XML path language
XSD	XML schema definition
VERUNK	version unknown

4 Overview of data element exchange (DEX) specification

4.1 General

The objective of DEX specification is to describe a message exchange framework for communicating a subset of administered data element definitions with an ISO/IEC 11179-3 MDR. It defines message semantics, protocols and bindings for a set of transactions allowing the exchange of a subset of administered data element metadata with an ISO/IEC 11179-3 MDR.

Two actors are defined as a part of this specification:

— Metadata source: The metadata source is responsible for the creation of the data element list matching the selection criteria and the creation of metadata for a selected data element per request from the metadata consumer. The metadata source is associated with an ISO/IEC MDR.

— 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 the selection criteria.

The following data element message exchange patterns are supported between the metadata source and metadata consumer actors:

— Retrieving a data element list from an ISO/IEC 11179-3 MDR matching the selection criteria.

— Retrieving metadata of a selected data element from an ISO/IEC 11179-3 MDR.

Corresponding to these message exchange patterns, two transaction specifications are provided:

— retrieve data element list;

— retrieve metadata.

The retrieve data element list transaction is an optional preparatory act to retrieve the identification information for the list of data elements matching the given the selection criteria, which can be used in the second retrieve metadata transaction to collect the metadata of the selected data element. The core content to be exchanged as a result of the retrieve metadata message exchange pattern is “data element metadata”. In 4.2, details of this content are examined first since the search criteria as a part of retrieve data element list also depends on this content specification. In 4.3 and 4.4, the transaction specifications of retrieve data element list and retrieve metadata are presented.

4.2 Data element metadata

The data element metadata is a flattened subset of the metadata attributes defined in the ISO/IEC 11179 series as depicted in Table 1. A mapping of DEX attributes to ISO/IEC 11179-3 attributes is available in Annex C. On top of the ISO/IEC 11179 series-based metadata of a data element, the attribute Mapping_Specification has been added to specify the mapping of an abstract data element definition to different target data models.

The attribute names in Tables 1 through 9 are based on ISO/IEC 11179-3. An ISO/IEC 11179 series class attribute is specified by using the class name and attribute name separated by a period e.g. 11179_class_name.attribute_name. The attribute name is written in the form of 11179_Class_Name if the attribute is composing inner attributes defined within a separate table. The optionality field can have the following values with their associated meanings:

R required

R2 required if the information is available

O optional

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

Table 1 — Data_Element metadata details

Attribute name	Optionality	Is repeatable	Type	Description
identifier	R	No	string	The universally unique identifier of the data element. This identifier should be the same as the identifier in the received retrieve metadata request message.
registration_authority_identifier	R	No	string	The authority who has defined and registered the data element to the metadata source. EXAMPLES CDISC, HITSP, NCI. See ISO/IEC 11179-3:2013 6.3.8.2. This attribute is comprised of international_code_designator, organization_identifier, organization_part_identifer. All these attributes can be used to create the string for the registration_authority_identifier. This is a mandatory field since the data elements must be administered for this specification.
version	R	No	string	The version of the data element.
designation.sign	R	No	string	The designation (name) of the data element that can be used for display purposes.
definition.text	R	No	string	The definition that gives an unambiguous description of the data element and its use.

Table 1 *(continued)*

Attribute name	Optionality	Is repeatable	Type	Description
registry_specifiation.context	R2	No	string	The specific domain in which this data element is defined. EXAMPLES CDASH, SDTM. If such a context is defined by the registration authority for this data element in the MDR, then this attribute is mandatory.
creation_date	R	No	date	The date when this data element is created.
effective_date	R	No	date	The date when this data element becomes effective to be used.
until_date	R2	No	date	The date when the data element is no longer expected to be used.
last_change_date	R2	No	date	The date when the data element was last revised.
change_description	R2	No	string	A note that indicates the revision reason and description of the updates.
Data_Element_Concept	R	No	See Table 2 for the details of Data_Element_Concept	The concept which is the meaning part of the data element definition. A data element is created with an association of a data element concept and a value domain.
Value_Domain	R	No	See Table 3 for the details of Value_Domain	The domain from which the data element takes its values. Each data element is composed of a data element concept and a value domain.
Mapping_Specification	R	Yes	See Table 5 for the details of Mapping_Specification	The exact specification to locate the data element in a target data model. This attribute is an extension on top of ISO/IEC 11179-3.

Table 2 — Data_Element_Concept details

Attribute name	Optionality	Is repeatable	Type	Description
identifier	R	No	string	The universally unique identifier of the data element concept.
version	R	No	string	The version of the data element concept.
designation.sign	R	No	string	The textual representation of the data element concept.
object_class.designation.sign	R2	No	string	An object class represents a set of ideas, abstractions, or things in the real world that are identified with explicit boundaries and meaning and whose properties and behaviour follow the same rules. This attribute is the name of the object class of the data element concept.
property.designation.sign	R2	No	string	A property is a characteristic common to all members of an object class. This attribute is the name of the property of the data element concept.

Table 3 — Value_Domain details

Attribute name	Optionality	Is repeatable	Type	Description
identifier	R	No	string	The universally unique identifier of the value domain.
type	R	No	string	The type of the value domain. Valid types are defined, enumerated and described.
datatype.name	R	No	string	The data type which represents the characteristics of the permissible values for the property of the data element. EXAMPLE xsd:string.
unit_of_measure	R2	No	string	Actual units in which the associated values of the property of the data element are measured.
source_uri	R2	No	string	A reference to the external value set, if the value domain's type is "defined" (ISO/IEC 11179-3:2013/Amd 1:2020).
Permissible_Value	R2	Yes	See Table 4 for the details of Permissible_Value.	The permissible value set from which the values of this data element can be selected.

