

Foundations of a metadata repository for databases of registers and trials

Jürgen STAUSBERG ^a, Matthias LÖBE ^b, Philippe VERPLANCKE ^c,
Johannes DREPPER ^d, Heinrich HERRE ^b, Markus LÖFFLER ^b

^a *IBE, Medical Faculty, Ludwig-Maximilians-Universität München, Germany*

^b *Institute for Medical Informatics (IMISE), Universität Leipzig, Germany*

^c *XClinical GmbH, Munich, Germany*

^d *Telematikplattform für Medizinische Forschungsnetze (TMF) e. V., Berlin,
Germany*



Who is TMF ?

- Organisation for Medical Research Networks in Germany (Telematikplattform für Medizinische Forschungsnetze)
 - Meta-organisation of the medical research associations
 - 71 members [2009-08-19]
 - Funded by the German Ministry of Education and Research (BMBF)
 - Founded in 1999 parallel to the establishment of the
 - Competence networks in medicine (KN)
 - Coordinating centres for clinical trials (KKS)
 - Parallel initiative to health telematics in the area of health care (electronic health card etc.)
 - National central authority for integrated medical research

Metadata Repository

- Metadata
 - data that defines and describes other data
- Metadata registry
 - information system for registering metadata
- Metadata repository

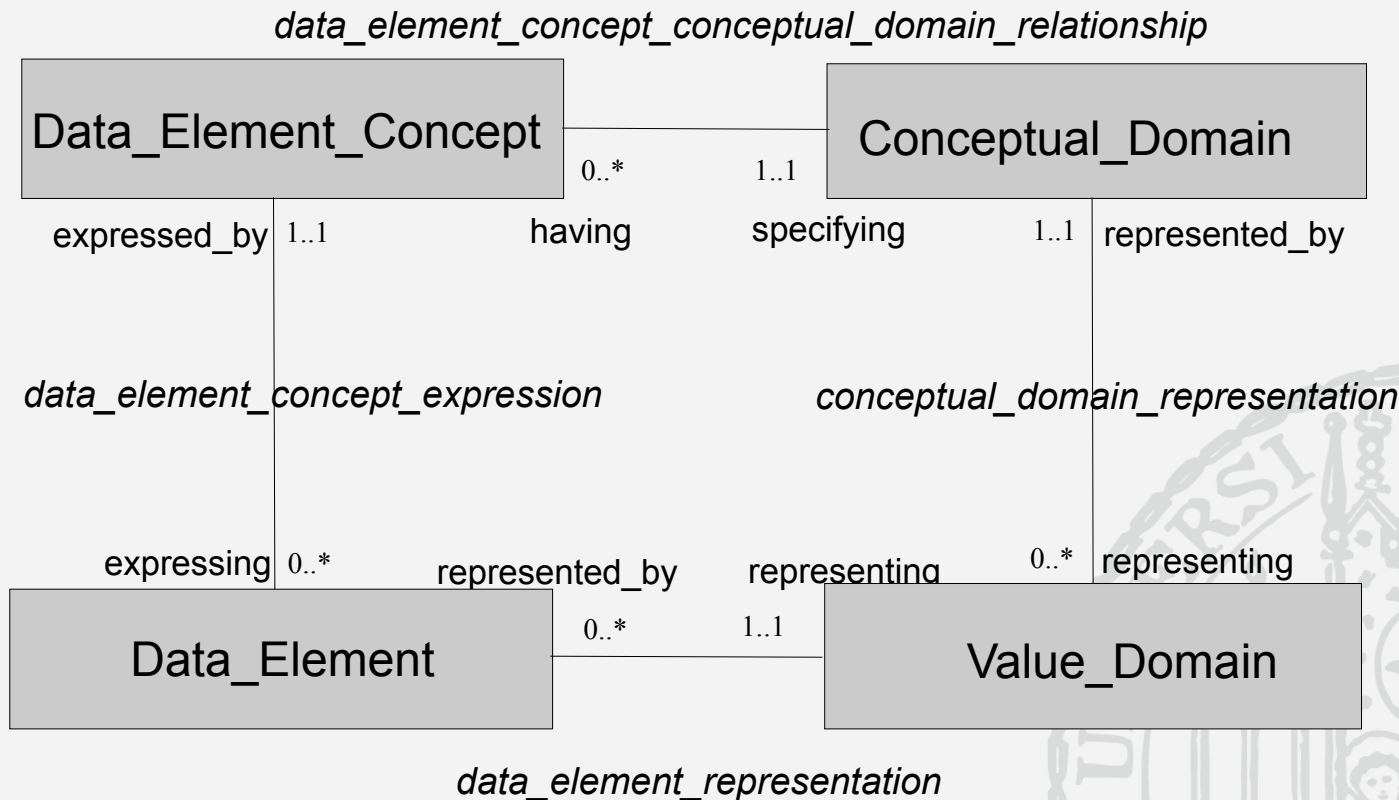
Search	Most Recent Queries	Time	Result
#2	Search "metadata repository"	14:21:37	7
#1	Search "metadata registry"	14:20:58	6

- Aims of our metadata repository are:
 - to make the creation of CRFs and data models easier
 - to improve the quality of CRFs and data models
 - to harmonize variables and value lists
 - and to support the mapping of metadata and data

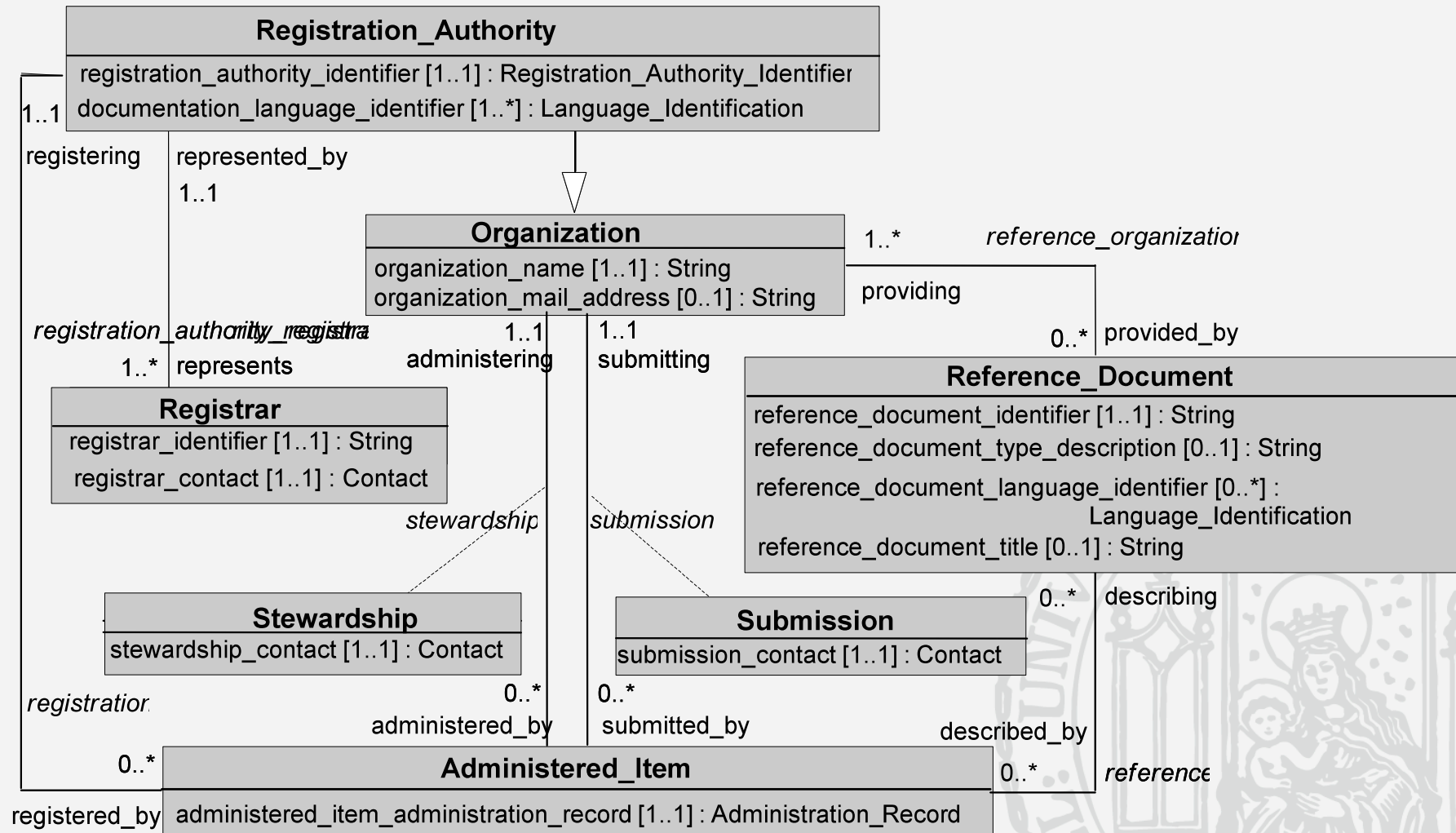
Use cases

- Single organization
 - Maintain metadata - to specify a CRF or a catalogue of variables
 - Import metadata - to establish a pool of metadata
 - Mapping of metadata - to transform data from one model to another
 - Queries for multiple versions of metadata - to support study series
- Multiple organizations
 - Queries for multiple metadata - to support pooling of data
 - Select projects - to identify projects covering specific variables
 - Review of metadata - to harmonize variables and value lists
- National level
 - Queries for multiple metadata - to support pooling of data
 - Select projects - to identify projects covering specific variables
 - Maintain standards - to harmonize CRFs and databases
 - Improve standards - to identify gaps in data standards or terminologies

ISO/IEC 11179 Information technologies - Metadata registries

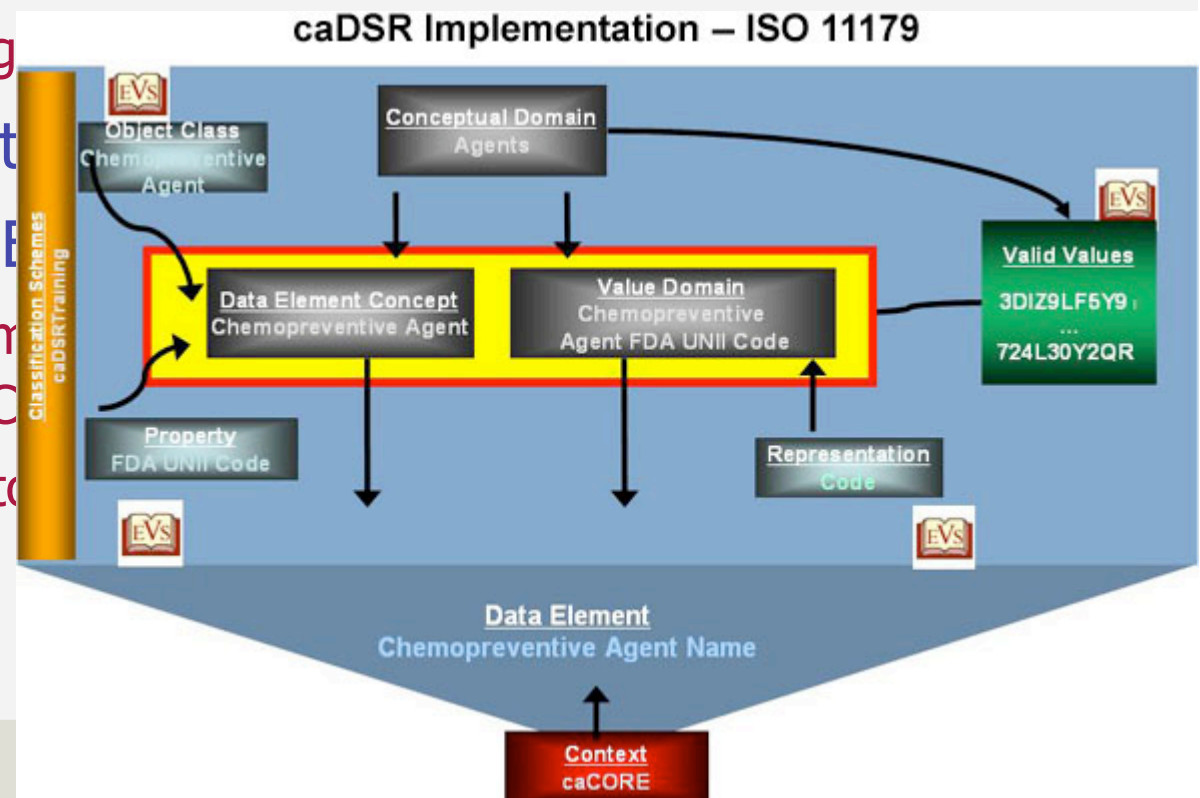


ISO/IEC 11179 Information technologies - Metadata registries



Example 1 - Cancer Data Standards Registry and Repository (caDSR)

- Part of caBIG® (cancer Biomedical Informatics Grid®): information network enabling all constituencies in the cancer community to share data and knowledge.
- caDSR goal: use of common data elements
 - <http://ncicb.nci.nih.gov>
- Based on Oracle data
- Extensions to ISO/IEC 11179
 - additional type "Form Case Report Form (CRF)"
 - additional type "Protocol"



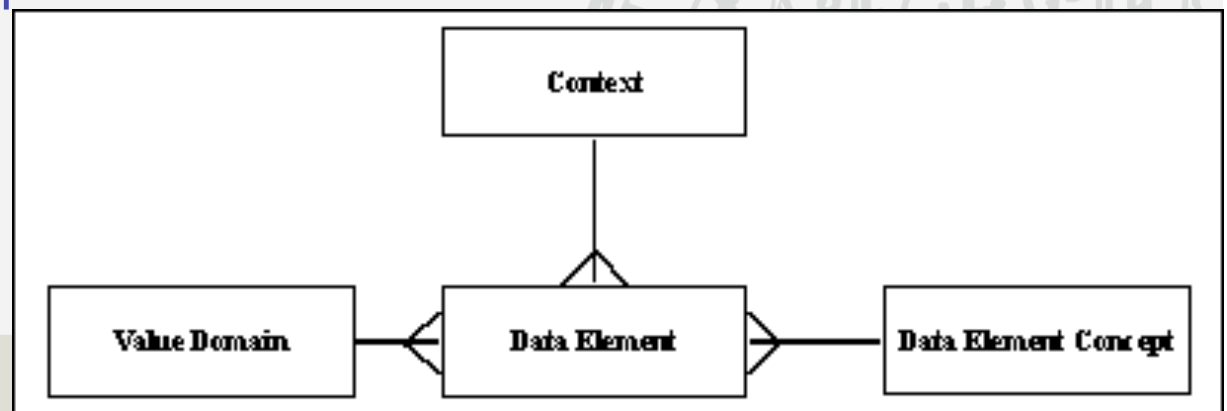


Example 2 - eXtended MetaData Registry (XMDR) Project

- Live prototype + free download
- Extension of ISO/IEC 11179
 - decentralized stewardship by central storage
 - terminological model
 - enhanced capabilities for terminologies, classification schemes, ontologies
 - capture the semantic specification in terms of a description logic
 - ...
- High-level Use Cases
 - Support of Application Development and Maintenance - Single System
 - Support of Application Development and Maintenance – Multiple System
 - Support of Data Migration or Exchange
 - Support a Portal or Data Warehouse - Single Organization
 - Support a Portal or Data Warehouse - Multiple Organizations
 - Support a Data Grid or an Online Transaction Network
 - Support for Development of a "Universal" Grid

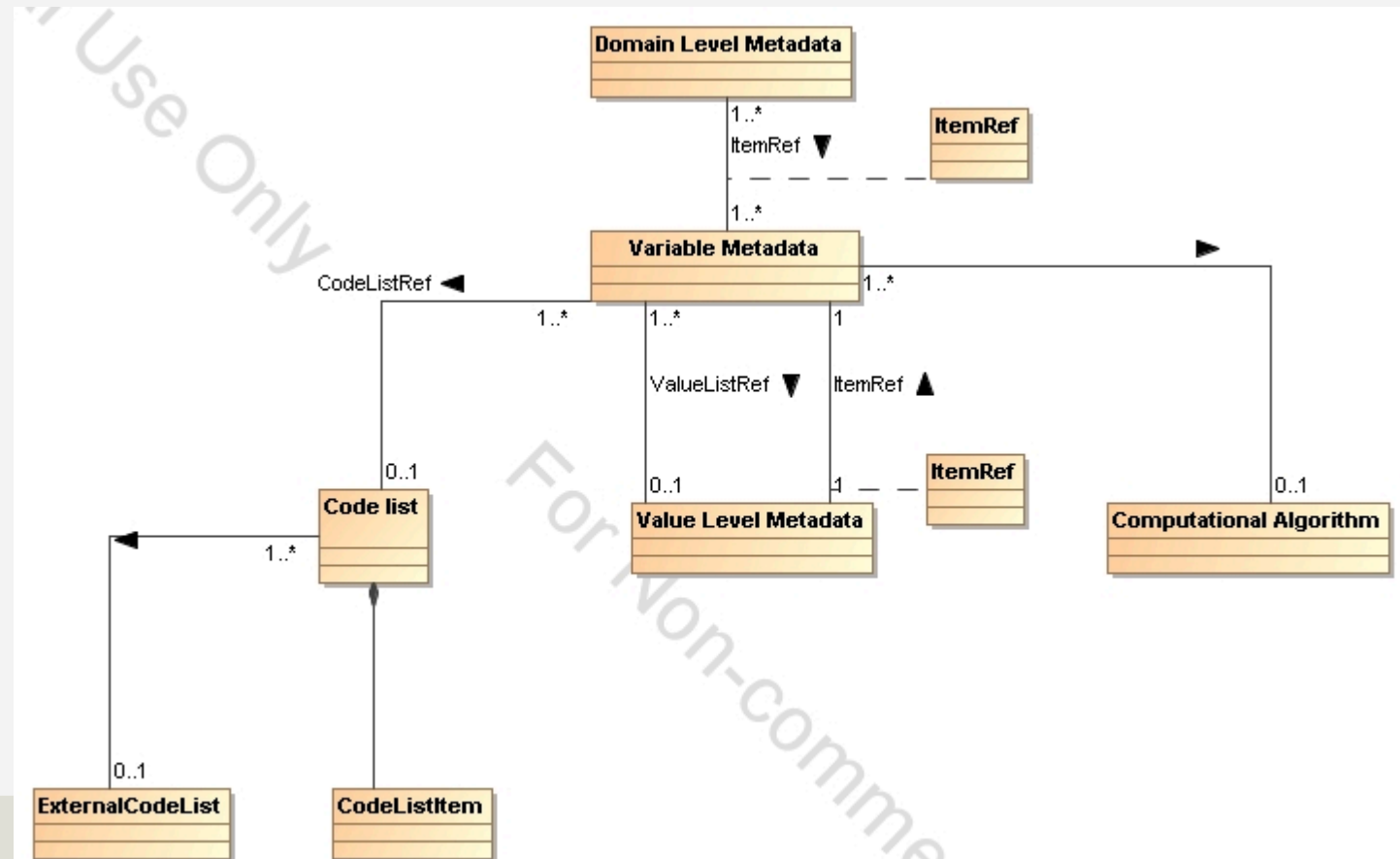
Example 3 - OneData MDR with 'Lite' model

- Commercial implementation by Data Foundations
 - <http://www.datafoundations.com/>
- OneData MDR
 - with ISO 11179 Model
 - with 'Lite' Model
 - quickly implementation
 - physical entities in the underlying database conform to the objects in the application



Alternative: Clinical Data Interchange Standards Consortium (CDISC)

- Case Report Tabulation Data Definition Specification Version 1.0 (CRT-DDS, define.xml)





Future prospects: national metadata repository for Germany

- ISO/IEC 11179 Edition 2
 - + decentral organization
 - + explicit representation of controlled vocabularies
- Integration with trial management and data management systems
- Import/export of metadata with CDISC Operational Data Model (ODM)
- Definition of business processes for acquisition and maintenance of content
- Basic collection of standard set of items





LUDWIG-
MAXIMILIANS-
UNIVERSITÄT
MÜNCHEN

End

