

A metadriven approach for definition and management of clinical standards within a CDW repository environment, current challenges and visions for improvements iCDW

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Outline

CDW Operations

The Standards in CDW

Metadata in CDW

Clinical Standards Ontology

Clinical System Architecture

iCDW

CDW Operations

Development and support of the Clinical Data Warehouse system

- Metadata entry & mapping application
- Data model
- Statistical computing environment

Development and maintenance of Use of System components

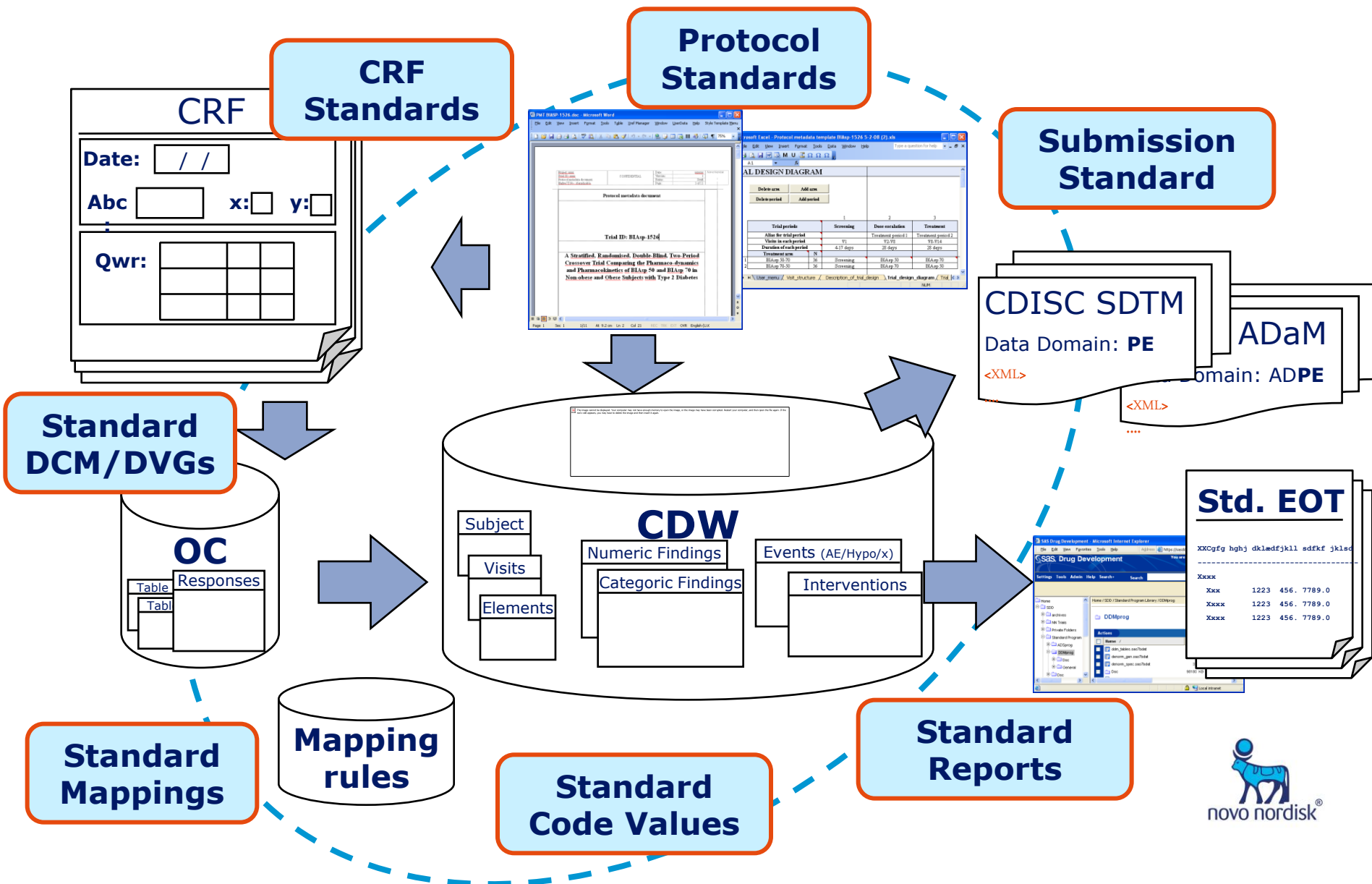
- Controlled terminology
- Mapping of data from CDMS to the Clinical Data Warehouse
- Standard programs
 - Data enrichment
 - Statistical output

How are we organised?

- Part of Clinical Systems & Data Management in Global Development
- Twenty employees
- Standard Supporters, Programmers and Specialists within these areas

The Standards in CDW

- ensuring reusability, traceability and consistency

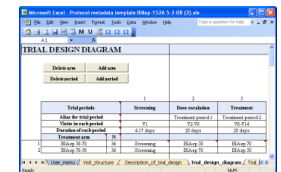
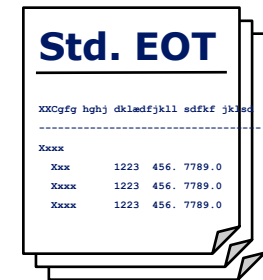


Benefits of using metadata

- See previous presentations:
 - Standardisation of Trial Design Definitions in CDW at Novo Nordisk
 - Mikkel Traun, Novo Nordisk, CDISC User Group 2008
 - Data Standardisation, Clinical Data Warehouse and SAS® Standard Programs
 - Jean-Marc Ferran, Novo Nordisk, PhUSE Manchester 2008
 - Managing your metadata efficiently
 - Kirsten Langendorf, Novo Nordisk, PhUSE Basel 2009
 - Metadata and Standard Programs
 - Marianne Carames & Martin Lindhard, Novo Nordisk, PhUSE Basel 2009

Standards, Controlled Terminology and General Clinical Metadata in CDW

- **Standards** – Structure and content
 - These are specific areas where you have agreed upon a standard: Protocol, CRF and Report/Business Rules standards
- **Controlled Terminology** – Input & Output Content
 - Codes, labels and the content definition
- **Clinical Metadata** – CDW implementation
 - How Standards and Controlled Terminology is implemented in CDW



Challenges when using metadata

2.3 Table 1 Demographics and Baseline Characteristics – Summary – Full Analysis

Complex dependencies and prerequisites between:

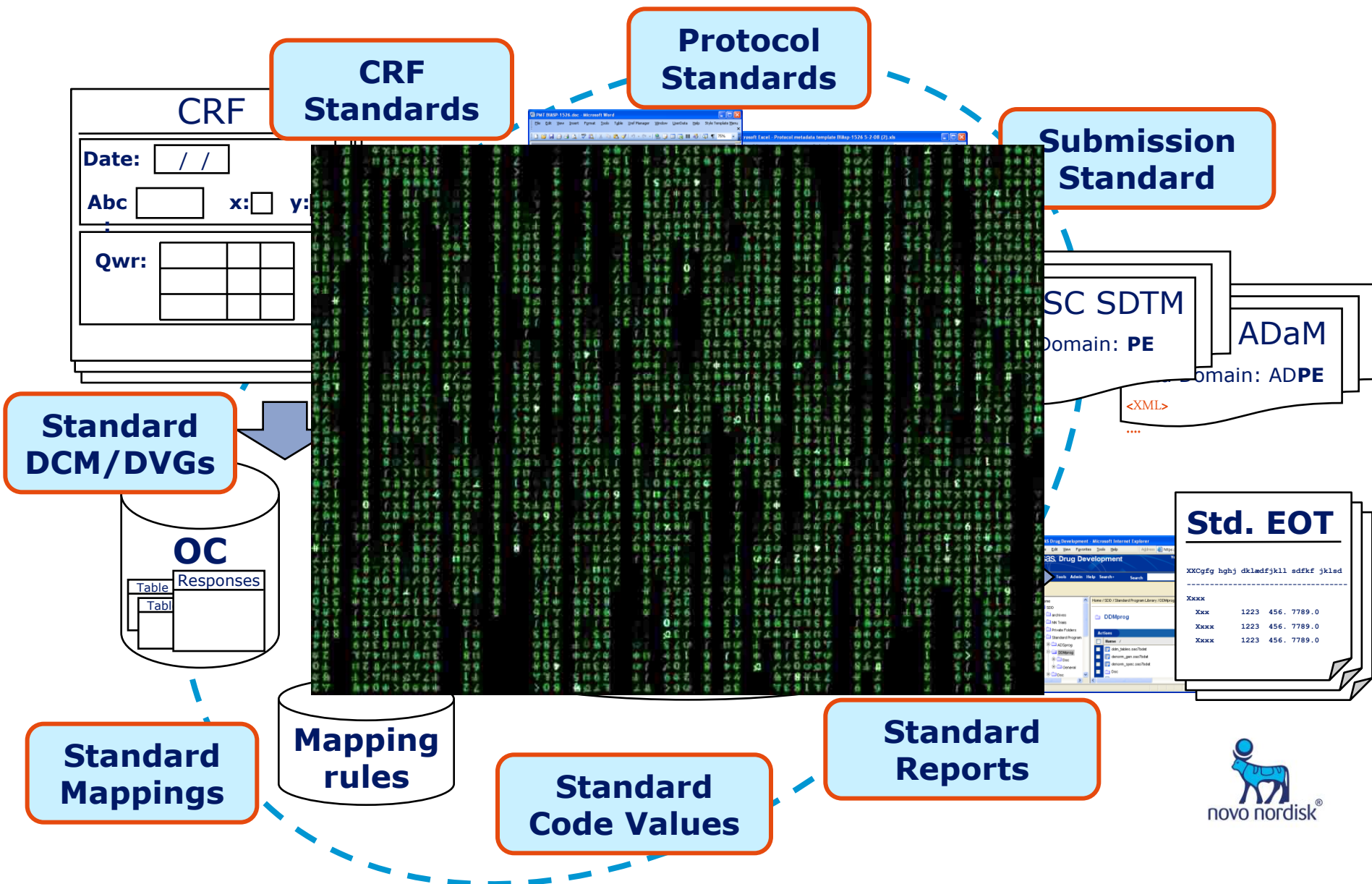
	Treatment1	Treatment2	Comparator	Total
Number of Subjects	xxxx	xxxx	xxxx	xxxxx
Age Group, N (%)				
N	xxxx (100.0)	xxxx (100.0)	xxxx (100.0)	xxxxx (100.0)
Adults (below 65)	xxxx (xxx.x)	xxxx (xxx.x)	xxxx (xxx.x)	xxxxx (xxx.x)
Elderly (65 or older)	xxxx (xxx.x)	xxxx (xxx.x)	xxxx (xxx.x)	xxxxx (xxx.x)
Sex, N (%)				
N	xxxx (100.0)	xxxx (100.0)	xxxx (100.0)	xxxxx (100.0)
Female	xxxx (xxx.x)	xxxx (xxx.x)	xxxx (xxx.x)	xxxxx (xxx.x)
Male	xxxx (xxx.x)	xxxx (xxx.x)	xxxx (xxx.x)	xxxxx (xxx.x)
Country of Residence, N (%)				
N	xxxx (100.0)	xxxx (100.0)	xxxx (100.0)	xxxxx (100.0)
Australia	xxxx (xxx.x)	xxxx (xxx.x)	xxxx (xxx.x)	xxxxx (xxx.x)
Germany	xxxx (xxx.x)	xxxx (xxx.x)	xxxx (xxx.x)	xxxxx (xxx.x)
Norway	xxxx (xxx.x)	xxxx (xxx.x)	xxxx (xxx.x)	xxxxx (xxx.x)
Sweden	xxxx (xxx.x)	xxxx (xxx.x)	xxxx (xxx.x)	xxxxx (xxx.x)
USA	xxxx (xxx.x)	xxxx (xxx.x)	xxxx (xxx.x)	xxxxx (xxx.x)
Ethnicity, N (%)				
N	xxxx (100.0)	xxxx (100.0)	xxxx (100.0)	xxxxx (100.0)
Hispanic or Latino	xxxx (xxx.x)	xxxx (xxx.x)	xxxx (xxx.x)	xxxxx (xxx.x)
Not Hispanic or Latino	xxxx (xxx.x)	xxxx (xxx.x)	xxxx (xxx.x)	xxxxx (xxx.x)
Race, N (%)				
N	xxxx (100.0)	xxxx (100.0)	xxxx (100.0)	xxxxx (100.0)
American Indian or Alaska Native	xxxx (xxx.x)	xxxx (xxx.x)	xxxx (xxx.x)	xxxxx (xxx.x)
Asian	xxxx (xxx.x)	xxxx (xxx.x)	xxxx (xxx.x)	xxxxx (xxx.x)
Black or African American	xxxx (xxx.x)	xxxx (xxx.x)	xxxx (xxx.x)	xxxxx (xxx.x)
Native Hawaiian or Other Pacific Islander	xxxx (xxx.x)	xxxx (xxx.x)	xxxx (xxx.x)	xxxxx (xxx.x)
White	xxxx (xxx.x)	xxxx (xxx.x)	xxxx (xxx.x)	xxxxx (xxx.x)
Other	xxxx (xxx.x)	xxxx (xxx.x)	xxxx (xxx.x)	xxxxx (xxx.x)

Subjects from France did not report race

<Therapeutic Area>/<Clinical Programme>/<project>/<trial>/<instance>
<date> - <programme name>/<output name>

The Standards in the Reporting & Data Flow

- ensuring reusability, traceability and consistency



What Is An Ontology

- An **ontology** is an explicit description of a domain:
 - concepts
 - properties and attributes of concepts
 - constraints on properties and attributes
 - Individuals (*instances*)
- An ontology defines
 - a common vocabulary
 - a shared understanding

Ontology - From Wikipedia

In computer science and information science, an **ontology** is a formal representation of the knowledge by a set of concepts within a domain and the relationships between those concepts. It is used to reason about the properties of that domain, and may be used to describe the domain.

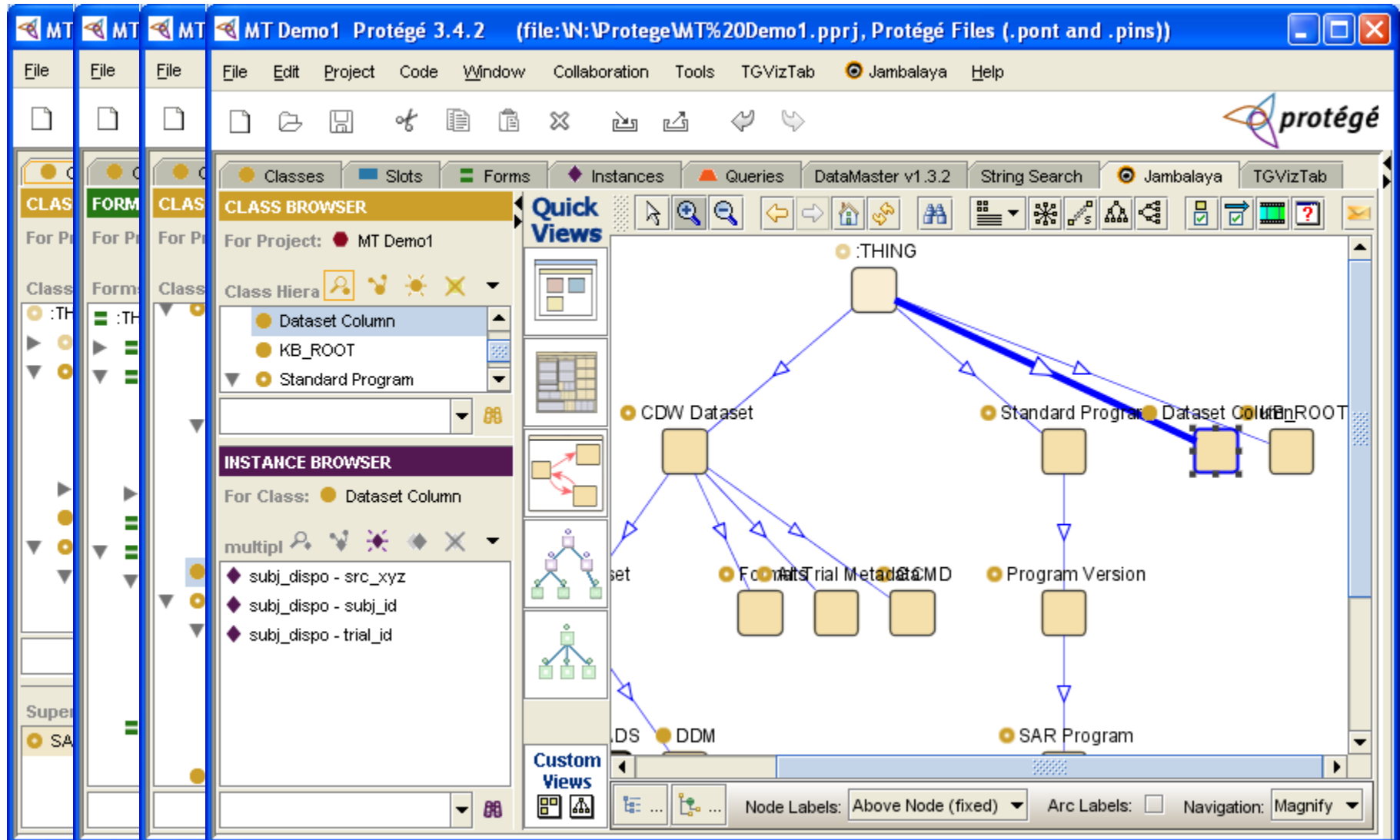
In theory, an ontology is a "formal, explicit specification of a shared conceptualisation".^[1] An ontology provides a shared vocabulary, which can be used to model a domain — that is, the type of objects and/or concepts that exist, and their properties and relations.^[2]

Ontologies are used in artificial intelligence, the Semantic Web, systems engineering, software engineering, biomedical informatics, library science, enterprise bookmarking, and information architecture as a form of knowledge representation about the world or some part of it. The creation of domain ontologies is also fundamental to the definition and use of an enterprise architecture framework.

Clinical Standards Ontology

- Domain model of clinical standards and their end-to-end relationship and dependencies
 - Not an implemented system model
- Why develop an ontology of clinical standards?
 - To share common understanding of the structure of clinical information among people and systems
- A Clinical Standards Ontology can:
 - Support requirement specifications
 - Support program development and testing
 - Improve documentation
 - Improve user guidance and support
 - Improve system maintenance

Ontology tool - Protégé



An ontology driven clinical architecture

- When you have a mature and stable ontology model of all relationships and dependencies in the clinical standards and data flow in the clinical development process
- Then make a clinical system architecture that utilise this model in a shared master data repository
- **iCDW**

iCDW

- How is your vision of an iCDW?

