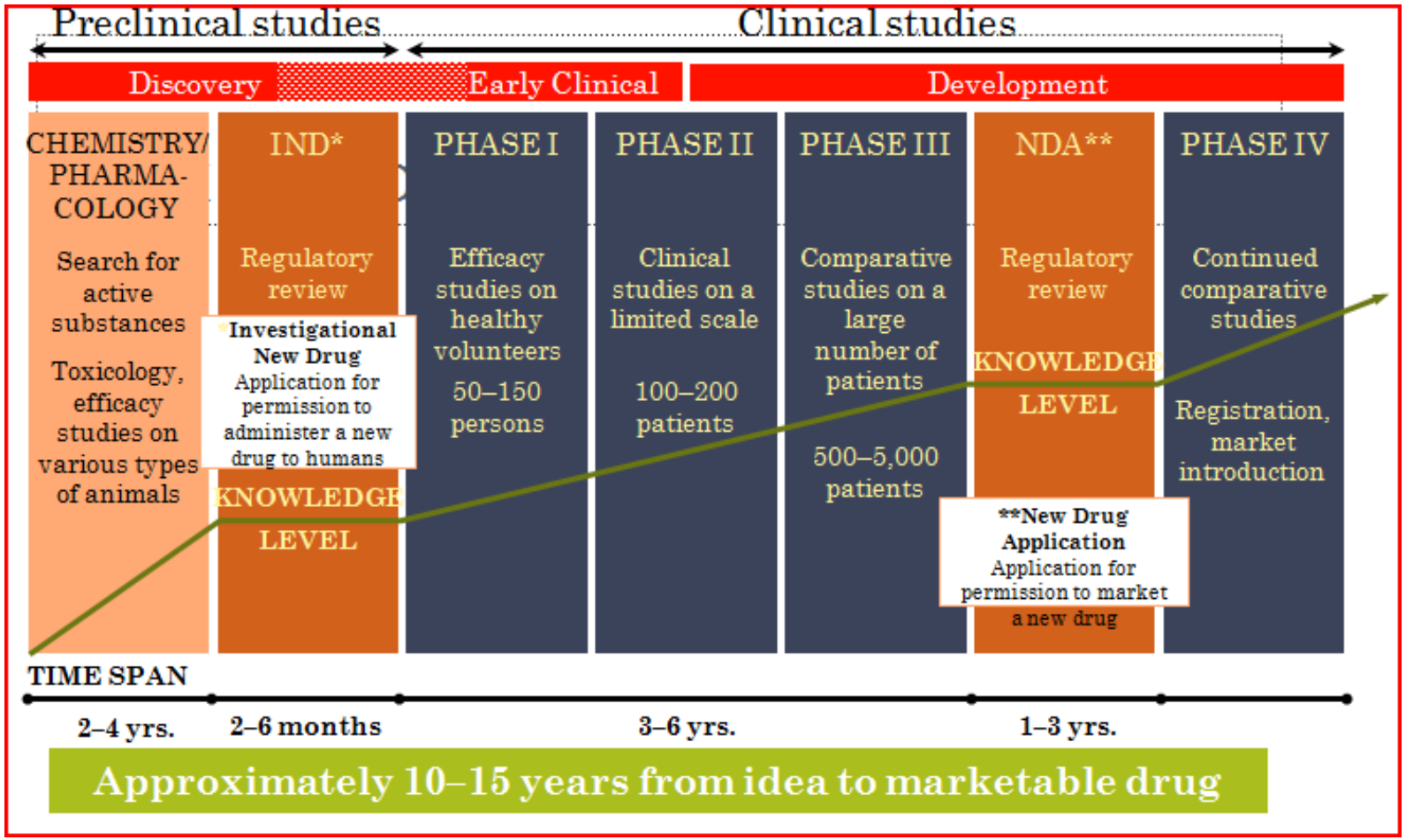
Linking Clinical Data Standards

Kerstin Forsberg
AstraZeneca, R&D Information

kerstin.l.forsberg@astrazeneca.com

kerfors on Twitter, Google+, LinkedIn, Slideshare, Blogspot

Pharmaceutical Research and Development



INDUSTRY VERTICALS, LINKED DATA, SCIENTIFIC AND RESEARCH APPLICATIONS

Clinical Studies And The Road To Linked Data

By Jennifer Zaino on February 11, 2013 8:00 AM

Clinical studies aren't what they used to be. In the past, the process was one-off: You conducted a study, gathered a lot of data, analyzed it, wrote a report, and submitted it to the authorities. But, says long-time Linked Data advocate Kerstin Forsberg, an information architect at AstraZeneca, that's all changed in the last few years.

"A study is not a study on its own," says Forsberg. Today, the goal is to do meta-analysis across many studies, so parties ranging from pharmaceuticals companies to contract research organizations to government authorities all are 'customers' of clinical data, so to speak. Data from various studies must be shared among all these parties. "It puts a new context around clinical trial data, that it must be easy to link data together, to link across several different studies," she says.

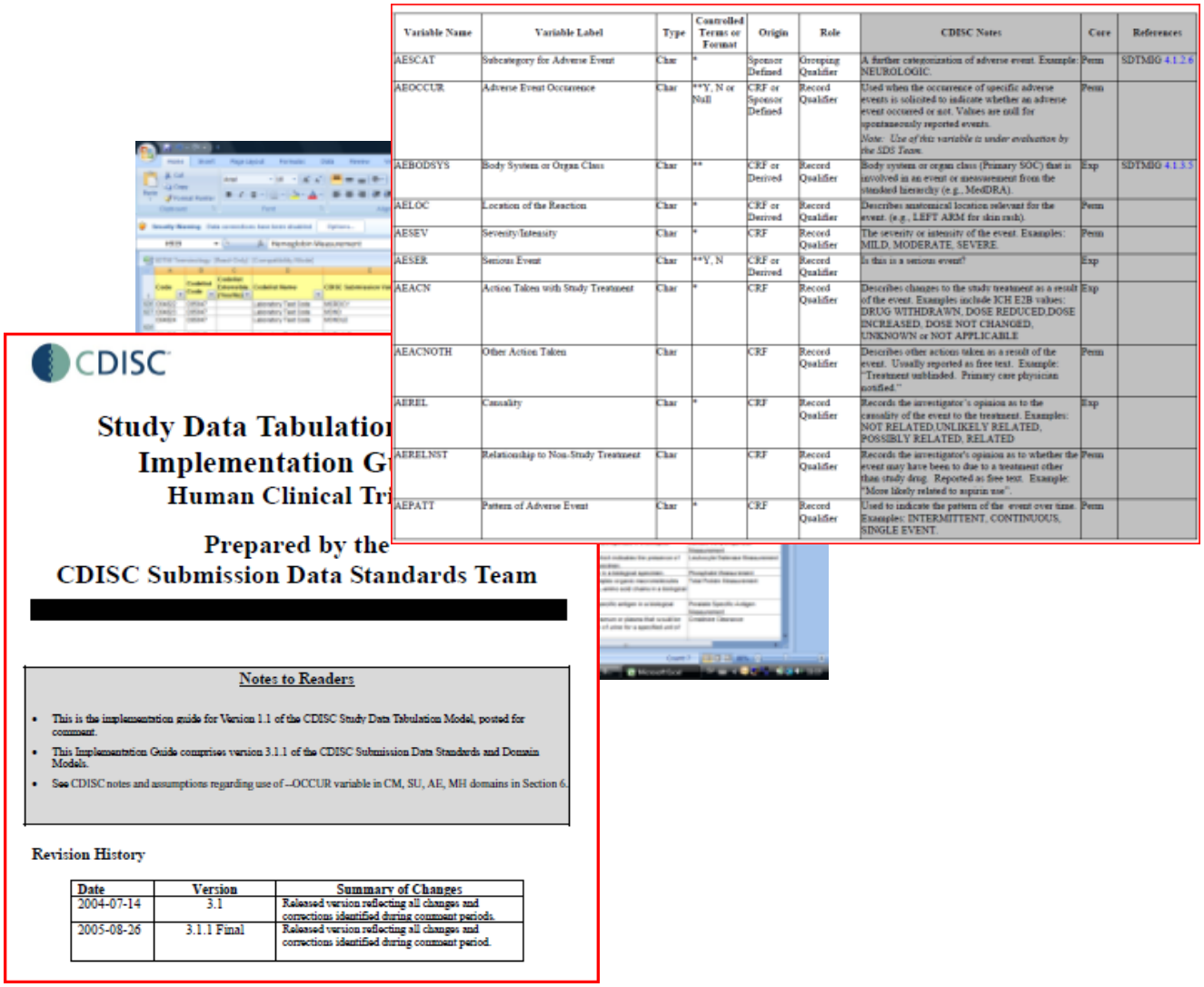
The case is there to use modern information standards, like semantic web standards and Linked Data principles, to address this need. It's why Forsberg is one of the individuals spearheading a volunteer effort to create RDF and OWL representations of the standards published by the Clinical Data Interchange Standards Consortium (CDISC) an international, non-profit organization that develops and supports global data standards for medical research.

The problem is that CDISC publishes its standards in huge PDF documents, with Excel matrices and some first-generation XML implementations, she notes. "If I want to know how to exchange lab data with a number of different measurements, I must pick up the PDF document to see how to structure the data sets, what elements are in them," she says. That's fine for a human to do, but better yet would be to represent the standards data in RDF format so that it would be machine-readable and thus seamless to refer to a single element in a full data set of labs data.

http://semanticweb.com/clinical-studies-and-the-road-to-linked-data_b35252

Data standard organisation

Human readable standards



Variable Name	Variable Label	Type	Controlled Terms or Format	Origin	Role	CDISC Notes	Core	References
AESCAT	Subcategory for Adverse Event	Char	*	Sponsor Defined	Grouping Qualifier	A further categorization of adverse event. Example: NEUROLOGIC.	Perm	SDTMIG 4.1.2.6
AEOCCUR	Adverse Event Occurrence	Char	"Y, N or Null	CRF or Sponsor Defined	Record Qualifier	Used when the occurrence of specific adverse events is solicited to indicate whether an adverse event occurred or not. Values are null for spontaneously reported events. *Note: Use of this variable is under evaluation by the SDS Team.*	Perm	
AEBODSYS	Body System or Organ Class	Char	**	CRF or Derived	Record Qualifier	Body system or organ class (Primary SOC) that is involved in an event or measurement from the standard hierarchy (e.g., MedDRA).	Exp	SDTMIG 4.1.3.5
AELOC	Location of the Reaction	Char	*	CRF or Derived	Record Qualifier	Describes anatomical location relevant for the event. (e.g., LEFT ARM for skin rash).	Perm	
AESEV	Severity/Intensity	Char	*	CRF	Record Qualifier	The severity or intensity of the event. Examples: MILD, MODERATE, SEVERE.	Perm	
AESER	Serious Event	Char	"Y, N	CRF or Derived	Record Qualifier	Is this is a serious event?	Exp	
AEACN	Action Taken with Study Treatment	Char	*	CRF	Record Qualifier	Describes changes to the study treatment as a result of the event. Examples include ICH E2B values: DRUG WITHDRAWN, DOSE REDUCED,DOSE INCREASED, DOSE NOT CHANGED, UNKNOWN or NOT APPLICABLE	Exp	
AEACNOTH	Other Action Taken	Char		CRF	Record Qualifier	Describes other actions taken as a result of the event. Usually reported as free text. Example: "Treatment unblinded. Primary care physician notified."	Perm	
AEREL	Causality	Char	*	CRF	Record Qualifier	Records the investigator's opinion as to the causality of the event to the treatment. Examples: NOT RELATED,UNLIKELY RELATED, POSSIBLY RELATED, RELATED	Exp	
AERELNST	Relationship to Non-Study Treatment	Char		CRF	Record Qualifier	Records the investigator's opinion as to whether the event may have been to due to a treatment other than study drug. Reported as free text. Example: "Most likely related to aspirin use".	Perm	
AEPATT	Pattern of Adverse Event	Char	*	CRF	Record Qualifier	Used to indicate the pattern of the event over time. Examples: INTERMITTENT, CONTINUOUS, SINGLE EVENT.	Perm	

CDISC

Study Data Tabulatio
Implementation G
Human Clinical Tr

Prepared by the
CDISC Submission Data Standards Team

[redacted]

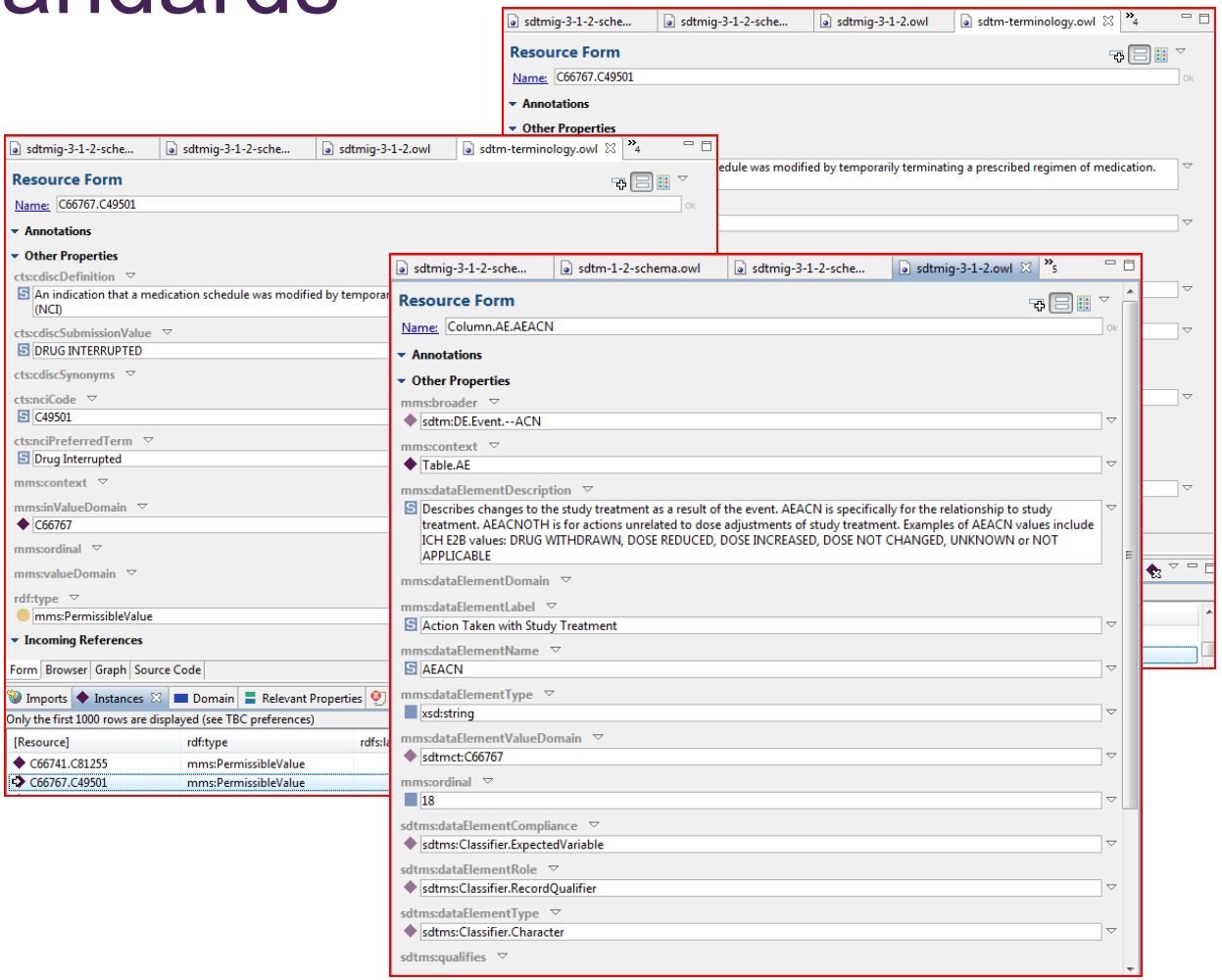
Notes to Readers

- This is the implementation guide for Version 1.1 of the CDISC Study Data Tabulation Model, posted for comment.
- This Implementation Guide comprises version 3.1.1 of the CDISC Submission Data Standards and Domain Models.
- See CDISC notes and assumptions regarding use of --OCCUR variable in CM, SU, AE, MH domains in Section 6.

Revision History

Date	Version	Summary of Changes
2004-07-14	3.1	Released version reflecting all changes and corrections identified during comment periods.
2005-08-26	3.1.1 Final	Released version reflecting all changes and corrections identified during comment period.

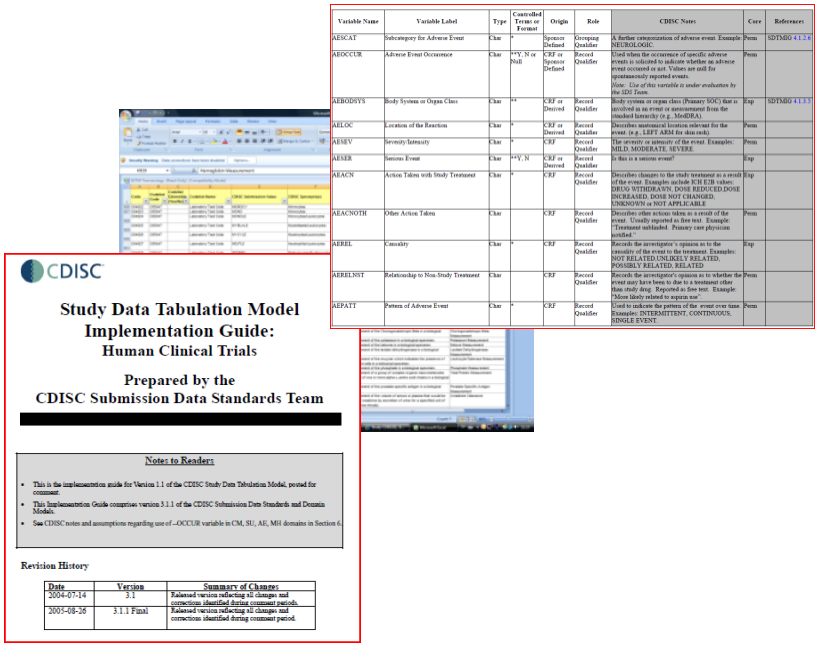
Machine computable and queryable standards



Screenshots from the ontology tool:
TopBraid Composer

We want to push back to CDISC, and other public and internal standard groups, and show in practice how to:
"Use (semantic web) standards for standards"

Human readable standards



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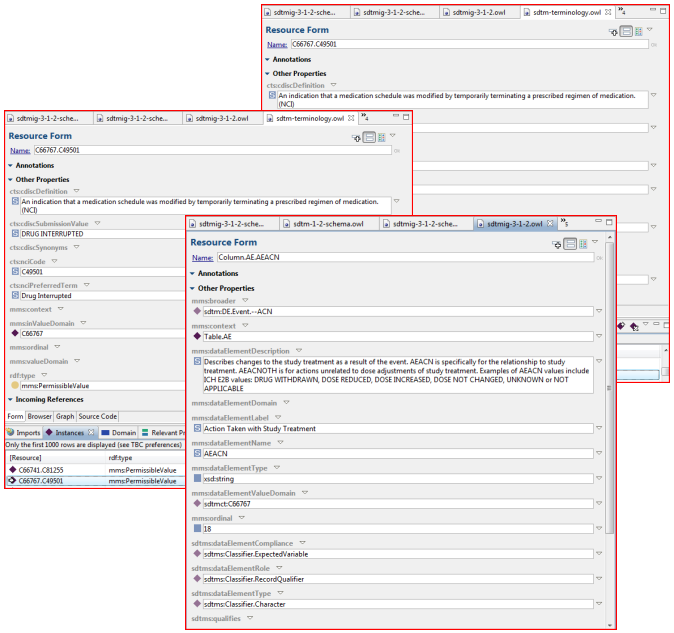

CDISC2RDF

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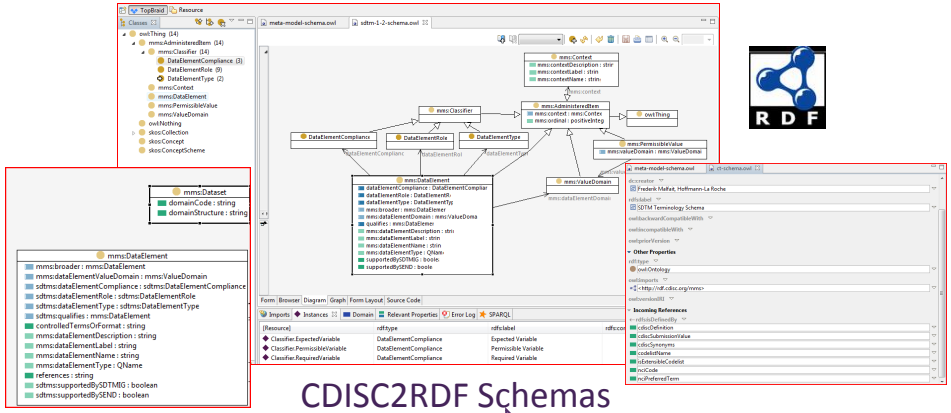
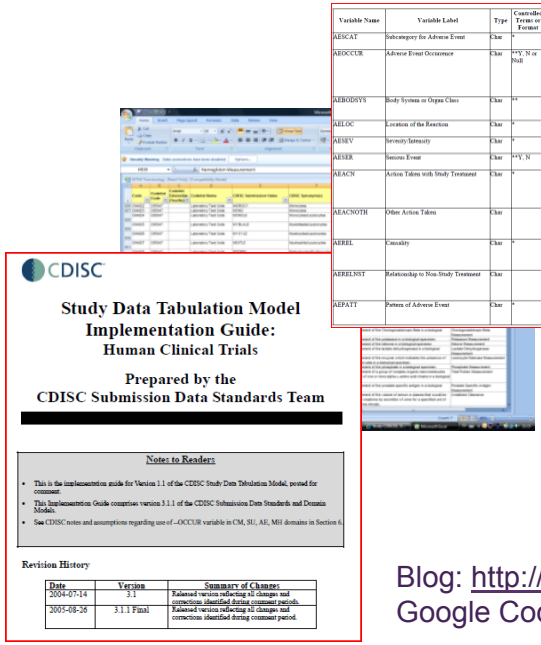
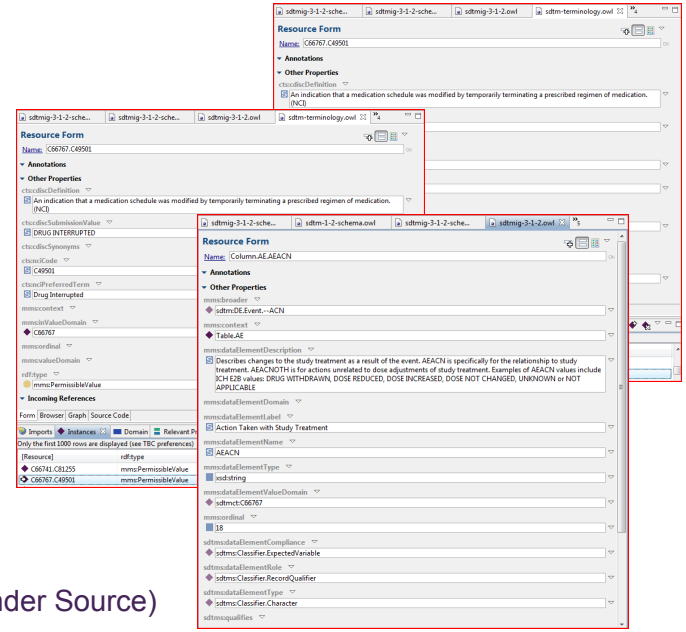


CDISC2RDF Schemas

Human readable standards



Machine computable and queryable standards



Blog: http://cdisc2rdf.com/
Google Code: https://code.google.com/p/cdisc2rdf/ (under Source)

Next step

- A general approach to the use of multiple standards that collectively support standardized data/meta-data exchange and re-purposing
  - Standards-as-is
  - Standards-in-context
  - Interoperability across standards and the data collected using them

U.S. Food and Drug Administration
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Overview to the Semantic Web Technologies

Mitra Rocca
Medical Informatician
FDA/CDER/OTS

28 January 2013

Partnerships for Innovation ...

Research Project Description

Semantic Web Technologies Fellowship
Office of Translation Sciences
Center for Drug Evaluation and Research
U.S. Food and Drug Administration
Silver Spring, MD

FDA-CDER-2013-0009

Project Description:

A postdoctoral fellowship is available within the Office of Translation Sciences (OTS) in the Center for Drug Evaluation and Research (CDER) of the U.S. Food and Drug Administration (FDA). The selected participant will be involved with efforts to use Semantic Web technologies to develop clinical data standards for various therapeutic areas at CDER.

The participant may be involved in one or more of the following aspects of the project:

- Reviewing artifacts, such as case report forms (CRF)
- Sampling data
- Gathering requirements from subject matter experts/reviewers at CDER
- Conducting research utilizing Semantic Web technologies for data warehousing and re-use of Electronic Health Record (EHR) for clinical research.

This project aims to improve the efficiency of human drug review through required electronic submissions and standardization of electronic drug application data utilizing Semantic Web technologies.