RAPID Clinical Working Group

Charge for Informatics Working Group

James Tcheng, MD
Duke Clinical Research Institute

Friday November 6, 2015
ACC Heart House
Washington DC

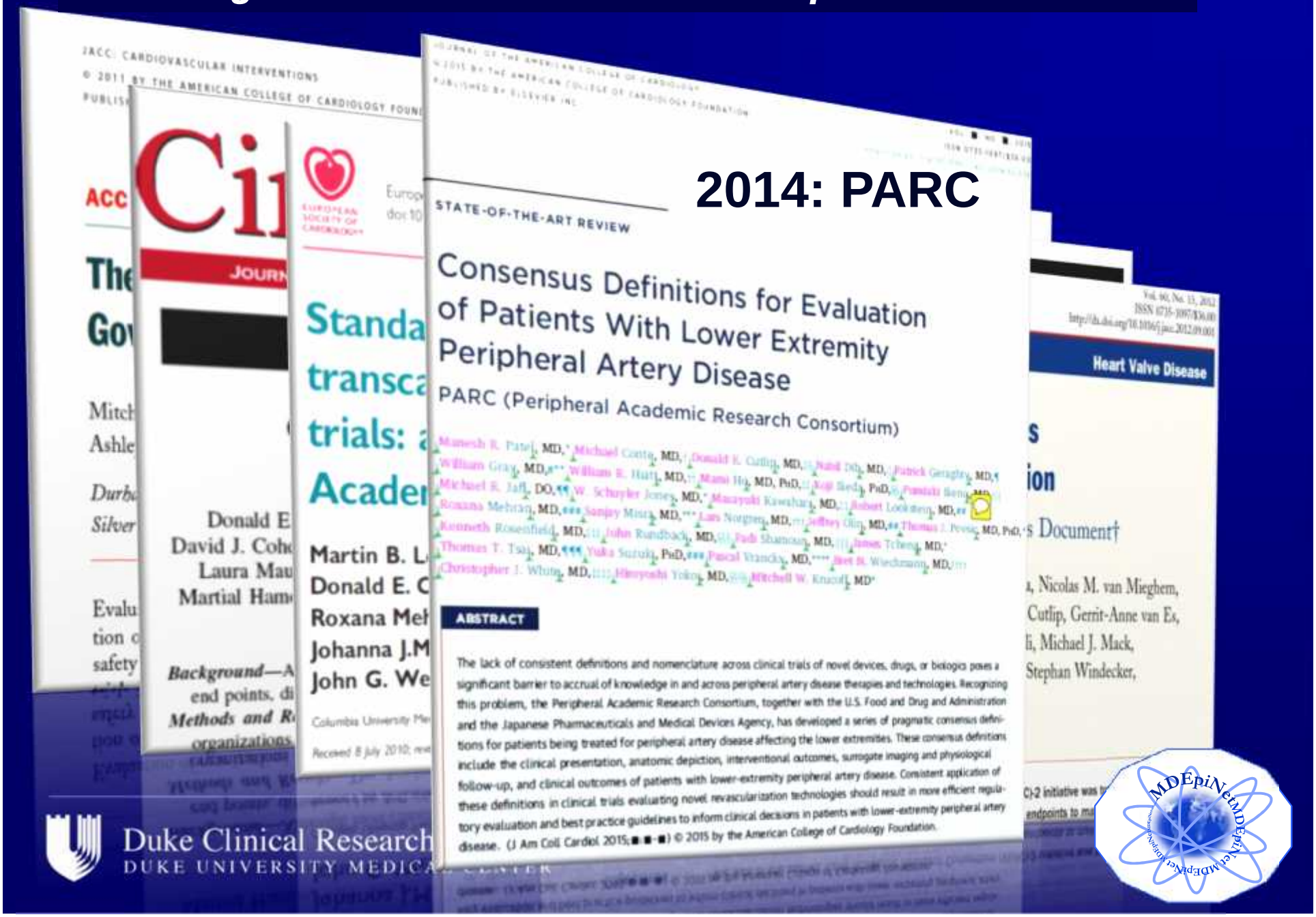
IMDRF International Medical Device Regulators Forum

IMDRF Registry Workgroup Report

Key Registry (Informatics) Desiderata

- Use of controlled vocabularies (standardized data dictionaries)
- Use of a common data model (e.g. OMOP)
- Inclusion of device identifier, performance and outcomes information
- Implementation of a data quality plan
- Governance that anticipates the conduct of analyses across different types of analysis frameworks

ARC: *Pragmatic consensus definitions for pivotal device trials*



2014: PARC

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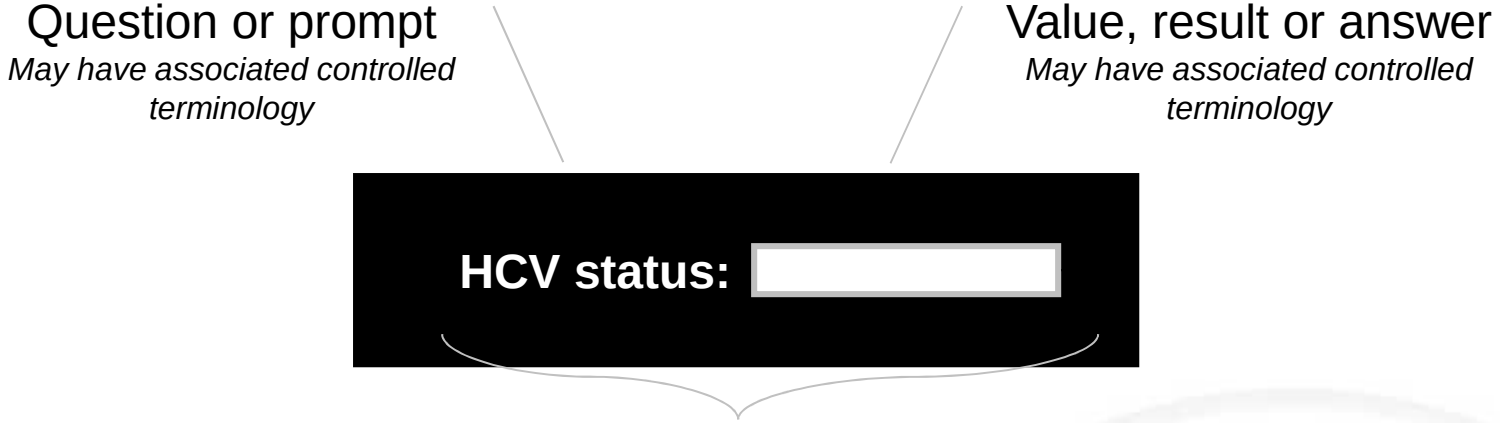
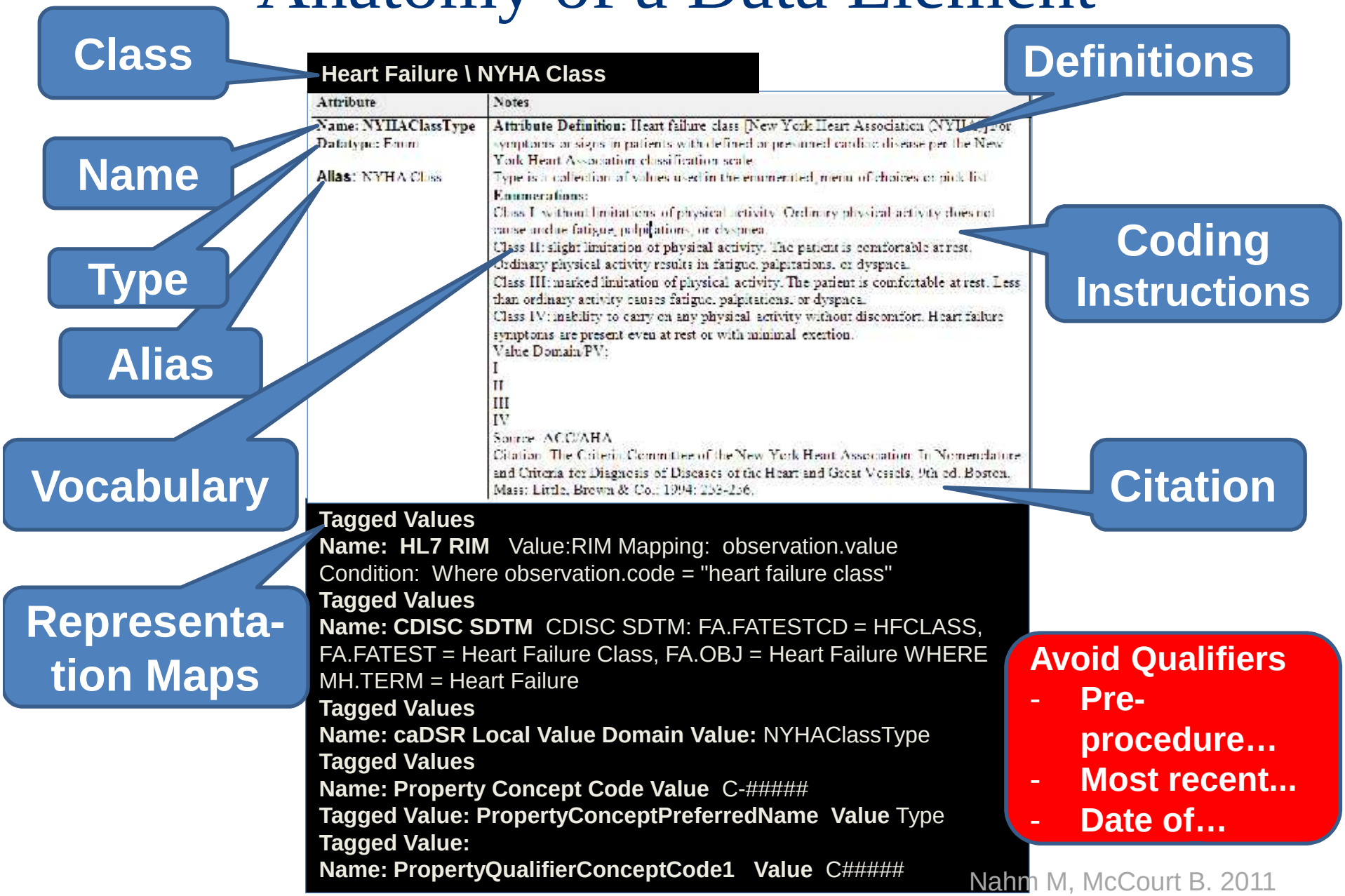
What is a Data Element?



- A data element is a question – value pair
- Considered the smallest meaningful unit of data exchange
- Formally defined in ISO/IEC 11179-1 and 11179-3
- Typically have a unique identifier, a definition, and valid values
- Interpretation requires context (e.g., date/time of collection, method of measurement, or person, place or thing to which the data pertains)

Anatomy of a Data Element



Nahm M, McCourt B. 2011

Attributes

- Definition
  - Clinical
  - Contextual
- Name
  - Preferred name – clinical term
  - Short display name
  - Synonyms
  - Language
- Category
- Class/classification

Attribute Set

- Units
- Data type
- How measured
- Purpose
- Value set
- Links (relational, knowledge, use, …)
- Authoritative source / citation

Management Attributes

- Steward
- Submitting organization
- Registration authority
- Status
- Version
- Date

Data Element Standardization Process

- **Identify** & **synthesize** data elements
  - Pivotal CRFs from new drug approvals
  - Literature Review
  - Clinical Guidelines
  - EVS and caDSR
  - Forms

  Clinical Expert Review Committee (CERC)

  Define data elements
  - Clinical definitions
  - Computational representation
- **Public comment** and **ballot** through American National Standards Institute (ANSI) accredited standards development organization, here, Health Level Seven (HL7) Clinical Interoperability Council
  - Clinical Professional Societies approached to convene working groups to review & comment
- Create research **secondary use representation**, here, Clinical Data Interchange Standards Consortium (CDISC) Submission Data Tabulation Model (SDTM) for regulatory submission.

Duke Standards Work

	Data Standards Projects	Published as Standard	Projected Publication	Funders
CDISC and HL7 Standards	**Cardiovascular ACS**	2008		NIH
	Pulmonary Tuberculosis	2008		NIH
	Anesthesia Preoperative Plan	2011 (Balloted)		Anesthesia, Duke
	Cardiovascular ACC/AHA Top 100	2012		ACC, NIH
	Schizophrenia	2014		FDA
	Cardiovascular Imaging			FDA
	Major Depressive Disorder	2014		FDA
	Cardiovascular Endpoints	2014		FDA
	Pediatric Tuberculosis	2015		FDA, Duke, Gates Foundation
	Bipolar Disorder		2016	FDA
	General Anxiety Disorder		2016	FDA
Internal Duke Project	**Duke Biorepository**		2013	Duke

For Industry

Data Standards

- Data Council
- Structured Product Labeling
- Individual Case Safety Reports
- Regulated Product Submission
- Study Data Standards
- Stability Data Standard
- Substance Registration System - Unique Ingredient Identifier (UNII)
- XForms

FDA Resources for Data Standards

Sign up for email updates.

The FDA Data Standards Council coordinates the evaluation, development, maintenance, and adoption of health and regulatory data standards to ensure that common data standards are used throughout the agency.

Data Standards Catalog (XLS) **The spreadsheet provides a listing of supported and/or required standards, their uses, the date FDA will begin (or has begun) to support a particular standard, and the date support ends (or will end), the date the requirement to use a particular standard will begin (or has begun) and the date such requirement ends (or will end), as well as other pertinent information. For Centers other than CBER and CDER there may be additional supported standards, please check with the specific Center.**

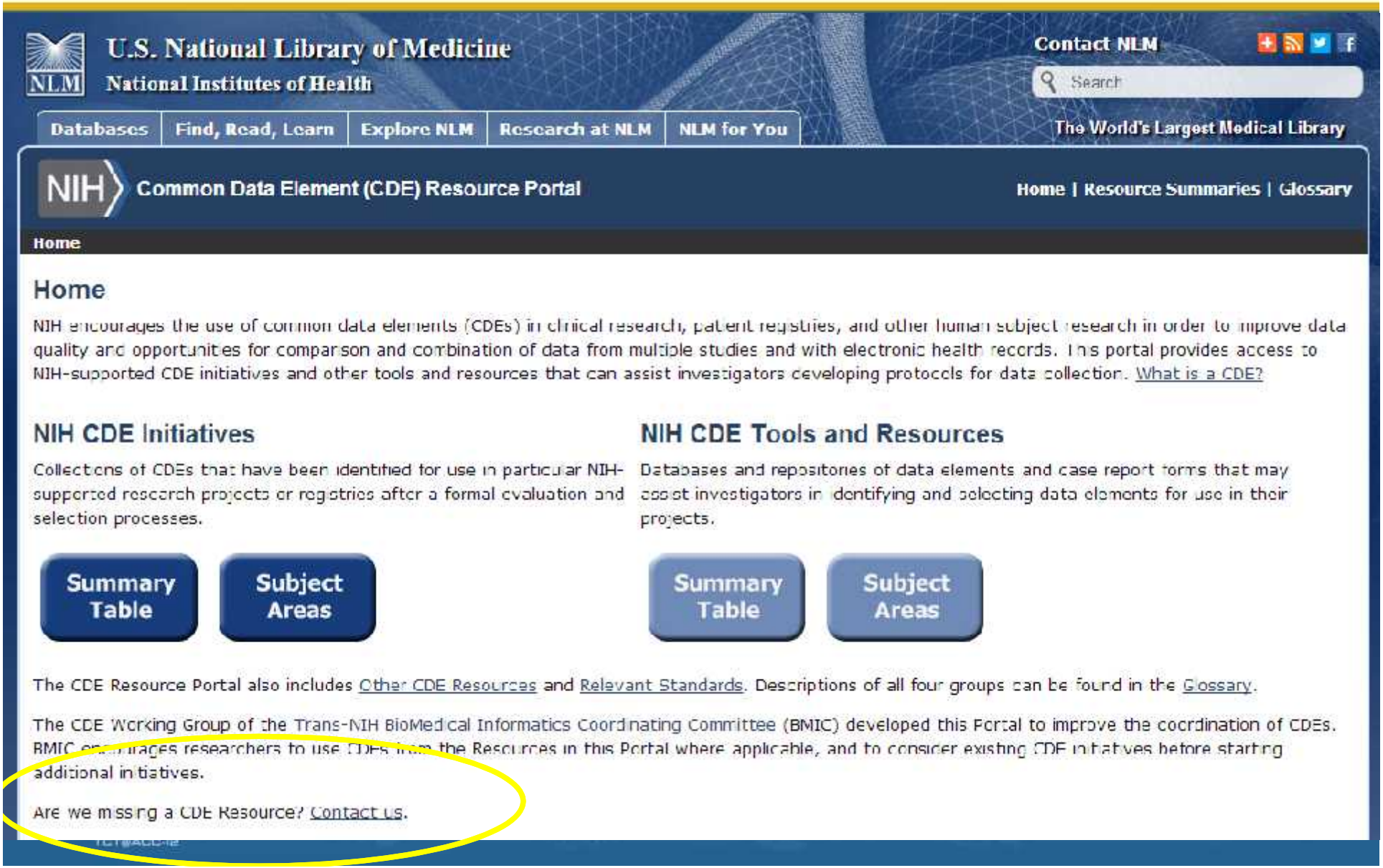
Please note that the first tab in the spreadsheet includes instructions.

Data Standards Resources

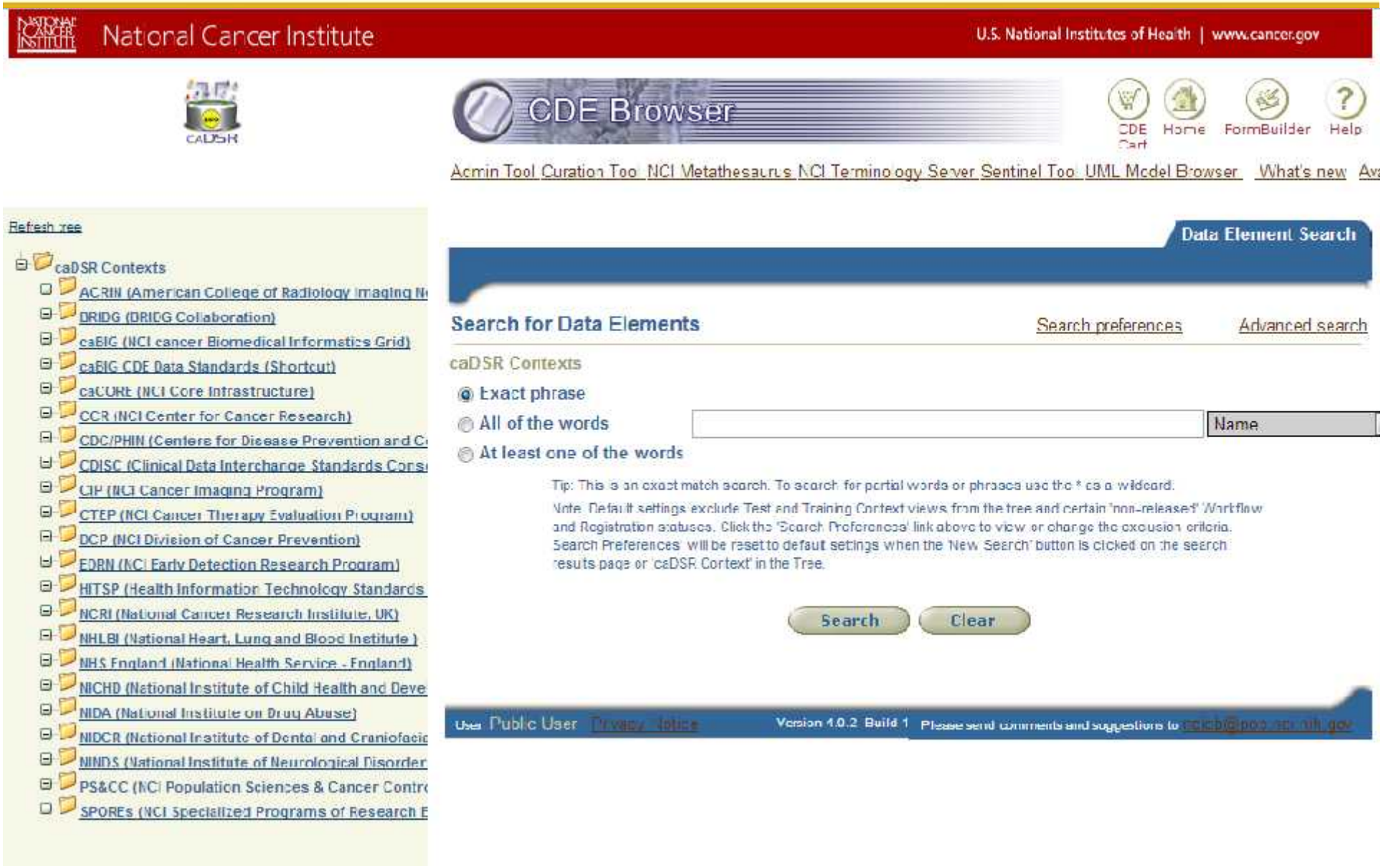
Structured Product Labeling
Individual Case Safety Report
Regulated Product Submission
Study Data Standards
Stability Data Standard
Substance Registration System - Unique Ingredient Identifier (UNII)
Federal Medication Terminology hosted by NCI Enterprise Vocabulary Services
FDA Terminology hosted by NCI Enterprise Vocabulary Services
XForms
Validators

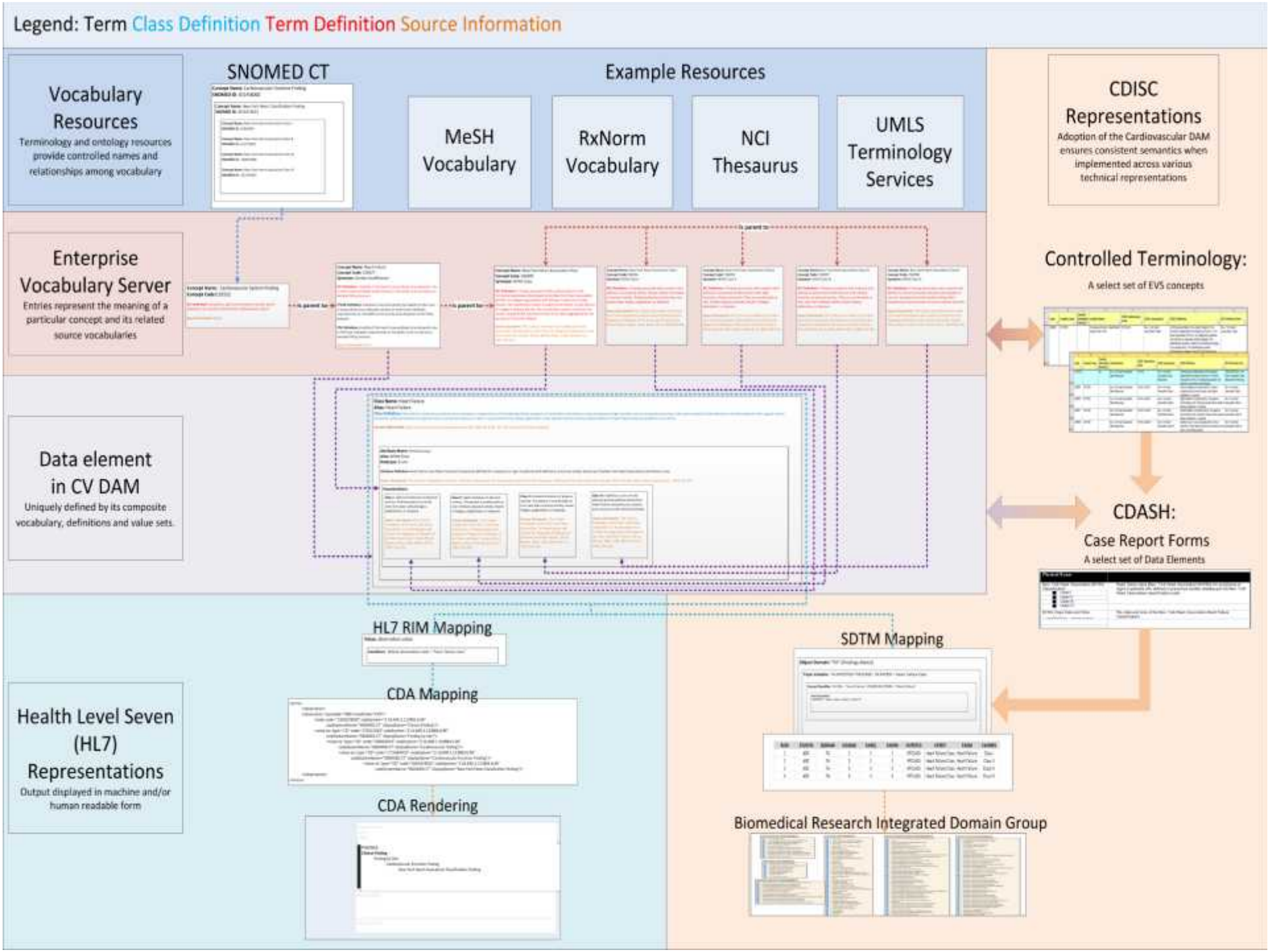
age Last Updated: 02/13/2015
ote: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

NLM Common Data Element Portal



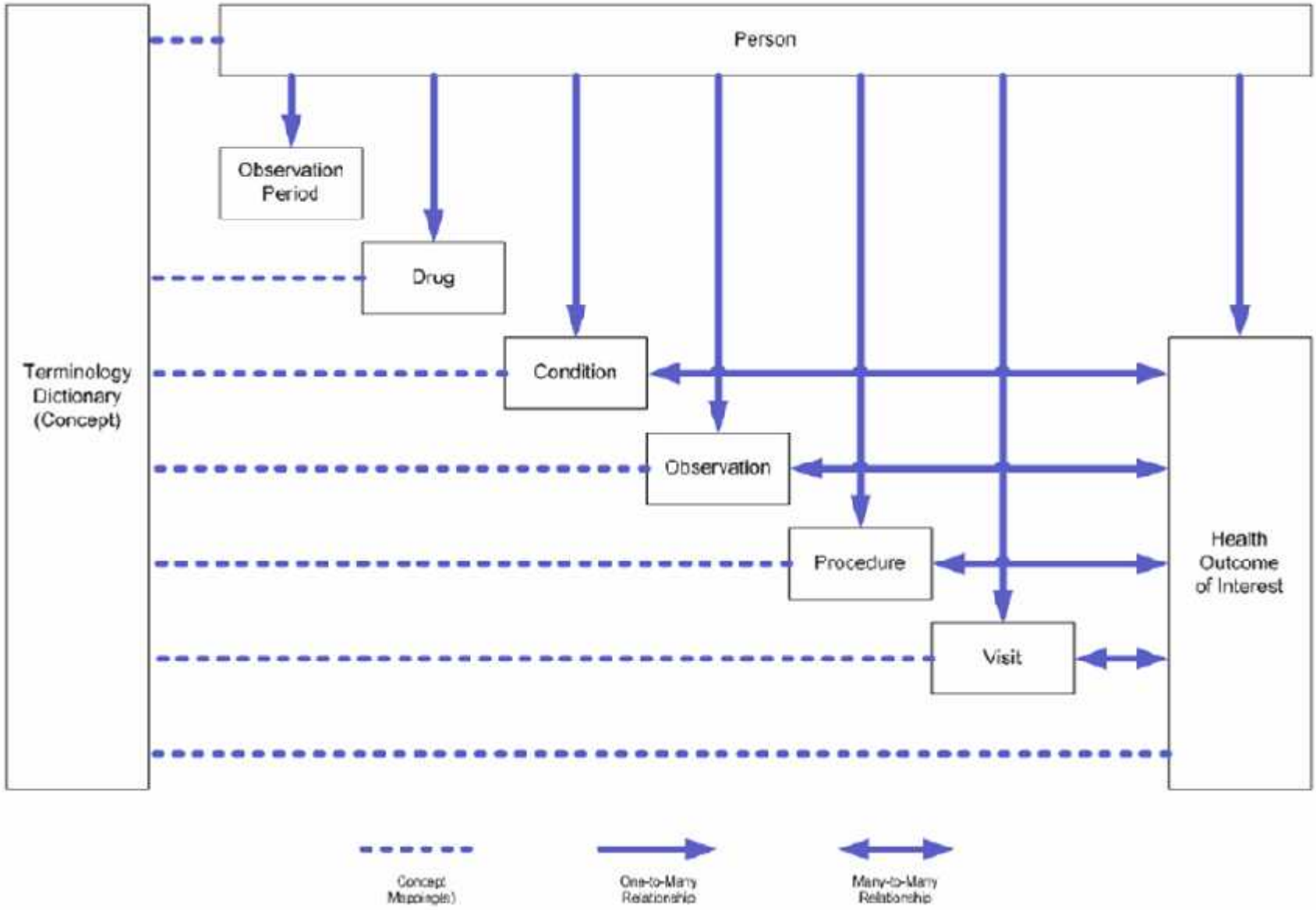
NCI caDSR - ISO 11179 Spec. Data Standards Repository




Legend: Term Class Definition Term Definition Source Information
Vocabulary Resources
Terminology and ontology resources provide controlled names and relationships among vocabulary
SNOMED CT
Example Resources
MeSH Vocabulary
RxNorm Vocabulary
NCI Thesaurus
UMLS Terminology Services
CDISC Representations
Adoption of the Cardiovascular DAM ensures consistent semantics when implemented across various technical representations
Enterprise Vocabulary Server
Entries represent the meaning of a particular concept and its related source vocabularies
Controlled Terminology:
A select set of EVS concepts
Data element in CV DAM
Uniquely defined by its composite vocabulary, definitions and value sets.
CDASH:
Case Report Forms
A select set of Data Elements
HL7 RIM Mapping
SDTM Mapping
CDA Mapping
Health Level Seven (HL7) Representations
Output displayed in machine and/or human readable form
CDA Rendering
Biomedical Research Integrated Domain Group

Common Data Model

Observational Medical Outcomes Partnership (OMOP)



Informatics Working Group Volunteers

First Name:	Last Name:	Organization or Affiliation:
Carrie	Bosela	Society for Vascular Surgery
Cliff	Cavanaugh	HealthJump, Inc
Jeremy	Durack	Society of Interventional Radiology
Brian	Fortier	Aorta Medical Inc.
Rie	Fukaya	Pharmaceut (PMDA)
Elisa	Hebb	Volcano Cor
Greg	Lange	M2S
Danica	Marinac-Dabic	FDA/CDRH
Michael	Matheney	Vanderbilt
Brian	McCourt	Duke Clinica

First Name:	Last Name:	Organization or Affiliation:
Caroline	Morgan	American College of Cardiology
Takashi	Ouchi	Pharmaceuticals and Medical Devices Agency (PMDA)
Andrew	Rygiel	American College of Cardiology - NCDR
Mark	Roche	ONC
Christopher	Ronk	Food and Drug Administration
Bret	Shillingstad	Epic
Joseph	Su	FDA/CDRH
James	Tcheng	Duke
Emily	Tucker	American College of Cardiology - NCDR
Ke	Zhang	M2S

Informatics Working Group Responsibilities

- Contribute to the use cases through clarifications and additions necessary to drive workgroup activities.
- Participate in the identification and definition of data elements for the RAPID core data set, including the technical specifications for data elements to the level of detail needed to be implemented in the piloting effort and future RAPID projects.
- Provide input toward the interface requirements and identification of GUDID data elements necessary within the RAPID data element set enabling linkage of devices used in a patient to the GUDID device data.
- Lead the planning, development and pilot of the data infrastructure, methods and tools for the RAPID pilot activities and future initiatives.

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Informatics Working Group Break-out Session

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Specific Details of Work Today

- Describe the content and format of the specifications for the data elements
- Describe how data elements specified in Phase I will be evaluated for readiness of use in Phase II & III
- Describe how the implementation plans for Phase II and III will be approached and what decisions are required to inform Phase I
- Outline the work plan, including needs for meeting
- Describe the key challenges to accomplishing Phase I and approaches to address these