



RAPID Clinical Working Group

Charge for Informatics Working Group

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Duke Clinical Research Institute

Friday November 6, 2015
ACC Heart House
Washington DC





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

JACC: CARDIOVASCULAR INTERVENTIONS
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STATE-OF-THE-ART REVIEW

Consensus Definitions for Evaluation of Patients With Lower Extremity Peripheral Artery Disease

PARC (Peripheral Academic Research Consortium)

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ABSTRACT

The lack of consistent definitions and nomenclature across clinical trials of novel devices, drugs, or biologics poses a significant barrier to accrual of knowledge in and across peripheral artery disease therapies and technologies. Recognizing this problem, the Peripheral Academic Research Consortium, together with the U.S. Food and Drug Administration and the Japanese Pharmaceuticals and Medical Devices Agency, has developed a series of pragmatic consensus definitions for patients being treated for peripheral artery disease affecting the lower extremities. These consensus definitions include the clinical presentation, anatomic depiction, interventional outcomes, surrogate imaging and physiological follow-up, and clinical outcomes of patients with lower-extremity peripheral artery disease. Consistent application of these definitions in clinical trials evaluating novel revascularization technologies should result in more efficient regulatory evaluation and best practice guidelines to inform clinical decisions in patients with lower-extremity peripheral artery disease. (J Am Coll Cardiol 2015; ■■■) © 2015 by the American College of Cardiology Foundation.

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ACC CIRCULATION

EUROPEAN SOCIETY OF CARDIOLOGY

Standards for transcatheter aortic valve trials: an Academic Research Consortium Document†

Donald E. Cutlip, MD,* David J. Cohen, MD,† Laura Mauri, MD,‡ Martial Hamy, MD,§

Martin B. Leon, MD,†† Donald E. Cutlip, MD,‡‡ Roxana Mehran, MD,§§ Johanna J. Vanoverschelde, MD,¶¶ John G. Webb, MD,***

Background—Aortic stenosis is a common valvular disease. End points, definitions, and methods and reporting standards for transcatheter aortic valve trials are not uniform across organizations.

Methods and Results—The Academic Research Consortium (ARC) was formed to develop pragmatic consensus definitions for patients being treated for aortic stenosis. These definitions include the clinical presentation, anatomic depiction, interventional outcomes, surrogate imaging and physiological follow-up, and clinical outcomes of patients with aortic stenosis. Consistent application of these definitions in clinical trials evaluating novel transcatheter aortic valve technologies should result in more efficient regulatory evaluation and best practice guidelines to inform clinical decisions in patients with aortic stenosis.

Heart Valve Disease

ARC Document†

1, Nicolas M. van Mieghem, MD,‡‡ Cutlip, Gerrit-Anne van Es, MD,§§ Li, Michael J. Mack, MD,¶¶ Stephan Windecker, MD,†††



What is a Data Element?

Question or prompt
May have associated controlled terminology

Value, result or answer
May have associated controlled terminology

HCV status:

Data Element

May have associated controlled terminology

- 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)



*Helping Cardiovascular Professionals
Learn. Advance. Heal.*

Anatomy of a Data Element

Class

Heart Failure \ NYHA Class

Definitions

Name

Name: NYHA ClassType

Datatype: Enum

Type

Alias: NYHA Class

Alias

Coding Instructions

Attribute	Notes
Name: NYHA ClassType Datatype: Enum Alias: NYHA Class	<p>Attribute Definition: Heart failure class [New York Heart Association (NYHA)] prior symptoms or signs in patients with defined or presumed cardiac disease per the New York Heart Association classification scale.</p> <p>Type is a collection of values used in the enumerated menu of choices or pick list.</p> <p>Enumerations:</p> <p>Class I: without limitations of physical activity. Ordinary physical activity does not cause undue fatigue, palpitations, or dyspnea.</p> <p>Class II: slight limitation of physical activity. The patient is comfortable at rest. Ordinary physical activity results in fatigue, palpitations, or dyspnea.</p> <p>Class III: marked limitation of physical activity. The patient is comfortable at rest. Less than ordinary activity causes fatigue, palpitations, or dyspnea.</p> <p>Class IV: inability to carry on any physical activity without discomfort. Heart failure symptoms are present even at rest or with minimal exertion.</p> <p>Value Domain PV:</p> <p>I II III IV</p> <p>Source: ACC/AHA Citation: The Criteria Committee of the New York Heart Association. In Nomenclature and Criteria for Diagnosis of Diseases of the Heart and Great Vessels, 9th ed. Boston, Mass: Little, Brown & Co; 1994: 258-266.</p>

Vocabulary

Citation

Representation Maps

Tagged Values

Name: HL7 RIM Value: RIM Mapping: observation.value

Condition: Where observation.code = "heart failure class"

Tagged Values

Name: CDISC SDTM CDISC SDTM: FA.FATESTCD = HFCLASS, FA.FATEST = Heart Failure Class, FA.OBJ = Heart Failure WHERE MH.TERM = Heart Failure

Tagged Values

Name: caDSR Local Value Domain Value: NYHA ClassType

Tagged Values

Name: Property Concept Code Value C-#####

Tagged Value: PropertyConceptPreferredName Value Type

Tagged Value:

Name: PropertyQualifierConceptCode1 Value C#####

Avoid Qualifiers

- Pre-procedure...
- Most recent...
- Date of...

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

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For Industry

[Home](#) | [For Industry](#) | [Data Standards](#)

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](#)

Page Last Updated: 02/13/2015

Note: If you need help accessing information in different file formats, see [Instructions for Downloading Viewers and Players](#).

NLM Common Data Element Portal

The screenshot shows the homepage of the NLM Common Data Element Resource Portal. At the top, there is a navigation bar with the NLM logo and text: "U.S. National Library of Medicine National Institutes of Health". To the right, there is a "Contact NLM" link and social media icons. Below this is a search bar and the tagline "The World's Largest Medical Library". A secondary navigation bar contains links for "Databases", "Find, Read, Learn", "Explore NLM", "Research at NLM", and "NLM for You". The main header features the NIH logo and the title "Common Data Element (CDE) Resource Portal", with links for "Home", "Resource Summaries", and "Glossary".

Home

NIH encourages the use of common data elements (CDEs) in clinical research, patient registries, and other human subject research in order to improve data quality and opportunities for comparison and combination of data from multiple studies and with electronic health records. This portal provides access to NIH-supported CDE initiatives and other tools and resources that can assist investigators developing protocols for data collection. [What is a CDE?](#)

NIH CDE Initiatives

Collections of CDEs that have been identified for use in particular NIH-supported research projects or registries after a formal evaluation and selection processes.

NIH CDE Tools and Resources

Databases and repositories of data elements and case report forms that may assist investigators in identifying and selecting data elements for use in their projects.

Summary Table **Subject Areas** **Summary Table** **Subject Areas**

The CDE Resource Portal also includes [Other CDE Resources](#) and [Relevant Standards](#). Descriptions of all four groups can be found in the [Glossary](#).

The CDE Working Group of the Trans-NIH Biomedical Informatics Coordinating Committee (BMIC) developed this Portal to improve the coordination of CDEs. BMIC encourages researchers to use CDEs from the Resources in this Portal where applicable, and to consider existing CDE initiatives before starting additional initiatives.

Are we missing a CDE Resource? [Contact Us](#).

NCI caDSR - ISO 11179 Spec. Data Standards Repository



National Cancer Institute

U.S. National Institutes of Health | www.cancer.gov



[Admin Tool](#) [Curation Tool](#) [NCI Metathesaurus](#) [NCI Terminology Server](#) [Sentinel Tool](#) [UML Model Browser](#) [What's new](#) [Av](#)

[Refresh tree](#)

- caDSR Contexts
 - ACRIN (American College of Radiology Imaging N
 - DRIDG (DRIDG Collaboration)
 - caBIG (NCI cancer Biomedical Informatics Grid)
 - caBIG CDE Data Standards (Shortcut)
 - caCORE (NCI Core Infrastructure)
 - CCR INCI (Center for Cancer Research)
 - CDC/PHIN (Centers for Disease Prevention and C
 - CDISC (Clinical Data Interchange Standards Cons
 - CIP (NCI Cancer Imaging Program)
 - CTEP (NCI Cancer Therapy Evaluation Program)
 - DCP (NCI Division of Cancer Prevention)
 - EDRN (NCI Early Detection Research Program)
 - HITSP (Health Information Technology Standards
 - NCRI (National Cancer Research Institute, UK)
 - NHLBI (National Heart, Lung and Blood Institute)
 - NHS England (National Health Service - England)
 - NICHD (National Institute of Child Health and Deve
 - NIDA (National Institute on Drug Abuse)
 - NIDCR (National Institute of Dental and Craniofac
 - NINDS (National Institute of Neurological Disorder
 - PS&CC (NCI Population Sciences & Cancer Contr
 - SPOREs (NCI Specialized Programs of Research E

Data Element Search

Search for Data Elements

[Search preferences](#)

[Advanced search](#)

caDSR Contexts

- Exact phrase
- All of the words
- At least one of the words

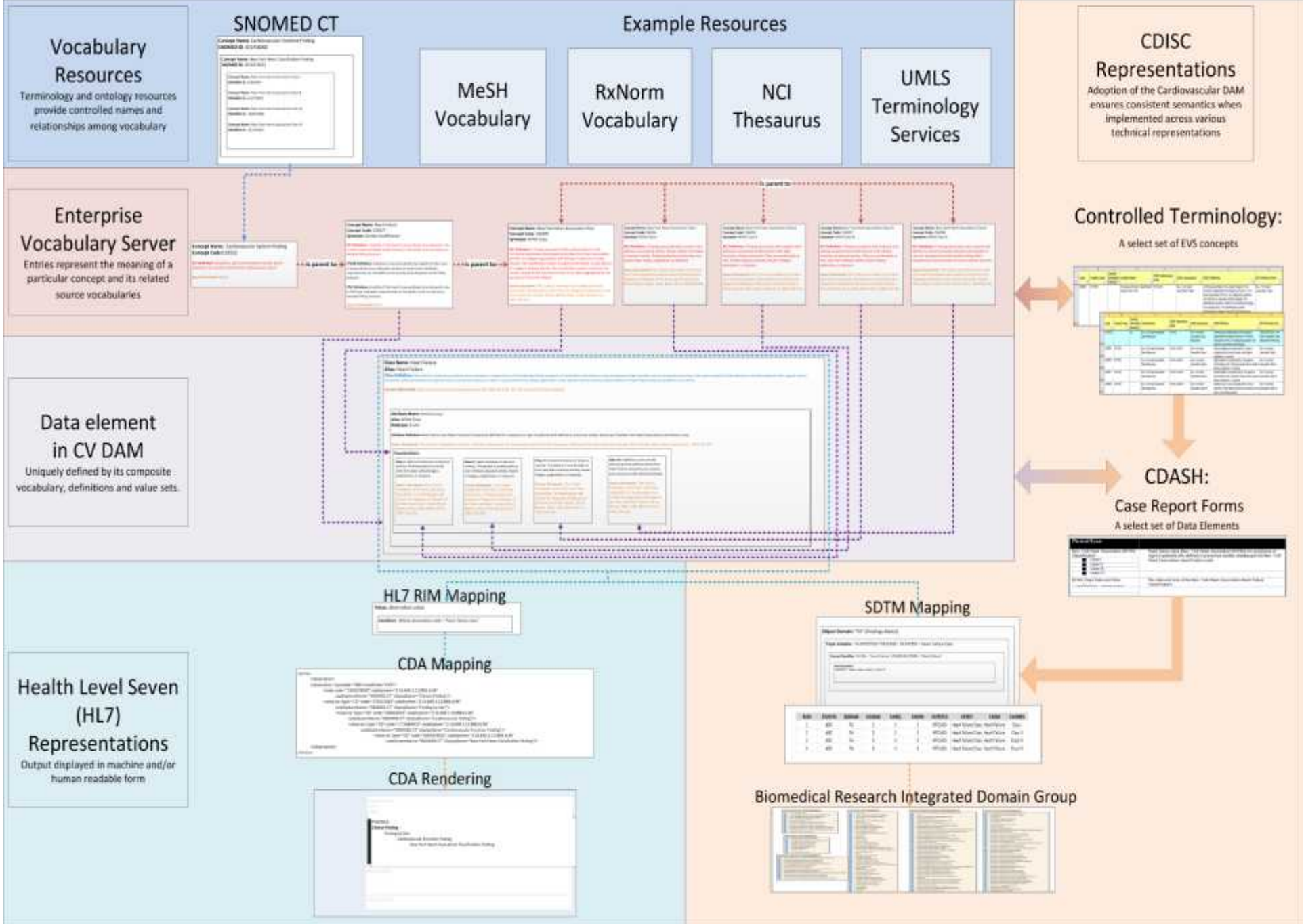
Tip: This is an exact match search. To search for partial words or phrases use the * as a wildcard.

Note: Default settings exclude Test and Training Context views from the tree and certain 'non-release' Workflow and Registration statuses. Click the 'Search Preferences' link above to view or change the exclusion criteria. Search Preferences will be reset to default settings when the 'New Search' button is clicked on the search results page or 'caDSR Context' in the Tree.

User: Public User [Privacy Notice](#)

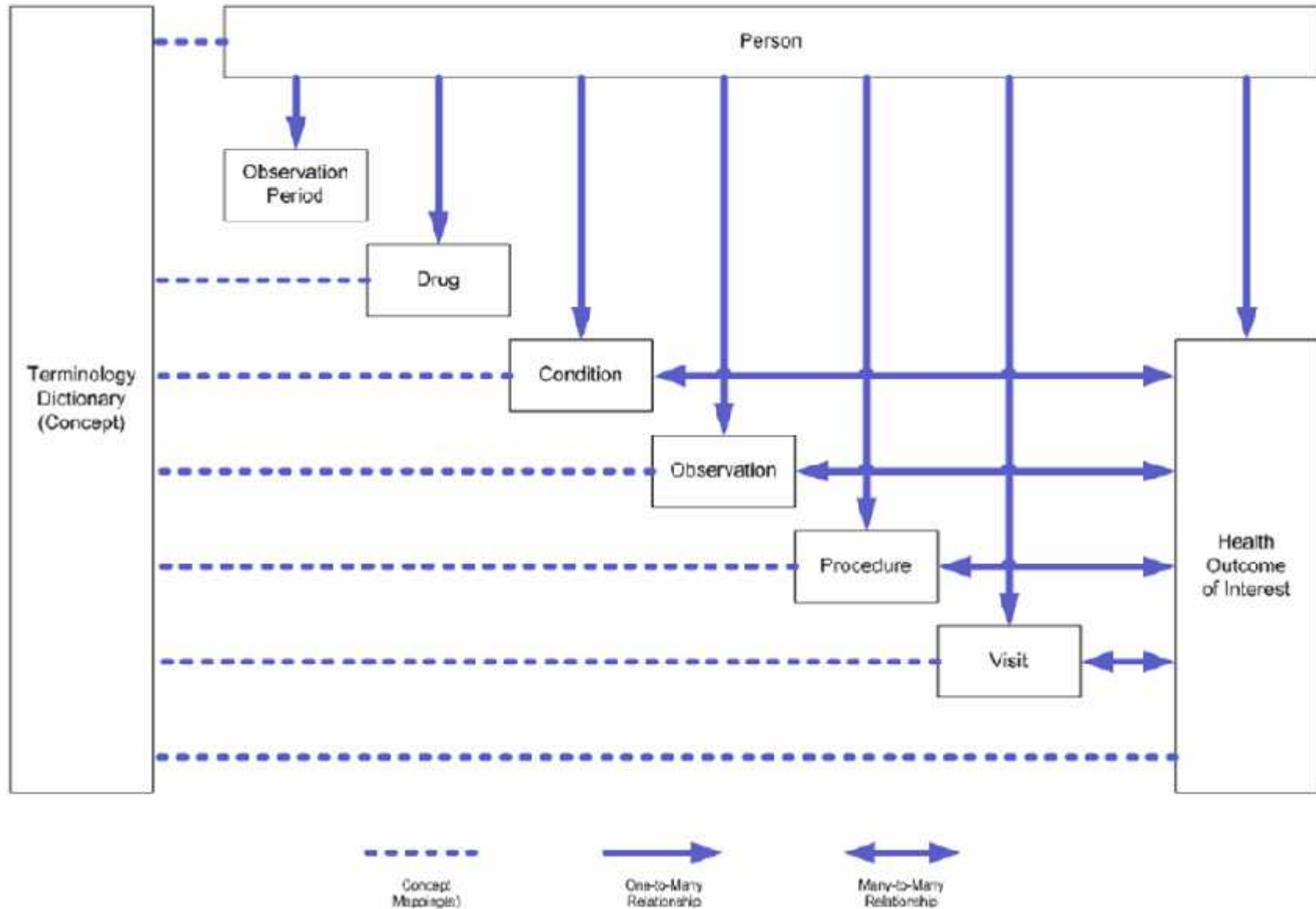
Version 4.0.2 Build 1 Please send comments and suggestions to caDSR@nci.nih.gov

Legend: Term **Class** Definition Term Definition Source Information



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.
First Name:	Last Name:	Organization or Affiliation:
Rie	Fukaya	Pharmaceut (PMDA)
Elisa	Hebb	Volcano Cor
Greg	Lange	M2S
Danica	Marinac-Dabic	FDA/CDRH
Michael	Matheney	Vanderbilt
Brian	McCourt	Duke Clinica
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.





RAPID Clinical Working Group

**Informatics Working Group Break-out
Session**

**James Tcheng, MD
Duke Clinical Research Institute**

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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

