Therapeutic Area User Guide – Cardiovascular V1.0
Public Review Webinar
April 3, 2014

CDISC®

CLINICAL DATA INTERCHANGE STANDARDS CONSORTIUM

The CDISC Vision is to Inform Patient Care & Safety Through Higher Quality Medical Research

Therapeutic Area User Guide – CV V1.0
Public Review Webinar
April 3, 2014

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Strength *through Collaboration*

Standardized Collection and Submission of Cardiovascular Data for Clinical Research

April 3, 2014

FDA Grant: 1R24FD004411-01

Strength *through Collaboration*

Duke Clinical Research Institute

AMERICAN COLLEGE *of* CARDIOLOGY

CDISC

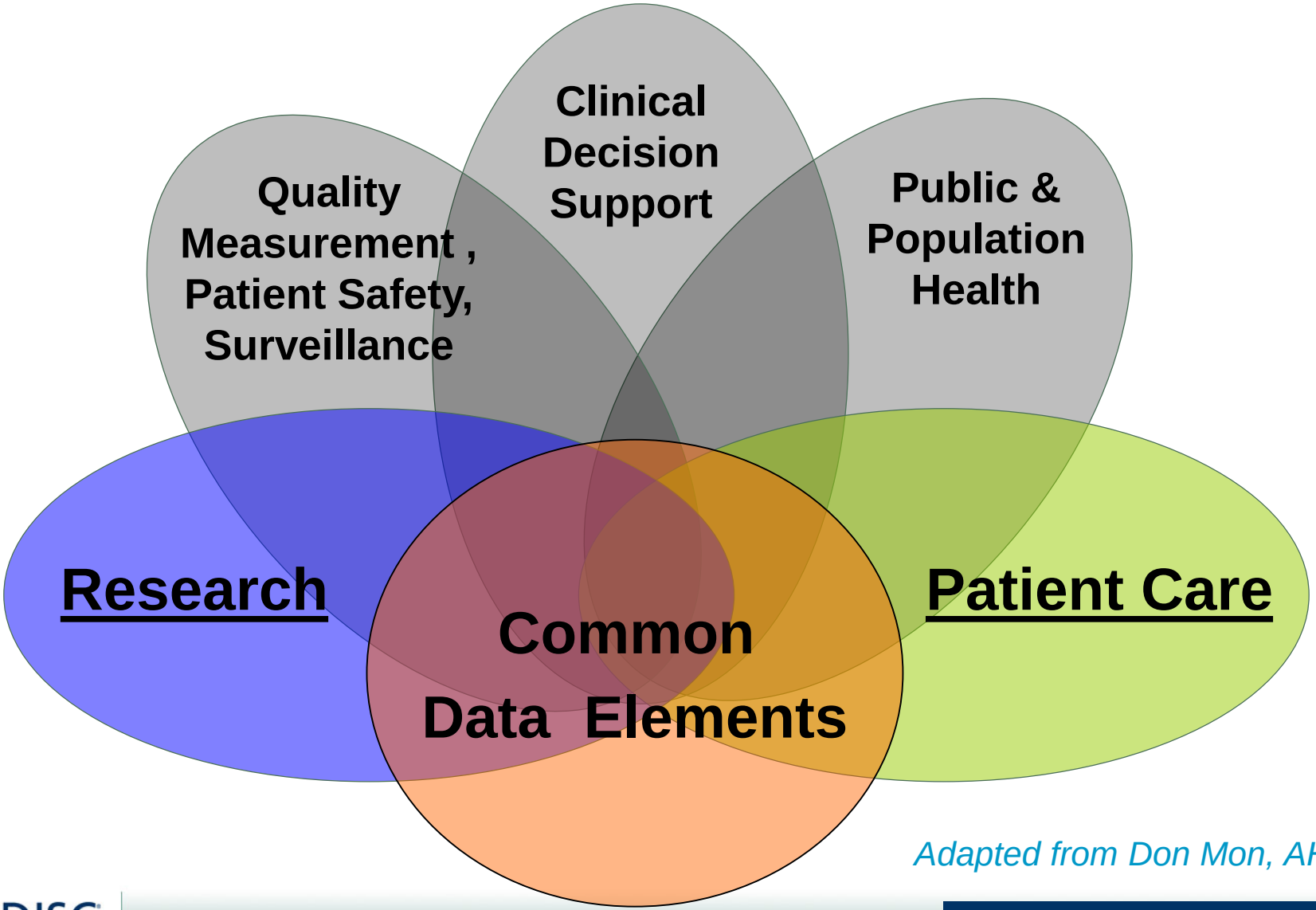
CV Data Standards Initiative

- Background
- Current status
- CV Endpoints Project
- Significance
- Next steps

The Purpose …

… to identify and harmonize, via a collaborative and public consensus process, the definitions of key data elements useful in the *interpretation and analysis of cardiovascular data*.

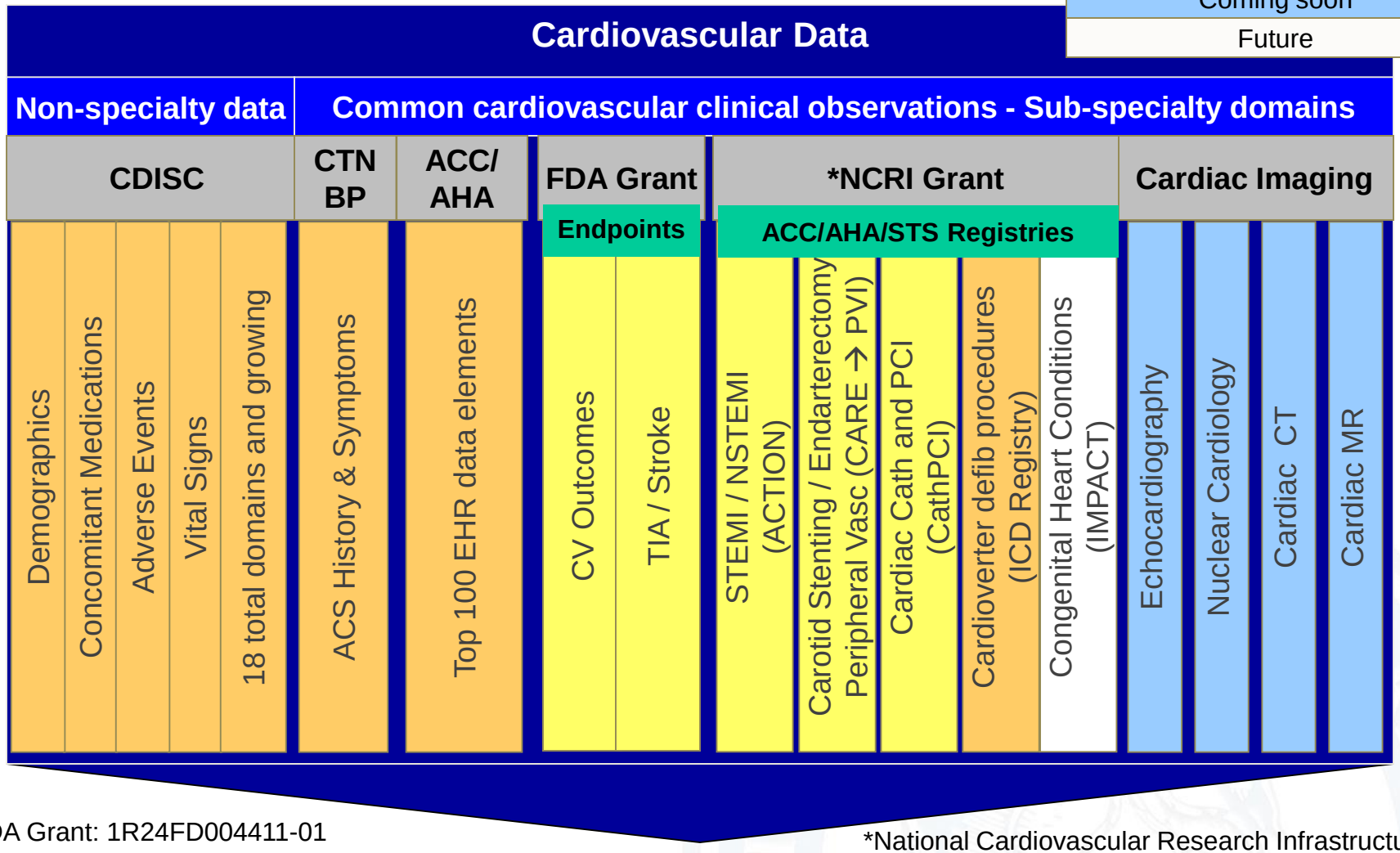
Scope: Use Case



Adapted from Don Mon, AHIMA

Projects Overview

Completed
Consider for this discussion
Coming soon
Future



FDA Grant: 1R24FD004411-01

*National Cardiovascular Research Infrastructure

CV Clinical
- Data Elements
- Event definitions
- Clinical terminology and data definitions

CDISC
- SDTM standard for FDA submission
- Controlled Terminology alignment
- CRF templates
- Stds adoption by researchers

HL7
- Mappings to HL7 standards
- Adoption support for EHR's
- CCHIT EHR Certification (future)

CDE Development Process

Domain Experts

Data Standards Workgroups

1. Identify data element sources

2. Aggregate, align for review

3. Select or author definitions (incl. valid values)

4. Annotate with vocabulary, relationships and mapping to technical representations

5. Iterate until clean

Informatics Teams

6. Public comment & ballot

7. Publish

8. Maintain

Current Status

CV Data Standards efforts to date include efforts evaluating and harmonizing data elements related to:

- Acute coronary syndrome
- Heart failure
- Cardiac catheterization / PCI
- ICD, stent, carotid revascularization
- **CV Endpoints**

What is an Endpoint?

- An **endpoint** is the occurrence of anything of interest that can be used to qualify or quantify the effect, effectiveness and / or safety of a diagnostic or therapeutic approach
- *Endpoint data elements include diagnoses, procedures, observations, and even hospitalizations - and can be manifest as:*
  - A clinical change (e.g., a new symptom, finding, diagnosis, death)
  - An unanticipated need for the application of health care resources (e.g., procedure, hospitalization)

Importance of CV Endpoint Standards

Objectively and consistently:

- Assess patient outcomes
- Assess responses to therapy
- Support device surveillance, pharmacovigilance
- Support aggregate analysis of event data across large clinical trial datasets
- Support advanced analytics (identification of safety signals, event rates, comparative effectiveness, trends analysis)

- across research and clinical care domains -

CV Endpoint Concepts

- Death (attribution of cause of death)
- Myocardial infarction (MI)
- Stroke / transient ischemic attack (TIA)
- Percutaneous coronary intervention (PCI)
- Peripheral vascular intervention (PVI)
- Unstable angina hospitalization
- Heart failure event

Basis of Endpoint Elements

Draft Definitions for Testing November 9, 2012

Standardized Definitions for Cardiovascular and Stroke End Point Events in Clinical Trials

Karen A. Hicks, H. M. James Hung, Kenneth W. Mahaffey, Roxana Mehran, Steven E. Nissen, Norman L. Stockbridge, Shari L. Targum, Robert Temple;
on behalf of the Standardized Data Collection for Cardiovascular Trials Initiative

TASK FORCE MEMBERS

Chairpersons: Karen A. Hicks, Kenneth W. Mahaffey, Roxana Mehran, Steven E. Nissen

Working Groups: Kenneth W. Mahaffey, Roxana Mehran, and Steven E. Nissen, Co-ordinators; Steven S. Brooks, Paul Burton, Kenneth J. Cavanaugh, Bernard R. Chaitman, B. Christine Clark, Charles Cooper, Donald E. Cutlip, Akshay S. Desai, Michael J. Domanski, Billy Dunn, Andrew Farb, Heather D. Fitter, C. Michael Gibson, Stephen M. Grant, Karen A. Hicks, H. M. James Hung, Kachikwu Illoh, Ilan Irony, Michael R. Jaff, Cheri Janning, Hylton V. Joffe, Bron Kisler, Judith M. Kramer, Rebecca Kush, Martin J. Landray, Alexandra Lansky, Jonathan G. Levine, Eldrin F. Lewis, A. Michael Lincoff, John R. Marler, Laura Mauri, Brian McCourt, John McMurray, Yale Mitchel, Jean Morgan, David A. Morrow, Christopher M. O'Connor, Mary H. Parks, Douglas Peddicord, Marc A. Pfeffer, Kenneth Rosenfield, Leonard Sacks, Cathy A. Sila, Benjamin M. Scirica, Karen Snowdon-Way, Scott D. Solomon, Steven R. Steinhubl, Norman L. Stockbridge, Ana Szarfman, Barbara E. Tardiff, Shari L. Targum, James E. Tcheng, John R. Teerlink, Robert Temple, Chris Tolk, Ellis F. Unger, Christopher J. White, Stephen D. Wiviott, and Bram Zuckerman

With special thanks to Rhonda Bartley, Leanne Madre, and MariJo Mencini, Co-ordinators (Clinical Trials Transformation Initiative) and to Rachel E. Hartford, Anna Park, and Lori Anne Wachter, Co-ordinators (Food and Drug Administration).

Aims of the R24

FDA Grant: 1R24FD004411-01

The overall objective of this application is to formalize the key cardiovascular endpoint data elements, represent, vet and publish them as an informative Clinical Data Interchange Standards Consortium (CDISC) standard (Controlled Terminology, Study Data Tabulation Model), and deliver a demonstration data set from one or more clinical trials using the standardized cardiovascular endpoint data elements.
The Specific Aims are as follows:

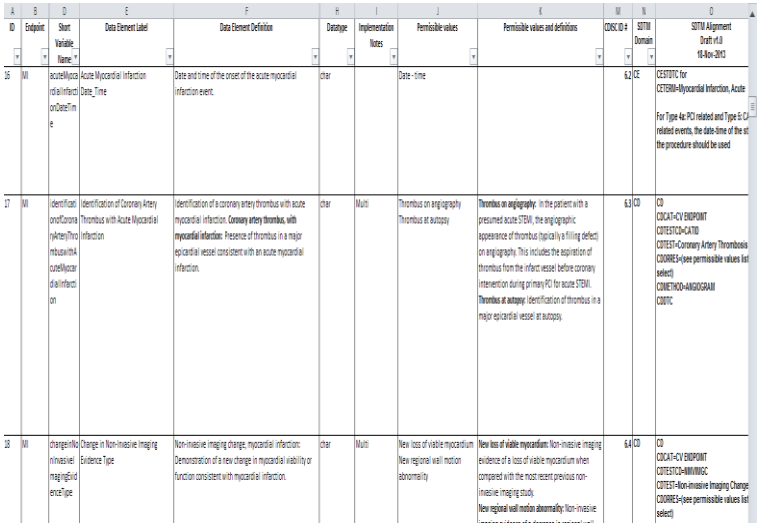
Aim 1 – Harmonize, finalize, and publish a key set of clinical specifications for cardiovascular endpoint data elements, inclusive of the required data to be collected for documentation and/or adjudication of those endpoints.

Aim 2 – Advance the adoption of the data elements and artifacts thereof by the research, regulatory, and clinical communities, by (a) representing the cardiovascular endpoint data element concepts in the CDISC Controlled Terminology, (b) modeling the data elements as a UML Domain Analysis Model, and (c) generating a Study Data Tabulation Model (SDTM) Implementation Guide for these data elements.

Aim 3 –Further the utility to stakeholders by providing a demonstration data set containing examples of trial data in the SDTM format using data from several existing clinical trials.

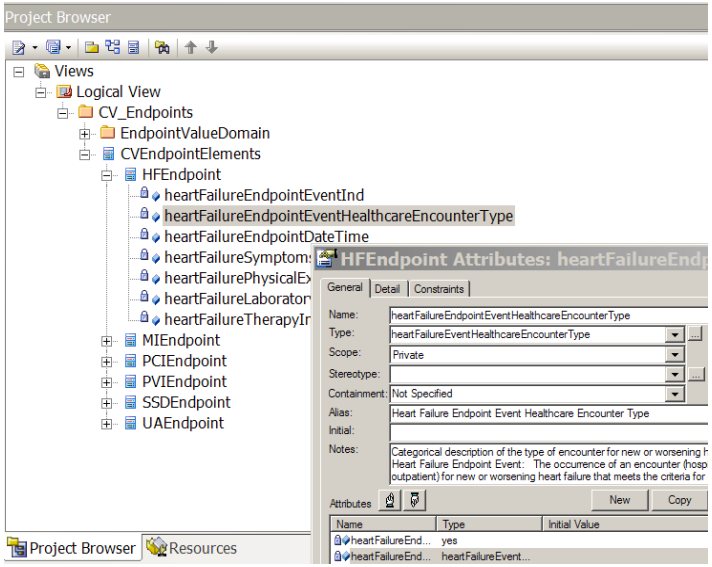
Work Products

Clinical Data Elements

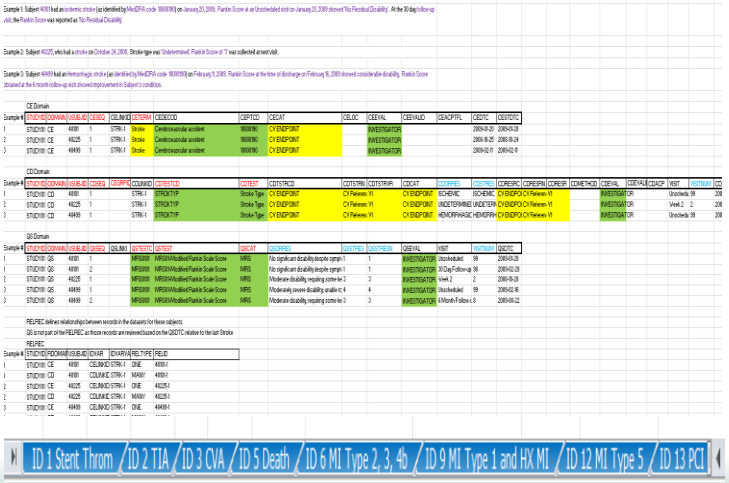


ID	Endpoint	Short Variable Name	Data Element Label	Data Element Definition	Datatype	Implementation Notes	Permissible values	Permissible values and definitions	CDISC ID #	SDTM Domain	SDTM Alignment Draft v1.0 18-Nov-2013
16	MI	acuteMyocardialInfarctionDateTime	Acute Myocardial Infarction Date_Time	Date and time of the onset of the acute myocardial infarction event.	char		Date - time		6.2	CE	CESTDTC for CETERM=Myocardial Infarction, Acute For Type 4a: PCI related and Type 5: CABG related events, the date-time of the st the procedure should be used
17	MI	identificationofCoronaryArteryThrombusin24-hrsofAcuteMyocardialInfarction	Identification of Coronary Artery Thrombus with Acute Myocardial Infarction	Identification of a coronary artery thrombus with acute myocardial infarction. **Coronary artery thrombus, with myocardial infarction:** Presence of thrombus in a major epicardial vessel consistent with an acute myocardial infarction.	char	Multi	Thrombus on angiography Thrombus at autopsy	**Thrombus on angiography:** In the patient with a presumed acute STEMI, the angiographic appearance of thrombus (typically a filling defect) on angiography. This includes the aspiration of thrombus from the infarct vessel before coronary intervention during primary PCI for acute STEMI. **Thrombus at autopsy:** Identification of thrombus in a major epicardial vessel at autopsy).	6.3	CD	CD CDCAT=CV ENDPOINT CDTESTCD=CATID CDTEST=Coronary Artery Thrombosis CDORRES=(see permissible values list select) CDMETHOD=ANGIOGRAM CDDTC
18	MI	changeinNoninvasiveImagingEvidenceType	Change in Non-Invasive Imaging Evidence Type	Non-invasive imaging change, myocardial infarction: Demonstration of a new change in myocardial viability or function consistent with myocardial infarction.	char	Multi	New loss of viable myocardium New regional wall motion abnormality	**New loss of viable myocardium:** Non-invasive imaging evidence of a loss of viable myocardium when compared with the most recent previous non-invasive imaging study. **New regional wall motion abnormality:** Non-invasive	6.4	CD	CD CDCAT=CV ENDPOINT CDTESTCD=NMWMSC CDTEST=Non-invasive Imaging Change CDORRES=(see permissible values list select)

UML Model



Representative Test Data



CV Data Standards

Next steps …

- ACC stewardship of ongoing development & maintenance of CDISC SDTM model and CV terminology
- Repository for **CV Data Standards** materials will be the ACC website, cardiosource.org
- *? inclusion in a future version of the CV DAM*

Karen A. Hicks, MD – *Chair*

James E. Tcheng, MD – *Vice-Chair &*

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AMERICAN COLLEGE of CARDIOLOGY FOUNDATION

American Heart Association®

CV Endpoints Informatics Team

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Robert Anderson	Amy Palmer	
James Topping	Bernice Yost	
Rebecca Wilgus		

Duke Clinical Research Institute

AMERICAN COLLEGE of CARDIOLOGY

Cardiovascular Disease TA

- Developed as part of the CFAST Program
- Development Principles
- Enhancements
- Concepts covered in this TA Guide and SDTM Modeling issues
- Use cases and examples
  - *Domains*
  - *Variables*
  - *Controlled Terminology*
- Public Review
  - Areas to focus
  - How to submit comments
- Q & A

Development Principles

- Scope
  - core, clinically meaningful concepts
  - manage content to meet defined timelines (10-12 months)
- Re-use existing standards (SDTM)
  - include examples only for situations not covered by existing implementation guide(s)
- Propose new variables for existing domains or new domains
  - only where needed
- Propose new controlled terminology
  - only where needed

What is Different from Previous CDISC TA Standards?

- Disease background & context
- Concept maps
  - To diagram the relationships between concepts and among attributes of a concept
- Regulatory and medical references
  - To help ensure regulatory compliance and medical appropriateness
- Focused indication and population under study
  - Studies of drugs for cardiovascular disease in adult subjects

Concept Maps

- Illustrates relationships among concepts and attributes
- Facilitates understanding (semantic interoperability) among functions involved in standards development

Concept Maps

Regulatory and Medical References

- Regulatory and key medical literature is being reviewed and referenced.
- Bibliography and footnotes included

Appendix G: References

1. Easton JD, Saver JL, Albers GW, et al. Definition and evaluation of transient ischemic attack: a scientific statement for healthcare professionals from the American Heart Association/American Stroke Association Stroke Council; Council on Cardiovascular Surgery and Anesthesia; Council on Cardio. *Stroke*. 2009;40(6):2276-93. doi: 10.1161/STROKEAHA.108.192218.
2. Sacco RL, Kasner SE, Broderick JP, et al. An updated definition of stroke for the 21st century: a statement for healthcare professionals from the American Heart Association/American Stroke Association. *Stroke*. 2013;7(2064-89):44. doi: 10.1161/STR.0b013e318296aeca.
3. **Thygesen K, Alpert JS, Jaffe AS, al e. Third universal definition of myocardial infarction.** *Circulation*. 2012;126(16):2020-35. doi: 10.1161/CIR.0b013e31826e1058.

Appendix G1: Further Reading

- Anderson JL, Adams CD, Antman EM, et al. ACC/AHA 2007 guidelines for the management of patients with unstable angina/non ST-elevation myocardial infarction: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Revise the 2002 Guidelines for the Management of Patients With Unstable Angina/Non ST-Elevation Myocardial Infarction): developed in collaboration with the American College of Emergency Physicians, the Society for Cardiovascular Angiography and Interventions, and the Society of Thoracic Surgeons: endorsed by the American Association of Cardiovascular and Pulmonary Rehabilitation and the Society for Academic Emergency Medicine. Circulation. 2007;116(7):e148-e304. [PMID: 17679616]
- Binanay C, Califf RM, Hasselblad V, et al. Evaluation study of congestive heart failure and pulmonary artery catheterization effectiveness: the ESCAPE trial. JAMA. 2005;294(13):1625-33. [PMID: 16204662]
- Butman SM, Ewy GA, Standen JR, et al. Bedside cardiovascular examination in patients with severe chronic heart failure: importance of rest or inducible jugular venous distension. J Am Coll Cardiol. 1993;22(4):968-74. [PMID: 8409071]

Cardiovascular – Public Review – New Draft Domain

- One new SDTM Draft Domain for review
- Cardiovascular Physiology (CV)

6 Domain Models Based on the General Observation Classes

6.3 FINDINGS

CARDIOVASCULAR PHYSIOLOGY (CV)

CV - DESCRIPTION/OVERVIEW FOR CARDIOVASCULAR PHYSIOLOGY DOMAIN MODEL

The CV domain has been designed to store data on cardiovascular physiological findings that include information relating to the heart, blood vessels, and circulation, such as ischemic myocardium percentage, stenosis, and New York Heart Association Class.

cv.xpt, *Cardiovascular Physiology*— Findings, Version 3.3. One record per finding or result per time point per visit per subject, Tabulation

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	CV	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req

Therapeutic Area Data Standards User Guide for Cardiovascular Disease

Version 1.0 Draft

Prepared by the

CFAST Cardiovascular Team

Organization of the TAUG-CV

- Section 1- Introduction
- Section 2- Cardiovascular Endpoints
  - Adjudication of Events
  - Transient Ischemic Attack (TIA) and Stroke
  - Myocardial Infarction (MI)
  - Percutaneous Coronary Intervention (PCI)
  - Peripheral Vascular Intervention (PVI)
  - Heart Failure Event
  - Unstable Angina Hospitalization
- Section 3- Acute Coronary Syndrome
  - Examples of ACS

TAUG-CV Domain Examples

Domains from SDTMIG	Section in the User Guide	SDTMIG Version
Interventions		
PR – Procedures	2.5.1, 2.6.1, 2.7.1, 3.1	3.2
Events		
CE – Clinical Events	2.4.1, 2.5.1, 2.6.1, 2.8.1, 2.9.1, 3.1	3.2
DS – Disposition	2.3.1	3.2
HO – Healthcare Encounters	2.5.1, 2.8.1, 2.9.1, 3.1	3.2
MH – Medical History	2.5.1, 2.8.1, 3.1	3.2
Findings		
CV – Cardiovascular Physiology*	2.6.1	3.3
DD – Death Details	2.3.1	3.2
DI – Device Identifiers	3.1	SDTMIG-MD 1.0
EG – ECG Test Results	2.5.1, 3.1	3.2
LB – Laboratory Test Results	2.5.1, 2.7.1, 3.1	3.2
TU – Tumor and Lesion Identification	2.6.1, 2.7.1, 3.1	3.2
TR – Tumor and Lesion Results	2.6.1, 2.7.1, 3.1	3.2
MO – Morphology	2.6.1, 2.7.1, 3.1	3.2
QS – Questionnaires	2.4.1	3.2
Findings About Events or Interventions		
FA – Findings About	2.4.1, 2.5.1, 2.6.1, 2.7.1, 2.8.1, 2.9.1, 3.1	3.2

Define.xml Representation

- **The American College of Cardiology (ACC) CV ENDPOINTS CDE definitions and permissible value sets are referenced using** Define.xml.
- The Define.xml will reference the External Dictionary "ACC Common Data Elements". Each version in use within the submission should be referenced.

External Dictionaries

Reference Name	External Dictionary	Dictionary Version
ACC CV Endpoint CDE (CL.ACCCVCDE)	ACC Common Data Elements	V1.0 Draft

```
</CodeList>
<!-- Example of a reference to an ExternalCodelist.
  Note that the names of the codelists may change with the final publication. -->
<CodeList OID="CL.ACCCVCDE"
  Name="ACC CV Endpoint CDE" DataType="text">
  <ExternalCodeList Dictionary="ACC Common Data Elements"
    Version="V1.0 Draft"
    href="http://www.services.acc.org"/>
</CodeList>
```

Cardiovascular Endpoints Review Topics

- The Cardiovascular Endpoints Section of this TAUG is organized by listing the seven groupings of endpoints of interest (Death; Transient Ischemic Attack and Stroke; Myocardial Infarction; Percutaneous Coronary Intervention; Peripheral Vascular Intervention; Heart Failure Event, Unstable Angina Hospitalization).

- In order to implement the cardiovascular endpoint CDE's in the CDISC SDTM domain standard, it was necessary to request a number of new SDTM variables. The following variables are being requested as additions in the next release of the SDTMIG.

Proposed variables as additions to the Events class

Variable Name	Variable Label	Type	Role	Description
--EVAL	Evaluator	Char	Record Qualifier	Role of the person who provided the evaluation. Used only for results that are subjective (e.g., assigned by a person or a group). Examples: ADJUDICATION COMMITTEE, INDEPENDENT ASSESSOR, RADIOLOGIST.
--EVALID	Evaluator Identifier	Char	Variable Qualifier of --EVAL	Used to distinguish multiple evaluators with the same role recorded in --EVAL. Examples: RADIOLOGIST1 or RADIOLOGIST2

Cardiovascular Endpoints Review Topics

Adjudication of Events

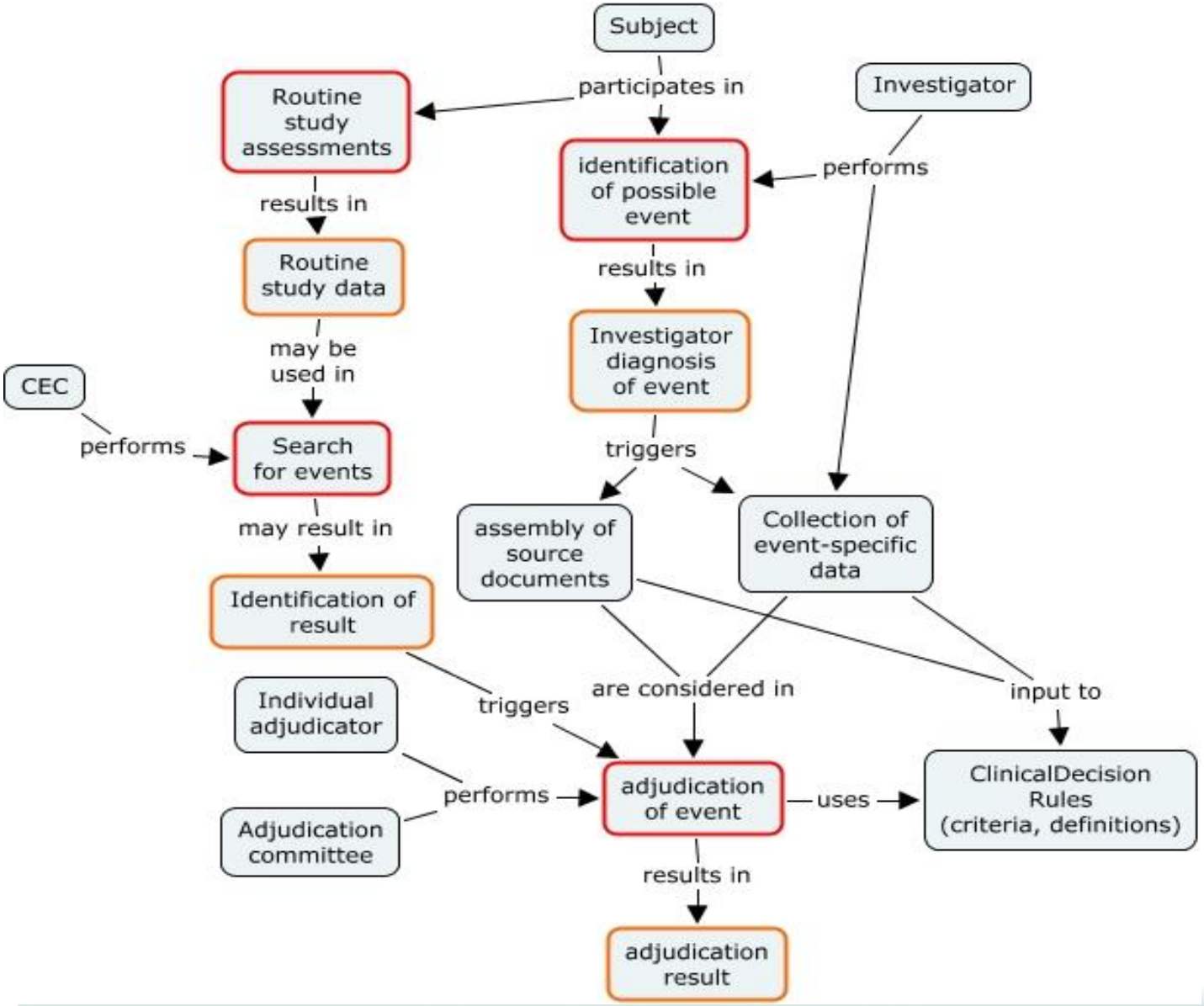
- Another important aspect of the CV ENDPOINTS data standards implementation deals with the adjudication of events. A number of examples included in this user guide demonstrate how the adjudication records are handled.

- With recent updates in global regulatory requirements, the need for formal adjudication of clinical events or endpoints in clinical trials is becoming critical. Trials involving adjudication require effective communication and adjudication processes which are enhanced by electronic systems that offer real-time information on patient outcome data. Communication between sponsors, clinical event committee (CEC) members, Clinical Safety, Data Management, and Investigators may work on a singular system, which allows the CEC to review and rapidly arrive at the critical endpoint for study decisions. Streamlining adjudications and communication not only allows all relevant patient data to flow quickly to all decision makers, but also keeps the trial timelines intact by managing endpoint target numbers.

- Committee rosters usually include highly accredited, independent interventional cardiologists, non-interventional cardiologists, cardiothoracic surgeons, neurologists, and other specialists as well as biostatisticians. This adjudication process ensures that trial data is consistent, reliable, and of high quality.

- **When domain examples in this user guide contain adjudication data, the –EVAL variable will identify the evaluator of those results.**

Event Adjudication Concept Map



SDTM Modeling Issues

- **Adverse Events vs Clinical Events**

  The CV Endpoints standards team reviewed the question of whether the cardiovascular events expected in CV Endpoint studies should be recorded as an adverse event or a clinical event in SDTM. The team decided they should be clinical events when being evaluated as a CV Endpoint, since they are expected to occur in CV Endpoint studies. These specific cardiovascular event terms are listed in the ACC CV Endpoints CDE definitions in order to record them consistently for CV Endpoint studies. If these events are not considered a CV Endpoint in other therapeutic areas, they should be recorded as adverse events and follow the sponsors adverse event reporting rules.

- **Cardiovascular Biomarkers**

  The CV Endpoint CDEs included additional laboratory data collected that is not contained in the LB domain and are populated in the SUPPLB domain. The CV Endpoint CDEs included the 99th percentile from the distribution of values for a population who would be expected to have normal values for the lab. This is more specific than and different from the upper limit of normal, which is typically, though not always, the 95th percentile for such a population. The 99th percentile would be supplied by the laboratory.

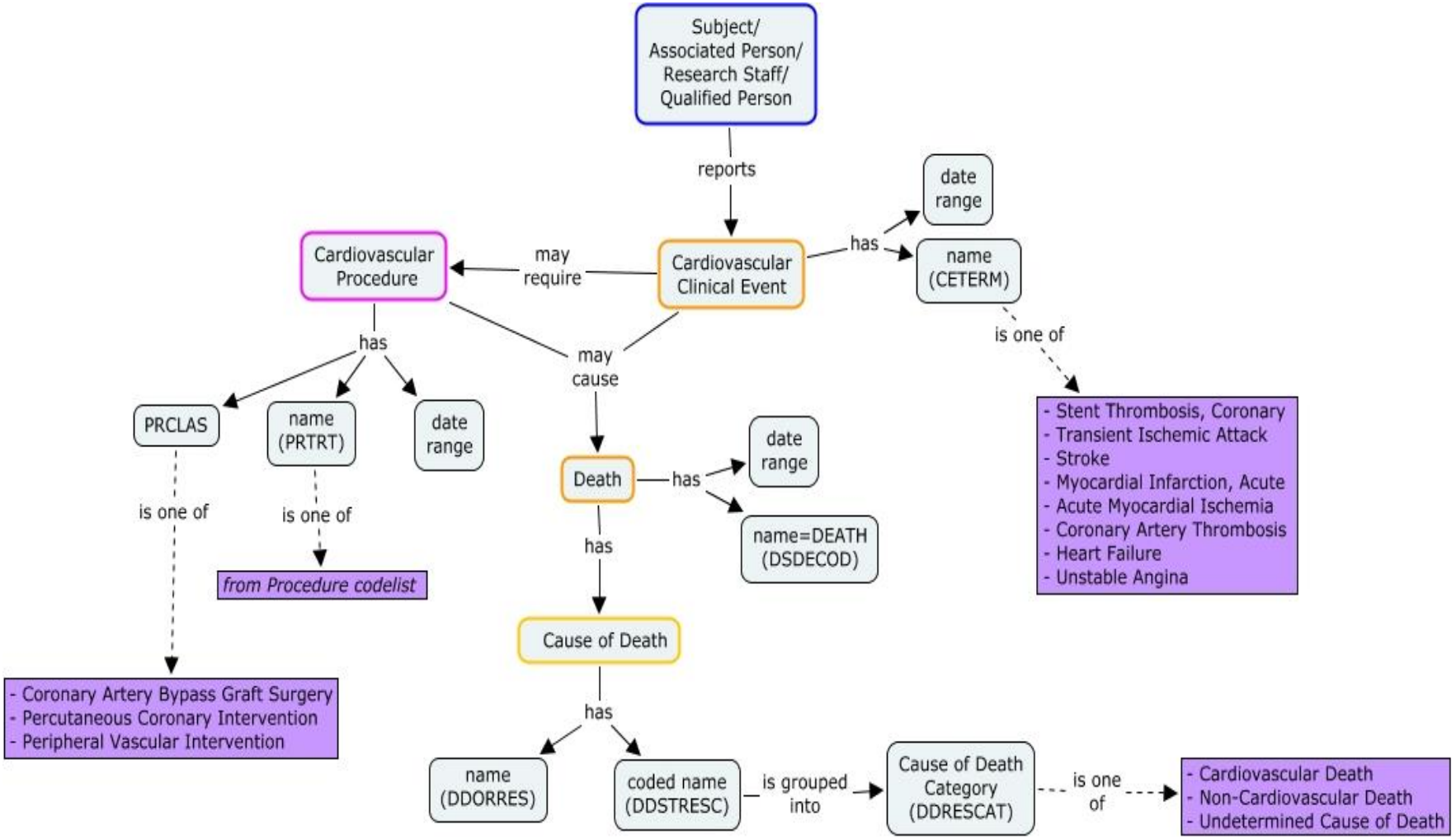
- **Cardiovascular Lesions**

  The concept of identifying lesions and recording lesion results was addressed by the CDISC Oncology Sub-Team relative to tumors when they released the Tumor Identification (TU) and Tumor Results (TR) domains in the SDTMIG 3.1.3. The CDISC SDS Leadership Team reviewed the cardiovascular and other therapeutic area lesion CDEs and decided it best to populate the lesion data in the existing TU and TR domains instead of creating new domains for non-oncology data. The TU and TR domain names will be revised in the next version of the SDTMIG to Tumor and Lesion Identification (TU) and Tumor and Lesion Results (TR).

- **Cardiovascular Judgments**

  The CV Endpoints CDEs contain a number of clinical judgments which are based on multiple sources of routine collected data. These clinical judgments are made about clinical events and surgical interventions. Examples are the identification of symptoms, the evaluation of heart failure and unstable angina endpoint events, along with procedure status and procedure urgency. The Findings About (FA) domain is used to record the clinical judgments with the object variable (FAOBJ) referring to the related clinical event or procedure.

Concept Map for Endpoint of Death



Endpoint of Death Data Example

Deaths that occur in subjects are submitted as disposition events in the DS (Disposition) domain as referenced in the current SDTMIG. The related cause of death and other details are recorded in the DD (Death Details) domain, as shown below. The example below shows the primary and secondary causes of death for this subject. This example is included to illustrate the use of the controlled terminology developed for cause of death. The value list for the DDSTRESC values will be included in the define.xml.

Row 1: Shows USUBJID=40945 death disposition record, that recorded the death date as November 27 2007, with the DSTERM=Death due to Stroke. DSLNKID was used to relate the death to other relevant data.

Row	STUDYID	DOMAIN	USUBJID	DSSEQ	DSLNKID	DSTERM	DSDECOD	DSCAT	DSDTC	DSSTDTC
1	STUDY01	DS	40945	1	DTH-1	Death due to stroke	DEATH	DISPOSITION EVENT	2007-11-27	2007-11-27

Rows 1-2: Show the primary cause of death standardized as CARDIOVASCULAR: STROKE and the secondary cause of death standardized as RENAL FAILURE. The CV Endpoint cause of death value is populated in the DDSTRESC variable and the result is categorized in the DDRESCAT variable. DDLNKID is used to link the death details to the disposition record.

Row	STUDYID	DOMAIN	USUBJID	DDSEQ	DDLNKID	DDTESTCD	DDTEST	DDORRES	DDSTRESC
1	STUDY01	DD	40945	1	DTH-1	PRCDTH	Primary Cause of Death	DEATH DUE TO STROKE	CARDIOVASCULAR: STROKE
2	STUDY01	DD	40945	2	DTH-1	SECDTH	Secondary Cause of Death	KIDNEY FAILURE	RENAL FAILURE

Row	DDRESCAT	VISITNUM	DDDTC
1 (cont)	CARDIOVASCULAR DEATH	9	2007-11-27
2 (cont)	NON-CARDIOVASCULAR DEATH	9	2007-11-27

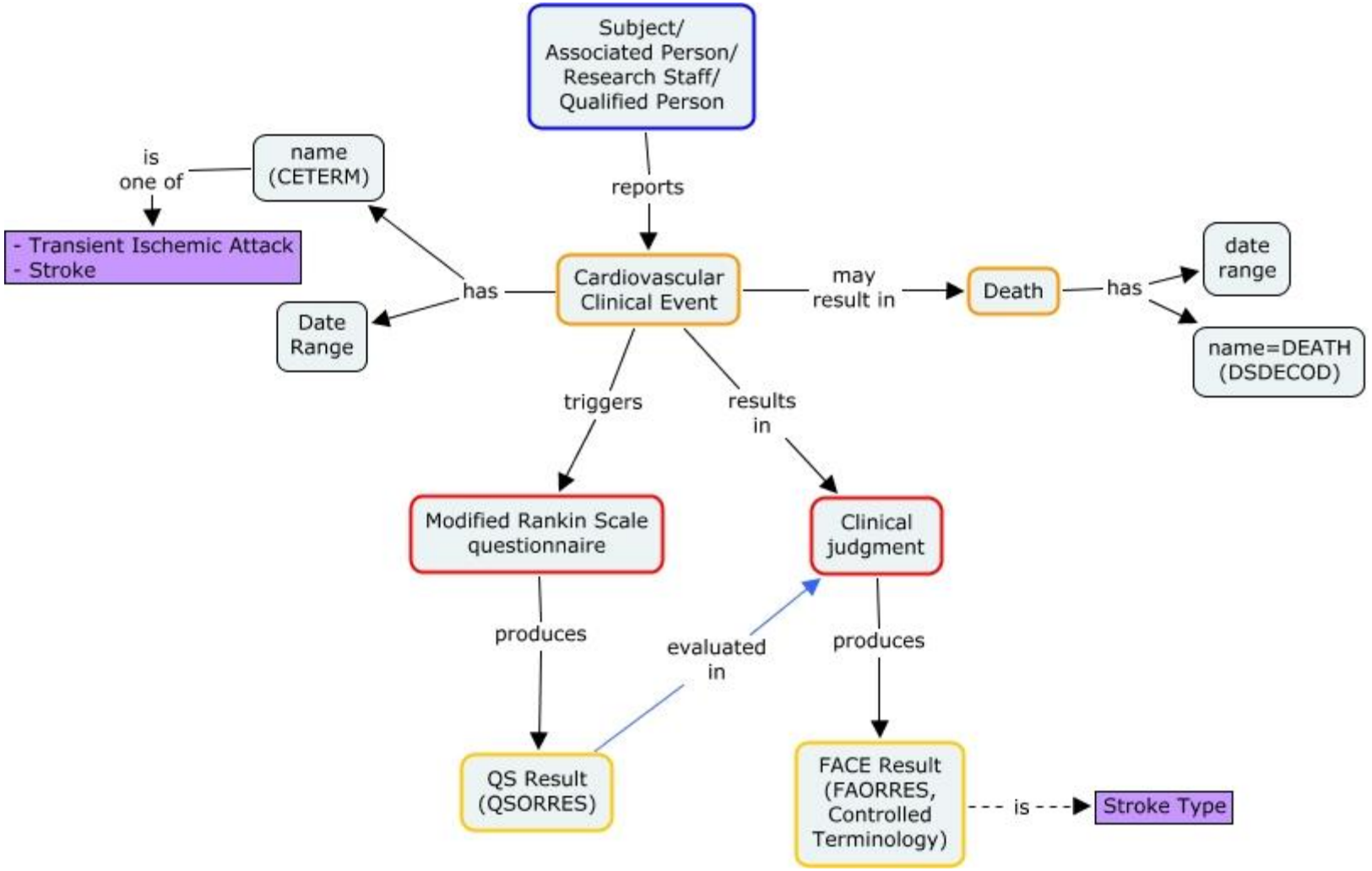
Dataset Relationships Example

The RELREC domain defines dataset relationships between these domain records for all subjects.

Rows 1-2: Show the relationship between the disposition and death details domains via the DSLNKID and DDLNKID variable

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
1	STUDY01	DS		DSLNKID		ONE	DSDD
2	STUDY01	DD		DDLNKID		MANY	DSDD

Concept Map for TIA & Stroke



Endpoint of TIA Data Example

The investigator reported that USUBJID=40523 had a transient ischemic attack (TIA) on October 15, 2008. The clinical event was re-evaluated by the clinical evaluation committee (CEC) and the CEC adjudicator also considered the event to be a TIA.

Row 1: Shows USUBJID=40523 transient ischemic attack clinical event record. The CEEVAL indicates that the Investigator reported the TIA.

Row 2: Shows USUBJID=40523 transient ischemic attack clinical event record that was re-evaluated by the CEC adjudicator (CEEVAL) approximately one month after the investigator result. CEGRPID groups the source and adjudicated records.

Row	STUDYID	DOMAIN	USUBJID	CESEQ	CEGRPID	CETERM	CEEVAL	CEACPTFL	CEDTC	CESTDTC
1	STUDY01	CE	40523	1	1	Transient Ischemic Attack	INVESTIGATOR		2008-10-15	2008-10-15
2	STUDY01	CE	40523	2	1	Transient Ischemic Attack	CEC ADJUDICATOR	Y	2008-11-15	2008-10-15

Endpoint of Stroke Data Example

Subject 40101 had an ischemic stroke on January 20, 2009. The investigator judged the stroke to be "Ischemic" based on the subject's presentation of signs and symptoms, and the criteria identified in the ACC CV ENDPOINT CDE v1.0 located on the ACC website. The Rankin Scale was administered at an unscheduled visit on January 21, 2009 and had "No Significant Disability Despite Symptoms; Able to Carry Out All Usual Duties and Activities". At the 30-day follow-up visit on February 20, 2009, the Rankin scale had the same result. Note: This stroke event was not adjudicated.

Row 1: Shows USUBJID=40101 stroke clinical event record with the start date of January 20, 2009.

Row	STUDYID	DOMAIN	USUBJID	CESEQ	CELNKID	CETERM	CEDTC	CESTDTC	CEENDTC
1	STUDY01	CE	40101	1	STRK-1	Stroke	2009-01-20	2009-01-20	2009-01-20

Row 1: Shows USUBJID=40101 clinical judgment regarding the stroke type using the predefined criteria identified in the ACC CV ENDPOINT CDE v1.0 located on the ACC website. FAOBJ=STROKE in order to link the clinical event type to the appropriate clinical event of stroke.

Row	STUDYID	DOMAIN	USUBJID	FASEQ	FALNKID	FATESTCD	FATEST	FAOBJ	FAORRES	FASTRESC	VISITNUM	VISIT	FADTC
1	STUDY01	FA	40101	1	STRK-1	EVNTTYPE	Event Type	STROKE	ISCHEMIC	ISCHEMIC	1.1	UNSCHEDULED	2009-01-21

Endpoint of Stroke Data Example

Row 1: Shows USUBJID=40101 Modified Rankin Scale score at the time of the stroke.
Row 2: Shows USUBJID=40101 Modified Rankin Scale score at the 30-day follow-up visit.

Row	STUDYID	DOMAIN	USUBJID	QSSEQ	QSTESTCD	QSTEST	QSCAT	QSORRES
1	STUDY01	QS	40101	1	MRS0101	MRS01-MODIFIED RANKIN SCALE SCORE	MRS	NO SIGNIFICANT DISABILITY DESPITE SYMPTOMS; ABLE TO CARRY OUT ALL USUAL DUTIES AND ACTIVITIES
2	STUDY01	QS	40101	2	MRS0101	MRS01-MODIFIED RANKIN SCALE SCORE	MRS	NO SIGNIFICANT DISABILITY DESPITE SYMPTOMS; ABLE TO CARRY OUT ALL USUAL DUTIES AND ACTIVITIES

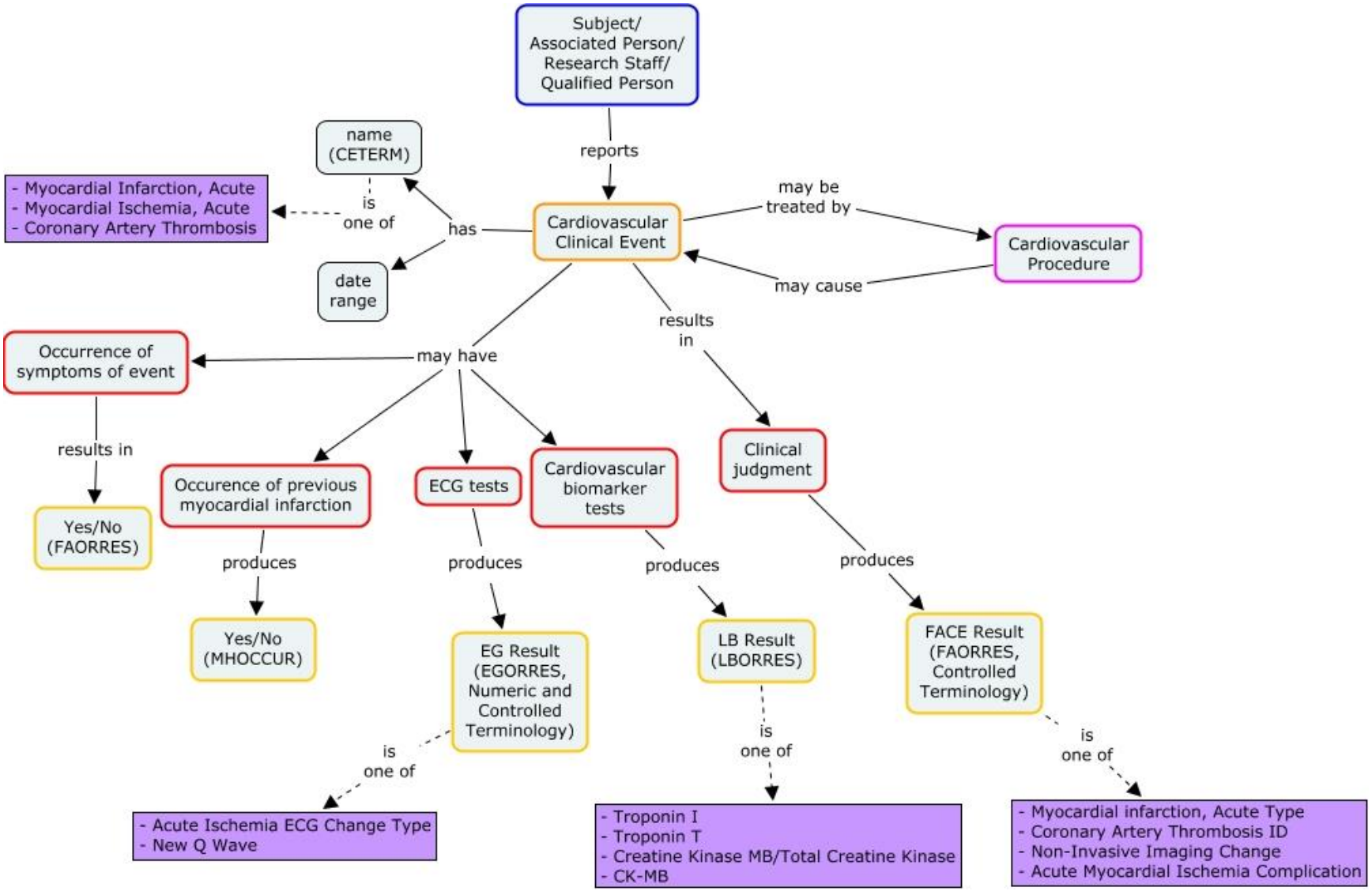
Row	QSSTRESC	QSSTRESN	QSEVAL	VISITNUM	VISIT	QSDTC
1 (cont)	1	1	INVESTIGATOR	1.1	UNSCHEDULED	2009-01-21
2 (cont)	1	1	INVESTIGATOR	5	30-DAY FOLLOW-UP	2009-02-20

The RELREC domain defines dataset relationships between these domain records for the subject.

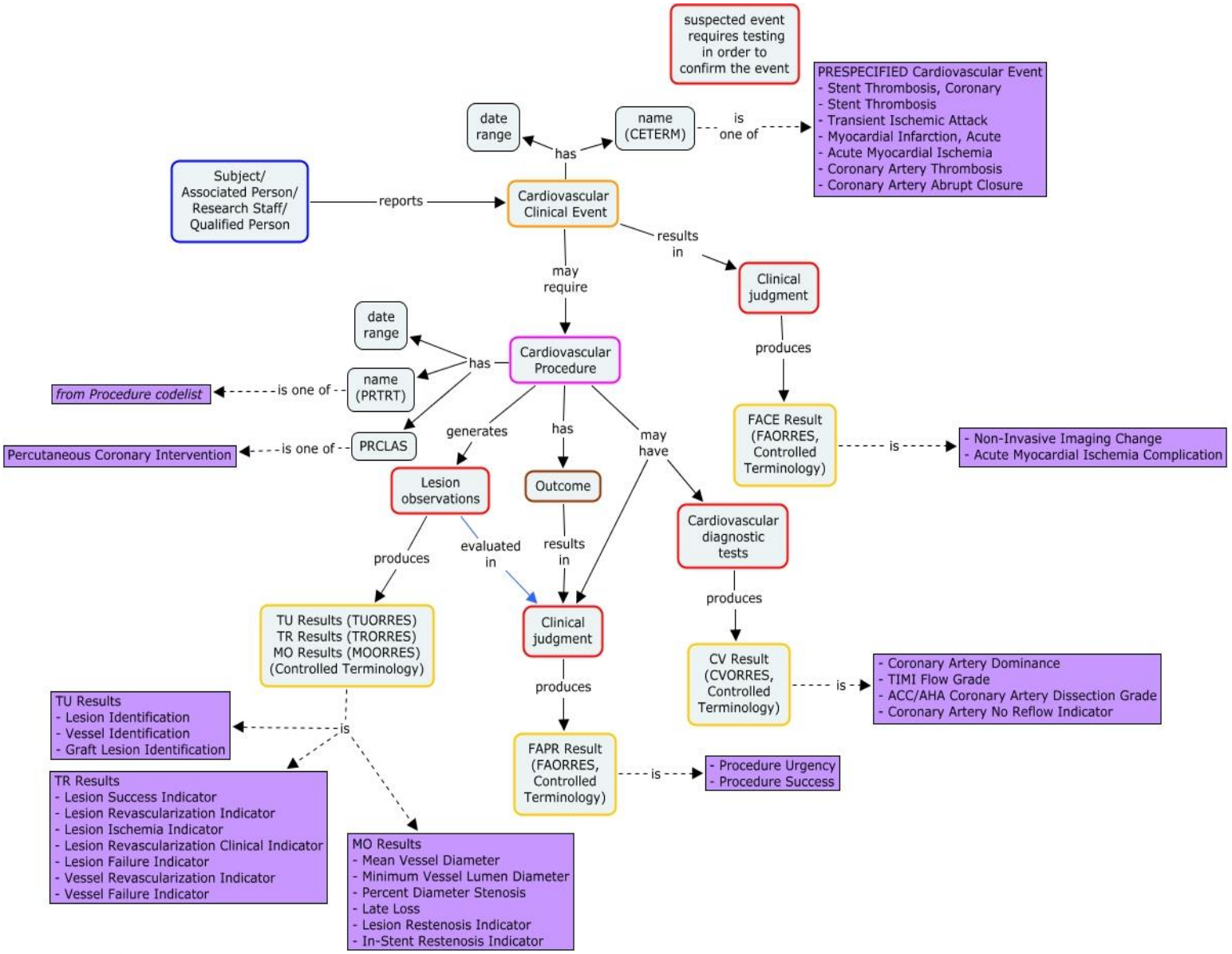
Rows 1-2: Show the relationship between the clinical event and clinical decision domains via the CELNKID and FALNKID variables.

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
1	STUDY01	CE		CELNKID		ONE	CEFA
2	STUDY01	FA		FALNKID		MANY	CEFA

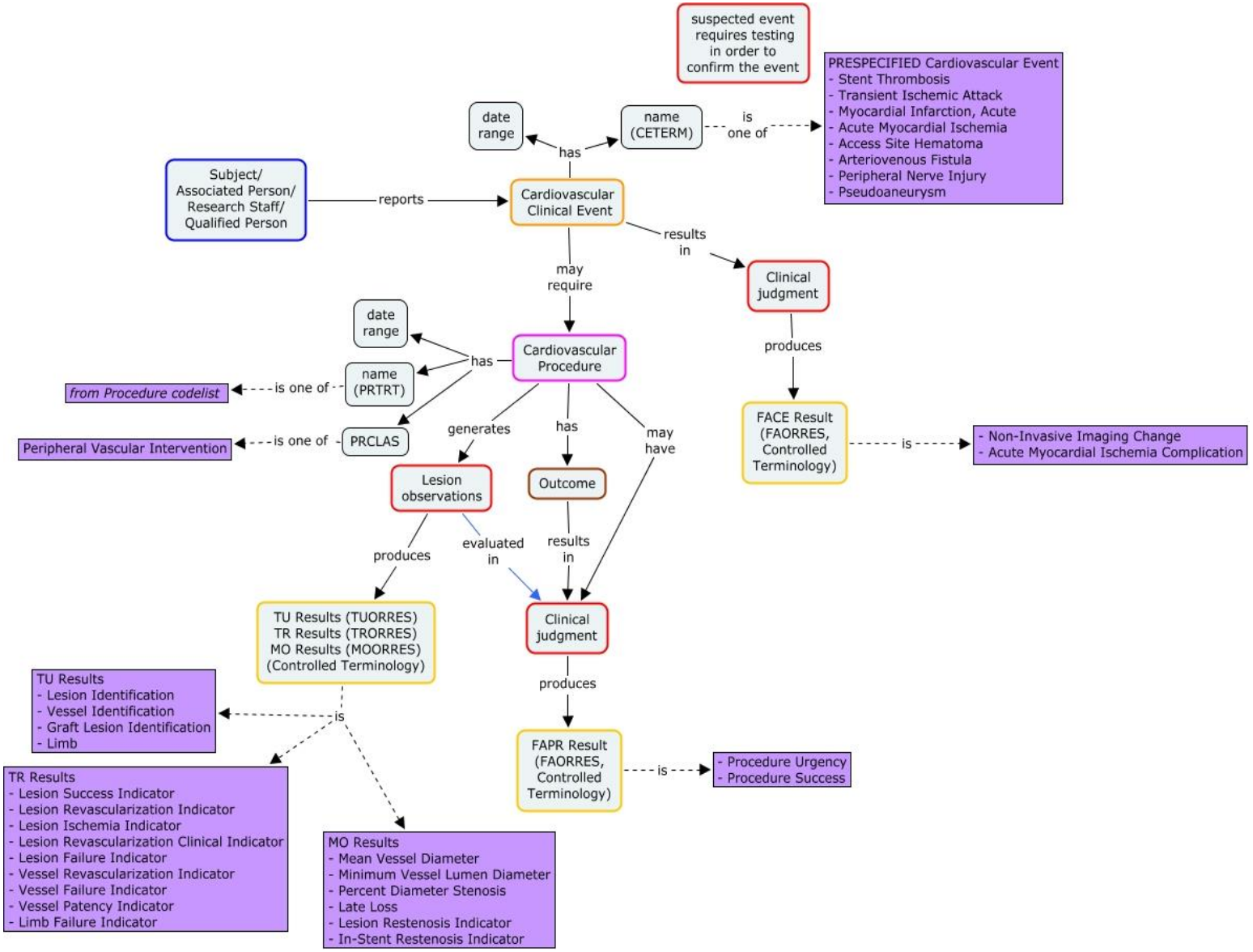
Concept Map for Myocardial Infarction



Concept Map for PCI



Concept Map for PVI



Endpoint of PVI Data Example #1

Subject 40779 had an initial PVI on the left leg with balloon angioplasty (SUPPPR) (PR) in the left superficial femoral artery on April 12, 2009; the investigator reported that the status was elective and the procedure was unsuccessful. A PVI with stent implantation was on April 20, 2009; Status was elective and this procedure was successful (FA). The CEC adjudicator agreed with balloon angioplasty status and lack of success but said the PVI with stent implantation status was urgent. The CEC adjudicator agreed second procedure was successful (FA).

Rows 1-2: Shows USUBJID=40779 initial PVI on 2009-04-12 and second PVI on 2009-04-20.

Row	STUDYID	DOMAIN	USUBJID	PRSEQ	PRGRPID	PRLINKID	PRTRT	PRCLAS	PRLOC	PRSTDTC	PRENDTC
1	STUDY01	PR	40779	1	A1	PVI-1	BALLOON ANGIOPLASTY	PERCUTANEOUS VASCULAR INTERVENTION	LEFT SUPERFICIAL FEMORAL ARTERY	2009-04-12	2009-04-12
2	STUDY01	PR	40779	2	A2	PVI-2	STENT IMPLANTATION	PERCUTANEOUS VASCULAR INTERVENTION	LEFT SUPERFICIAL FEMORAL ARTERY	2009-04-20	2009-04-20

Endpoint of PVI Data Example #1

Rows 1-2: Show USUBJID=40779 clinical judgment records for the first procedure, the investigator judged the PVI as elective, but not successful.

Rows 3-4: Show USUBJID=40779 clinical judgment records for the first procedure adjudicated by a CEC adjudicator. The CEC adjudicator agreed with the investigator's judgment.

Rows 5-6: Show USUBJID=40779 clinical judgment records for the second procedure, the investigator judged the PVI as elective and successful.

Rows 7-8: Show USUBJID=40779 clinical judgment records for the second procedure adjudicated by a CEC adjudicator. The CEC adjudicator agreed that the PVI was successful, but judged it to be urgent rather than elective.

FAGRPID groups the FA records according to the related procedure.

Row	STUDYID	DOMAIN	USUBJID	FASEQ	FAGRPID	FALNKID	FATESTCD	FATEST	FAOBJ
1	STUDY01	FA	40779	1	1	PVI-1	PRSUCESS	Procedure Success	PERCUTANEOUS VASCULAR INTERVENTION
2	STUDY01	FA	40779	2	2	PVI-1	PRSTAT	Procedure Status	PERCUTANEOUS VASCULAR INTERVENTION
3	STUDY01	FA	40779	3	1	PVI-1	PRSUCESS	Procedure Success	PERCUTANEOUS VASCULAR INTERVENTION
4	STUDY01	FA	40779	4	2	PVI-1	PRSTAT	Procedure Status	PERCUTANEOUS VASCULAR INTERVENTION
5	STUDY01	FA	40779	5	3	PVI-2	PRSUCESS	Procedure Success	PERCUTANEOUS VASCULAR INTERVENTION
6	STUDY01	FA	40779	6	4	PVI-2	PRSTAT	Procedure Status	PERCUTANEOUS VASCULAR INTERVENTION
7	STUDY01	FA	40779	7	3	PVI-2	PRSUCESS	Procedure Success	PERCUTANEOUS VASCULAR INTERVENTION
8	STUDY01	FA	40779	8	4	PVI-2	PRSTAT	Procedure Status	PERCUTANEOUS VASCULAR INTERVENTION

Row	FAORRES	FASTRESC	FALOC	FALAT	FAEVAL	FAACPTFL	VISITNUM	VISIT	FADTC
1 (cont)	NO	N	LEG	LEFT	INVESTIGATOR		1	BASELINE	2009-04-13
2 (cont)	ELECTIVE	ELECTIVE	LEG	LEFT	INVESTIGATOR		1	BASELINE	2009-04-13
3 (cont)	NO	N	LEG	LEFT	CEC ADJUDICATOR	Y	1	BASELINE	2009-05-15
4 (cont)	ELECTIVE	ELECTIVE	LEG	LEFT	CEC ADJUDICATOR	Y	1	BASELINE	2009-05-15
5 (cont)	YES	Y	LEG	LEFT	INVESTIGATOR		2	VISIT 1	2009-04-20
6 (cont)	ELECTIVE	ELECTIVE	LEG	LEFT	INVESTIGATOR		2	VISIT 1	2009-04-20
7 (cont)	YES	Y	LEG	LEFT	CEC ADJUDICATOR	Y	2	VISIT 1	2009-05-22
8 (cont)	URGENT	URGENT	LEG	LEFT	CEC ADJUDICATOR	Y	2	VISIT 1	2009-05-22

Endpoint of PVI Data Example #2

Subject 40913 had a PVI (PR) on February 1, 2007. A target lesion (L01) was identified in the infrarenal aorta [within the aorto-iliac vessel (L01-1) (TU)]. The CEC adjudicator agreed with vessel and lesion identification. The TR domain contains related lesion results in which the investigator and adjudicator were in agreement. The MO domain reflects results for the following measurements obtained by angiogram: mean vessel diameter single view; minimal lumen diameter single view; percent diameter stenosis; late loss, restenosis, lesion; restenosis in stent were reported along with the adjudicator's agreement records.

During the same PVI procedure, the subject also had a target graft lesion (L01-G) identified in the left femoro-popliteal graft (L01-G1). The lesion location was noted within the graft anastomosis proximal, the type was a synthetic graft composed of Gortex, and the anastomosis was in the Left Popliteal Artery. This description was provided by the investigator: "This lesion was 5mm from the origin of the graft." PVI target vessel is left popliteal artery [L01-G1]. CEC adjudicator indicated the location was the 'graft body' and agreed about the type and anastomosis of the graft. The TR domain contains related lesion results in which the investigator and adjudicator were in agreement. The MO domain reflects results for the following measurements: mean vessel diameter single view; minimal lumen diameter for single view; percent diameter stenosis; late loss, restenosis, lesion; restenosis in stent were reported along with the adjudicator's agreement records.

The PVI procedure data is not part of this example.

Endpoint of PVI Data Example #2

Rows 1-2: Show USUBJID=40913 target lesion located in the infrarenal aorta and within the aorta-iliac vessel.

Rows 3: Show USUBJID=40913 PVI target limb in which the graft lesion is located identified by the investigator.

Rows 4-5: Show USUBJID=40913 target graft lesion located in the left femoro-popliteal graft and within the femoro-popliteal vessel.

Rows 6-7: Show USUBJID=40913 target lesion and vessel identification records adjudicated by a radiologist who agreed with the investigator.

Rows 8: Show USUBJID=40913 PVI target limb identified by the radiologist who agreed with the investigator.

Rows 9-10: Show USUBJID=40913 target graft lesion and vessel identification records adjudicated by a radiologist who agreed with the investigator

Row	STUDYID	DOMAIN	USUBJID	TUSEQ	TULNKID	TUTESTCD	TUTEST	TUORRES	TUSTRESC	TUNAM	TULOC
1	STUDY01	TU	40913	1	L01	LESIONID	Lesion Identification	TARGET	TARGET		INFRARENAL AORTA
2	STUDY01	TU	40913	2	L01-1	VESSELID	Vessel Identification	TARGET	TARGET		AORTO-ILIAC
3	STUDY01	TU	40913	3	L01-2	LIMB	Limb	TARGET	TARGET		LEG
4	STUDY01	TU	40913	4	L01-G	GRFLESID	Graft Lesion Identification	TARGET	TARGET		LEFT FEMORO-POPLITEAL GRAFT
5	STUDY01	TU	40913	5	L01-G1	VESSELID	Vessel Identification	TARGET	TARGET		FEMORO-POPLITEAL
6	STUDY01	TU	40913	6	R-L01	LESIONID	Lesion Identification	TARGET	TARGET	ACME VENDOR	INFRARENAL AORTA
7	STUDY01	TU	40913	7	R-L01-1	VESSELID	Vessel Identification	TARGET	TARGET	ACME VENDOR	AORTO-ILIAC
8	STUDY01	TU	40913	8	R-L01-2	LIMB	Limb	TARGET	TARGET	ACME VENDOR	LEG
9	STUDY01	TU	40913	9	R-L01-G	GRFLESID	Graft Lesion Identification	TARGET	TARGET	ACME VENDOR	LEFT FEMORO-POPLITEAL GRAFT
10	STUDY01	TU	40913	10	R-L01-G1	VESSELID	Vessel Identification	TARGET	TARGET	ACME VENDOR	FEMORO-POPLITEAL

Endpoint of PVI Data Example #2

Row	TULAT	TUMETHOD	TUEVAL	TUACPTFL	VISITNUM	VISIT	TUDTC
1 (cont)	LEFT	PERIPHERAL ANGIOGRAPHY	INVESTIGATOR		1	SCREEN	2007-02-01
2 (cont)		PERIPHERAL ANGIOGRAPHY	INVESTIGATOR		1	SCREEN	2007-02-01
3 (cont)	LEFT		INVESTIGATOR		1	SCREEN	2007-02-01
4 (cont)		PERIPHERAL ANGIOGRAPHY	INVESTIGATOR		1	SCREEN	2007-02-01
5 (cont)		PERIPHERAL ANGIOGRAPHY	INVESTIGATOR		1	SCREEN	2007-02-01
6 (cont)	LEFT	PERIPHERAL ANGIOGRAPHY	RADIOLOGIST	Y	1	SCREEN	2007-04-10
7 (cont)		PERIPHERAL ANGIOGRAPHY	RADIOLOGIST	Y	1	SCREEN	2007-04-10
8 (cont)	LEFT		RADIOLOGIST	Y	1	SCREEN	2007-04-10
9 (cont)		PERIPHERAL ANGIOGRAPHY	RADIOLOGIST	Y	1	SCREEN	2007-04-10
10 (cont)		PERIPHERAL ANGIOGRAPHY	RADIOLOGIST	Y	1	SCREEN	2007-04-10

The CV Endpoint CDEs included additional data collected for peripheral graft lesions identified in the TU domain and are populated in the SUPPTU domain as indicated below. The original peripheral artery bypass procedure would include some of these variables in the PR domain or SUPPPR if that is reported. A subsequent procedure to perform a revascularization of a lesion would not have this information. These variables would apply to the lesion revascularization only and need to be recorded in SUPPTU. These data are listed below with their related standard values.

QNAM	QLABEL	QVAL
PAGLL	Peripheral Graft Lesion Location	Graft anastomosis - proximal Graft body Graft anastomosis - distal
PAGT	Peripheral Artery Graft Type	Peripheral Artery Graft Type Codelist
PAGAMAST	Peripheral Artery Graft Anastomosis	Anatomical Location Codelist
OTHLDSC	Other Lesion Description	"text"
PAGSM	Peripheral Artery Graft Synthetic Material	Gortex Polytetrafluoroethylene (PTFE) Polyester Dacron Polyurethane

Endpoint of PVI Data Example #2

Row 1: Shows the investigator's target graft lesion (TULNKID= L01-G) peripheral artery graft lesion location in the graft anastomosis proximal of the graft.

Row 2: Shows the investigator's target graft lesion (TULNKID= L01-G) peripheral artery graft type being a synthetic graft.

Row 3: Shows the investigator's target graft lesion (TULNKID= L01-G) peripheral artery graft anastomosis in the left popliteal artery.

Row 4: Shows the investigator's target graft lesion (TULNKID= L01-G) other lesion description of "lesion is 5mm from the origin of the graft".

Row 5: Shows the investigator's target graft lesion (TULNKID= L01-G) peripheral artery graft synthetic material of Gortex.

Row 6: Shows the radiologist's result for the target graft lesion (TULNKID= L01-G) peripheral artery graft lesion location in the graft body.

Row 7: Shows the radiologist's result for the target graft lesion (TULNKID= L01-G) peripheral artery graft type being a synthetic graft.

Row 8: Shows the radiologist's result for the target graft lesion (TULNKID= L01-G) peripheral artery graft anastomosis in the left popliteal artery.

Row 9: Shows the radiologist's result for the target graft lesion (TULNKID= L01-G) peripheral artery graft synthetic material of Gortex.

ROW	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG	QEVAL
1	STUDY01	TU	40913	TUSEQ	4	PAGLL	Peripheral Graft Lesion Location	GRAFT ANASTOMOSIS PROXIMAL	CRF	INVESTIGATOR
2	STUDY01	TU	40913	TUSEQ	4	PAGT	Peripheral Artery Graft Type	SYNTHETIC GRAFT	CRF	INVESTIGATOR
3	STUDY01	TU	40913	TUSEQ	4	PAGAMAST	Peripheral Artery Graft Anastomosis	LEFT POPLITEAL ARTERY	CRF	INVESTIGATOR
4	STUDY01	TU	40913	TUSEQ	4	OTHLDSC	Other Lesion Description	LESION IS 5MM FROM THE ORIGIN OF THE GRAFT	CRF	INVESTIGATOR
5	STUDY01	TU	40913	TUSEQ	4	PAGSM	Peripheral Artery Graft Synthetic Material	GORTEX	CRF	INVESTIGATOR
6	STUDY01	TU	40913	TUSEQ	9	PAGLL	Peripheral Artery Graft Lesion Location	GRAFT BODY	CRF	RADIOLOGIST
7	STUDY01	TU	40913	TUSEQ	9	PAGT	Peripheral Artery Graft Type	SYNTHETIC GRAFT	CRF	RADIOLOGIST
8	STUDY01	TU	40912	TUSEQ	9	PAGAMAST	Peripheral Artery Graft Anastomosis	LEFT POPLITEAL ARTERY	CRF	RADIOLOGIST
9	STUDY01	TU	40912	TUSEQ	9	PAGSM	Peripheral Artery Graft Synthetic Material	GORTEX	CRF	RADIOLOGIST

Endpoint of PVI Data Example #2

Rows 1-8: Show USUBJID=40913 target lesion and vessel result records made by the investigator.
Rows 9-14: Show USUBJID=40913 target graft lesion and vessel result records made by the investigator.
Rows 15-22: Show USUBJID=40913 target lesion and vessel result records adjudicated by an independent assessor.
Rows 23-28: Show USUBJID=40913 target graft lesion and vessel result records adjudicated by an independent assessor.

Row	STUDYID	DOMAIN	USUBJID	TRSEQ	TRGRPID	TRLNKGRP	TRLNKID	TRTESTCD	TRTEST	TRORRES	TRSTRESC
1	STUDY01	TR	40913	1	TARGET	L-A1	L01	LESRVIND	Lesion Revascularization Indicator	No	N
2	STUDY01	TR	40913	2	TARGET	L-A1	L01	LRISCIND	Lesion Revas. Ischemia Indicator	No	N
3	STUDY01	TR	40913	3	TARGET	L-A1	L01	LRVCLIND	Lesion Revas. Clinical Indicator	Yes	Y
4	STUDY01	TR	40913	4	TARGET	L-A1	L01	LESFLINF	Lesion Failure Indicator	No	N
5	STUDY01	TR	40913	5	TARGET	L-A1	L01	LESSCIND	Lesion Success Indicator	Yes	Y
…	…	…	…	…	…	…	…	…	…	…	…
15	STUDY01	TR	40913	15	TARGET	L-A1	R-L01	LESRVIND	Lesion Revascularization Indicator	No	N
16	STUDY01	TR	40913	16	TARGET	L-A1	R-L01	LRISCIND	Lesion Revas. Ischemia Indicator	No	N
17	STUDY01	TR	40913	17	TARGET	L-A1	R-L01	LRVCLIND	Lesion Revas. Clinical Indicator	Yes	Y
18	STUDY01	TR	40913	18	TARGET	L-A1	R-L01	LESFLINF	Lesion Failure Indicator	No	N
19	STUDY01	TR	40913	19	TARGET	L-A1	R-L01	LESSCIND	Lesion Success Indicator	Yes	Y
…	…	…	…	…	…	…	…	…	…	…	…
28	STUDY01	TR	40913	28	TARGET	L-A1	R-L01-G1	VSLPTIND	Vessel Patency Indicator	No	N

Row	TRNAM	TRMETHOD	TREVAL	TRACPTFL	VISITNUM	VISIT	TRDTC
1 (cont)		PERIPHERAL ANGIOGRAPHY	INVESTIGATOR		1	SCREEN	2007-02-01
2 (cont)		PERIPHERAL ANGIOGRAPHY	INVESTIGATOR		1	SCREEN	2007-02-01
3 (cont)		PERIPHERAL ANGIOGRAPHY	INVESTIGATOR		1	SCREEN	2007-02-01
4 (cont)		PERIPHERAL ANGIOGRAPHY	INVESTIGATOR		1	SCREEN	2007-02-01
5 (cont)		PERIPHERAL ANGIOGRAPHY	INVESTIGATOR		1	SCREEN	2007-02-01
…	…	…	…	…	…	…	…
15 (cont)	ACME VENDOR	PERIPHERAL ANGIOGRAPHY	RADIOLOGIST	Y	1	SCREEN	2007-04-10
16 (cont)	ACME VENDOR	PERIPHERAL ANGIOGRAPHY	RADIOLOGIST	Y	1	SCREEN	2007-04-10
17 (cont)	ACME VENDOR	PERIPHERAL ANGIOGRAPHY	RADIOLOGIST	Y	1	SCREEN	2007-04-10
18 (cont)	ACME VENDOR	PERIPHERAL ANGIOGRAPHY	RADIOLOGIST	Y	1	SCREEN	2007-04-10
19 (cont)	ACME VENDOR	PERIPHERAL ANGIOGRAPHY	RADIOLOGIST	Y	1	SCREEN	2007-04-10
…	…	…	…	…	…	…	…
28 (cont)	ACME VENDOR	PERIPHERAL ANGIOGRAPHY	RADIOLOGIST	Y	1	SCREEN	2007-04-10

Endpoint of PVI Data Example #2

Rows 1-6: Show USUBJID=40913 target lesion vessel morphology result records including mean vessel diameter, minimum lumen diameter, percent diameter stenosis, late loss, PVI restenosis, lesion and in-stent. These results were provided by the investigator.

Rows 7-12: Show USUBJID=40913 target graft lesion vessel morphology result records including mean vessel diameter, minimum lumen diameter, percent diameter stenosis, late loss, PVI restenosis, les ion and in-stent. These results were provided by the investigator.

Rows 13-18: Show USUBJID=40913 target lesion vessel morphology result records adjudicated by a radiologist, who agreed with the investigator's findings.

Rows 19-24: Show USUBJID=40913 target graft lesion vessel morphology result records adjudicated by a radiologist, who agreed with the investigator's findings.

Row	STUDYID	DOMAIN	USUBJID	MOSEQ	MOGRPID	MOLNKGRP	MOLNKID	MOTESTCD	MOTEST	MOORRES	MOORRESU
1	STUDY01	MO	40913	1	TARGET	L-A1	L01-1	MEANVDIA	Mean Vessel Diameter	3	mm
2	STUDY01	MO	40913	2	TARGET	L-A1	L01-1	MINLDIAM	Minimum Vessel Lumen Diameter	2	mm
3	STUDY01	MO	40913	3	TARGET	L-A1	L01-1	PCTDIAST	Percent Diameter Stenosis	30	%
4	STUDY01	MO	40913	4	TARGET	L-A1	L01-1	LATELOSS	Late Loss	0.75	mm
5	STUDY01	MO	40913	5	TARGET	L-A1	L01-1	LRSTIND	Lesion Restenosis Indicator	No	
6	STUDY01	MO	40913	6	TARGET	L-A1	L01-1	INRSTIND	In-Stent Restenosis Indicator	No	
...	...	...	...	...	...	...	...	...	...	...	...
13	STUDY01	MO	40913	13	TARGET	L-A1	R-L01-1	MEANVDIA	Mean Vessel Diameter	3	mm
14	STUDY01	MO	40913	14	TARGET	L-A1	R-L01-1	MINLDIAM	Minimum Vessel Lumen Diameter	2	mm
15	STUDY01	MO	40913	15	TARGET	L-A1	R-L01-1	PCTDIAST	Percent Diameter Stenosis	30	%
16	STUDY01	MO	40913	16	TARGET	L-A1	R-L01-1	LATELOSS	Late Loss	0.75	mm
17	STUDY01	MO	40913	17	TARGET	L-A1	R-L01-1	LRSTIND	Lesion Restenosis Indicator	No	
18	STUDY01	MO	40913	18	TARGET	L-A1	R-L01-1	INRSTIND	In-Stent Restenosis Indicator	No	
...	...	...	...	...	...	...	...	...	...	...	...
24	STUDY01	MO	40913	24	TARGET	L-A1	R-L01-G1	INRSTIND	In-Stent Restenosis Indicator	No	

Endpoint of PVI Data Example #2

Row	MOSTRESC	MOSTRESN	MOSTRESU	MONAM	MOMETHOD	MOEVAL	MOACPTFL	VISITNUM	VISIT	MODTC
1 (cont)	3	3	mm		QUANTITATIVE PERIPHERAL ANGIOGRAPHY	INVESTIGATOR		1	SCREEN	2007-02-01
2 (cont)	2	2	mm		QUANTITATIVE PERIPHERAL ANGIOGRAPHY	INVESTIGATOR		1	SCREEN	2007-02-01
3 (cont)	30	30	%		QUANTITATIVE PERIPHERAL ANGIOGRAPHY	INVESTIGATOR		1	SCREEN	2007-02-01
4 (cont)	0.75	0.75	mm		QUANTITATIVE PERIPHERAL ANGIOGRAPHY	INVESTIGATOR		1	SCREEN	2007-02-01
5 (cont)	N				QUANTITATIVE PERIPHERAL ANGIOGRAPHY	INVESTIGATOR		1	SCREEN	2007-02-01
6 (cont)	N				QUANTITATIVE PERIPHERAL ANGIOGRAPHY	INVESTIGATOR		1	SCREEN	2007-02-01
…	…	…	…	…	…	…	…	…	…	…
13 (cont)	3	3	mm	ACME VENDOR	QUANTITATIVE PERIPHERAL ANGIOGRAPHY	RADIOLOGIST	Y	1	SCREEN	2007-04-10
14 (cont)	2	2	mm	ACME VENDOR	QUANTITATIVE PERIPHERAL ANGIOGRAPHY	RADIOLOGIST	Y	1	SCREEN	2007-04-10
15 (cont)	30	30	%	ACME VENDOR	QUANTITATIVE PERIPHERAL ANGIOGRAPHY	RADIOLOGIST	Y	1	SCREEN	2007-04-10
16 (cont)	0.75	0.75	mm	ACME VENDOR	QUANTITATIVE PERIPHERAL ANGIOGRAPHY	RADIOLOGIST	Y	1	SCREEN	2007-04-10
17 (cont)	N			ACME VENDOR	QUANTITATIVE PERIPHERAL ANGIOGRAPHY	RADIOLOGIST	Y	1	SCREEN	2007-04-10
18 (cont)	N			ACME VENDOR	QUANTITATIVE PERIPHERAL ANGIOGRAPHY	RADIOLOGIST	Y	1	SCREEN	2007-04-10
…	…	…	…	…	…	…	…	…	…	…
24 (cont)	N			ACME VENDOR	QUANTITATIVE PERIPHERAL ANGIOGRAPHY	RADIOLOGIST	Y	1	SCREEN	2007-04-10

Endpoint of PVI Data Example #2

The CV Endpoint CDEs included additional data collected for CV that are not contained in the MO domain and are populated in the SUPPMO domain as indicated below. The additional data is the angiogram view, which can either be a single view or two views, in this case the angiograms were both single view.

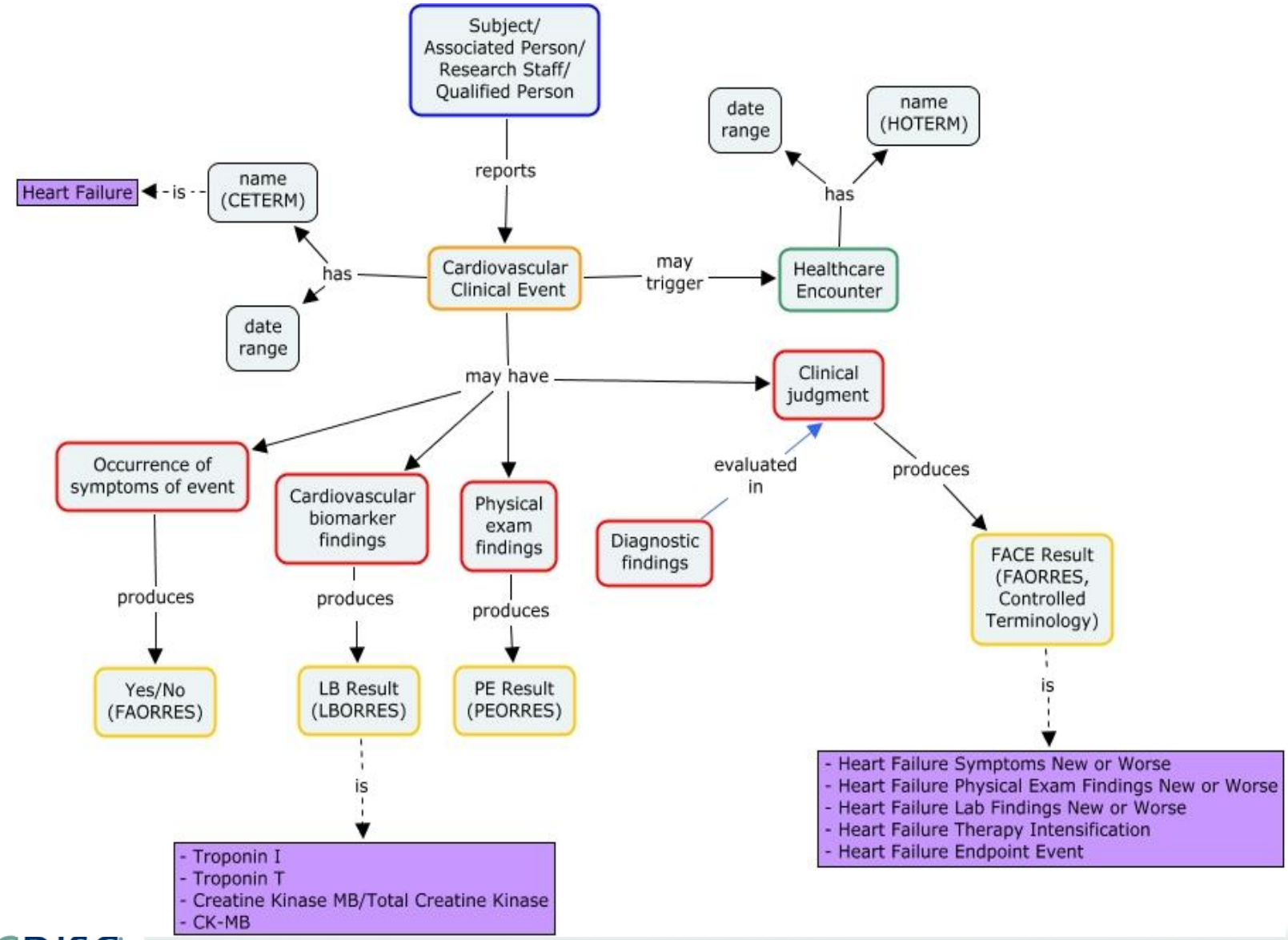
Rows 1-2: Show USUBJID=40913 angiogram view records related to the measurements for mean vessel diameter and minimum lumen diameter. QORIG and QEVAL are not populated, since this is an objective result.

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG	QEVAL
1	STUDY01	MO	40913	MOTESTCD	MEANVDIA	AGIO_VW	Angiogram View	SINGLE VIEW		
2	STUDY01	MO	40913	MOTESTCD	MINLDIAM	AGIO_VW	Angiogram View	SINGLE VIEW		

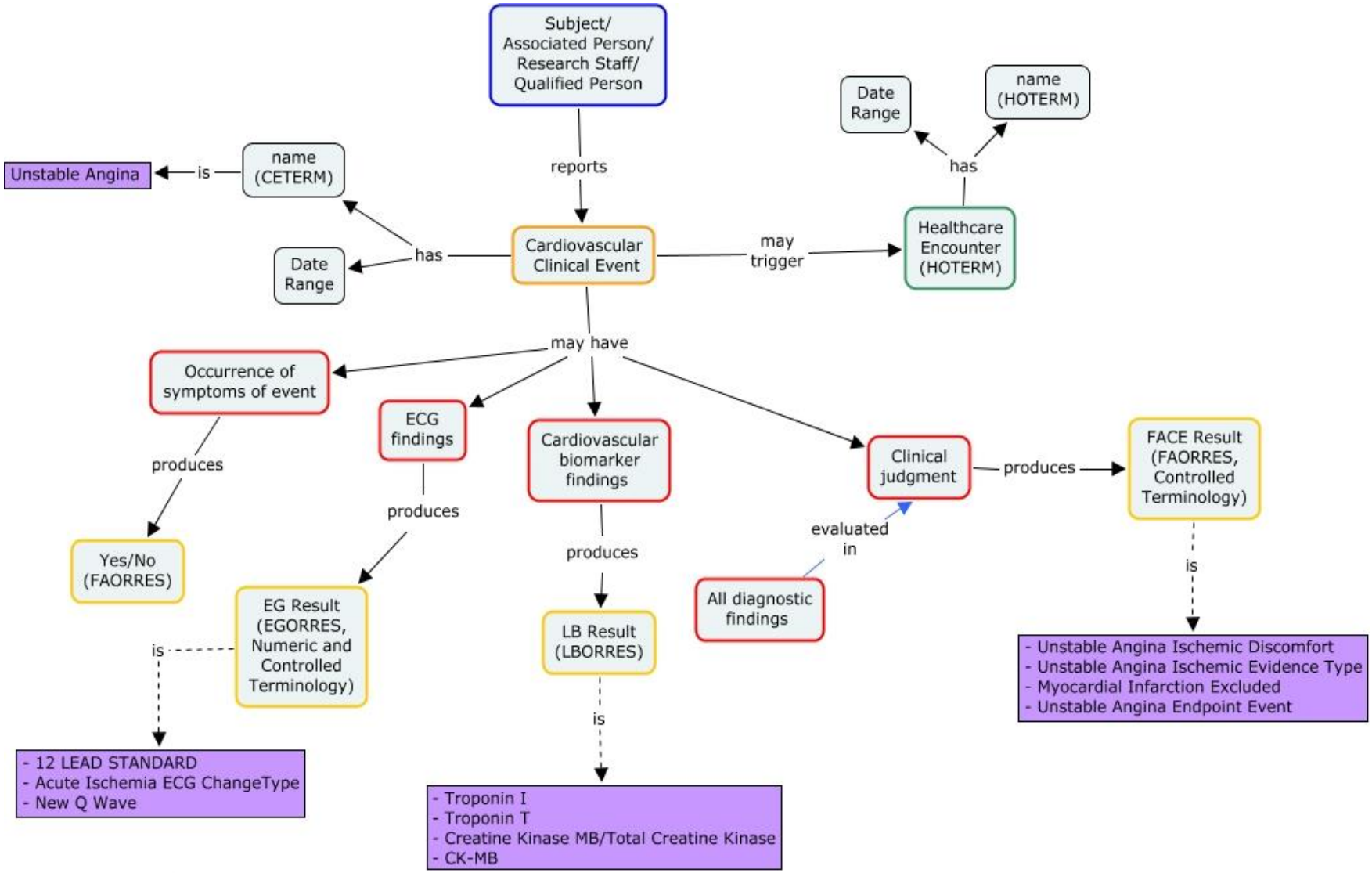
Rows 1-3: Show the relationship between the lesion identification, lesion results and the morphology domains via the TULNKID, TRLNKID and MOLNKID variables.

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
1	STUDY01	TU		TULNKID		ONE	TUTRMO
2	STUDY01	TR		TRLNKID		MANY	TUTRMO
3	STUDY01	MO		MOLNKID		MANY	TUTRMO

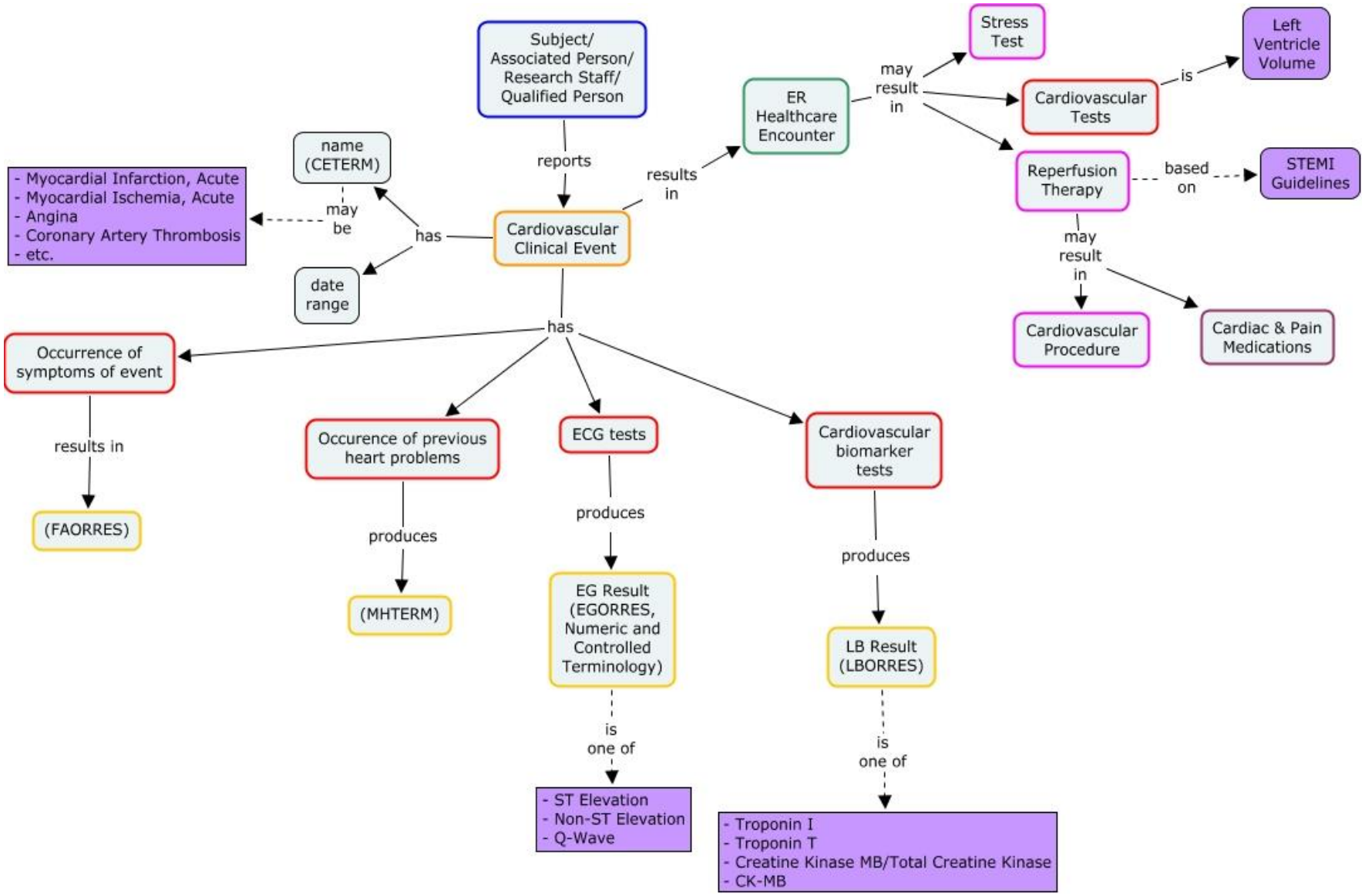
Concept Map for Heart Failure Event



Concept Map for Unstable Angina Hospitalization



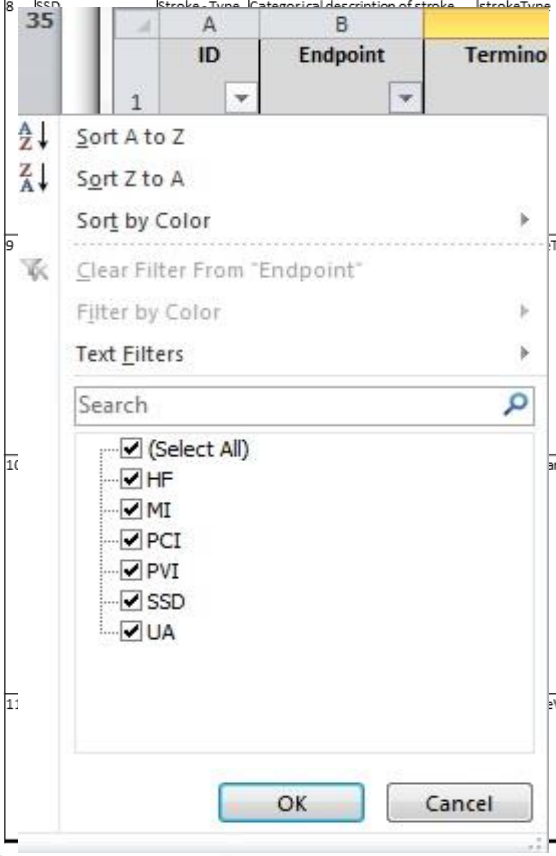
Concept Map for Acute Coronary Syndrome



ACC CV Endpoints CDEs

CDE Names, Definitions, and Permissible Values

ID	Endpoint	Terminology Concept	Concept Definition	Short Data Element Name	Data Element Label	Data Element Description	UML Representation	Datatype	Implementation Notes	Permissible values	Permissible values and definitions
7	SSD	Stroke	An acute episode of focal or global neurological dysfunction caused by brain, spinal cord, or retinal vascular injury as a result of hemorrhage or infarction.	strokeInd	Stroke Indicator	Indicates the occurrence of a stroke.	Indicates the occurrence of a stroke. **Stroke:** An acute episode of focal or global neurological dysfunction caused by brain, spinal cord, or retinal vascular injury as a result of hemorrhage or infarction.	char		Yes	**Yes:** The affirmative response to a question. (NCI C49488)
8	SSD	Stroke - Type	Categorical description of stroke	strokeType	Stroke Type	Categorization of the type of stroke.	Categorization of the type of stroke. **Stroke - Type:** Categorical description of stroke type, classified into one of three mutually exclusive categories (ischemic, hemorrhagic, undetermined).	char	Unique	Ischemic Hemorrhagic Undetermined	**Ischemic:** An acute episode of focal cerebral, spinal, or retinal dysfunction caused by infarction of central nervous system tissue. **Note:** Hemorrhage may be a consequence of ischemic stroke. In this situation, the stroke is an ischemic stroke with hemorrhagic transformation and not a hemorrhagic stroke. **Hemorrhagic:** An acute episode of focal or global cerebral or spinal dysfunction caused by intraparenchymal, intraventricular, or subarachnoid hemorrhage. **Note:** Subdural hematomas are intracranial hemorrhagic events and not strokes. **Undetermined:** An acute episode of focal or global neurological dysfunction caused by presumed brain, spinal cord, or retinal vascular injury as a result of hemorrhage or infarction but with insufficient information to allow categorization as either ischemic or hemorrhagic.
9				-Time	Stroke Date_Time	Date and time of the onset of a stroke.	Date and time of the onset of a stroke.	char		Date - time	
10				ankinS	Modified Rankin Scale Value	Categorization of disability following a stroke per the modified Rankin Scale.	Categorization of disability following a stroke per the modified Rankin Scale. **Modified Rankin Scale:** Validated scale for the assessment of disability following a stroke. Note: Measure disability with the Modified Rankin Scale at each visit and 90 days after the event.	Int	Unique	0 1 2 3 4 5 6	**0** No symptoms at all. **1** No significant disability despite symptoms; able to carry out all usual duties and activities. **2** Slight disability; unable to carry out all previous activities, but able to look after own affairs without assistance. **3** Moderate disability; requiring some help, but able to walk without assistance. **4** Moderately severe disability; unable to walk without assistance and unable to attend to own bodily needs without assistance. **5** Severe disability; bedridden, incontinent and requiring constant nursing care and attention. **6** Dead.
11				eValu	Rankin Scale Value Date_Time	Date and time of the assessment to determine Rankin scale value.	Date and time of the assessment to determine Rankin scale value. **Modified Rankin Scale - Date Time:** Date and time of neurological assessment to determine Rankin scale grade.	char		Date - time	



Appendix D: CV Terminology References

The ACC CV ENDPOINTS definitions are stored in the NCI/EVS, separate from the CDISC controlled terminology codelists. The individual CV ENDPOINT definitions can be referenced separately for cardiovascular endpoint details that are not included in the more general CDISC controlled terminology codelists.

CDISC Controlled Terminology Cardiovascular Findings About TESTCD/TEST codelist:

ACC CV ENDPOINTS CDE Definition:

Data Element Label	Data Element Description	Permissible values
Stroke Type	Categorization of the type of stroke.	Ischemic Hemorrhagic Undetermined
Acute Myocardial Infarction Type	Categorization of the type of acute myocardial infarction.	**Type 1: spontaneous** **Type 2: ischemic imbalance** **Type 3: death, no biomarkers** **Type 4a: PCI related** **Type 4b: stent thrombosis** **Type 4c: stent restenosis** Type 5: CABG related

CDISC Findings About (FA) dataset

For the SDTM-based FATEST= Event Type there are different events (objects) that are being observed (ex. FAOBJ=STROKE or MYOCARDIAL INFARCTION). The FATEST and FAORRES values can be referenced to their detailed definitions in the ACC CV ENDPOINTS CDEs. The CDISC Submission Value is populated in the FAORRES and FASTRESC variables. In reviewing these FA variables in combination, they directly relate to the ACC CV ENDPOINTS CDE definitions for Stroke Type and Myocardial Infarction Type.

FATESTCD	FATEST	FAOBJ	FAORRES	FASTRESC
EVNTTYPE	Event Type	STROKE	ISCHEMIC STROKE	ISCHEMIC STROKE
EVNTTYPE	Event Type	Myocardial Infarction, Acute	TYPE 2 MYOCARDIAL INFARCTION	TYPE 2 MYOCARDIAL INFARCTION

Appendix D: CV Terminology References

CDISC Controlled Terminology Cardiovascular Clinical Events:

For ACC CV ENDPOINT CDE Clinical Events indicators, the CDISC CETERM value is not controlled by CDISC controlled terminology, but can be referenced in NCI/EVS.

ACC CV ENDPOINTS CDE Definition:

Data Element Label	Data Element Description	Permissible values
Stroke Indicator	Indicates the occurrence of a stroke.	Yes: The affirmative response to a question. (NCI C49488)
Myocardial Infarction, Acute Indicator	Indicates the occurrence of acute myocardial infarction.	Yes: The affirmative response to a question. (NCI C49488)

CDISC Clinical Events dataset

The CETERM value is listed in the ACC CV ENDPOINTS CDEs, along with their definitions. This provides consistent terminology for CETERM.

CETERM
STROKE
MYOCARDIAL INFARCTION, ACUTE

Appendix E: Cardiovascular Specific Findings Domain CDISC Codelist Relationship

DOMAIN	TESTCD CODELIST	(TEST)		RESULT CODELIST
CV – Cardiovascular Physiology*	**Cardiovascular Test Code**			
	TIMIFLOW	TIMI Flow		TIMI Coronary Thrombus Grade Responses
	CADGD	ACC/AHA Coronary Artery Dissection Grade		Coronary Artery Dissection Grade Responses
	CANOREFL	Coronary artery No Reflow		No Yes Response
DOMAIN	**TESTCD CODELIST**	**(TEST)**	**TUMETHOD**	**RESULT CODELIST**
TU – Tumor and Lesion Identification	**Tumor and Lesion Identification Test Code**			
	LESIONID	Lesion Identification	• CORONARY ANGIOGRAPHY • PERIPHERAL ANGIOGRAPHY	Lesion Identification Responses
	VESSELID	Vessel Identification	• CORONARY ANGIOGRAPHY • PERIPHERAL ANGIOGRAPHY	Lesion Identification Responses
	GRFLESID	Graft Lesion Identification	• CORONARY ANGIOGRAPHY • PERIPHERAL ANGIOGRAPHY	Lesion Identification Responses
	LIMB	Limb	PERIPHERAL ANGIOGRAPHY	Lesion Identification Responses
…	…	…	…	…

Cardiovascular – Public Review

- 30-day public review upcoming
- Download the document using Adobe Reader (http://get.adobe.com/reader/)
- Submit comments using the CDISC public commenting tool located on the CDISC website located here: http://cdiscportal.digitalinfuzion.com/CT/Review%20Documents/Forms/AllItems.aspx
- For questions please contact Amy Palmer (apalmer@cdisc.org) or Steve Kopko (skopko@cdisc.org)

Future Cardiovascular Training

- Future cardiovascular implementation training will include:
  - Implementation examples
  - Exercises
  - Tests to check knowledge level
  - And additional detail
- Training will be delivered online soon after publication of the standard
  - so you can train at your convenience

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Cardiovascular Public Review Webinar