The MRCT Center Clinical Research Glossary: New Words, New Opportunities

LOCATION:
Virtual

DATE:
April 2, 2024

TIME:
12pm – 1pm, EST

SPEAKERS:

DEB COLLYAR
Founder and President
Patient Advocates In Research

CHRIS DECKER
President and CEO
CDISC

ERIN MUHLBRADT
Biomedical/Clinical Information Specialist
NCI - Enterprise Vocabulary Services

MODERATED BY:

SYLVIA BAEDORF KASSIS
Program Director
MRCT Center

with KAYLEIGH TO
Project Manager

MULTI-REGIONAL CLINICAL TRIALS
THE MRCT CENTER OF BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

cdisc

Welcome!

Thank you for joining this webinar today!

Some tips and reminders for today's session

- Please use the Q&A function
  – we will do our best to answer
- Closed Captioning is enabled
- Relevant links will be dropped into the chat
- Slides and the recording will be available on our website

Warm welcome to our panelists:

Deborah Collyar

Founder and President

Patient Advocates in Research

Chris Decker

President and CEO

CDISC

Erin Muhlbradt

Biomedical/Clinical Information Specialist

NCI – EVS

Disclaimer

- The opinions contained are those of the speakers and are not intended to represent the position of Brigham and Women's Hospital, Harvard University, or any other entity.
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- We are committed to autonomy in our research and to transparency in our relationships. The MRCT Center—and its directors—retain responsibility and final control of the content of any products, results, and deliverables.

Session Overview and Objectives

- Introduction
- Glossary Highlights
- Prepared Remarks
- Panelist Discussion
- Next Steps
- Audience Q&A

By the end of the webinar, participants should be able to:

- Understand the need for this glossary from the patient and industry perspectives.
- Explain how the glossary has been improved since the original pilot.
- Identify opportunities to integrate the glossary content.

The MRCT Center

The MRCT Center is a research and policy center focused on addressing the conduct, oversight, ethics, and regulatory environment of clinical trials.

Our Vision

Improve the integrity, safety, and rigor of global clinical trials.

Our Mission

Engage diverse stakeholders to define emerging issues in global clinical trials and to create and implement ethical, actionable, and practical solutions.

www.mrctcenter.org

The MRCT Center and Health Literacy

2013-2017

2019

Glossary Pilot Project

2018-2019

2020

Clinical Research GLOSSARY

The Clinical Research Glossary Timeline

2021

2022

2023

2024

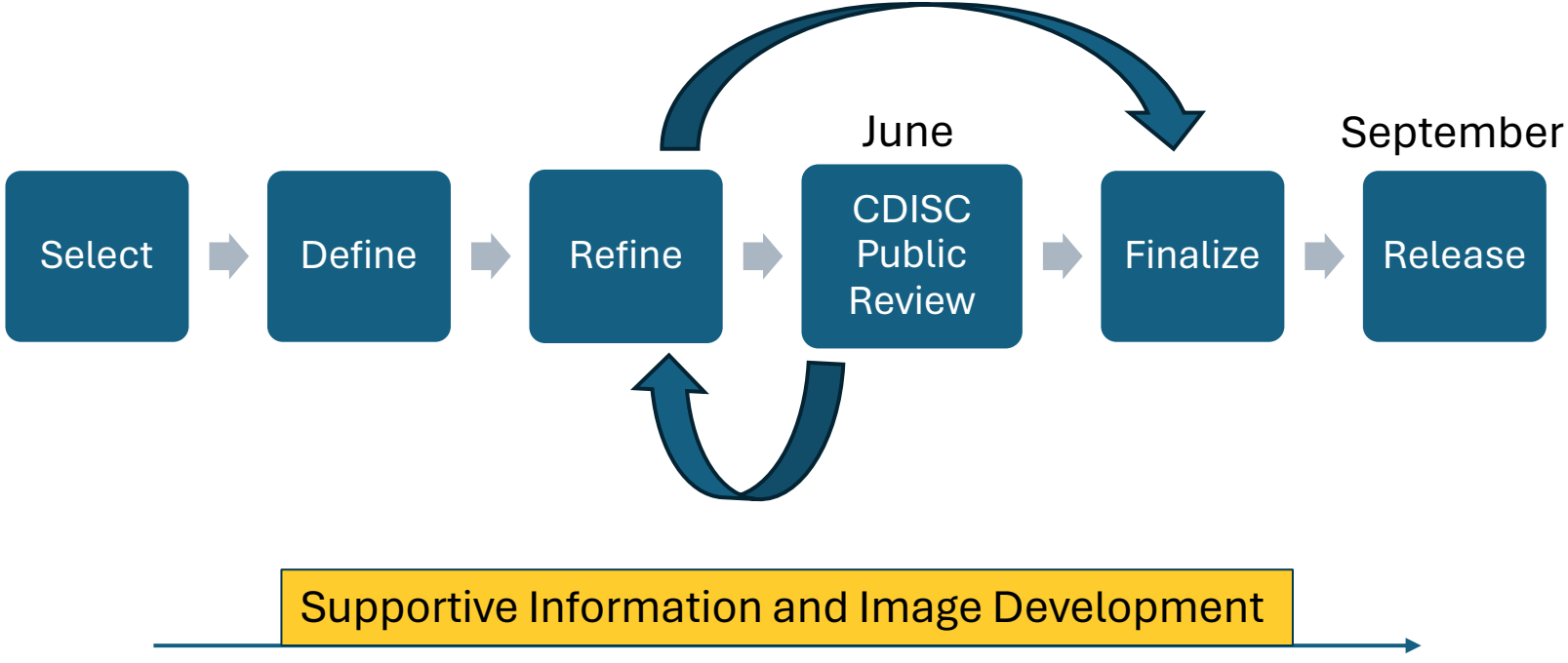
Clinical Research Glossary Expansion Efforts

Baedorf Kassis S, White S, & Bierer B. (2022). Developing a consensus-driven, plain-language clinical research glossary for study participants and the clinical research community. *Journal of Clinical and Translational Science,* 1-20. doi:10.1017/cts.2022.12

Baedorf Kassis, S., Facile, R., To, K., White, S., Bierer, B.E. (2023). **Use Plain Language to Increase Understanding: The MRCT Center Clinical Research Glossary.** *DIA Global Forum.*

MRCT Clinical Research GLOSSARY

The Clinical Research Glossary



Clinical Research GLOSSARY

Our Advocates Reflect

R. Bernard Coley
Care Partner Advocate

What makes this process work	Robust consideration of usage context Respect for patient perspectives Diversity of experienced perspectives
What this process, and collaboration with CDISC means for patients	Validated definitions Trustworthy and vetted content Bi-directional knowledge exchange

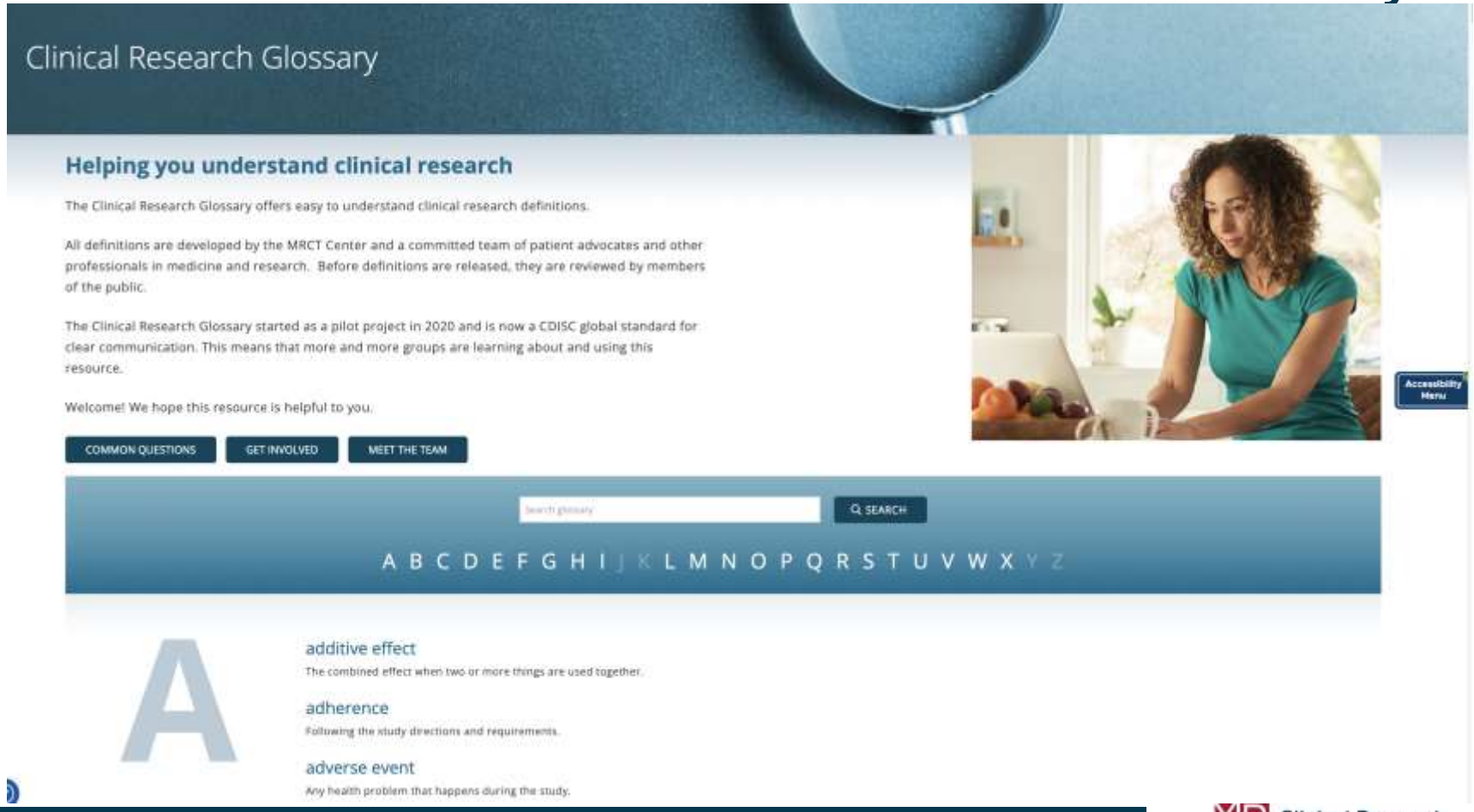
https://www.youtube.com/watch?v=ViQN0Emtkjk

New Words

Highlights of the Updated Glossary

- Living, governed resource
- Increased to 167 words
- Newly developed images
- A special section focused on personal considerations related to terms
- All content is useable and shareable under the MRCT Center Creative Commons License
- Cross-referenced and available through CDISC/NCI Thesaurus

The MRCT Center Clinical Research Glossary

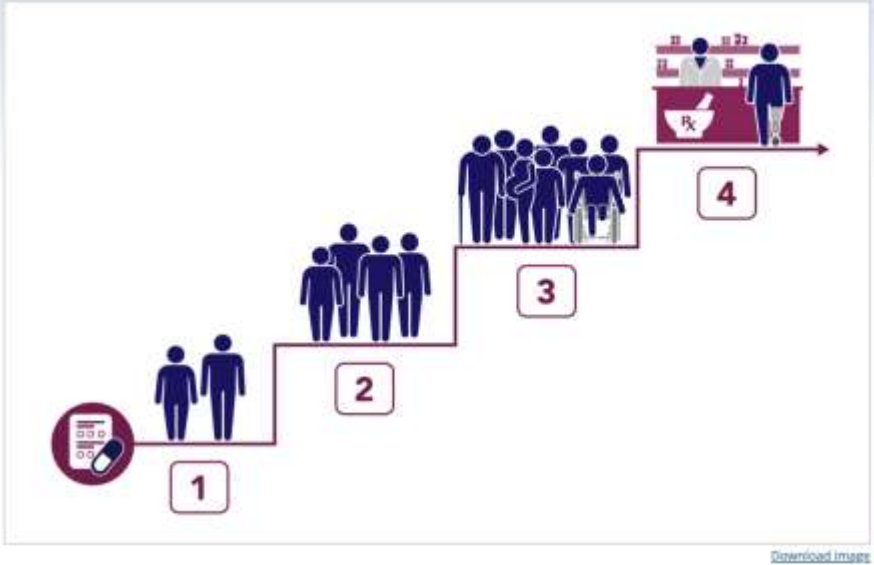


www.mrctcenter.org/clinical-research-glossary

phase

cdisc

A step in the overall clinical research process to test a new drug, device, or treatment.



Download Image

Accessibility Menu

Example of *phase* in a sentence

Research is done in *phases* to make sure a study treatment is safe and then whether it works before it is approved.

More Info

A phase is a step in the research process. Phases of research studies build on each other and each phase has a separate goal.

Phase 1 studies are usually the first to enroll humans and test for safety.

Phase 2 studies test if the drug, device or treatment works.

Phase 3 studies compare the study treatment to the usual, standard treatment.

Phase 4 studies continue to collect data after a study treatment is approved. These are sometimes called post-marketing studies.

Other info to think about when joining a study

You may see the term "phase" when you are reading about clinical trials.

Before you enroll in a clinical trial you may want to ask about what phase the study is in. You may also want to know more about the information the study team already has about the risks and benefits of the study treatment that is being tested.

Related Words

clinical research

clinical trial

preclinical study

Other Resources

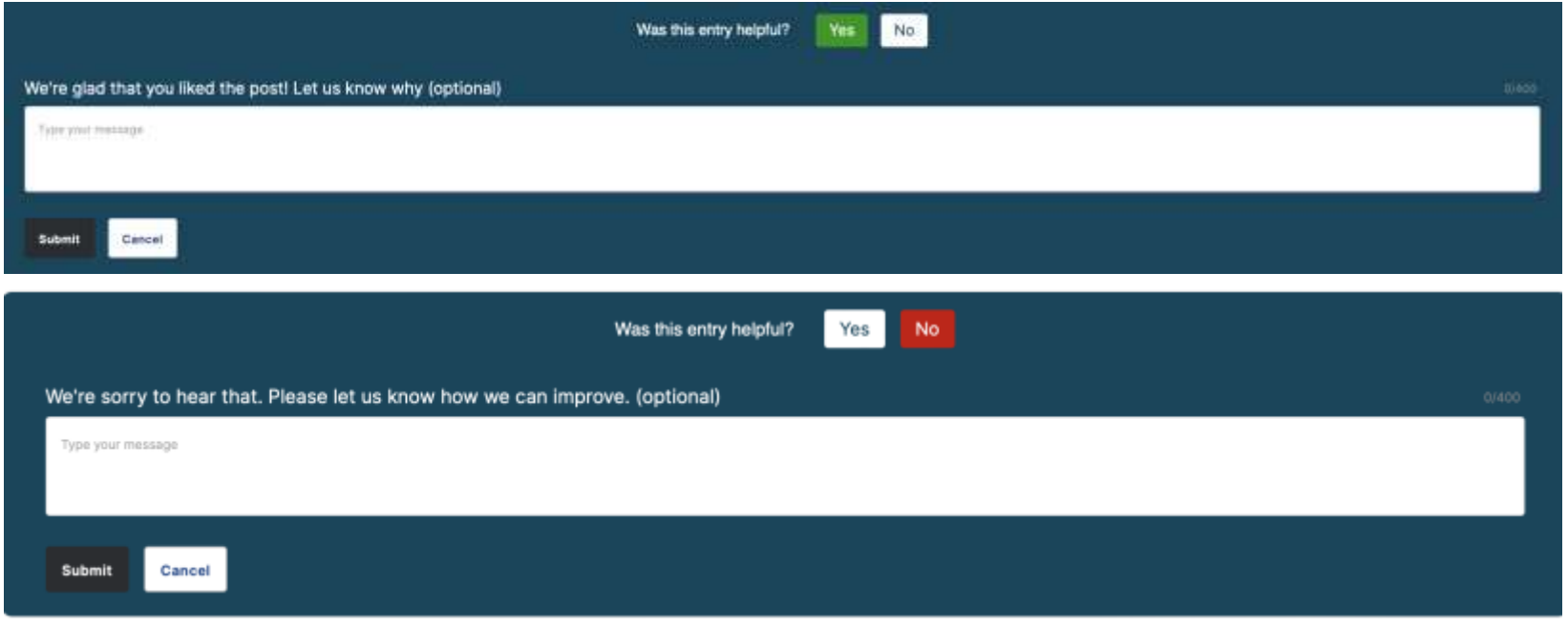
CDISC Controlled Terminology
NCI Thesaurus

FDA - The Drug Development Process, Step 3: Clinical Research

If you know of other resources we should link to to help explain this word, please contact us.

User engagement is a priority

- Immediate Opportunities for Feedback



Open invitation for feedback:

- suggest a **new** clinical research term that should be defined and added
- submit a comment on an **existing** definition or other content on the website
- submit a comment on an **existing** image on the website
- learn more about ways to help
    - share with your network
    - review definitions during the Public Review period (occurs every June)
    - translate content into other languages (as needed)
    - be notified when the next version of the Clinical Research Glossary is released
    - share a story of using and implementing the Clinical Research Glossary as a case study

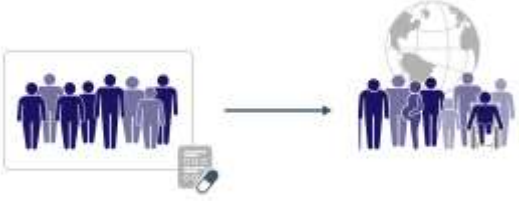
Additional Features

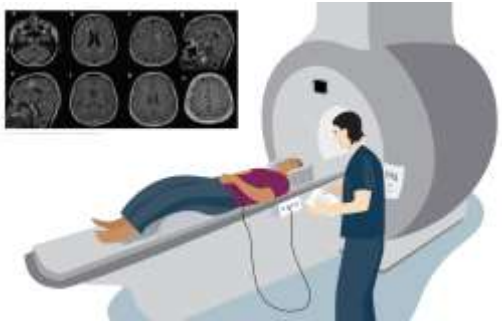
- Detailed FAQs about:
  - The people involved
  - The process we followed
  - How to use, share and reference this resource

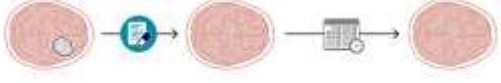
- Downloads
  - Excel
  - PDF
  - Individual images

More about the images

- Hallmarks include:
  - Iterative and engaged process
  - Internal team, graphic designers, workgroup reviewers
  - Mix of flowcharts, icons, and illustrations
  - Inclusion of various aspects related to representation
  - Special, individually developed alt-text for screen readers





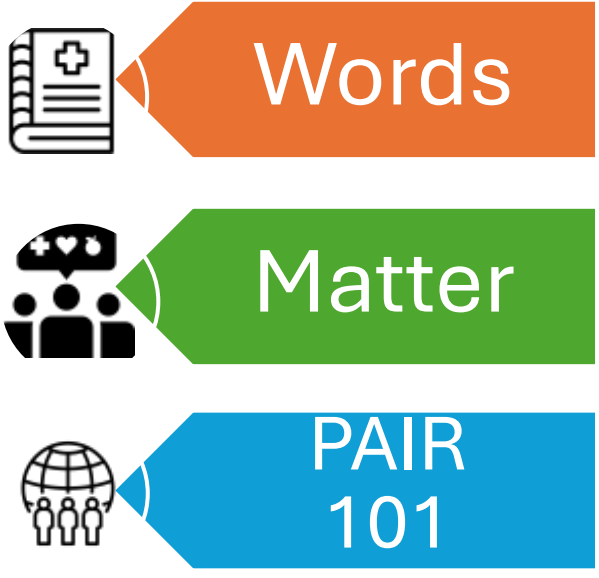


New Opportunities

Name: Deborah Collyar
Title: Founder and President
Organization: Patient Advocates In Research (PAIR)

The U.S. ~~healthcare~~ disease crisis system

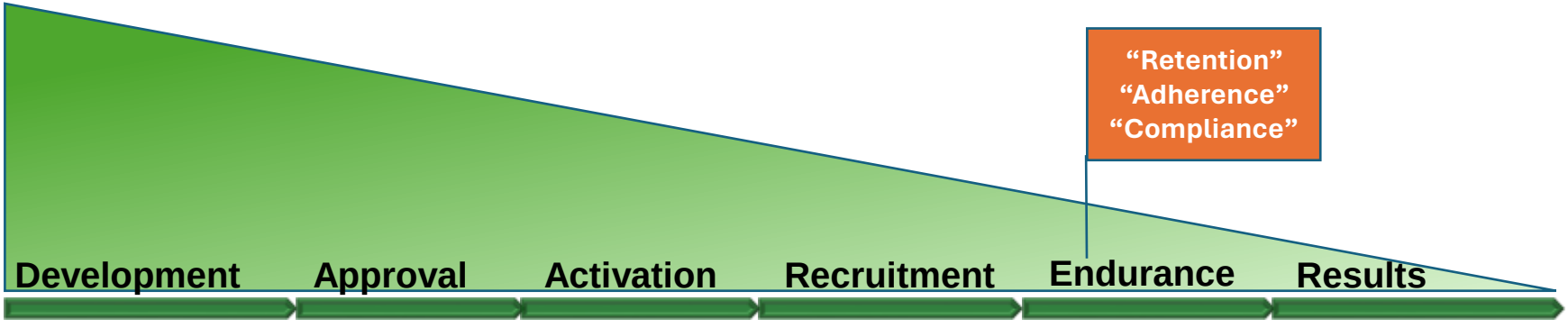
- **Patients are PEOPLE**
- Who just landed on a new planet with:
  - No roadmap
  - No dictionary
  - No survival training



Term	Scientific/Medical	Public Definition
Negative test	That's too bad	This is good, right?
Positive test	That's too bad	This is good, right?
Cure	5-year survival rate	Never again
Genomic profiling	Precision medicine	Targeting suspects?
Support services	Peripheral topics	Fit medical into life
Lay	Non-scientists	Down?
Environment	Patient controlled	External forces
Community	Non-academic center	Where I live
Medical advance	Incremental success	A cure
Clinical trial	Human research	Sterile, judgment
Biospecimens	Tissue for analysis	Mutant creature?

Clinical Research GLOSSARY

Patient involvement in clinical trials



Trial Development	
Concept + protocol development + patient burden	***Relevance***
Adaptive design + endpoints + eligibility + procedures	***Sanity check***
Recruitment: patient issues + site challenges & solutions + referrals	***Communication***
Diversity plans + systemic racism + disabilities	***Representation***
Informed consent: plain language + correlative science	***Respect & information***

Name: Chris Decker
Title: President and CEO
Organization: CDISC

phase

cdisc

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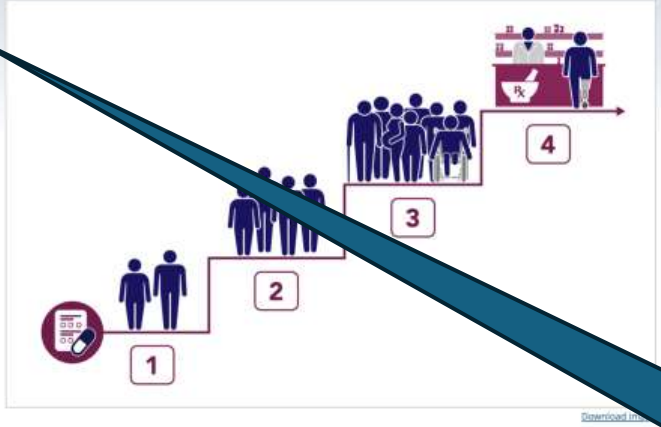

Download image

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cdisc

MRCT Clinical Research GLOSSARY

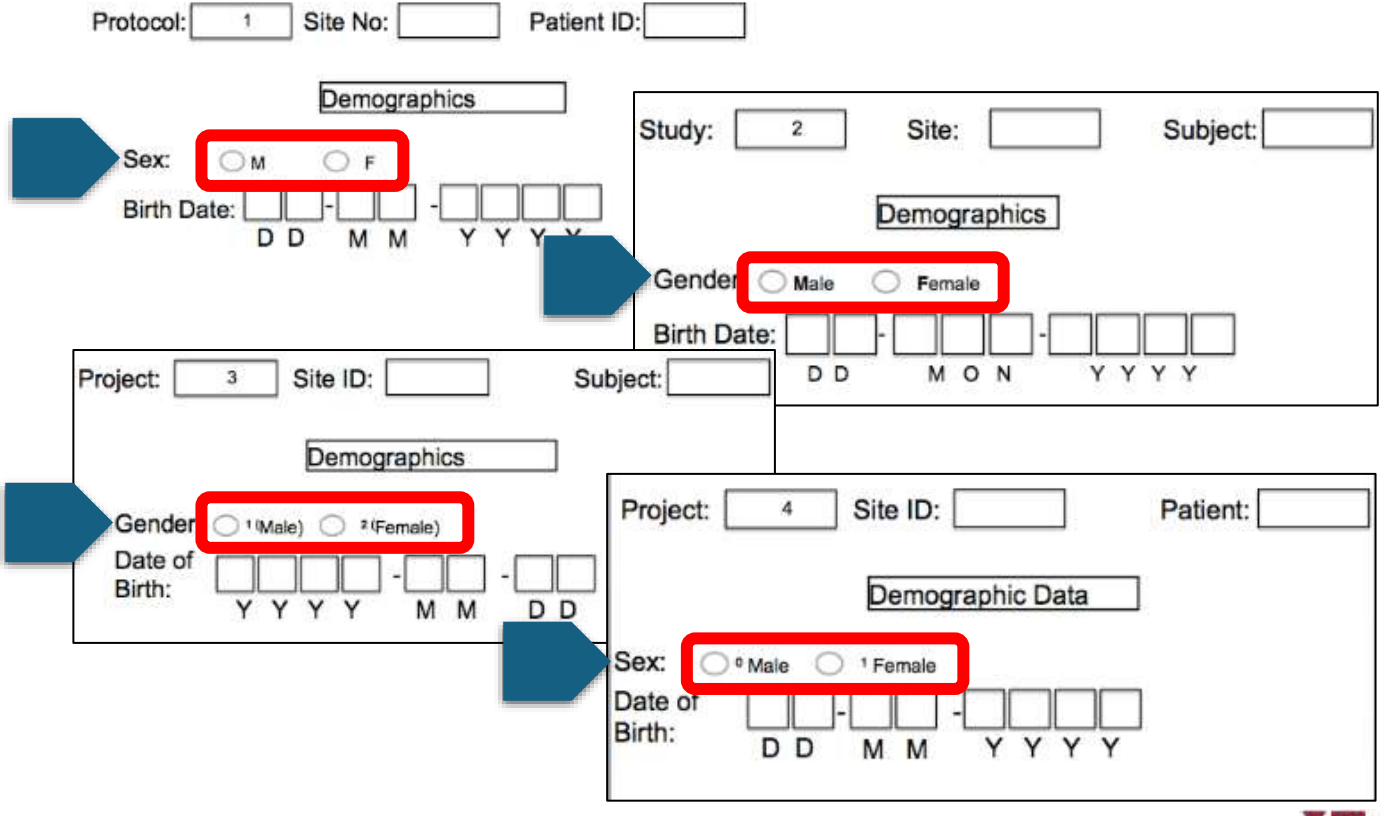
What is CDISC and what do we do?

- Founded in 1997 by Volunteers and established as a Global Standards Development Organization (SDO) non-profit organization in 2000
- Community consensus standards development for clinical and translational research with a network of >500 members and 1000+ industry experts
- Freely available & widely adopted clinical research data standards
- Several CDISC standards required by regulatory agencies

CDISC….

- Convenes a global community of experts to develop and advance data standards of the highest quality, CDISC helps to create clarity in clinical research.
- Together, we enable the accessibility, interoperability, and reusability of data for more meaningful and efficient research that has greater impact on global health

The Problem - Unnecessary Variability @ Collection



The Problem - Unnecessary Variability @ Tabulation

Name for Subject ID is not the same

Name for dataset varies

Gender or Sex - do these mean the same thing!?

Study #1 – demog.xpt

SUBJID	SEX
0001	M
0002	F
0003	F
0004	M
0005	F

Study #2 – dmg.xpt

ID	GENDER
A1	Male
A2	Male
A3	Female
A4	Female
A5	Male

Study #3 – dmgph.xpt

PTID	GENDER
0001	1
0002	1
0003	2
0004	2
0005	1

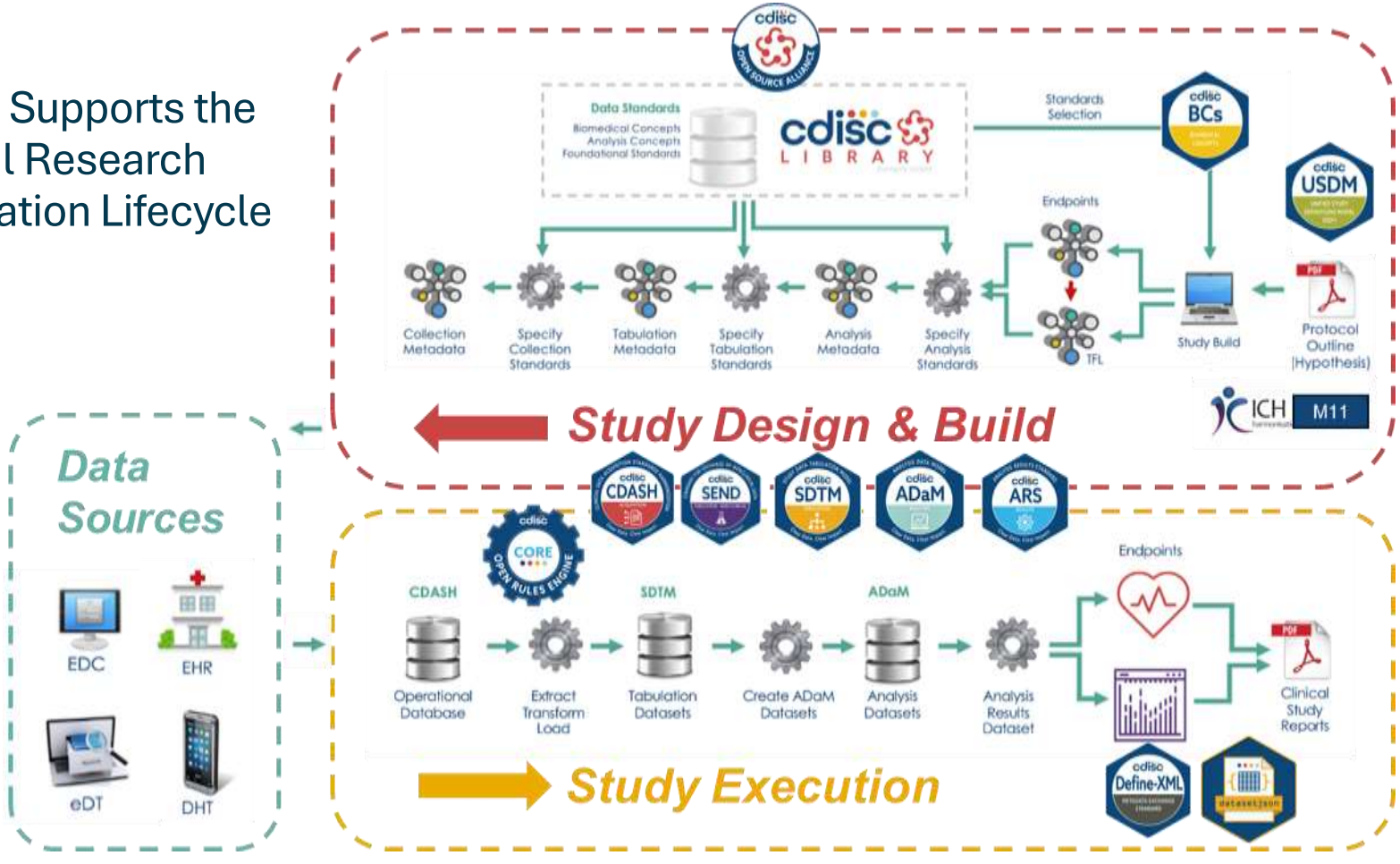
Study #4 – axd222.xpt

USUBID	SEX
00011	0
00012	1
00013	1
00014	0
00015	1

Is it Male or Female, M or F, 1 or 2, or 0 or 1?

What do the these numeric codes mean?

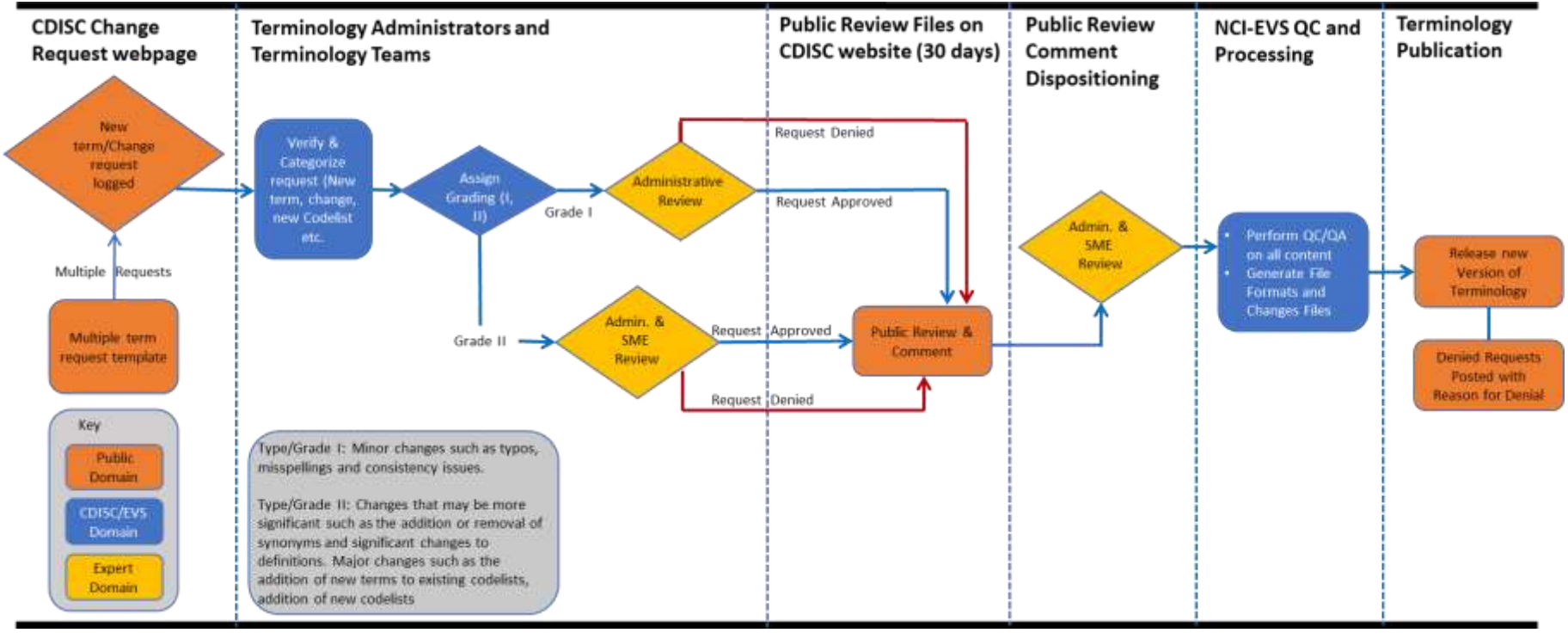
CDISC Supports the Clinical Research Information Lifecycle



Alliances and Partnerships Landscape

Name: Dr. Erin E Muhlbradt, PhD
Title: Biomedical/Clinical Information Specialist and CDISC Terminology Program Lead
Organization: Guidehouse Inc.

CDISC's terminology development program is governed by a robust terminology development process.



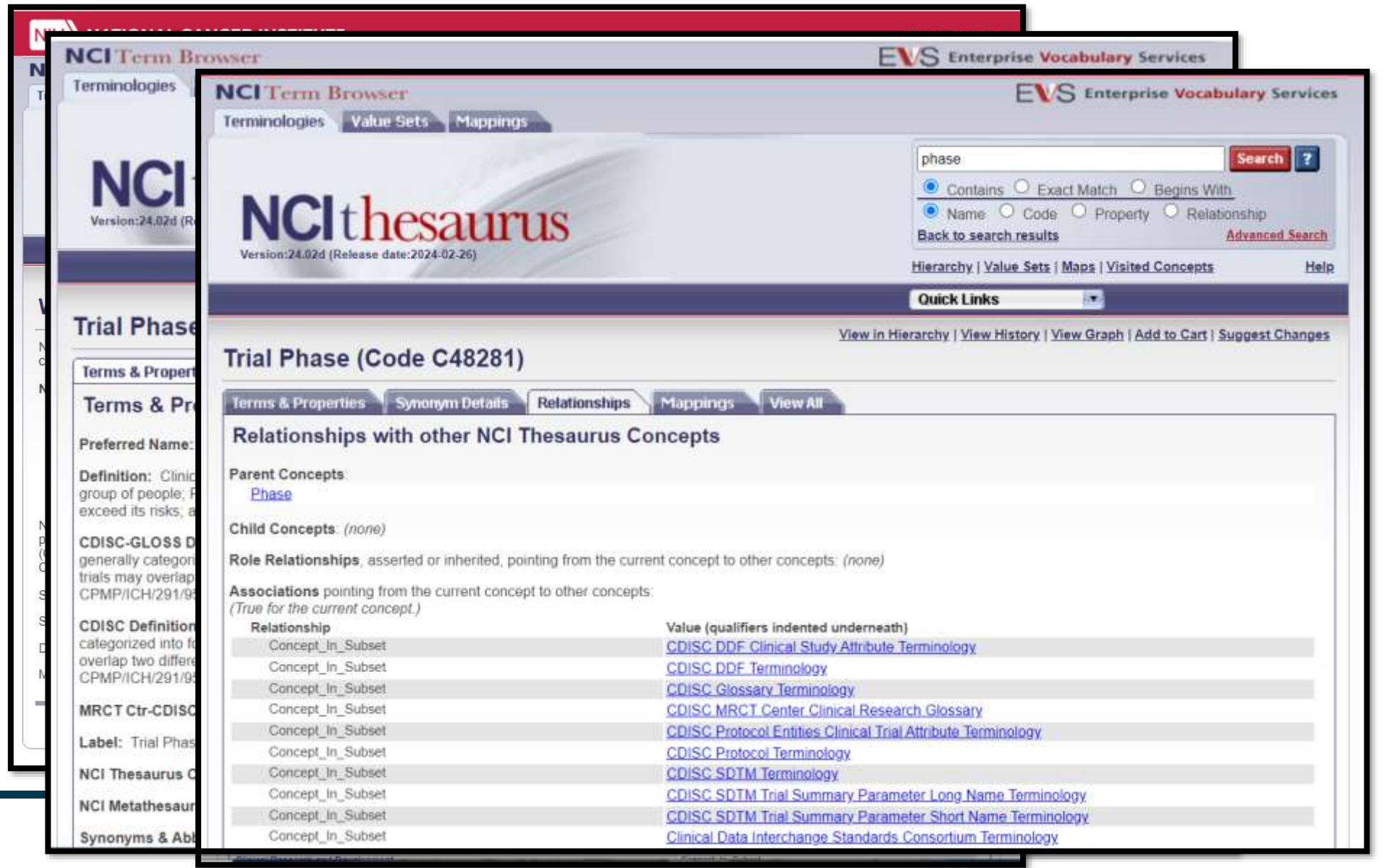
CDISC and MRCT Center Terminology Development Processes

- There are many similarities between the CDISC and MRCT processes:
  - Semantics are built by consensus within teams of subject matter experts with diverse backgrounds and experiences.
  - The terminology teams enforce Best Terminology Practices.
    - Clear, consistent, and precise language
  - Terms for development are identified based on user/community needs.
- The CDISC process enhances the MRCT Center's terminology development process by the addition of a public review step, prior to publication.
  - Public Review step fulfills the requirements of an SDO (standards development organization).
  - Ensures accessibility to draft standards, increasing the quality of the final product.

NCI Thesaurus (NCIt)

- The MRCT Clinical Research Glossary preferred terms and definitions will be stored in the NCI Thesaurus.
  - The definition will also contain the URL for the individual MRCT webpage for each glossary term.
- Advantages of putting the MRCT glossary in NCIt:
  - NCI C-codes ensure unambiguous coding for each concept
  - Terminology available in multiple file formats (Excel, Text, PDF, HTML, XML, OWL/RDF)
  - Terminology accessible by APIs
  - Searchable through public browsers
  - Plain language definition resides with a more technical CDISC definition (coded to the same concept)
    - two views of the same concept for a variety of audiences
    - traceability across the data's lifecycle

MRCT Clinical Research GLOSSARY


NCI Term Browser
EVS Enterprise Vocabulary Services
Terminologies
Value Sets
Mappings
NCI thesaurus
Version:24.02d (Release date:2024-02-26)
phase
Search
Contains
Exact Match
Begins With
Name
Code
Property
Relationship
Back to search results
Advanced Search
Hierarchy | Value Sets | Maps | Visited Concepts
Help
Quick Links
View in Hierarchy | View History | View Graph | Add to Cart | Suggest Changes
Trial Phase (Code C48281)
Terms & Properties
Synonym Details
Relationships
Mappings
View All
Relationships with other NCI Thesaurus Concepts
Parent Concepts
Phase
Child Concepts: (none)
Role Relationships, asserted or inherited, pointing from the current concept to other concepts: (none)
Associations pointing from the current concept to other concepts:
(True for the current concept.)
Relationship
Value (qualifiers indented underneath)
Concept_In_Subset
CDISC DDF Clinical Study Attribute Terminology
Concept_In_Subset
CDISC DDF Terminology
Concept_In_Subset
CDISC Glossary Terminology
Concept_In_Subset
CDISC MRCT Center Clinical Research Glossary
Concept_In_Subset
CDISC Protocol Entities Clinical Trial Attribute Terminology
Concept_In_Subset
CDISC Protocol Terminology
Concept_In_Subset
CDISC SDTM Terminology
Concept_In_Subset
CDISC SDTM Trial Summary Parameter Long Name Terminology
Concept_In_Subset
CDISC SDTM Trial Summary Parameter Short Name Terminology
Concept_In_Subset
Clinical Data Interchange Standards Consortium Terminology

Panelist Discussion

Deborah Collyar

Chris Decker

Erin Muhlbradt

Next Steps and Continuing Efforts

- Grow Public Review Participation
  - Next Public Review in June, and every June thereafter
- Keep creating content and release next version in September
  - And every September thereafter
- Use and share, share, share!
  - Please identify which people and groups in your network could benefit from using the Clinical Research Glossary and share the link with them.
  - Please share your success stories of implementing the Clinical Research Glossary
  - Please share how we can keep growing this resource to best meet your needs

Special Thanks

- All the volunteer contributors over the years
  - Workgroup – Development Team and Review Team
  - Expert Advisory Committee
- Our users!
- Internal team
  - Communications team, graphic designers, and extra helpers
  - MRCT Center leadership

Audience Q&A
and
Thank you!