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
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.

• The MRCT Center is supported by voluntary contributions from foundations, corporations, international organizations, academic institutions and government entities (see www.MRCTCenter.org), as well as by grants.

• 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

Glossary Pilot Project

The Clinical Research Glossary

Select → Define → Refine → June → CDISC Public Review → Finalize → September → Release

Supportive Information and Image Development
Our Advocates Reflect

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
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
Helping you understand clinical research

The Clinical Research Glossary offers easy to understand clinical research definitions.

All definitions are developed by the MRCT Center and a committed team of patient advocates and other professionals in medicine and research. Before definitions are released, they are reviewed by members of the public.

The Clinical Research Glossary started as a pilot project in 2020 and is now a CDISC global standard for clear communication. This means that more and more groups are learning about and using this resource.

Welcome! We hope this resource is helpful to you.

www.mrctcenter.org/clinical-research-glossary
A step in the overall clinical research process to test a new drug, device, or treatment.

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
- preclinical study
- clinical trial

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

Trial Development

<table>
<thead>
<tr>
<th>Concept + protocol development + patient burden</th>
<th>Relevance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adaptive design + endpoints + eligibility + procedures</td>
<td>Sanity check</td>
</tr>
<tr>
<td>Recruitment: patient issues + site challenges &amp; solutions + referrals</td>
<td>Communication</td>
</tr>
<tr>
<td>Diversity plans + systemic racism + disabilities</td>
<td>Representation</td>
</tr>
<tr>
<td>Informed consent: plain language + correlative science</td>
<td>Respect &amp; information</td>
</tr>
</tbody>
</table>
Name: Chris Decker
Title: President and CEO
Organization: CDISC
phase

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

Example of phase in a sentence
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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

Study #1 – demog.xpt

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<thead>
<tr>
<th>SUBJID</th>
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<tbody>
<tr>
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<tr>
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<tr>
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<td>0004</td>
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Name for dataset varies

Study #2 – dmg.xpt

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<tr>
<th>ID</th>
<th>GENDER</th>
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<tbody>
<tr>
<td>A1</td>
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<tr>
<td>A2</td>
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</tr>
<tr>
<td>A3</td>
<td>Female</td>
</tr>
<tr>
<td>A4</td>
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Study #3 – dmgph.xpt

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Study #4 – axd222.xpt

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<td>00014</td>
<td>0</td>
</tr>
<tr>
<td>00015</td>
<td>1</td>
</tr>
</tbody>
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Gender or Sex - do these mean the same thing!?

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

Name for dataset varies

What do 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.
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
Trial Phase (Code C48281)

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.)

<table>
<thead>
<tr>
<th>Relationship</th>
<th>Value (qualifiers indented underneath)</th>
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<tr>
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<td>CDISC SDTM Trial Summary Parameter Short Name Terminology</td>
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<tr>
<td>Concept_In_Subset</td>
<td>Clinical Data Interchange Standards Consortium Terminology</td>
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</table>
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

Meet the team!
https://mrctcenter.org/glossary/the-clinical-research-glossary-team-members-contributors/
Audience Q&A
and
Thank you!