



**MULTI-REGIONAL
CLINICAL TRIALS**

THE MRCT CENTER OF
BRIGHAM AND WOMEN'S HOSPITAL
and HARVARD

Featuring:

Amy Mirabella, HonorHealth
Claudine Moore, SCDM
Holly Parker, MGB Rally
Sophia Zilber, Cure Mito

ACTION AND INFLUENCE:

Implementing the Clinical Research Glossary and Your Critical Role in Public Review

Moderated by: Sylvia Baedorf Kassis, The MRCT Center

REGISTER NOW!

DATE:

June 4, 2024

TIME:

11 – 12 PM ET

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

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.

Warm welcome to our panelists:

Amy Mirabella

Claudine Moore

Holly Parker

Sophia Zilber



HonorHealth



Society for Clinical Data Management



Mass General Brigham Rally



Cure Mito

https://mrctcenter.org/wp-content/uploads/2024/06/2024-06-04_-HL-Public-review-bio-book.pdf

Session Overview and Objectives

- Instructions for Public Review
- Moderated Implementation Discussion
- Audience Q&A

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

- Understand and engage in the Clinical Research Glossary Public Review process
- Describe different ways the Clinical Research Glossary has been implemented
- Identify opportunities to implement the Clinical Research Glossary into their own work

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 Clinical Research Glossary

Clinical Research Glossary

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 community of professionals in medicine and research. Before definitions of the public.

The Clinical Research Glossary started as a pilot project in 2017 to improve clear communication. This means that more and more groups are using this resource.

Welcome! We hope this resource is helpful to you.

[COMMON QUESTIONS](#) [GET INVOLVED](#) [MEET THE TEAM](#)

A B

A

additive effect

The combined effect when two or more factors are added together.

adherence

Following the study directions.

adverse event

Any health problem that occurs during a study.

phase

cdisc

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 to reach 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.

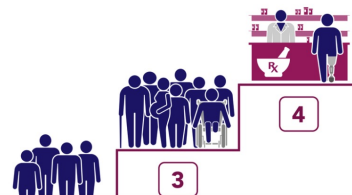
Phase 3 studies compare the study treatment to the usual, standard treatment.

Phase 4 studies continue to collect data after a study treatment is approved. These are called 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 will know more about the information the study team already has about the risks and benefits of the treatment that is being tested.



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

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Quick Links

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Trial Phase (Code C48281)

Terms & Properties

Synonym Details

Relationships

Mappings

View All

Terms & Properties

Preferred Name: Trial Phase

Definition: Clinical trials are broken into three or four phases: Phase I tests a new drug or treatment for safety in a small group; Phase II expands the study to a larger group of people; Phase III expands the study to an even larger group of people to measure whether the treatment actually benefits patients, and whether its benefits exceed its risks; and Phase IV takes place after the drug or treatment has been licensed and marketed.

CDISC-GLOSS Definition: A stage in the clinical research and development of a therapy from initial clinical trials to post-approval studies. NOTE: Clinical trials are generally categorized into four (sometimes five) phases. A therapeutic intervention may be evaluated in two or more phases simultaneously in different trials, and some trials may overlap two different phases. [21 CFR section 312.21; After ICH Topic E8 NOTE FOR GUIDANCE ON GENERAL CONSIDERATIONS FOR CLINICAL TRIALS]

A resource for everyone

www.mrctcenter.org/glossary

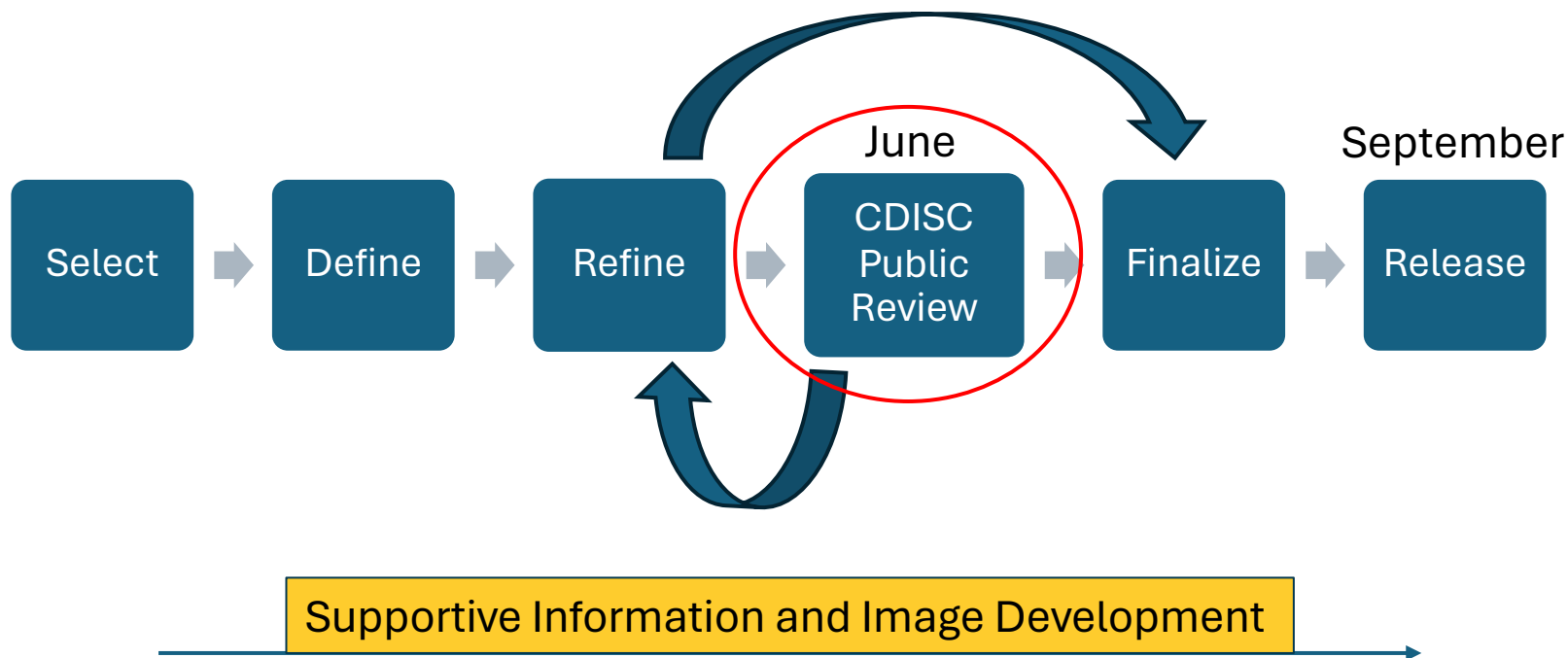
The glossary team welcomes you all year round:

- ☐ 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
- ☐ other ways to help:
 - ☐ share with your network
 - ☐ review definitions during the annual 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
 - ☐ develop a case study of how you are using the Clinical Research Glossary

<https://mrctcenter.org/glossary/contact-us/>

The Clinical Research Glossary – Process

A consensus-building process with a workgroup of patient advocates and other experts



What is CDISC?

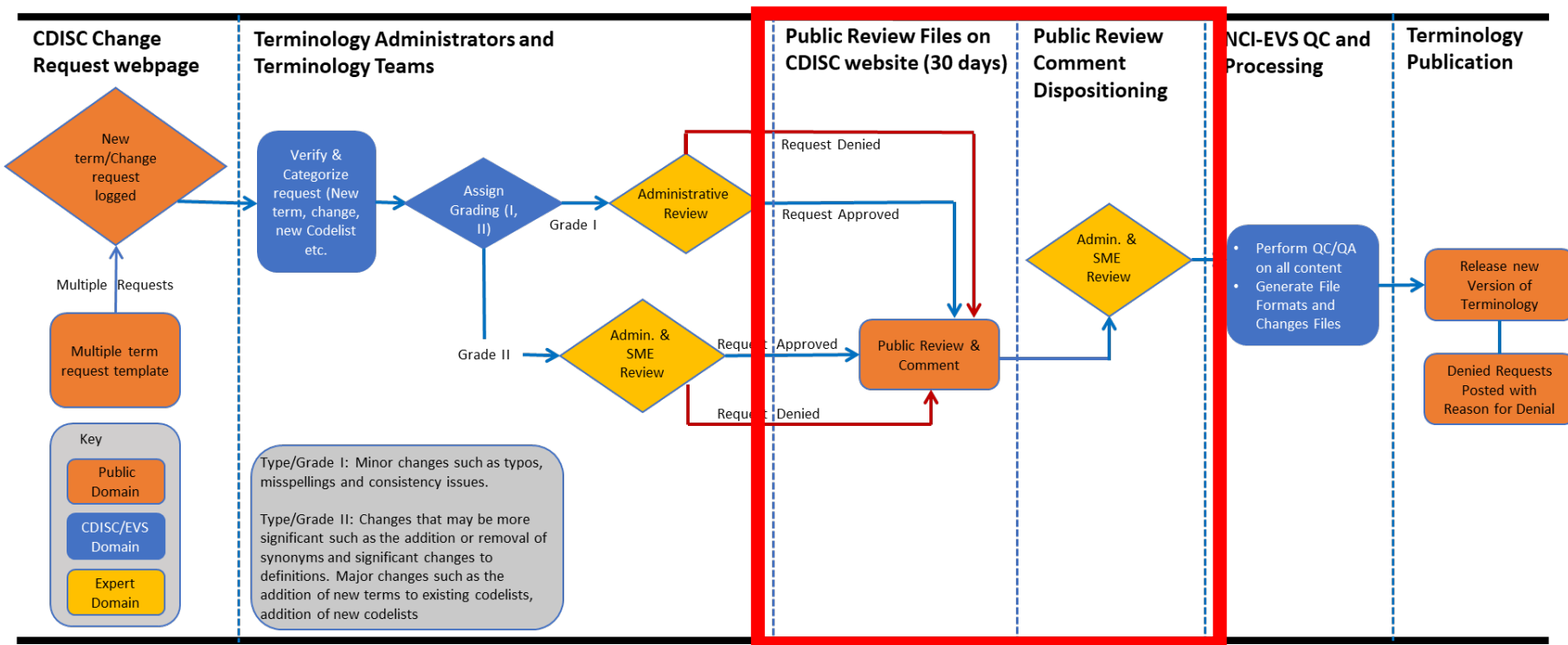
- Founded in 1997 by Volunteers and established as a Global Standards Development Organization (SDO) non-profit organization in 2000
- Community consensus standards development for clinical and translational research with a network of >500 members and 1000+ industry experts
- Freely available & widely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

Enables the accessibility, interoperability, and reusability of data for more meaningful and efficient research that has greater impact on global health.

CDISC's terminology development program = a robust terminology development process



2024 Clinical Research Glossary Public Review – opens June 7th!

- Public Review – available June 7th through July 5th
 - Twelve (12) definitions are ready for you to review.
- You can get involved in Public Review
 - Review new proposed definitions before they are released in September
 - Share the opportunity to review with your network
- You can help us expand our reach
 - Patients and participants
 - Advocacy organizations
 - Community-based programs
 - Students
 - Clinical Research Professionals



Media Kit

Content

Annual Review

1ST EDITION: JUNE 2024

MRCT Center Clinical Research Glossary Social Media Posts Suggestions

There are a few options to support sharing
of the public review period via social media:

1) Write your own posts!

For example, tell your network why you support the Clinical Research Glossary and invite them to be part of the process. You can feel free to use any images from the glossary to enhance your post.

2) Share MRCT Center posts on LinkedIn

You can follow us on LinkedIn to get our posts in your feed and then share with your network, or just search for us, and re-post any of our Clinical Research Glossary posts.

<https://www.linkedin.com/company/multi-regional-clinical-trials-center-of-brigham-and-women's-hospital-and-harvard/posts/?feedView=all>

3) Use our template language below to post on LinkedIn:

Plain language is for everyone! <I am or my organization is> excited to share that the @MRCT Center has new Clinical Research Glossary (CRG) definitions that are ready to be reviewed in this June 2024 CDISC Public Review.

Before publication and release all terms and their definitions are put out to the public for comments. Anyone interested in providing comments is free to do so! This is a great way to have your voice heard and bring up points that may not have been considered when creating the definitions.

Thank you for your interest in
sharing information about the
**MRCT Center Clinical Research Glossary
Annual Public Review Period.**

Please use the information within this media kit
to invite your network to join public review via:

- Social Media Posts
- Email/Newsletter
- PowerPoint Slides

How to give feedback during Public Review

- You will receive an email after June 7th with detailed instructions.
- The process of giving feedback involves filling out a simple survey.
- Reviewers will need to share their name, organization, and email address
 - Validates the entry
 - Allows for individual follow-up about how the comment was addressed

Public Review Form for the MRCT Center Clinical Research Glossary (CDISC Controlled Terminology)

[View survey instructions](#)

Background Information

The MRCT Center Clinical Research Glossary is a resource for the MRCT Center. The goal of this glossary is to provide a common language for all MRCT Center allies.

The MRCT Center partners with CDISC to develop and maintain the MRCT Center Clinical Research Glossary.

For CDISC Controlled Terminology Pa... clinical research definitions.

Some key points about the content

- These definitions went through a review process with patients, caregivers, and industry experts.
- These definitions are not intended to be a comprehensive list of all clinical research terms.
- Each definition will also have a brief supportive information here: [Supportive Information](#)



Public Review Instructions:

Please review each definition and check off whether or not you can accept the proposed definition.

If you would like to request a change, please describe your comment and suggest an updated plain language definition.

Even if you don't have any changes to request, please submit this form so we can count your review in our tally.

Plain Language - Reviewer Tips

Friendly Reminder: These definitions do not have to be "perfect" but rather should be clear and concise for clinical research.

Here are guidelines you can follow in writing definitions:

- Consider - "Is the change I am requesting necessary?"
- Keep definitions as a single sentence
- Avoid complex sentences with several clauses
- Avoid the use of several commas within a sentence
- Avoid long sentences. 10-15 words
- Do not use brackets to separate ideas
- Use short, simple words that don't require a dictionary (e.g., "conduct" opposed to "carry out a study").
- Use a tone that is more like how you would speak (e.g., "The patient will be asked to provide a sample of blood" vs. "The patient will be required to provide a sample of blood")
- Be precise and concise while leaving room for interpretation (e.g., "The patient will be asked to provide a sample of blood" vs. "The patient will be required to provide a sample of blood")
- Use active voice when possible ("The patient will be asked to provide a sample of blood" vs. "A sample of blood will be provided by the patient")

Term: study feasibility


Definition: How likely a study or task is to be completed.



I can accept this definition:

☐ Yes 

* must provide value

☒ No 



If no, please describe how the definition should be changed:

* must provide value



What happens to Public Review feedback

All feedback we receive is transferred into the CDISC Wiki for tracking

Comments are reviewed and addressed by the Clinical Research Glossary team, including a review by the workgroup

Transparency is a hallmark of the Public Review process

- email to reviewer who submitted the comment
- summary on public CDISC website

.....The new glossary content is released in September

Help us keep growing this resource!

Clinical Research Glossary Implementation Discussion

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HonorHealth



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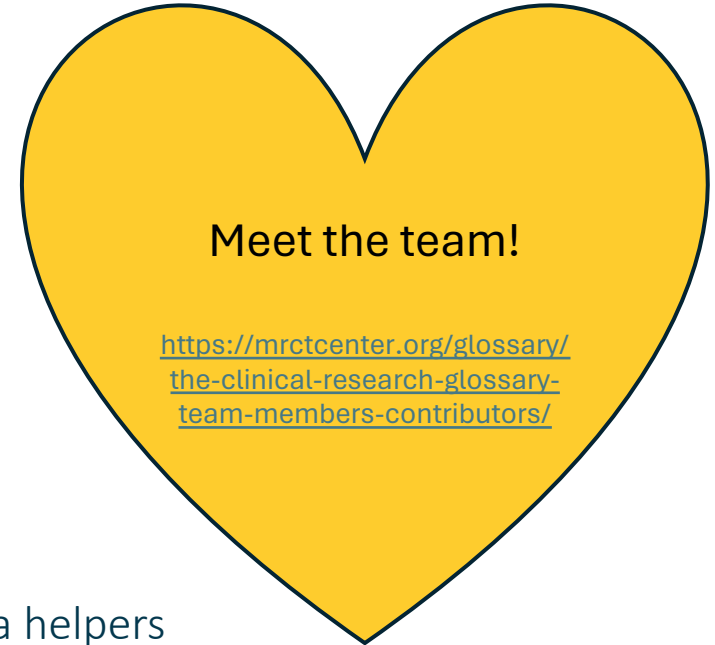
https://mrctcenter.org/wp-content/uploads/2024/06/2024-06-04_-HL-Public-review-bio-book.pdf

A Call to Action

- Join our Public Review Process!
 - You will receive an email of resources to join and share
 - Invite your friends, family, and colleagues
- Use and share, share, share the Clinical Research Glossary!
 - Please identify which people and groups in your network could benefit from using the Clinical Research Glossary and **share** the link with them.
www.mrctcenter.org/glossary
 - 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 and champions!
- The internal MRCT Center team
 - Communications team, graphic designers, and extra helpers
 - MRCT Center leadership



Thank you!

Questions?