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

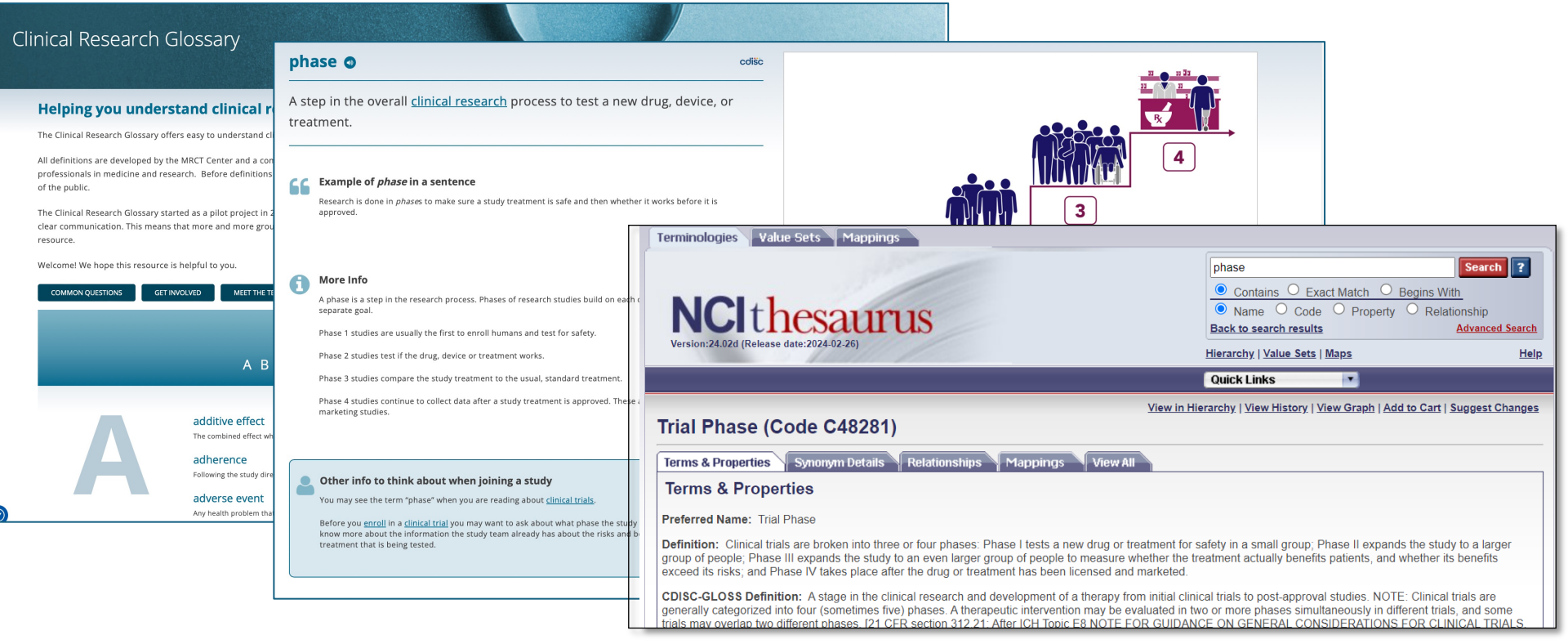
Improve the integrity, safety, and rigor of global clinical trials.

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



A resource for everyone

www.mrctcenter.org/glossary

MRCT Clinical Research GLOSSARY

The glossary team welcomes you all year round:

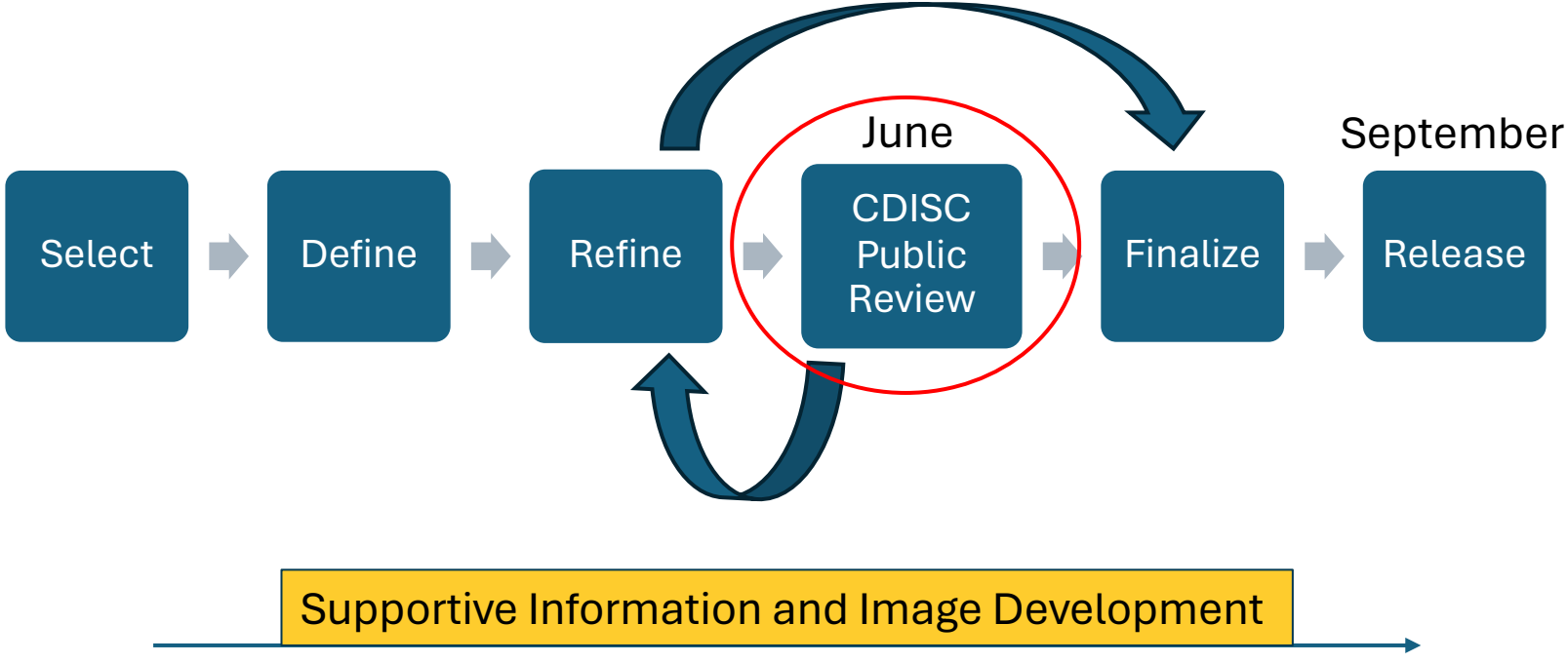
- ❑suggest a **new** clinical research term that should be defined and added
- ❑submit a comment on an **existing** definition or other content on the website
- ❑submit a comment on an **existing** image on the website
- ❑other ways to help:
  - ❑share with your network
  - ❑review definitions during 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/

MRCT Clinical Research GLOSSARY

The Clinical Research Glossary – Process

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



What is CDISC?

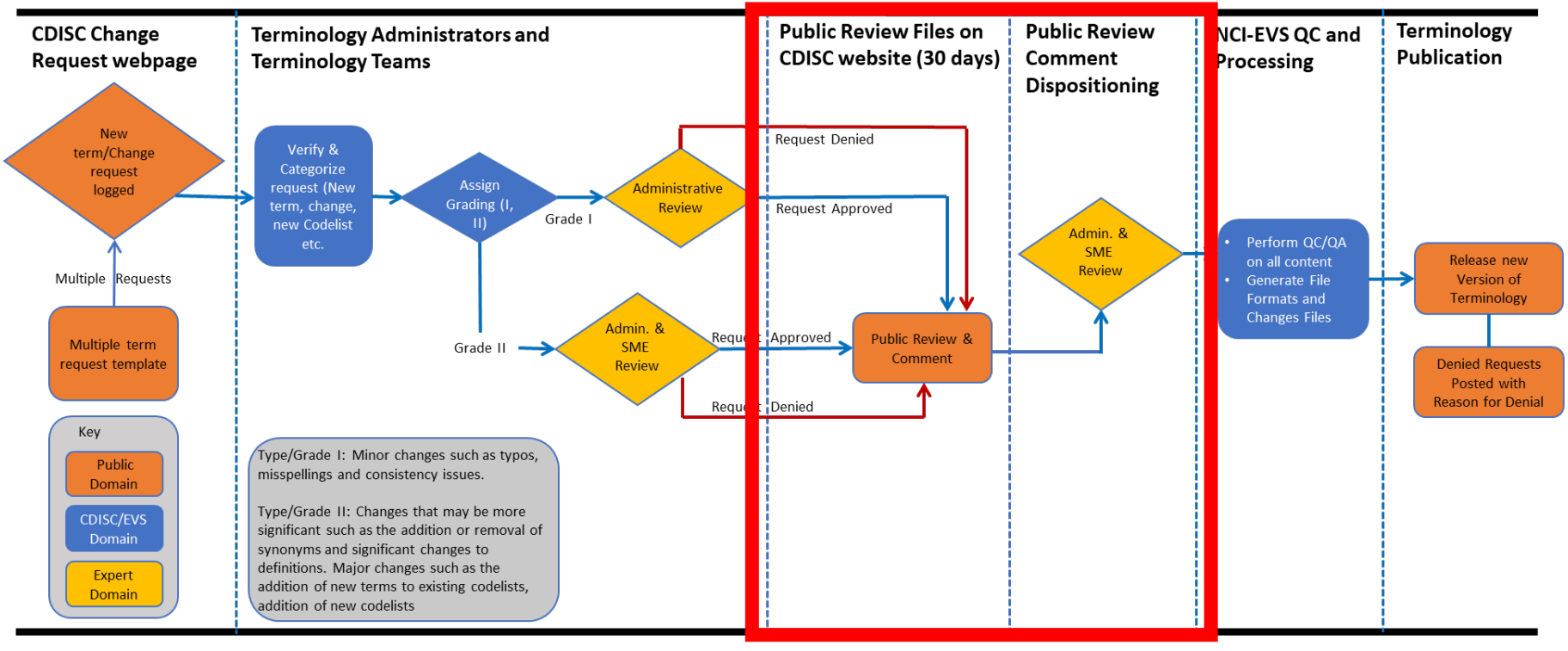
- Founded in 1997 by Volunteers and established as a Global Standards Development Organization (SDO) non-profit organization in 2000
- Community consensus standards development for clinical and translational research with a network of >500 members and 1000+ industry experts
- Freely available & widely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



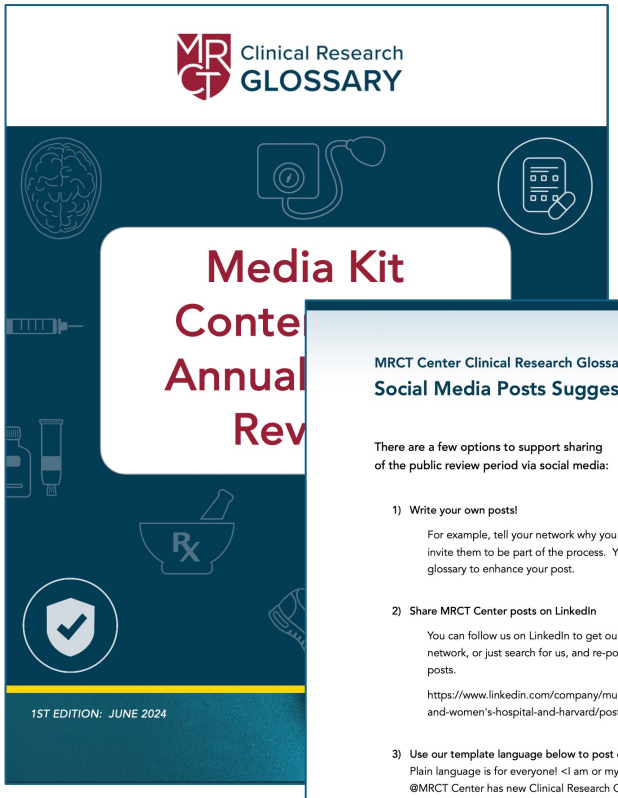
2024 Clinical Research Glossary Public Review – opens June 7th!

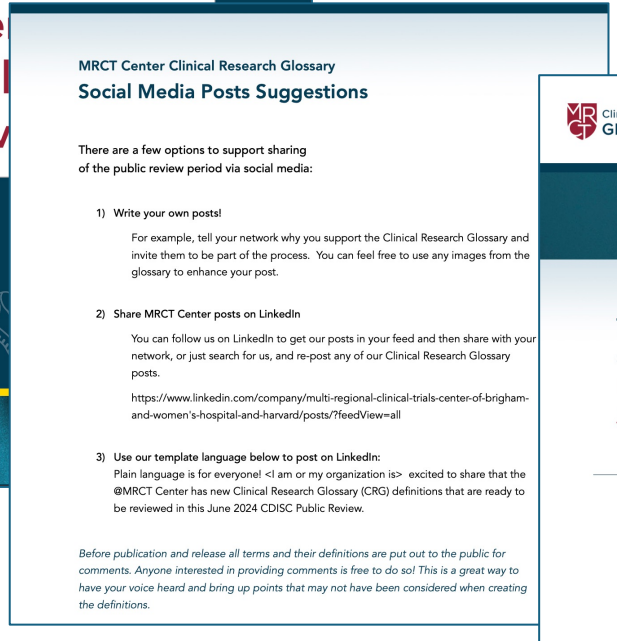
- Public Review – available June 7th through July 5th
  - Twelve (12) definitions are ready for you to review.

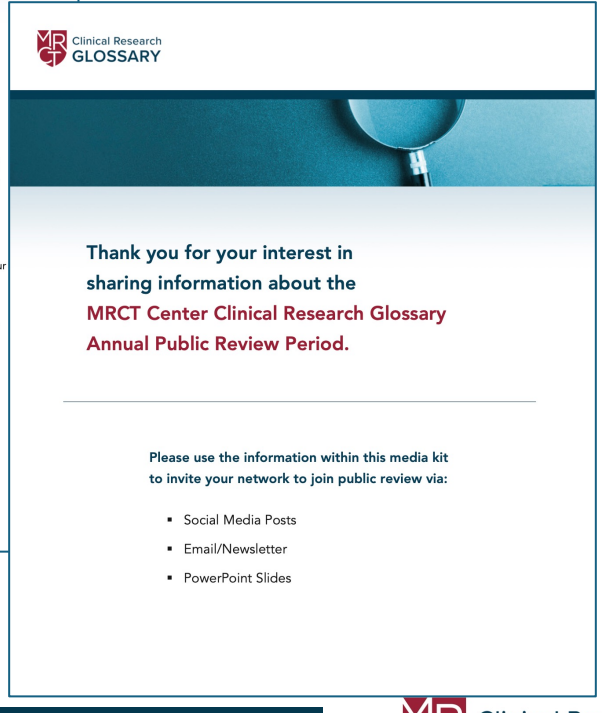
- You can get involved in Public Review
  - Review new proposed definitions before they are released in September
  - Share the opportunity to review with your network

- You can help us expand our reach
  - Patients and participants
  - Advocacy organizations
  - Community-based programs
  - Students
  - Clinical Research Professionals

Clinical Research GLOSSARY







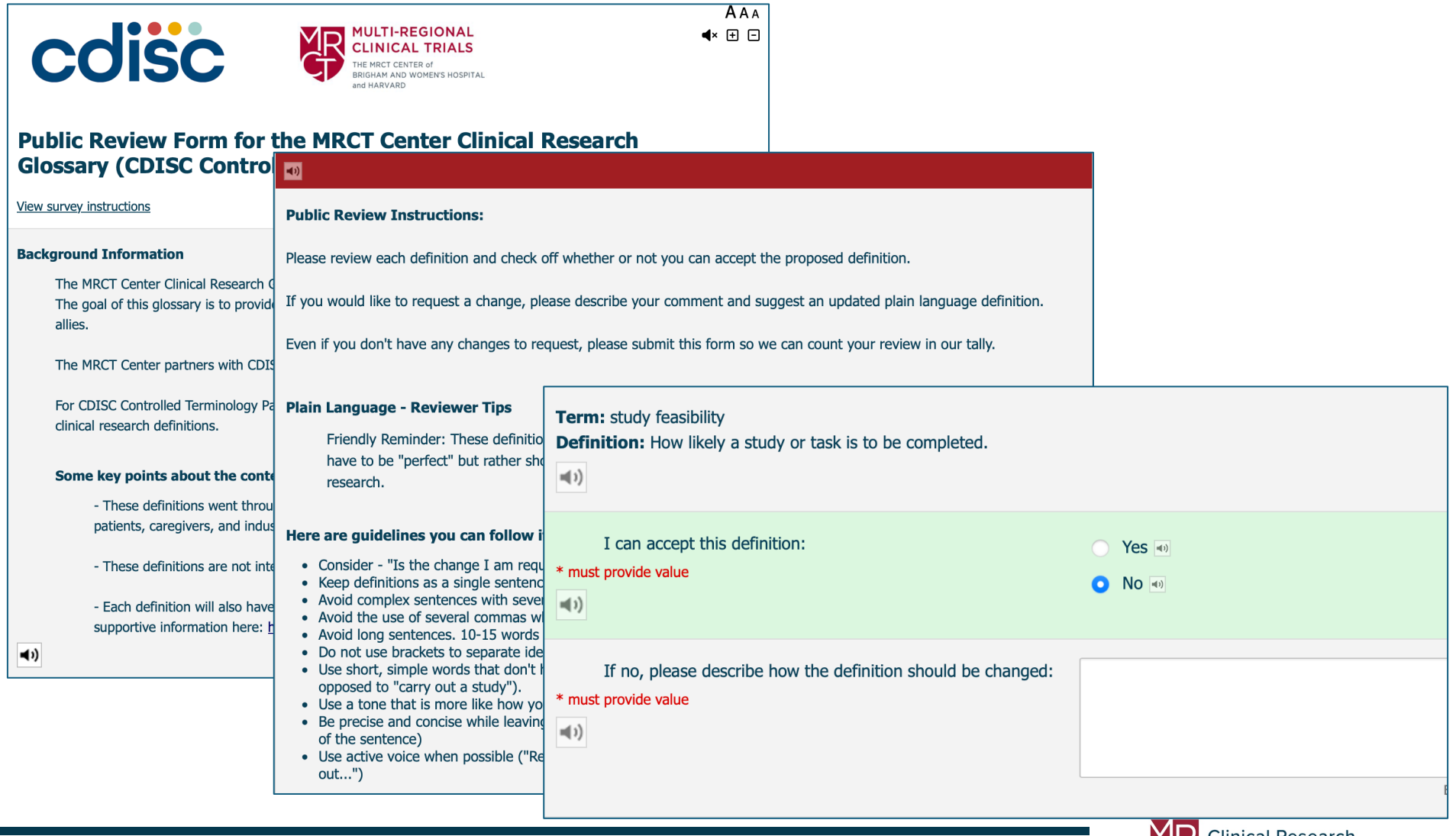
Clinical Research
GLOSSARY

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



Clinical Research GLOSSARY

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

Amy Mirabella	Claudine Moore	Holly Parker	Sophia Zilber
			
HonorHealth	Society for Clinical Data Management	Mass General Brigham Rally	Cure Mito

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Clinical Research GLOSSARY

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?