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

The recording and slides will be available ~1 week after the webinar

YOUR VOICE, GLOBAL IMPACT:

Join the Clinical Research Glossary's Annual Public Review Process

Sylvia Baedorf Kassis, MPH, MRCT Center
Erin Muhlbradt, PhD, NCI-EVS

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
- The slides and 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.

Session Overview and Objectives

- Clinical Research Glossary Overview
- Instructions for Public Review
- Use Case Examples
- Audience Q&A

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

- Describe the Clinical Research Glossary development process, the role of Public Review, and how to participate.
- Summarize how the Clinical Research Glossary has been implemented.
- Identify opportunities to use the Clinical Research Glossary in 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

2025 Engagement

10
Webinars and Forums

4
Public Comments

23
Active Projects

1064
Webinar Registrants

44
Unique Countries

3
Resources Published

732
Unique Workgroup Members

10
Journal Articles Published

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Clinical Data Interchange Standards Consortium

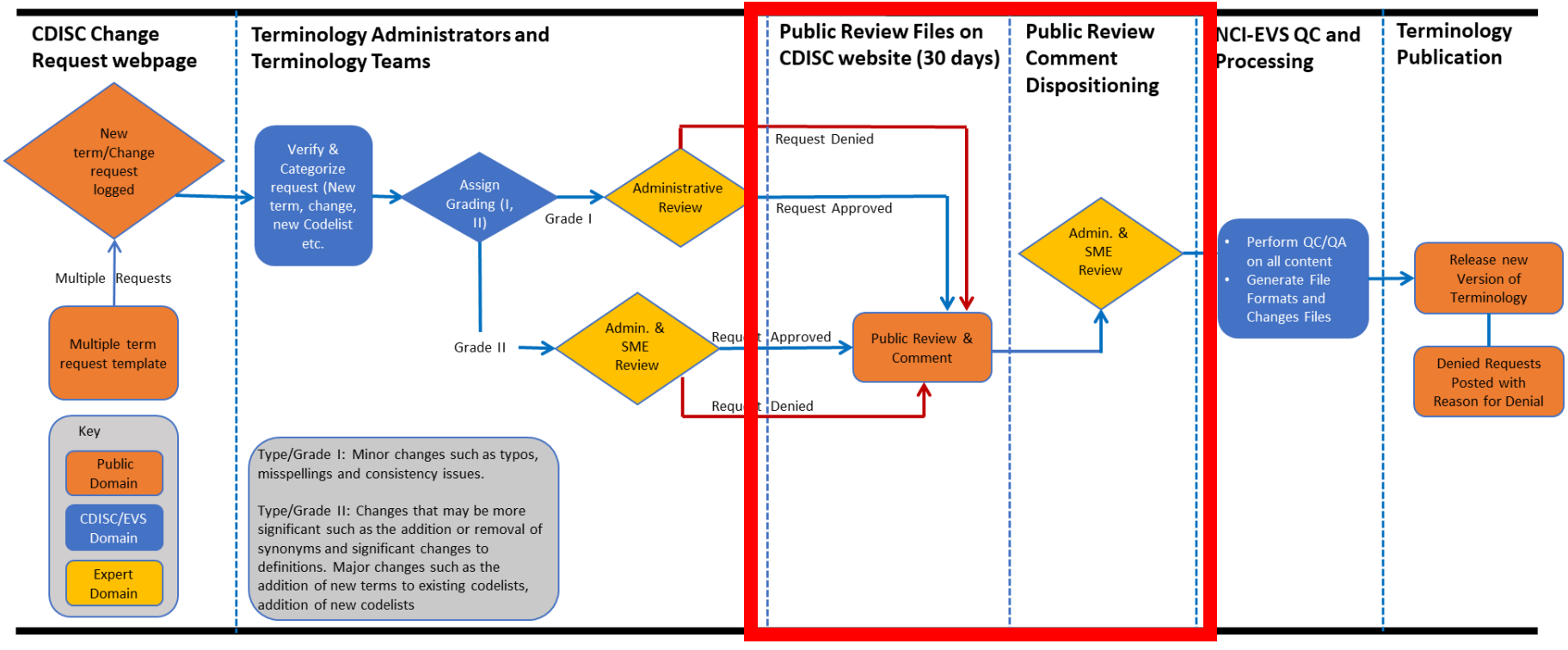
- Founded in 1997 by Volunteers and established as a Global Standards Development Organization (SDO) non-profit organization in 2000
- Community consensus standards development for clinical and translational research with a network of >500 members and 1000+ industry experts
- Freely available & widely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

CDISC

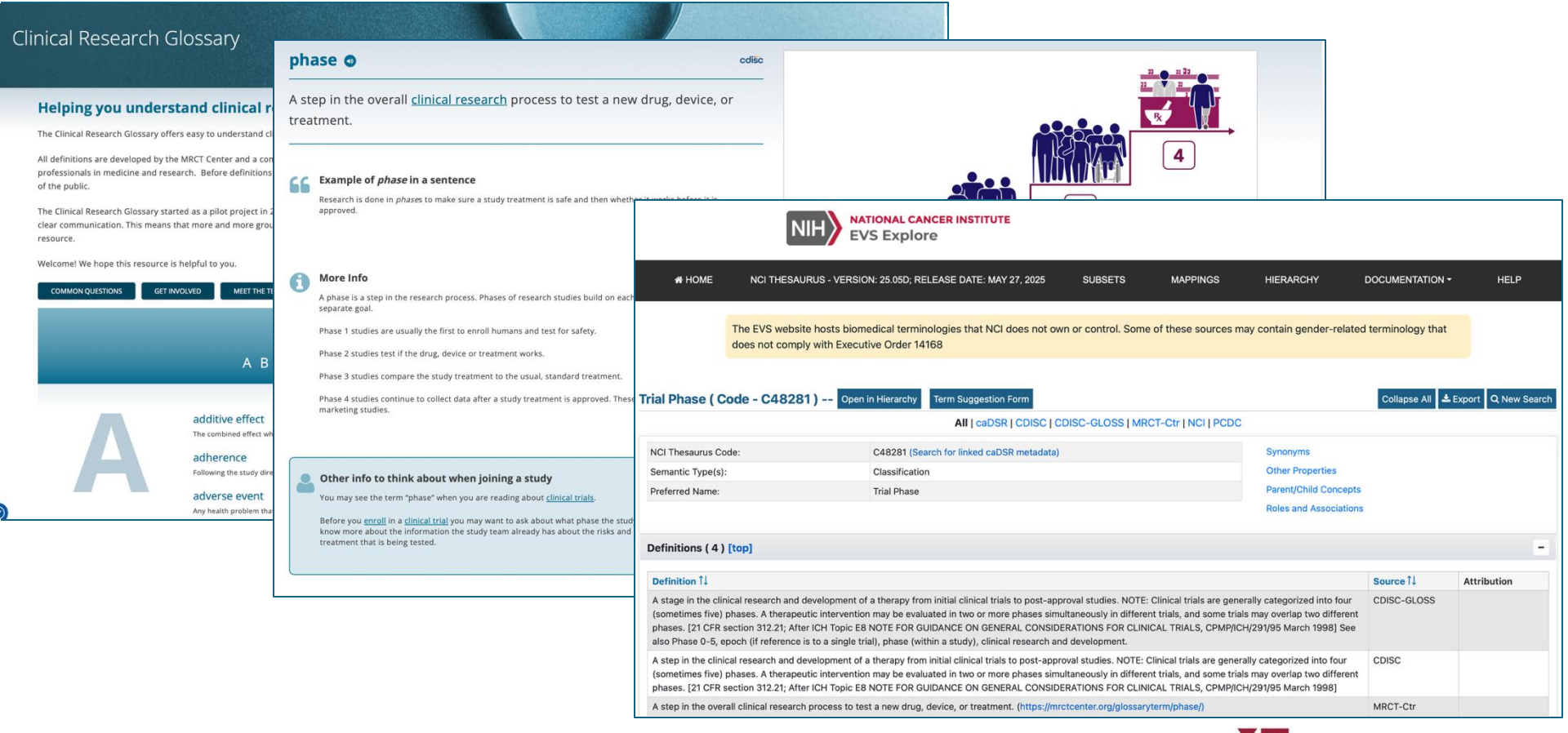
Convenes a global community of experts to develop and advance data standards of the highest quality, CDISC helps to create clarity in clinical research.

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 (and The MRCT Center is part of it!)



The MRCT Center Clinical Research Glossary



www.mrctcenter.org/glossary

Clinical Research GLOSSARY

User Stats - January to June, 2025

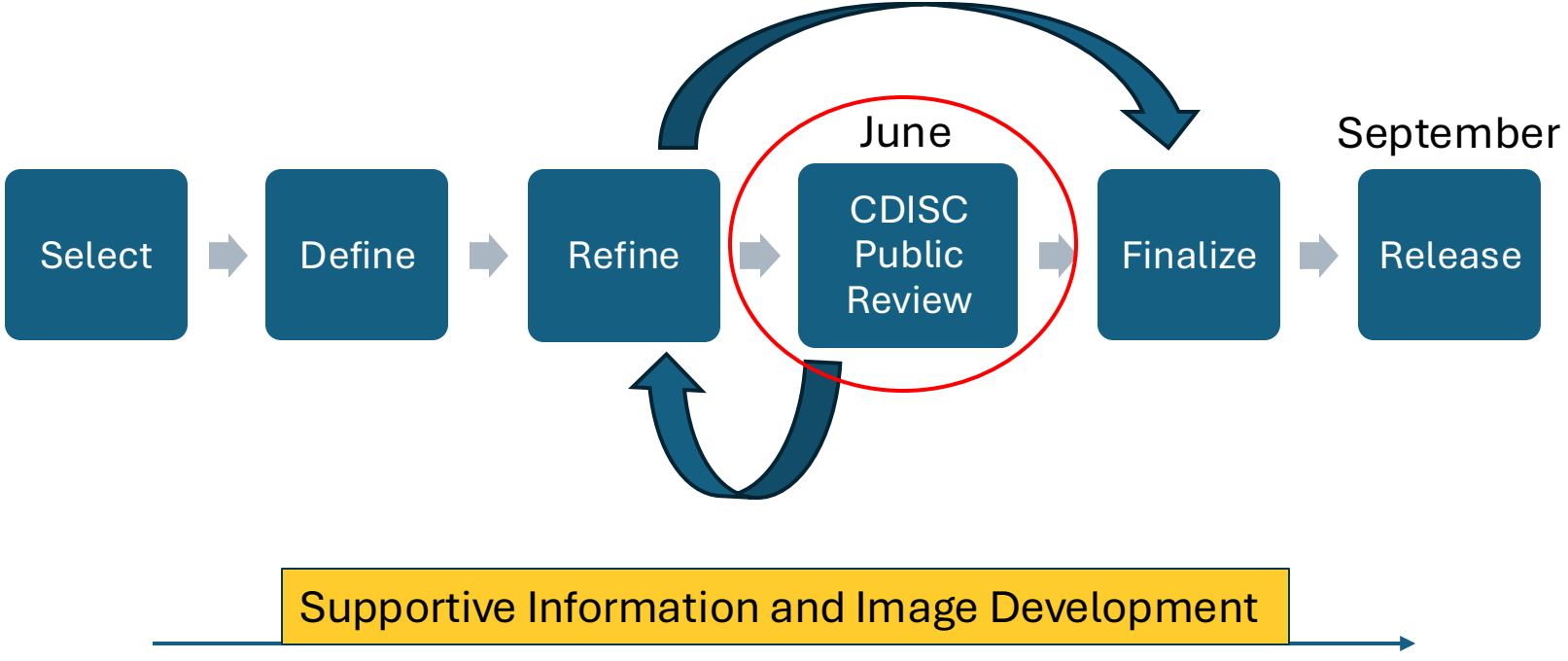
- 4731 Active Users
- 119 Countries
  - Top 10
    - USA
    - UK
    - India
    - Canada
    - China
    - Australia
    - Singapore
    - Germany
    - Spain
    - France

Top Words Searched

- PK study
- Synergistic effect
- Informed consent
- Observational study
- Single blind study
- Clinical trial
- Arm
- Baseline assessment
- Serious Adverse Event

The MRCT Center Clinical Research Glossary – Process

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



Clinical Research GLOSSARY

The glossary team welcomes feedback all year:

- ❑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/

Clinical Research GLOSSARY

2025 Clinical Research Glossary Public Review is open!

- Public Review – available June 6th through July 5th
  - 31 definitions up for review.

- Get involved!
  - Review proposed definitions before they are released in September
  - Share this opportunity with your network

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

Clinical Research GLOSSARY

How to give feedback during Public Review

1) MRCT Center REDCap Survey

2) CDISC Wiki JIRA

Path #1 –
MRCT Center REDCap Survey

- The process of giving feedback during Public Review involves filling out a simple survey.

- Reviewers will need to share their name and email address
  - Validates the entry
  - Allows for individual follow-up about how the comment was addressed

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Public Review Form for the MRCT Center Clinical Research Glossary (CDISC Controlled Terminology Package 60)

MRCT Center Clinical Research Glossary

Term: investigational device
Definition: A medical object or medical test that is not yet approved for the reason being studied.

I can accept this definition:
* must provide value

- Yes
- No

reset

If no, please describe how the definition should be changed:
* must provide value

Expand

Email
* must provide value

LinkedIn URL

Next Page >>

Clinical Research GLOSSARY

Path #2 –
CDISC Public Review Commenting Process

- Using CDISC JIRA Project

Public Review File

- Microsoft Excel file with Multiple Tabs:
  - ReadMe – includes general content explanation and process information
  - MRCT – contains list of terms and plain language glossary definitions to be reviewed.
- The file containing the MRCT Center Clinical Research Glossary will be named ‘Terminology_P##_MRCT’ with P## denoting the package number
  - For the Q2 2025 public review, the file will be named ‘Terminology_P60_MRCT’
- The file can be found on the CDISC Wiki starting on Friday June 6th
  - Terminology Call for Public Review Package P60 - Comments Due by 5 July 2025 - Controlled Terminology (CT) - Wiki

MRCT Public Review P60 Summary

- 30 new terms
- 1 change to an existing term

Codelist Name: MRCT Center Clinical Research Glossary

Codelist Description: The terminology relevant to the plain language glossary of the Multi-Regional Clinical Trial (MRCT) Center of Brigham and Women's Hospital and Harvard.

Codelist Extensible: <Null>

Addition(s) to an existing codelist

NCI/EVS Request Number	Codelist Short Name	NCI C-code	TESTCD, PARMCD or Submission Value	Plain Language Definition
Pending	MRCT	C923	vaccine	A type of medical product that helps the body's immune system to defend against a specific infection or disease.
Pending	MRCT	C72968	investigational device	A medical object or medical test that is not yet approved for the reason being studied.
Pending	MRCT	C82667	Investigational Device Exemption (IDE)	An approval given by the United States Food & Drug Administration to use a medical object or medical test in a research study that enrolls people.
Pending	MRCT	C215672	study doctor	A person with medical training who makes sure that the study procedures are followed and participants are cared for.
Pending	MRCT	C184727	sham (procedure)	Something that looks and feels like the treatment being studied, but is actually inactive.
Pending	MRCT	C41201	study monitor	A qualified person who checks that the study plan is being followed correctly.

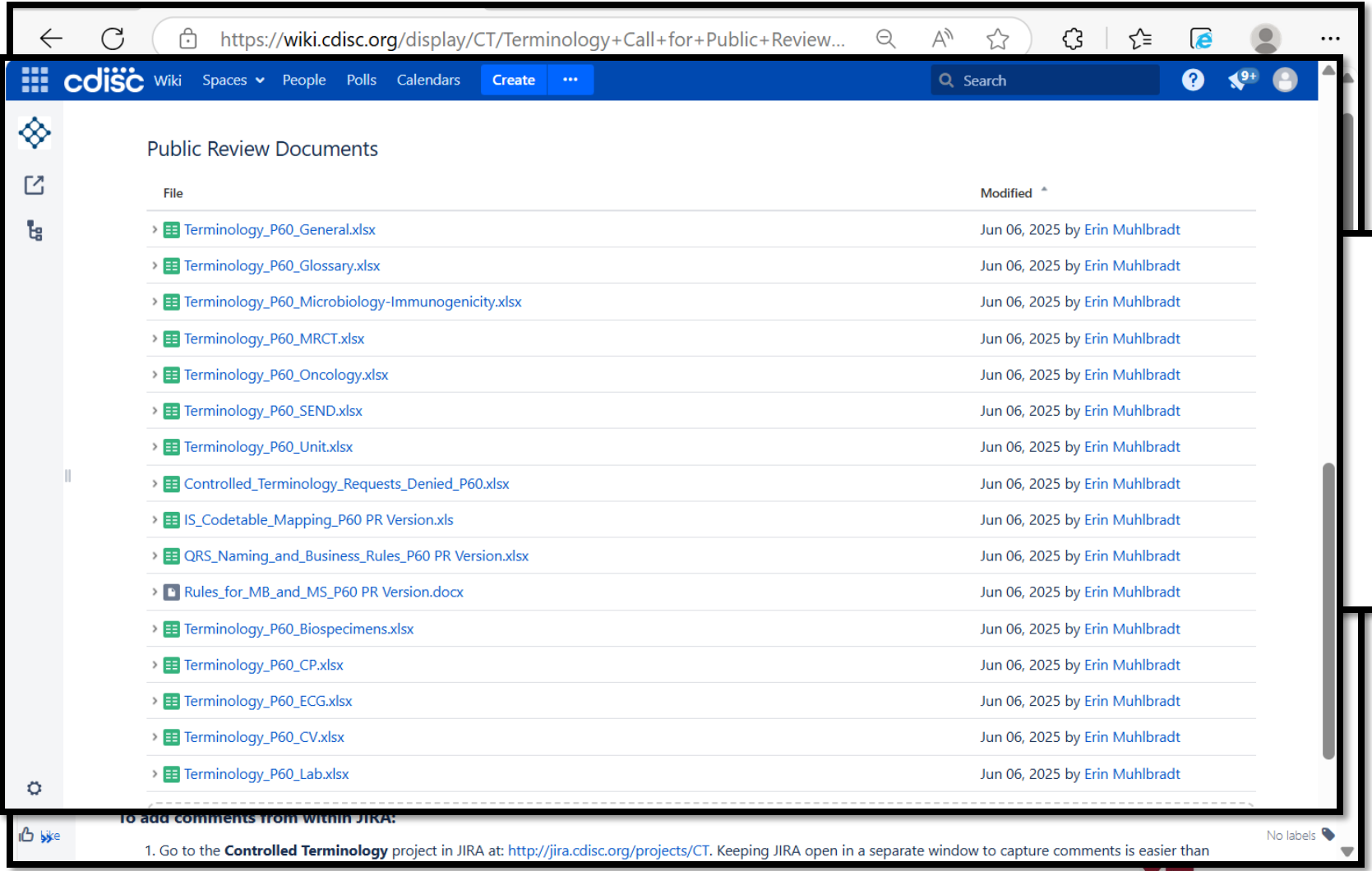
ReadMe | MRCT | Changes to Existing

NCI/EVS Request Number	Project Request	Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	CDISC Submission Value	CDISC Synonym(s)	CDISC Definition	NCI Preferred Term	Changes	URL
Pending	MRCT				MRCT Center Clinical Research Glossary	phase		~~A step in the overall clinical research process to test a new drug, device, or treatment.~~ A step in the overall clinical research process to test a new drug or treatment.		Update definition	(https://mrctcenter.org/glossaryterm/phase/)

ReadMe | MRCT | Changes to Existing

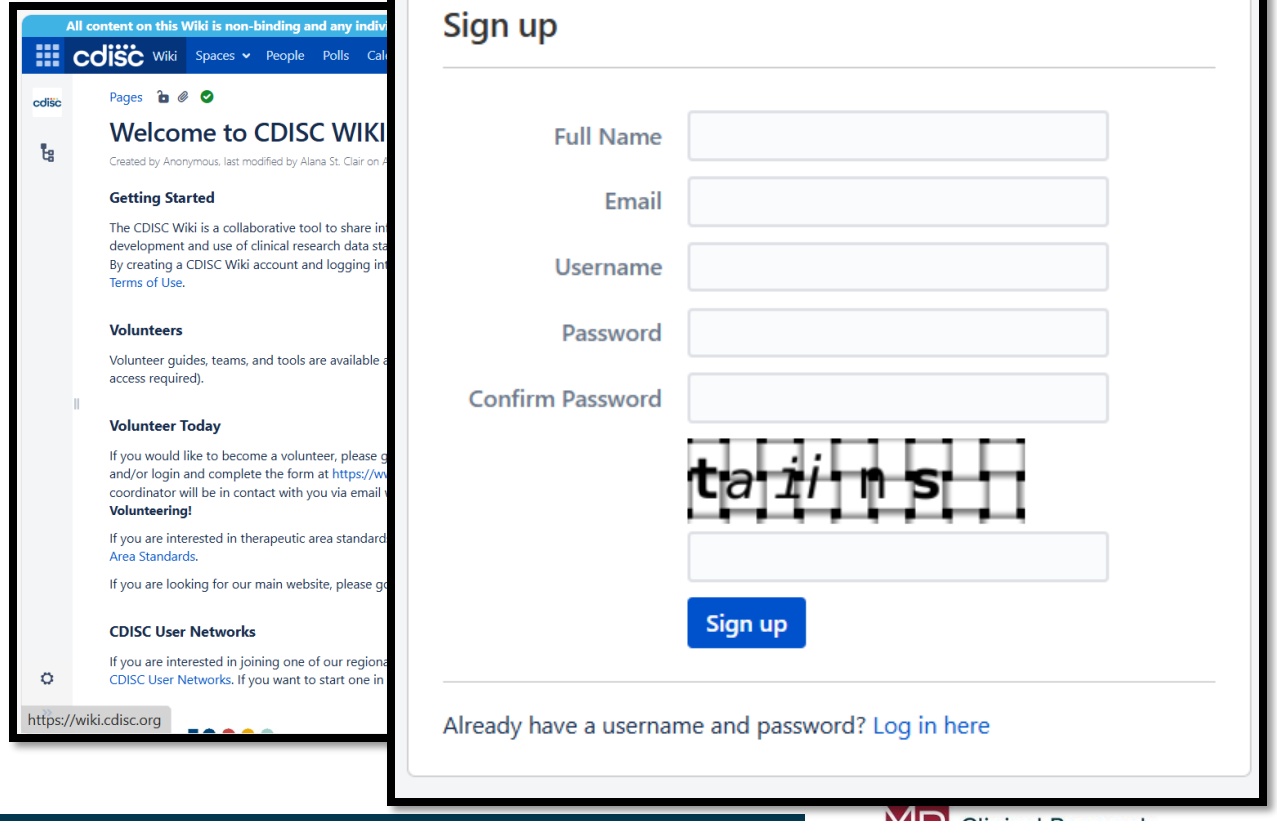
Ready | Accessibility: Investigate | 70%

MRCT Clinical Research GLOSSARY


https://wiki.cdisc.org/display/CT/Terminology+Call+for+Public+Review...
cdisc Wiki Spaces People Polls Calendars Create
Search
Public Review Documents
File
Modified
Terminology_P60_General.xlsx Jun 06, 2025 by Erin Muhlbradt
Terminology_P60_Glossary.xlsx Jun 06, 2025 by Erin Muhlbradt
Terminology_P60_Microbiology-Immunogenicity.xlsx Jun 06, 2025 by Erin Muhlbradt
Terminology_P60_MRCT.xlsx Jun 06, 2025 by Erin Muhlbradt
Terminology_P60_Oncology.xlsx Jun 06, 2025 by Erin Muhlbradt
Terminology_P60_SEND.xlsx Jun 06, 2025 by Erin Muhlbradt
Terminology_P60_Unit.xlsx Jun 06, 2025 by Erin Muhlbradt
Controlled_Terminology_Requests_Denied_P60.xlsx Jun 06, 2025 by Erin Muhlbradt
IS_Codetable_Mapping_P60 PR Version.xls Jun 06, 2025 by Erin Muhlbradt
QRS_Naming_and_Business_Rules_P60 PR Version.xlsx Jun 06, 2025 by Erin Muhlbradt
Rules_for_MB_and_MS_P60 PR Version.docx Jun 06, 2025 by Erin Muhlbradt
Terminology_P60_Biospecimens.xlsx Jun 06, 2025 by Erin Muhlbradt
Terminology_P60_CP.xlsx Jun 06, 2025 by Erin Muhlbradt
Terminology_P60_ECG.xlsx Jun 06, 2025 by Erin Muhlbradt
Terminology_P60_CV.xlsx Jun 06, 2025 by Erin Muhlbradt
Terminology_P60_Lab.xlsx Jun 06, 2025 by Erin Muhlbradt
To add comments from within JIRA:
1. Go to the Controlled Terminology project in JIRA at: http://jira.cdisc.org/projects/CT. Keeping JIRA open in a separate window to capture comments is easier than
No labels

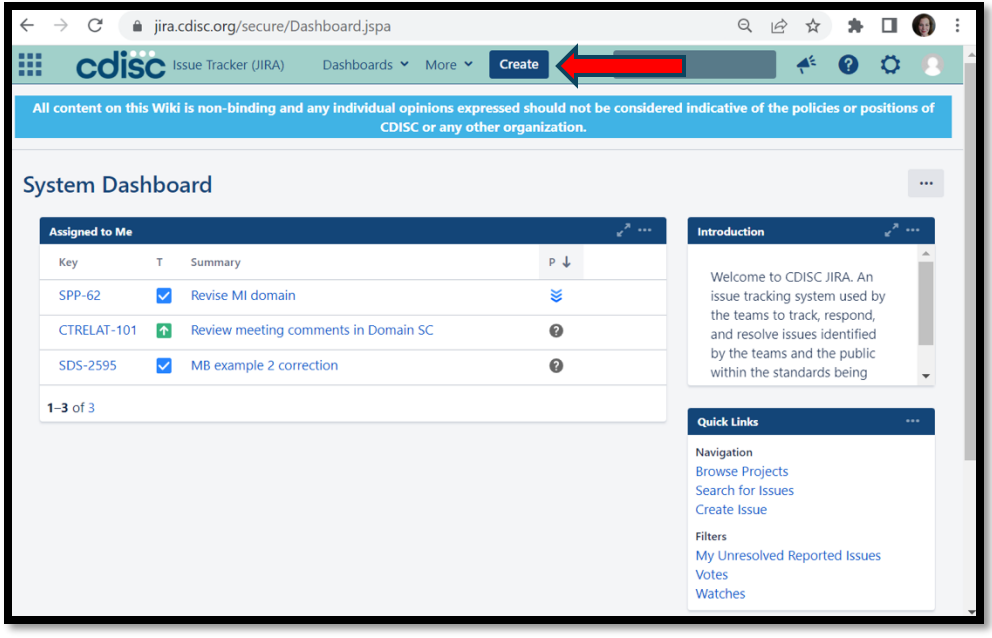
How to Get Access to CDISC JIRA

- Navigate to this page: https://wiki.cdisc.org/display/PUB/Welcome+to+CDISC+WIKI
  - Instructions on the top right hand corner (red box)
- https://wiki.cdisc.org/signup.action



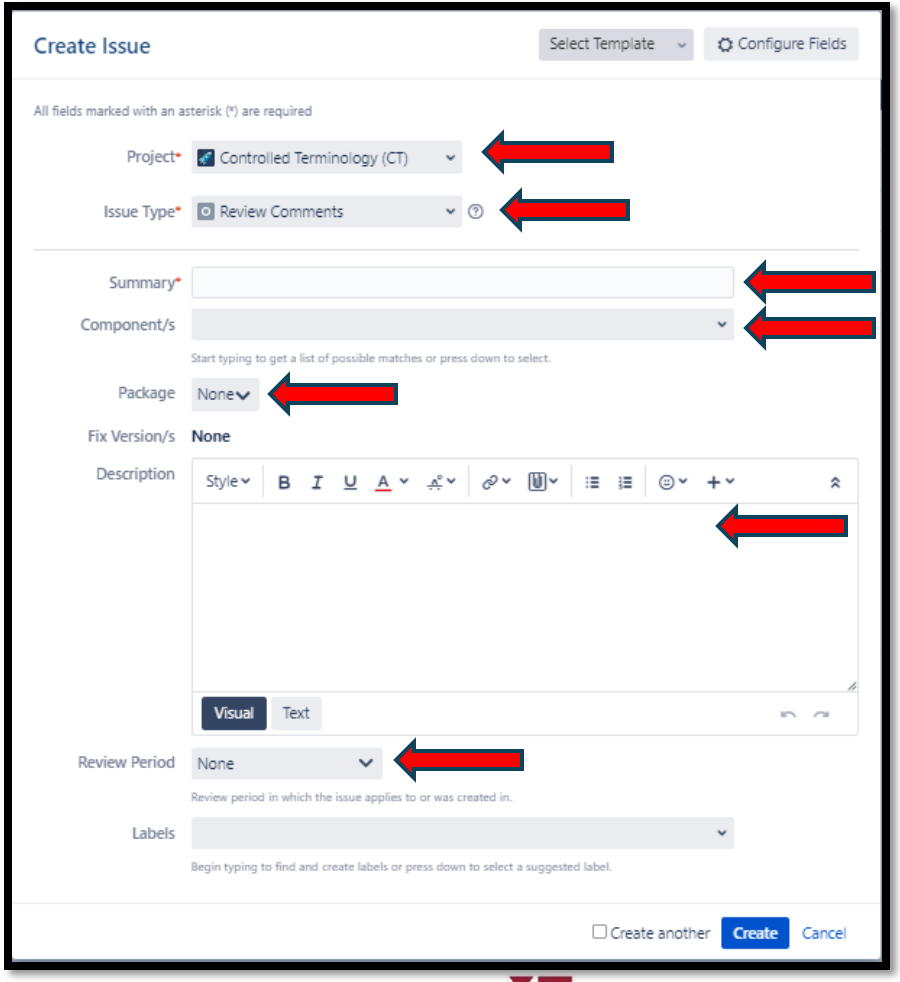
How to Submit Comments through CDISC JIRA

- Navigate to this page: https://jira.cdisc.org/secure/Dashboard.jspa
  - This will require a login
- Click on ‘Create’ button at the top of the page



Create a JIRA Issue

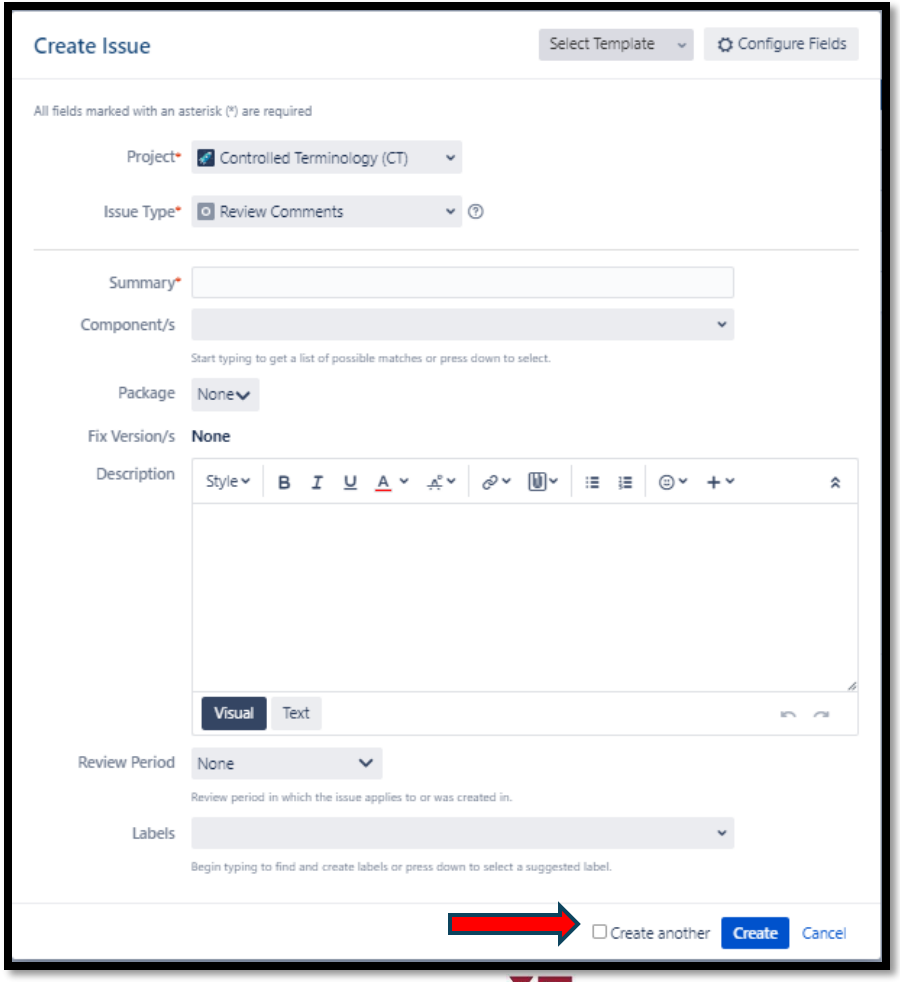
- Project (Dropdown)
  - *Controlled Terminology (CT)*
- Issue Type (Dropdown)
  - *Review Comments*
- Summary (*Free Text*)
- Component/s (Dropdown)
  - *MRCT*
- Package (Dropdown)
  - *60*
- Description (*Free Text*)
- Review Period
  - *Public Review*



Clinical Research GLOSSARY

Create a JIRA Issue

- Ignore the ‘Labels’ field
- Click the ‘Create’ button to generate the JIRA comment
- If you want to create more than one JIRA comment, click the ‘Create another’ box *BEFORE* clicking the ‘Create’ button.
- Issues with Accessibility:
  - *If you have any trouble at all with this process, please contact us and we can submit JIRAs on your behalf: muhlbradtee@mail.nih.gov*



How have public review comments changed MRCT language?

Example 1: MRCT term ‘procedures (study)’

- Publicly reviewed with P58
- Public review comment for Preferred Term
  - *It was suggested that instead of procedures (study), the term should be changed to: procedures (for participants) – The activities that participants will be asked to do during a study.*
- Public review comments for Definition:

Organization Name	If no, please describe how the definition should be changed (procedures [study]):
MRCT Center	study procedures goes beyond what participants will be asked to do
MRCT Center	Aren't procedures things that the study team does to carry out the study?
Amgen	Consider "the activities that participants, health care providers, and others involved will be asked to do during the study."
Texas Weight Loss Center	systematic steps to conduct a study.
DCUMC/CIMI, South Korea	'research' would be better than 'study'

- Final Disposition:
  - After careful consideration of all of the comments received on this particular term, the team has agreed to:
    1. Update the preferred term from 'procedures (study)' to 'procedures (for participants)'
    2. update the definition thusly: The activities that participants will be asked to do during the research study.

What happens to Public Review feedback?

Regardless of whether you follow Path #1 or Path #2:

All Public Review comments are 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

- Every reviewer who submitted a comment received a personalized email
- A summary of all comments and how they were resolved is on the public CDISC website

…..The new glossary content is released in September

2025 Public Review – New Terms

vaccine
investigational device
Investigational Device Exemption (IDE)
study doctor
sham (procedure)
study monitor
principal investigator
recruiting (status)
participant code
study identifier
medical device
screen failure
sample (study)
biobanking (research)
masking (study treatment)

personal data
opt-out
opt-in
blinding
decentralized clinical trial
human subject
case-control study
cohort study
long-term follow-up (research)
approval (IRB/ethics)
Serious Adverse Reaction (SAR)
study site
crossover trial
termination (of a research study)
eSignature

2025 Public Review - Change to Existing Term

Term: phase
Current Definiton: A step in the overall clinical research process to test a new drug, device, or treatment.

Requested New Definition: A step in the overall clinical research process to test a new drug or treatment.

I can accept the "Requested New Definition":

* must provide value

- ( ) Yes
- ( ) No

A Call to Action – we need your help!

- Join our Public Review process!

https://mrctcenter.org/the-clinical-research-glossary-public-review

Plain Language - Reviewer Tips

Friendly Reminder: These definitions are meant to be in plain language for the general public. These definitions do not have to be "perfect" but rather should be simple definitions that can help people who are learning more about clinical research.

Here are guidelines you can follow if you have feedback on a definition:

- Consider - "Is the change I am requesting really necessary? Can I accept the definition as written?"
- Keep definitions as a single sentence.
- Avoid complex sentences with several pieces of information within one sentence.
- Avoid the use of several commas which can make a sentence more complex.
- Avoid long sentences. 10-15 words per sentence is ideal; 20 or fewer words per sentence is acceptable.
- Do not use brackets to separate ideas, or symbols, or abbreviations such as "e.g." and "i.e."
- Use short, simple words that don't have more than one meaning or connotation (for example "to do a study" as opposed to "carry out a study").
- Use a tone that is more like how you might speak to someone.
- Be precise and concise while leaving out unnecessary words (i.e., omit words or terms that do not change the message of the sentence)
- Use active voice when possible ("Researchers do clinical trials to find out..." instead of "Clinical trials are done to find out...")

A Call to Action – we need your help!

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

Clinical Research Glossary

Home | Clinical Research Glossary | Clinical Research Glossary: Use Case Collection

Clinical Research Glossary: Use Case Collection

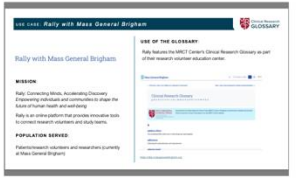
The MRCT Center Clinical Research Glossary is more than a reference—it's a tool for clarity, connection, and accessibility across the clinical research ecosystem. Organizations from patient advocacy groups to health systems, academic journals, and recruitment platforms are integrating the glossary to meet the distinct needs of their audiences.

Whether embedded in health literacy trainings, linked within patient education portals, or aligned with technical terminology in scholarly publications, these five implementation stories demonstrate the glossary's real-world utility in empowering patients, caregivers, professionals, and the public to engage with research using a shared, plain language vocabulary.

Glossary Case Use – Honor Health

Glossary Case Use – CureMito

Glossary Case Use – JSCDM



Glossary MGB Rally PDF

Glossary Case Use – TriCan Health

Your Story Here!

https://mrctcenter.org/glossary/clinical-research-glossary-use-case-collection/

Clinical Research GLOSSARY

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
- CDISC!!

Thank you!

Questions?