



**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](http://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](http://www.mrctcenter.org)

The MRCT Center

# 2025 Engagement

10

Webinars and  
Forums



4

Public  
Comments



23

Active  
Projects



1064

Webinar  
Registrants



3

Resources  
Published



732

Unique  
Workgroup  
Members



44

Unique  
Countries



10

Journal Articles  
Published



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# Clinical Data Interchange Standards Consortium



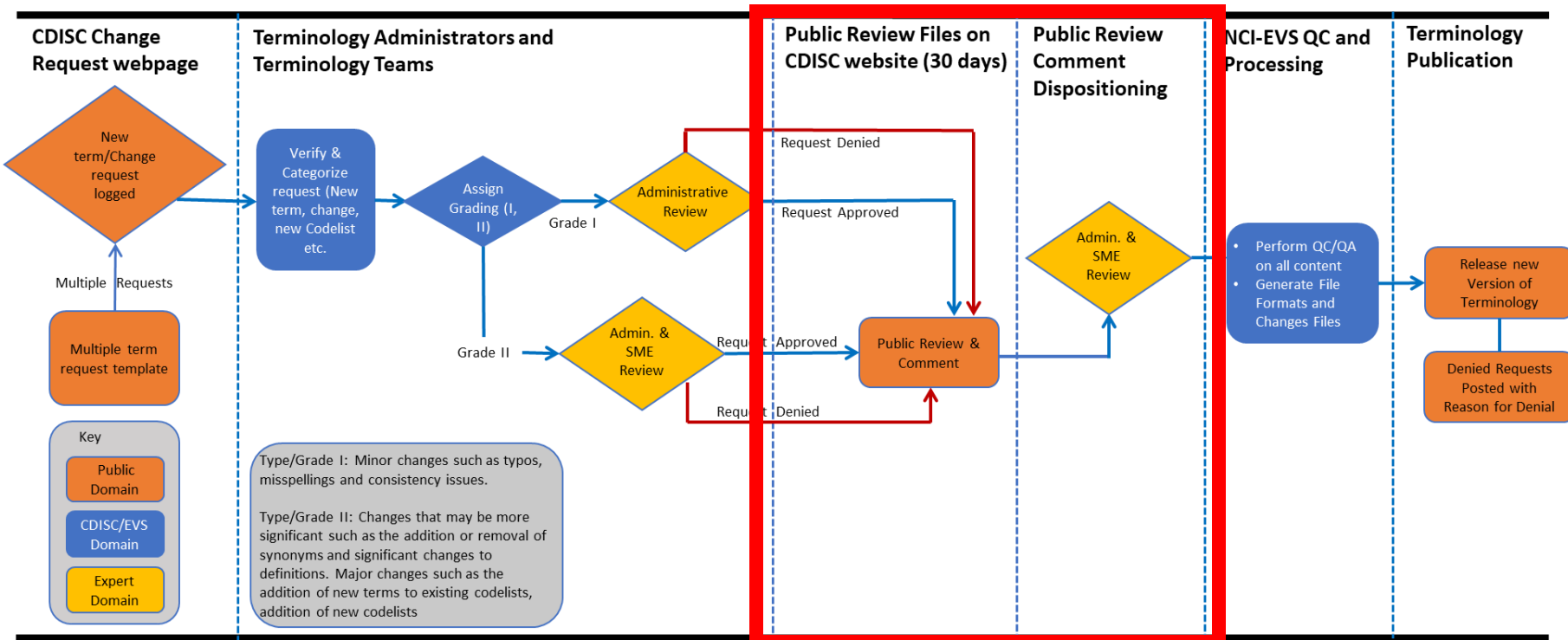
- Founded in 1997 by Volunteers and established as a Global Standards Development Organization (SDO) non-profit organization in 2000
- Community consensus standards development for clinical and translational research with a network of >500 members and 1000+ industry experts
- Freely available & widely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

## Clinical Research Glossary

### Helping you understand clinical research

The Clinical Research Glossary offers easy to understand definitions of clinical research terms. All definitions are developed by the MRCT Center and a group of professionals in medicine and research. Before definitions of the public.

The Clinical Research Glossary started as a pilot project in 2017 to provide 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 work together to produce a greater effect than each factor alone.

adherence  
Following the study directions.

adverse event  
Any health problem that occurs during a clinical trial.

### 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 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 can know more about the information the study team already has about the risks and treatment that is being tested.



NIH NATIONAL CANCER INSTITUTE EVS Explore

HOME NCI THESAURUS - VERSION: 25.05D; RELEASE DATE: MAY 27, 2025 SUBSETS MAPPINGS HIERARCHY DOCUMENTATION HELP

The EVS website hosts biomedical terminologies that NCI does not own or control. Some of these sources may contain gender-related terminology that does not comply with Executive Order 14168

Trial Phase ( Code - C48281 ) -- Open in Hierarchy Term Suggestion Form

Collapse All Export New Search

All | caDSR | CDISC | CDISC-GLOSS | MRCT-Ctr | NCI | PCDC

NCI Thesaurus Code:	C48281 (Search for linked caDSR metadata)
Semantic Type(s):	Classification
Preferred Name:	Trial Phase

Synonyms  
Other Properties  
Parent/Child Concepts  
Roles and Associations

#### Definitions ( 4 ) [top]

Definition ↑↓	Source ↑↓	Attribution
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, CPMP/ICH/291/95 March 1998] See also Phase 0-5, epoch (if reference is to a single trial), phase (within a study), clinical research and development.	CDISC-GLOSS	
A step 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, CPMP/ICH/291/95 March 1998]	CDISC	
A step in the overall clinical research process to test a new drug, device, or treatment. ( <a href="https://mrctcenter.org/glossaryterm/phase/">https://mrctcenter.org/glossaryterm/phase/</a> )	MRCT-Ctr	

# User Stats - January to June, 2025



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

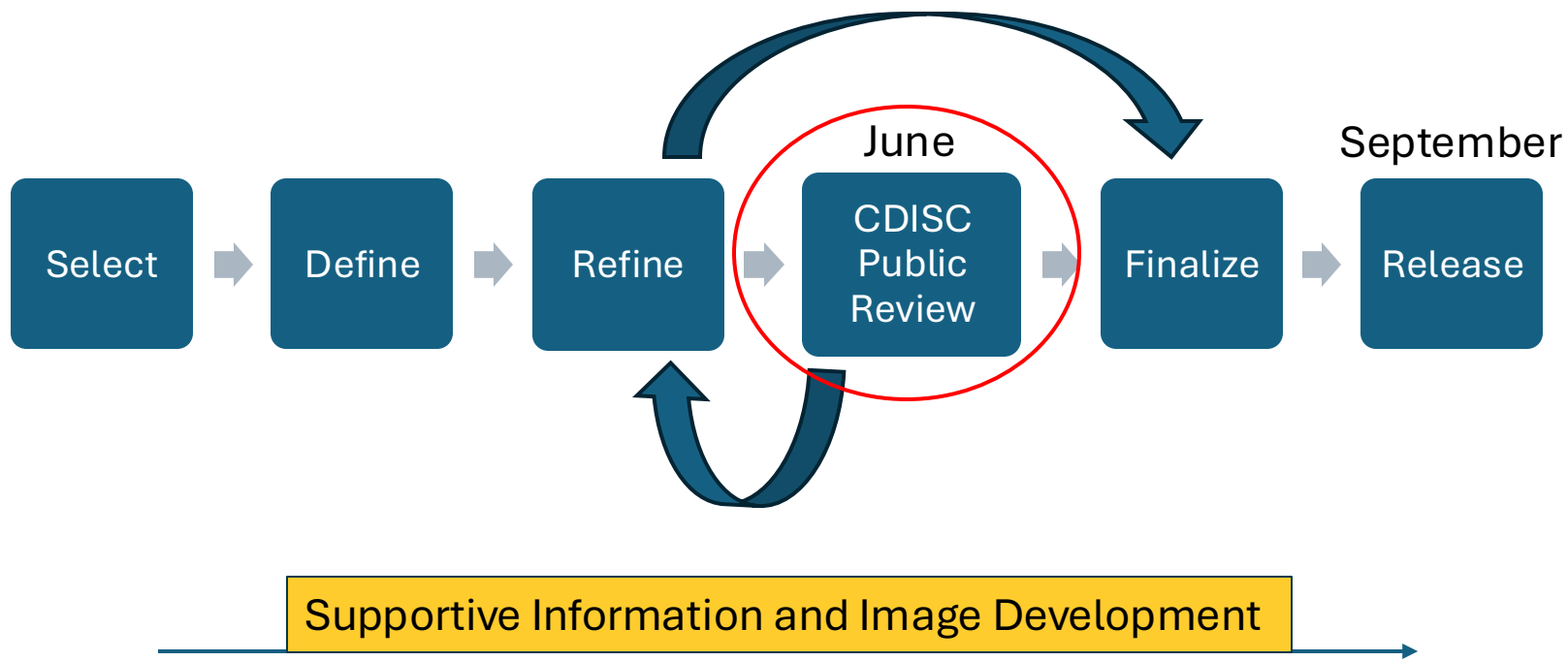
# Top Words Searched

- 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



# 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/>

# 2025 Clinical Research Glossary Public Review is open!

- Public Review – available June 6<sup>th</sup> through July 5<sup>th</sup>
  - 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



# 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



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

### MRCT Center Clinical Research Glossary CDISC Controlled Terminology Package 60

**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 >>

# 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

















				G	H
1	<b>Codelist Name: MRCT Center Clinical Research Glossary</b>				
2	<b>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.</b>				
3	<b>Codelist Extensible: &lt;Null&gt;</b>				
4					
5	<b>Addition(s) to an existing codelist</b>				
6	NCI/EVS Request Number	Codelist Short Name	NCI C-code	TESTCD, PARMCD or Submission Value	Plain Language Definition
7	Pending	MRCT	C923	vaccine	A type of medical product that helps the body's immune system to defend against a specific infection or disease.
8	Pending	MRCT	C72968	investigational device	A medical object or medical test that is not yet approved for the reason being studied.
9	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.
10	Pending	MRCT	C215672	study doctor	A person with medical training who makes sure that the study procedures are followed and participants are cared for.
11	Pending	MRCT	C184727	sham (procedure)	Something that looks and feels like the treatment being studied, but is actually inactive.
12	Pending	MRCT	C41201	study monitor	A qualified person who checks that the study plan is being followed correctly.





1	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
2	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
3											(https://mrctcenter.org/glossaryterm/phase/)
4											

← ↻ <https://wiki.cdisc.org/display/CT/Terminology+Call+for+Public+Review...> 🔍 🔊 ☆ ⚙️ ⭐️ 📧 👤 ⋮

**cdisc** Wiki Spaces ▾ People Polls Calendars Create ... 🔍 Search ? 🔊 9+ 👤


## Public Review Documents

File	Modified <sup>▲</sup>
>  Terminology_P60_General.xlsx	Jun 06, 2025 by <a href="#">Erin Muhlbradt</a>
>  Terminology_P60_Glossary.xlsx	Jun 06, 2025 by <a href="#">Erin Muhlbradt</a>
>  Terminology_P60_Microbiology-Immunogenicity.xlsx	Jun 06, 2025 by <a href="#">Erin Muhlbradt</a>
>  Terminology_P60_MRCT.xlsx	Jun 06, 2025 by <a href="#">Erin Muhlbradt</a>
>  Terminology_P60_Oncology.xlsx	Jun 06, 2025 by <a href="#">Erin Muhlbradt</a>
>  Terminology_P60_SEND.xlsx	Jun 06, 2025 by <a href="#">Erin Muhlbradt</a>
>  Terminology_P60_Unit.xlsx	Jun 06, 2025 by <a href="#">Erin Muhlbradt</a>
>  Controlled_Terminology_Requests_Denied_P60.xlsx	Jun 06, 2025 by <a href="#">Erin Muhlbradt</a>
>  IS_Codetable_Mapping_P60 PR Version.xls	Jun 06, 2025 by <a href="#">Erin Muhlbradt</a>
>  QRS_Naming_and_Business_Rules_P60 PR Version.xlsx	Jun 06, 2025 by <a href="#">Erin Muhlbradt</a>
>  Rules_for_MB_and_MS_P60 PR Version.docx	Jun 06, 2025 by <a href="#">Erin Muhlbradt</a>
>  Terminology_P60_Biospecimens.xlsx	Jun 06, 2025 by <a href="#">Erin Muhlbradt</a>
>  Terminology_P60_CP.xlsx	Jun 06, 2025 by <a href="#">Erin Muhlbradt</a>
>  Terminology_P60_ECG.xlsx	Jun 06, 2025 by <a href="#">Erin Muhlbradt</a>
>  Terminology_P60_CV.xlsx	Jun 06, 2025 by <a href="#">Erin Muhlbradt</a>
>  Terminology_P60_Lab.xlsx	Jun 06, 2025 by <a href="#">Erin Muhlbradt</a>

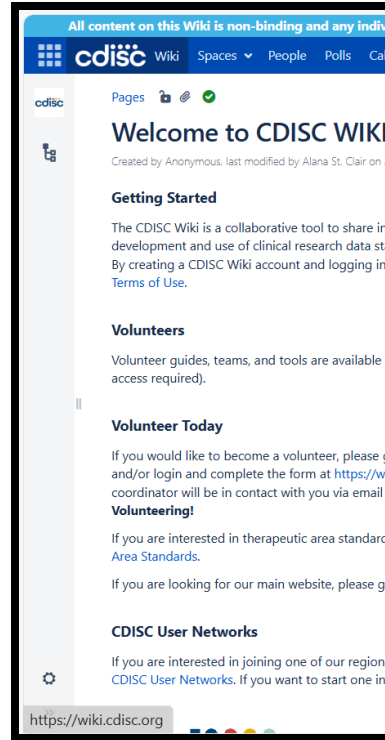
**To add comments from within JIRA:**

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 

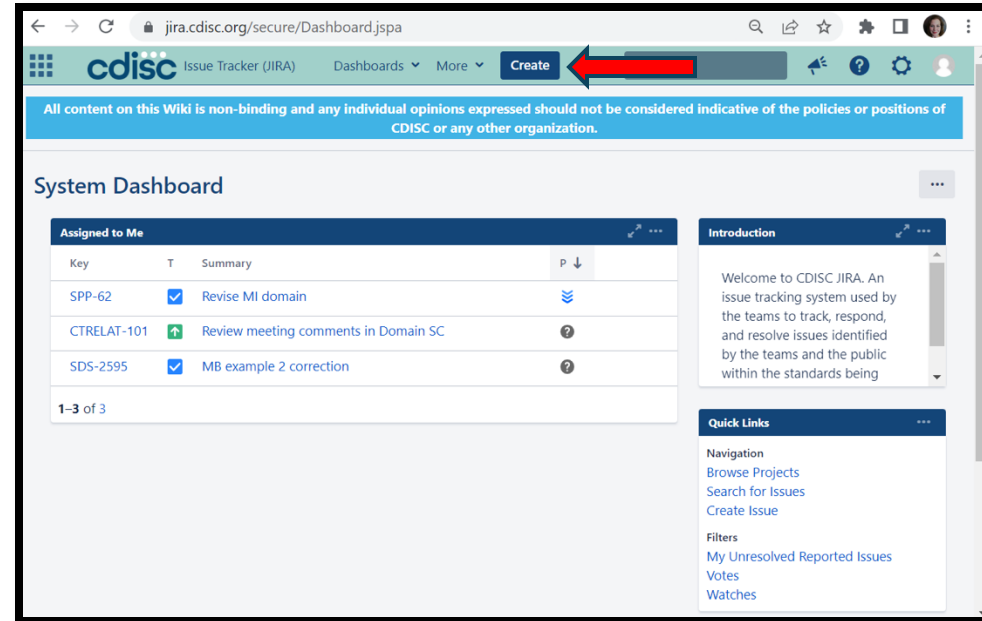
# How to Get Access to CDISC JIRA

- 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>

A screenshot of the 'Sign up' form on the CDISC Wiki. The form is titled 'Sign up' and contains several input fields: 'Full Name', 'Email', 'Username', 'Password', and 'Confirm Password'. Below these fields is a CAPTCHA image showing the word 'tarins' in a distorted font. At the bottom of the form is a blue 'Sign up' button. Below the button, there is a link that says 'Already have a username and password? Log in here'.

# 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*

The screenshot shows the 'Create Issue' form in JIRA. Red arrows point to the following fields:

- Project:** A dropdown menu showing 'Controlled Terminology (CT)'.
- Issue Type:** A dropdown menu showing 'Review Comments'.
- Summary:** A text input field.
- Component/s:** A dropdown menu.
- Package:** A dropdown menu showing 'None'.
- Description:** A large text area with a rich text editor toolbar.
- Review Period:** A dropdown menu showing 'None'.

At the bottom of the form, there is a checkbox for 'Create another' and buttons for 'Create' and 'Cancel'.



# 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](mailto:muhlbradtee@mail.nih.gov)*

## Create Issue


Select Template ⌵Configure Fields ⚙

All fields marked with an asterisk (\*) are required

Project\*

 Controlled Terminology (CT) ⌵

Issue Type\*

 Review Comments ⌵ ?

---

Summary\*

Component/s

Start typing to get a list of possible matches or press down to select.






Package

None ⌵

Fix Version/s



None

Description

Style ⌵**B***I*UA ⌵<sup>°</sup> ⌵ ⌵   + ⌵ ⌵

Visual

Text




Review Period

None ⌵

Review period in which the issue applies to or was created in.

Labels

Begin typing to find and create labels or press down to select a suggested label.



☐ Create another

Create

Cancel

# 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.
DOJMC/CIML 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 Definition:** 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](http://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

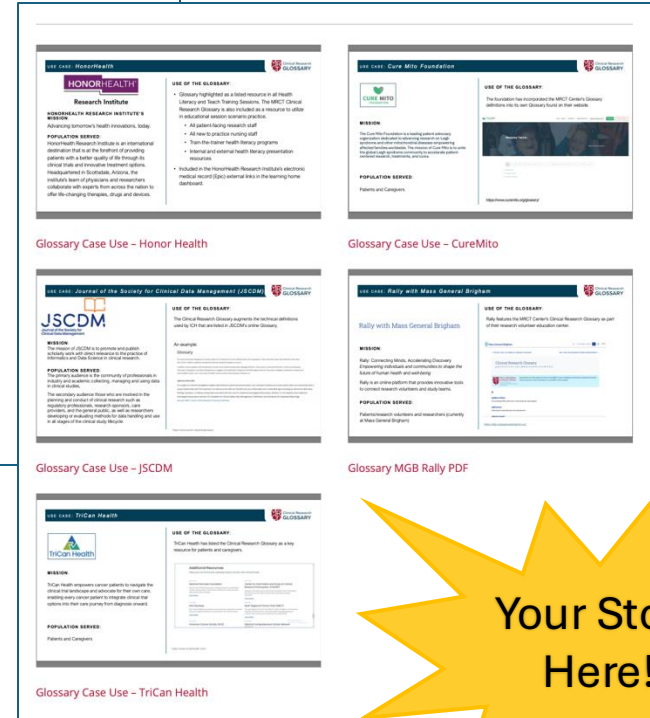
# Clinical Research Glossary

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.



Your Story Here!

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



# 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?