



MULTI-REGIONAL CLINICAL TRIALS

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

Announcing a Global Standard for Plain Language in Clinical Research

Our webinar with  will begin shortly.

Moderated by Barbara E. Bierer, MD
MRCT Center, Faculty Director

Disclaimer

- The opinions contained are those of the authors and are not intended to represent the position of Brigham and Women's Hospital or Harvard University.
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Announcing a Global Standard for Plain Language in Clinical Research

A joint webinar by the MRCT Center and CDISC
April 5, 2023 11 AM - 12 PM EDT

Clinical Research
GLOSSARY



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cdisc

Session Agenda

- Welcome and Introductions – MRCT Center and CDISC
- Glossary Background and Development
- Introduction to Public Review
- Q&A

Please note – the recording, slides and bio book will be available by the end of the week

Panelist Introductions



Sylvia Baedorf Kassis, MPH
MRCT Center



R. Bernard Coley, JD, MBA
Advocate



Dave Evans, MS
CDISC



Erin Muhlbradt, PHD
NCI EVS

The Multi-Regional Clinical Trials Center (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.



 **Brigham and Women's Hospital**
Founding Member, Mass General Brigham

 **HARVARD**
UNIVERSITY

 **cdisc**

Clinical Research
GLOSSARY



Longstanding Commitment to Health Literacy

2019 - Multi-stakeholder initiative to launch a publicly available Health Literacy in Clinical Research website

www.mrctcenter.org/health-literacy

2020 - Developed COVID-19 research pamphlets (in English & Spanish).

<https://mrctcenter.org/blog/resources/covid-19-clinical-research-flyers/>

2019 to present - Design and deliver health literacy trainings

2020-2021 - Launched the first pilot version of the Clinical Research Glossary through an agile iterative development process involving many stakeholders, patients, and their allies

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

2021 – Robust appreciation and utilization, prompting extensive further development

2022 – Collaboration with CDISC began

April 5, 2023



Introducing CDISC

- CDISC – Clinical Data Interchange Standards Consortium
 - Develops and advances **data standards** of the highest quality to transform incompatible formats, inconsistent methodologies, and diverse perspectives into a robust framework for generating accessible clinical research data.
 - Convenes a **global community** of research experts representing a range of experiences and backgrounds to harness the collective power to drive more meaningful clinical research.
 - Offers a **quarterly public review** period for new additions to its standards, a time when feedback can be collected from its users.
- *CDISC has always been an evolving transformational standards organization for information used in clinical research and regulatory submission.*

CDISC Alliances and Collaborations

CFAST & Therapeutic Area Partnerships

CDISC collaborates with many organizations to develop Therapeutic Area (TA) standards for multiple disease areas through the Coalition for Accelerating Standards and Therapies (CFAST) initiative, as well as other partnerships.



Standards Development Organizations (SDO) Collaborations

CDISC collaborates with other SDOs to develop standards that are synergistic to support a learning health system based upon high quality research.

Regulatory Collaborations

CDISC works closely with regulators around the world to ensure that CDISC standards will 1) streamline research from protocol/study design and trial registration through analysis and reporting; 2) facilitate the eSubmission review process; 3) ensure that clinical research is high quality; and 4) support the approvals of safe and efficacious medicines for patients.

Regulators also contribute to TA standards development



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH



CHINA NMPA



CDISC and PhUSE partner to further the mission of each organization collectively, with CDISC focusing on the development of global, platform-independent data standards, and PhUSE focusing on the implementation and use of the CDISC standards. The two organizations work to combine efforts on key initiatives around end-to-end standards, TA standards, and semantics, strengthening an interdependent process.

CDISC Standards Are Used by US NIH Centers for Many Kinds of Medical Research



Controlled Terminologies in NCI EVS, BRIDG model, Cloud Commons pilot



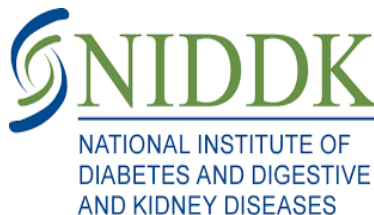
NINDS CDEs used in Parkinson's and TBI TAs for FDA submissions



Adopted CDISC standards for FDA submissions, HIV studies, pharmacovigilance, and meta-analyses



CDE contributors to Schizophrenia TA, Future CDE alignment to PTS TA



Part of C-Path Polycystic Kidney Disease TA consortium



Pediatric terminologies developed with NCI EVS and CDISC

Also in Europe



Vaccines Standard Training on collection, modeling and aggregation standards for interoperability



Mobile patient reported outcomes (PRO)



Standards Starter Pack Curation pipeline to TransMART



Data sharing recommendations



Use of standardized data for research sourced from multiple EHRs



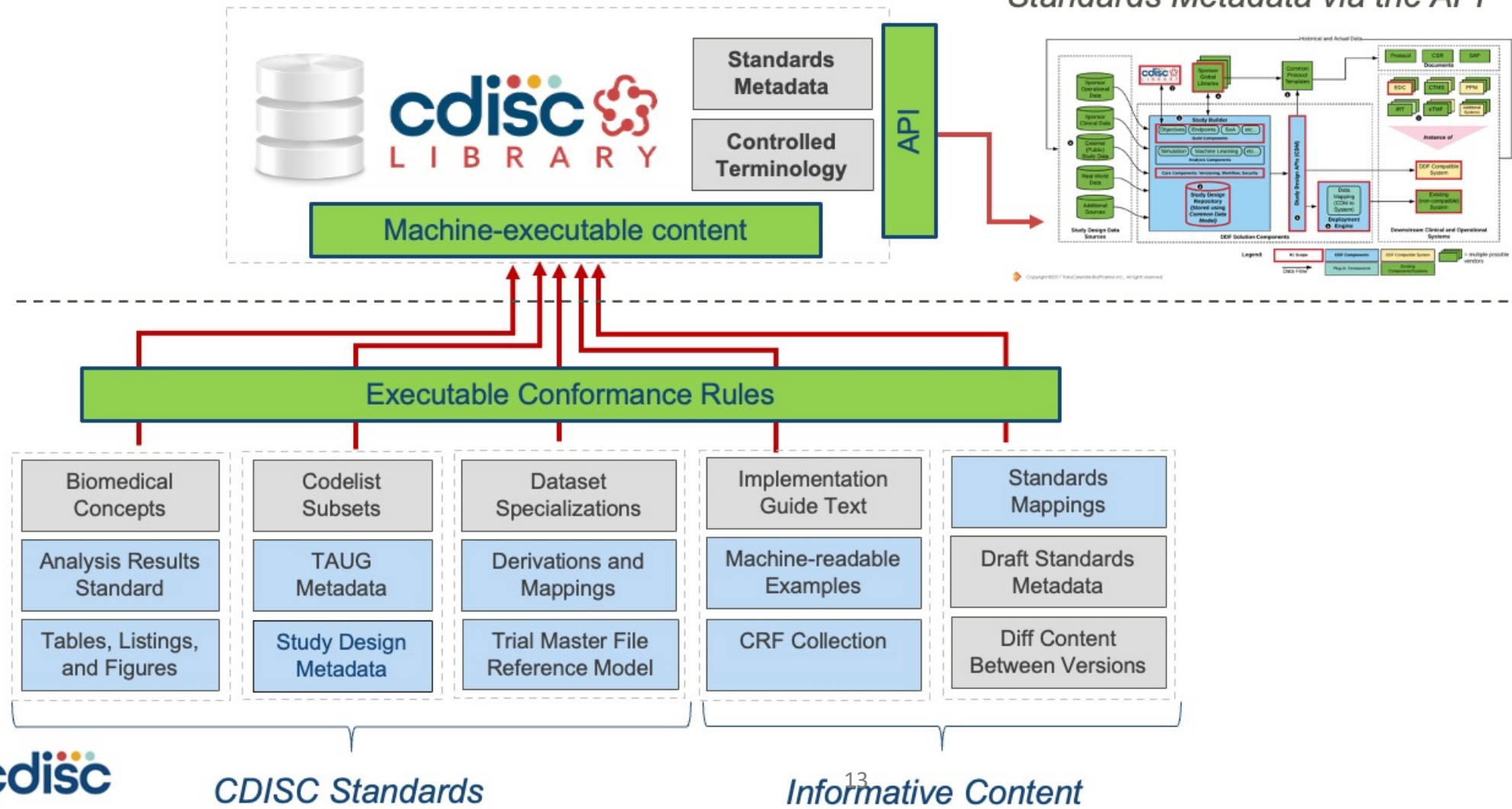
Infectious Diseases - field research data collection and aggregation support

CDISC Membership



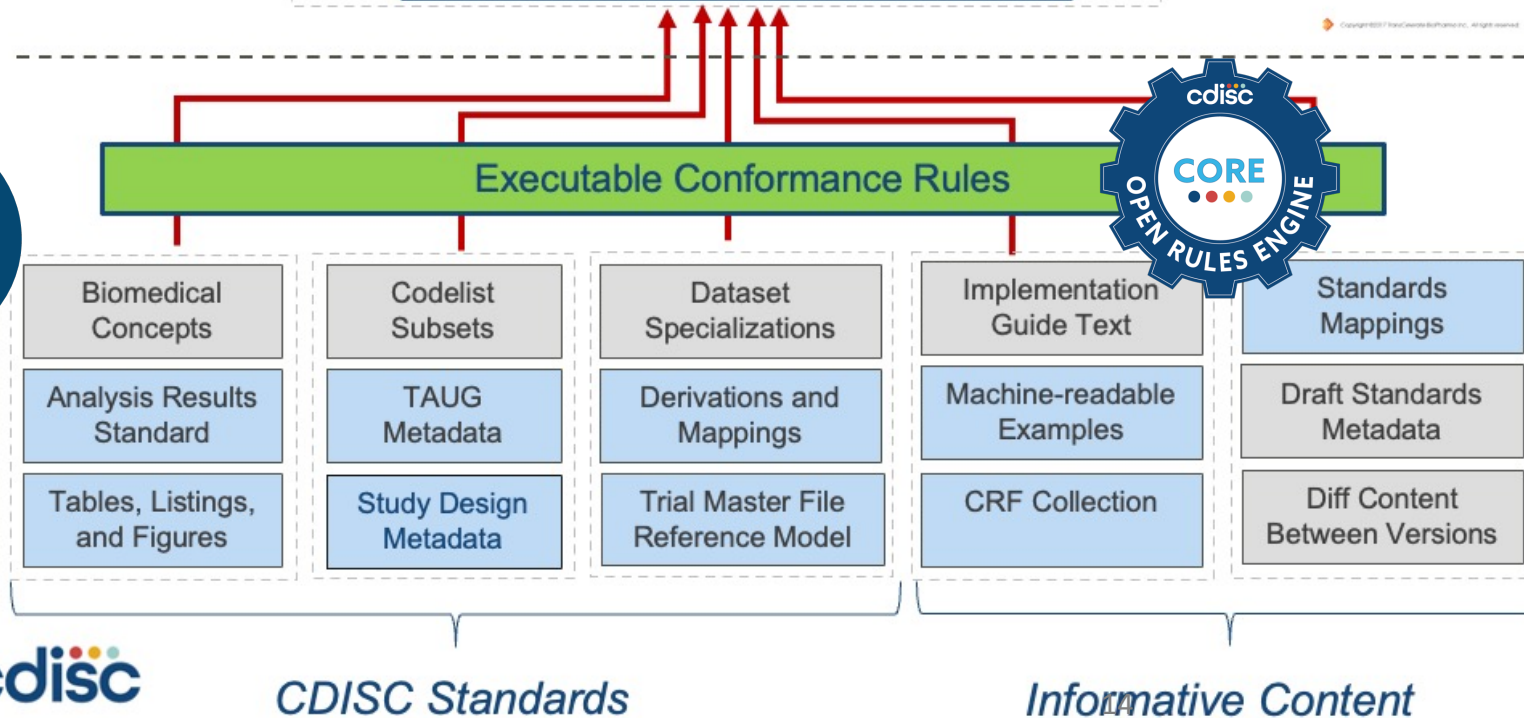
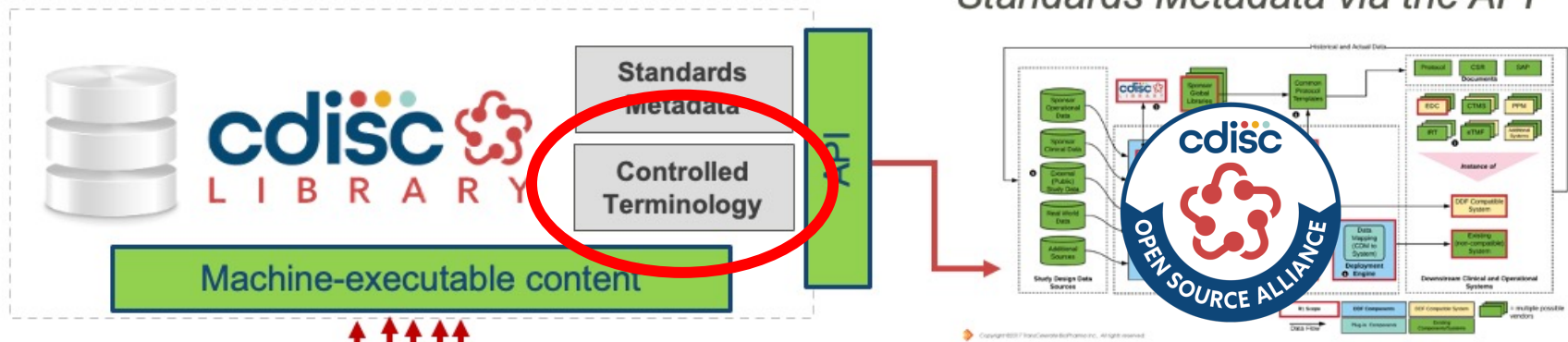
CDISC Library Provides the Foundation

Software Applications Consume Standards Metadata via the API



CDISC Library Provides the Foundation

Software Applications Consume Standards Metadata via the API



CDISC Strategy 2023

- Move towards providing all standards in machine-readable and the technology framework for standards metadata implementations
 - to allow for consistent and contextually accurate representations of clinical research information that can be shared efficiently among the community of researchers, companies and regulators
- Expand development of Biomedical Concepts/Trial Design/Protocol Models
- Create a digital data standards framework to accommodate multiple data collection settings and modalities for RWD
- Expand CDISC standards to address the challenges of RWD sources harmonization while maintaining contextual integrity including expanding the reach of standardized Controlled Terminology
- Expand standards development and maintenance to support clinical operations (e.g., Trial Master File RM) and additional Therapeutic Areas

Benefits of Collaboration

- Consistency
- Accuracy
- Reliability
- Transparency
- Trustworthiness

Efficiency

Dissemination

Governance

Interoperability

The Clinical Research Glossary - Need and Mission

- Before 2020, a resource of consistent, accurate, and simplified definitions for use across the research industry did not exist.
- Identified a need to develop a unified approach that best supports patients, participants and their caregivers.

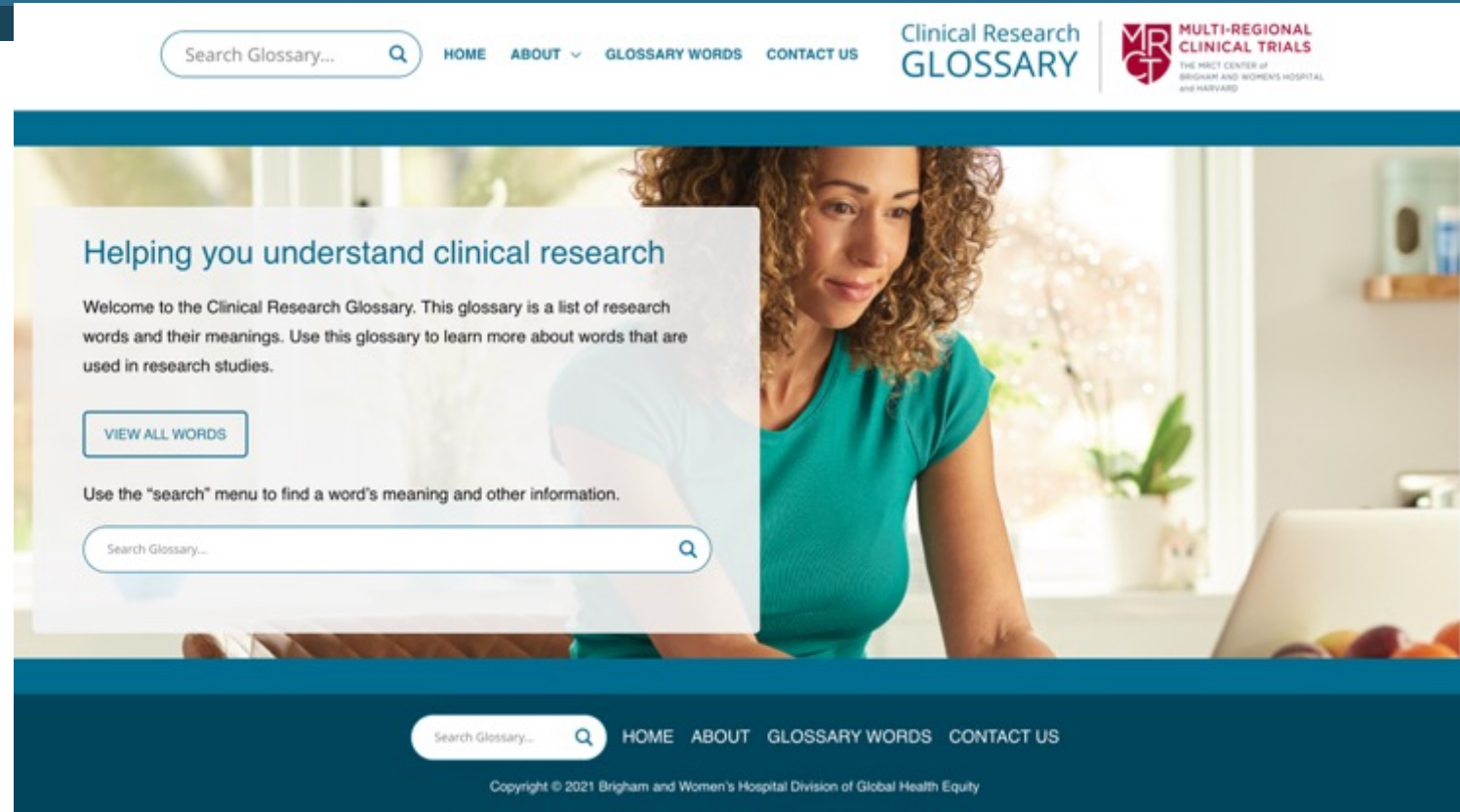
Mission to develop a plain language glossary that includes definitions that are:

- Co-created with patients, participants, and caregivers,
- Designed for public understanding,
- Accepted by industry and academic stakeholders across the clinical research ecosystem,
- Facilitating communication around research.

Clinical Research Glossary - Pilot

- Piloted in 2020
- 53 definitions released in 2021

www.mrctcenter.org/clinical-research-glossary



Baedorf Kassis S, White S, & Bierer B. (2022). [Developing a consensus-driven, plain-language clinical research glossary for study participants and the clinical research community](#). *Journal of Clinical and Translational Science*, 1-20. doi:10.1017/cts.2022.12

Current format for each definition:

Randomization

A way to use chance to place study participants into different study treatment groups.

How to say:  Randomization

Click image to enlarge



USE IN A SENTENCE

Researchers use **randomization** to make sure that study groups are similar and chosen fairly.

MORE INFO

Every **participant** has a chance to be put into one of the study groups. No one can choose which group a participant is placed in, because it is done by a computer program.

Randomization helps make sure the study groups can be compared against each other at the end of the study. This is a way to avoid bias.

WORDS RELATED TO RANDOMIZATION

arm
bias
random assignment
randomize
randomly assigned

WORDS OPPOSITE TO RANDOMIZATION



OTHER RESOURCES

- [Explaining Randomization in Clinical Trials](#)
- [Randomization and Bias in Cancer Clinical Trials](#)

If you know of another resource that could help explain this term, please contact us!

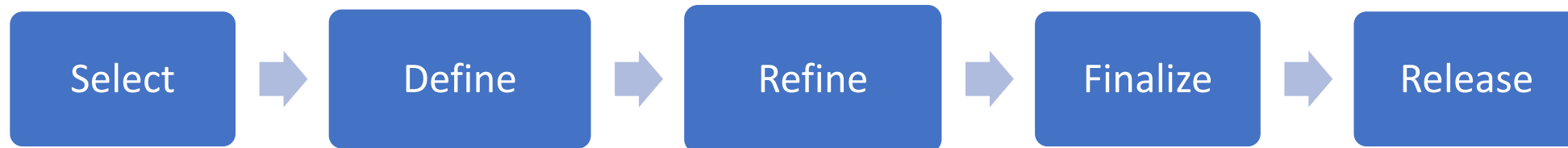
Audience:

- Patients, participants, caregivers, and the public
- People who create research materials for a non-technical audience
- Research sponsors and researchers to use common language

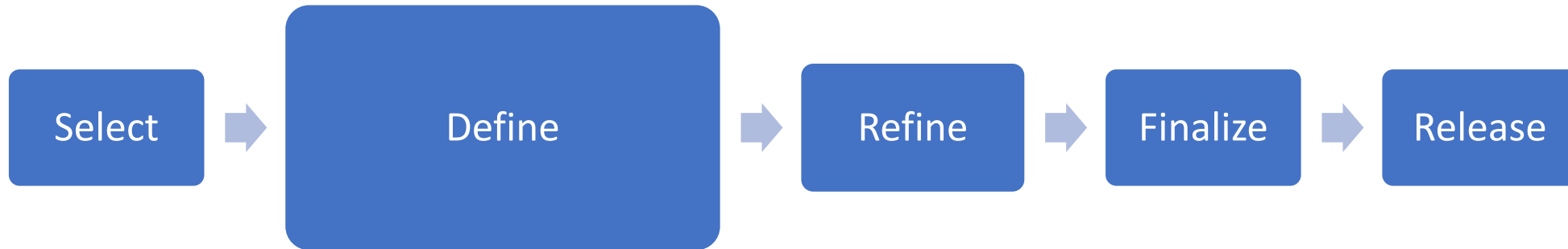
Clinical Research Glossary Expansion Activities

- Goal of 150 new definitions this year
- Diverse Workgroup
 - Development Team (DT)
 - 20+ members
 - Multi-stakeholder, including patient/caregiver advocates
 - CDISC representatives joined in January 2023
 - Review Team (RT)
 - Small group (~6)
 - All patient/caregiver advocates
- Monthly written feedback and consensus conversations

Clinical Research Glossary – Expansion Process to Date

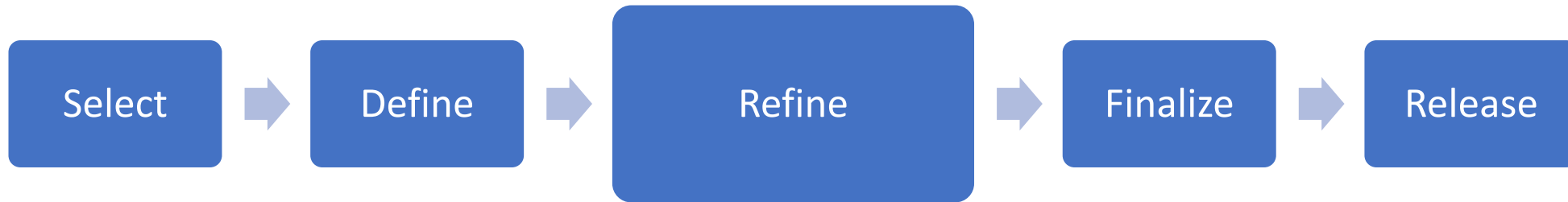


Clinical Research Glossary – How we Define



- * single sentence definition
- * no complex sentences
- * no long sentences
- * no parentheses, symbols, or abbreviations
- * short, simple words
- * tone that is conversational
- * no words or terms that do not change the message of the sentence
- * active voice whenever possible

Clinical Research Glossary – How we Refine



Clarity – is the content clear?

Accuracy – is the content accurate?

Consistency – is the content consistent with other similar glossary definitions?

Plain language – is the content in plain language?

Understandability – is the content understandable to patients/participants?

Agreement – does the content agree with other authoritative definitions?

Context – can the content be used across research contexts?

Other – are there any other concerns not noted above?

Can I accept this definition?

Reflections on the MRCT Center Process



What makes this process work

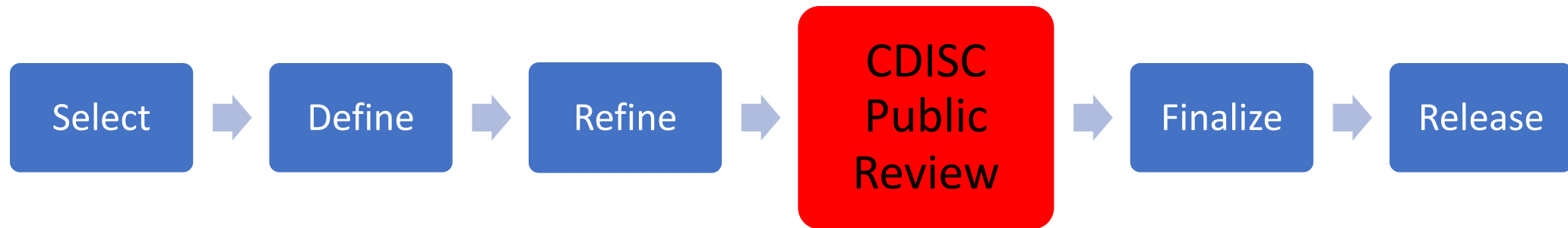
- Robust consideration of usage context
- Respect for lay perspectives
- Diversity of experienced perspectives



What this process, and collaboration with CDISC, means for patients

- Validated definitions
- Trustworthy and vetted content
- Bi-Directional knowledge exchange

Clinical Research Glossary – New addition starting March 2023



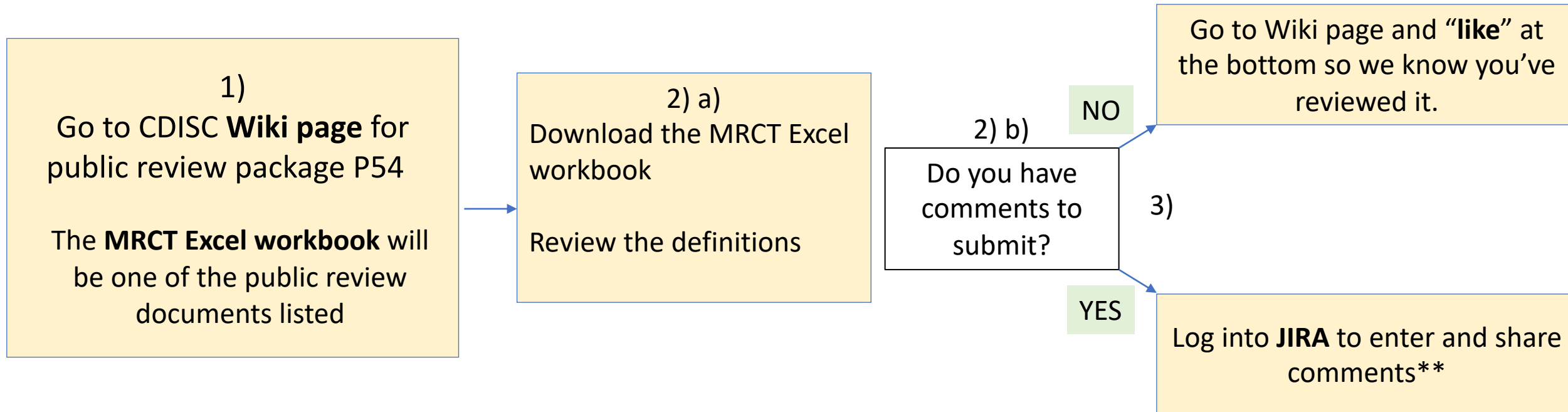
CDISC Public Review Process

The screenshot shows the CDISC Wiki interface. The top navigation bar includes the CDISC logo, 'Wiki Spaces', a search bar, and 'Log in Sign up' links. The left sidebar contains a 'Controlled Terminology (CT)' logo, 'SPACE SHORTCUTS' with a 'File lists' link, a search box, and a 'PAGE TREE' with a list of items including 'Guiding Principles', 'Public Review' (expanded to show 'Terminology Call for Public Review'), 'Terminology Teams', 'Change Control Logs', 'Requests Denied', 'CDISC CT Meeting Minutes', 'CDISC Controlled Terminology Anr', 'SDTMIG and SDS Team Work', and 'File lists'. The main content area has a breadcrumb 'Pages / Controlled Terminology / Public Review' and a title 'Terminology Call for Public Review Package P54 - Comments Due by 21 Apr 2023'. Below the title is the text 'Created by Ann White, last modified by Erin Muhlbradt on Mar 30, 2023'. The main text states 'CDISC invites you to submit comments during the Public Review for Controlled Terminology Package 54, which consists of the following 20 documents:' followed by a bulleted list: 'Controlled_Terminology_Requests_Denied_P54', 'IS Terminology Mapping Codetable_P54', 'QRS Naming and Business Rules', 'Rules for Immunogenicity Specimen Tests', 'Rules for MB and MS', 'Rules for PK', 'ADaM', 'Biospecimens', 'Cell Phenotyping', 'CV*', 'Define-XML', 'General', 'Lab*', 'Microbiology-Immunology', 'MRCT Plain Language Glossary (New!)', 'Oncology', 'PK', 'Protocol Entities', 'SEND', and 'UNIT'. A note below the list says 'An * indicates that changes or retirements of existing CDISC Submission Values are included on the "Changes to Existing" tab in the document. Please review these changes as there may be submission value changes or term deprecations.' At the bottom of the main content area are the sections 'Comments due: 21 Apr 2023' and 'Instructions for Reviewers'. The left sidebar also has 'Space tools' at the bottom.

Reviewers register and log into the CDISC WIKI to comment via JIRA

<https://wiki.cdisc.org/display/CT/Terminology+Call+for+Public+Review+Package+P54+--+Comments+Due+by+21+Apr+2023>

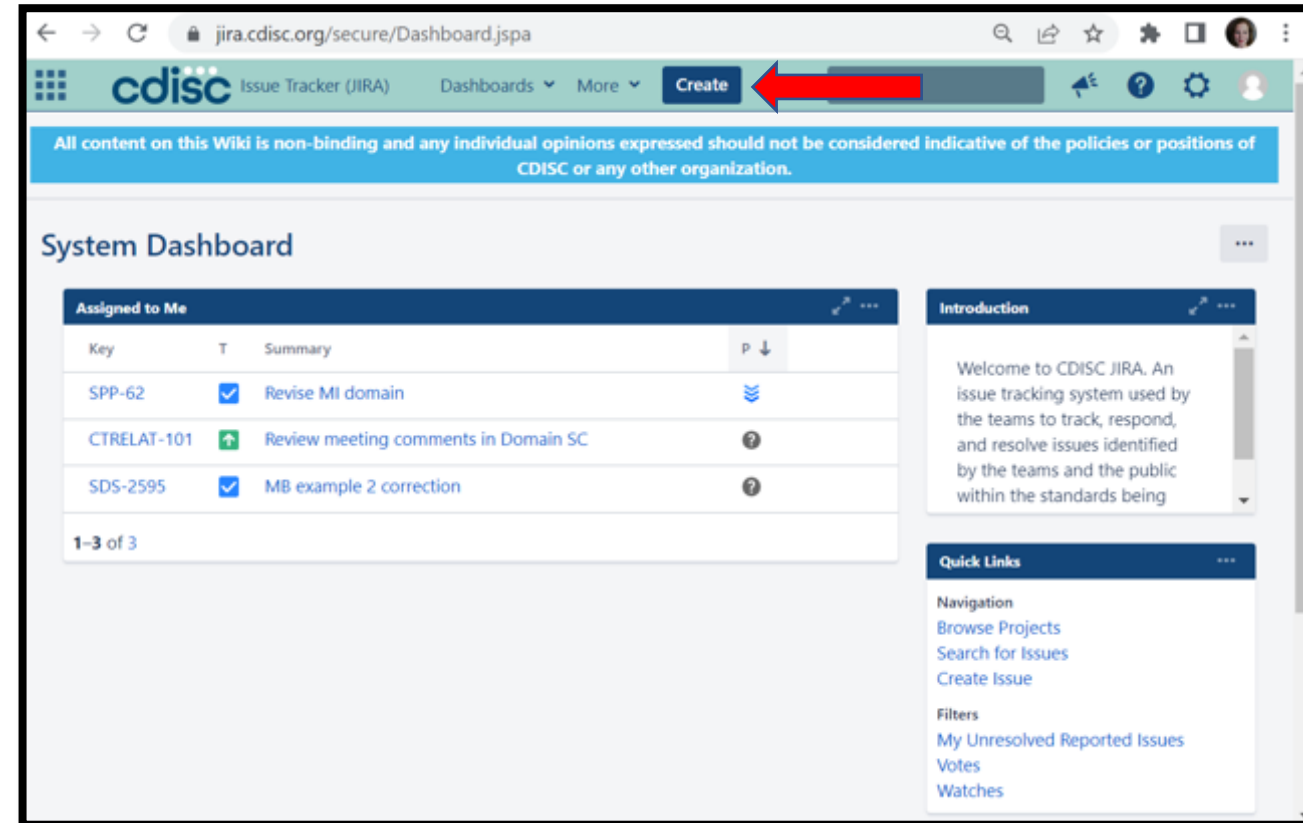
3 Steps for Public Review



** If you have difficulty with the JIRA process you can also provide feedback by email
muhlbradtee@mail.nih.gov

JIRA - How to Submit Comments through CDISC JIRA

- Navigate to the CDISC page:
<https://jira.cdisc.org/secure/Dashboard.jspa>
 - This will require a login
- Once you are logged into JIRA
 - Click on 'Create' button at the top of the page



← → ↻ 🔒 jira.cdisc.org/secure/Dashboard.jspa

cdisc Issue Tracker (JIRA) Dashboards More Create

All content on this Wiki is non-binding and any individual opinions expressed should not be considered indicative of the policies or positions of CDISC or any other organization.

System Dashboard

Key	T	Summary	P ↓
SPP-62	✓	Revise MI domain	☰
CTRELAT-101	↑	Review meeting comments in Domain SC	?
SDS-2595	✓	MB example 2 correction	?

1-3 of 3

Introduction

Welcome to CDISC JIRA. An issue tracking system used by the teams to track, respond, and resolve issues identified by the teams and the public within the standards being

Quick Links

Navigation
Browse Projects
Search for Issues
Create Issue

Filters
My Unresolved Reported Issues
Votes
Watches

Create a JIRA Issue (1 of 2)

- Project (Dropdown)
 - *Controlled Terminology (CT)*
- Issue Type (Dropdown)
 - *Review Comments*
- Summary (*Free Text*)
- Component/s (Dropdown)
 - *MRCT*
- Package (Dropdown)
 - *54*
- Description (*Free Text*)
- Review Period
 - *Public Review*

The screenshot shows the 'Create Issue' form in JIRA. At the top right, there are buttons for 'Select Template' and 'Configure Fields'. Below this, a note states 'All fields marked with an asterisk (*) are required'. The form fields are as follows:

- 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 with a search prompt: 'Start typing to get a list of possible matches or press down to select.'
- Package**: A dropdown menu showing 'None'.
- Fix Version/s**: A dropdown menu showing 'None'.
- Description**: A rich text editor with a toolbar containing options for style, bold, italic, underline, link, unlink, list, and image. Below the editor are 'Visual' and 'Text' tabs.
- Review Period**: A dropdown menu showing 'None'.
- Labels**: A dropdown menu with a search prompt: 'Begin typing to find and create labels or press down to select a suggested label.'

At the bottom right of the form, there are three buttons: 'Create another' (with a checkbox), 'Create', and 'Cancel'.

Create a JIRA Issue (2 of 2)

- 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.

Trouble entering feedback?

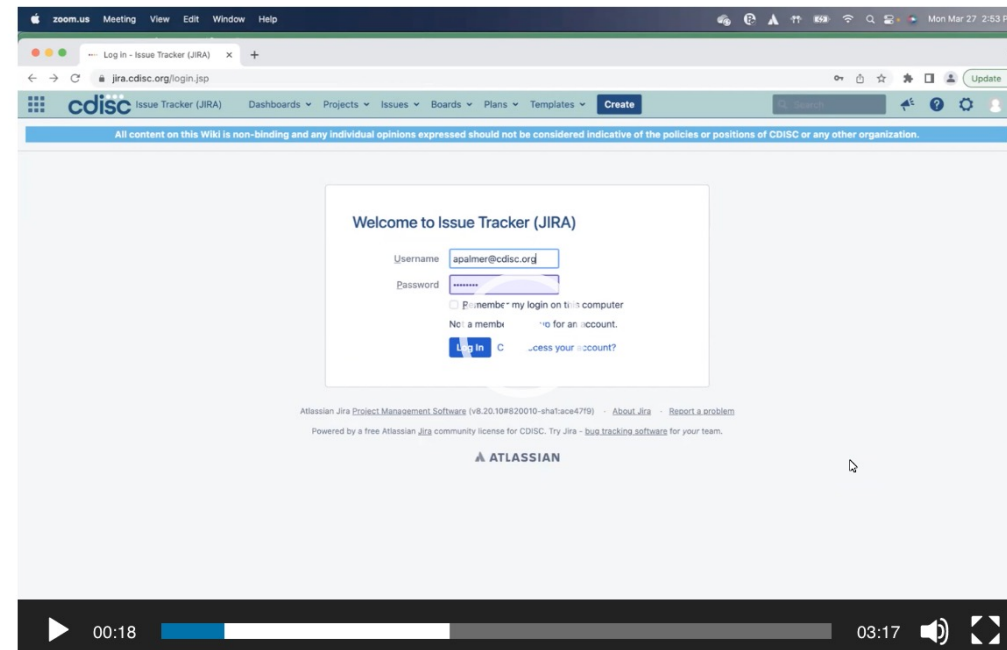
- *Please contact Dr. Erin Muhlbradt who can submit JIRAs on your behalf:
muhlbradtee@mail.nih.gov*

The screenshot shows the 'Create Issue' form in JIRA. At the top right, there are buttons for 'Select Template' and 'Configure Fields'. Below the title, a note states 'All fields marked with an asterisk (*) are required'. The form includes the following fields: 'Project' (Controlled Terminology (CT)), 'Issue Type' (Review Comments), 'Summary' (text input), 'Component/s' (dropdown), 'Package' (None), 'Fix Version/s' (None), 'Description' (rich text editor with 'Visual' and 'Text' tabs), 'Review Period' (None), and 'Labels' (dropdown). At the bottom right, there are three buttons: 'Create another' (with a checkbox), 'Create', and 'Cancel'. A green bracket highlights the 'Create another' and 'Create' buttons. A green line points from the 'Create another' button to the 'Labels' field, which is crossed out with a red 'X'.

HOW TO SUBMIT COMMENTS ON GLOSSARY DEFINITIONS VIA JIRA (VIDEO)

Date: March 30, 2023

Description: Clinical Data Interchange Standards Consortium (CDISC) offers a quarterly public review period, a time when feedback on its new standards can be collected from its users. The plain language definitions developed for the MRCT Center Clinical Research Glossary will be included as a CDISC standard starting in 2023 and will go through a public review process. This helpful video explains how to submit public comments to JIRA, a software application that tracks comments in an organized way.



<https://mrctcenter.org/blog/resources/how-to-jira-video/>

Clinical Research Glossary – What's Next

- Respond to March/April public review feedback.
- Continue developing definitions and content.
- Prepare for the June public review period.
- Develop a new glossary website with improved search functionality and usability.
- Release the updated MRCT Center Clinical Research Glossary with the CDISC plain language standard at the end of 2023.
- Ongoing considerations for translation into additional languages.

In Summary

- This collaboration with CDISC offers broadened dissemination and uptake opportunities, and a chance to hear directly from users.
- We will work together to meet the goal of releasing a new website with all our defined words plus all the definitions available as a CDISC standard by the end of 2023.
- New content will continue to be developed and added in 2024 and beyond....
- We encourage you to take part in the Public Review and use the glossary!

Thank you to our Expert Advisory Committee (EAC)

Current Members:

- Annlouise Assaf, Pfizer
- Jay Duhig, Abbvie
- Lori Hall, Legacy Health Strategies
- Julie Holtzople, AstraZeneca
- Barbara Kress, Merck
- Elisabeth Oehrlein, Applied Patient Experience
- Marian Ryan, Institute for Healthcare Advancement
- Karlin Schroeder, Parkinson's Foundation
- Christopher Trudeau, University of Arkansas
- Tianna Umann, Microsoft
- Robert Weker, Patient Advocate

Thank you to the workgroup members who contributed to the pilot

Behtash Bahador

Sarah Balay

Stephen Carr

Jessica Chaikof

Lisa Chamberlain James

Deborah Collyar

Jean-Marc Ferran

Helle Gawrylewski

Art Gertel

Lauren Hamill

Shannon Hamill

Julie Holtzople

Marilyn Neault

Elyssa Ott

Brandis Pickard

Robyn Rennick

Marian Ryan

T.J. Sharpe

Kamila Sroka-Saidi

Mary Stober Murray

Gloria Stone

Michelle Teufel

Desiree A.H. Walker

Robert Weker

Thank you to our current workgroup

Development Team

Behtash Bahador, *CISCRP*

Rebecca Baker, *CDISC*

Lisa Chamberlain James, *Trilogy Writing*

R Bernard Coley, *Advocate*

Deborah Collyar, *PAIR/Advocate*

Scott Finger, *CISCRP*

Helle Gawrylewski, *Hawkwood Consulting, LLC*

Art Gertel, *MedSciCom, LLC*

Julia Hild, *Boehringer-Ingelheim*

Monica Helton, *Eli Lilly*

Maureen Kashuba, *Merck & Co.*

Kevin Kwok, *Advocate*

Rena Lubker, *Medical University of South Carolina*

Keri McDonough, *Syneos*

Alice Miller, *Syneos*

Erin Muhlbradt, *NCI Enterprise Vocabulary Services*

Marilyn Neault (co-lead), Advocate

Robyn Rennick, *GlaxoSmithKline*

Harold Silverman, *argenx*

Gloria Stone, *G Stone Connections*

Jamie Tyrone, *Advocate*

Cornelia Weiss-Haljiti, *Boehringer-Ingelheim*

Review Team

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Jessica Chaikof, *Advocate*

Talia Cohavi, *Advocate*

Maura Cummings, *Advocate*

Anne Marie Mercurio, *Advocate*

Kimberly Richardson, *Advocate*

TJ Sharpe, *Advocate*

Desiree Walker (co-lead), Advocate

Time for questions

Join us:



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MRCTcenter.org



Thank you!