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 cdisc 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

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

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

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Panelist Introductions

Sylvia Baedorf Kassis, MPH
MRCT Center

R. Bernard Coley, JD, MBA
Advocate

Dave Evans, MS
CDISC

Erin Muhlbradt, PHD
NCI EVS

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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

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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

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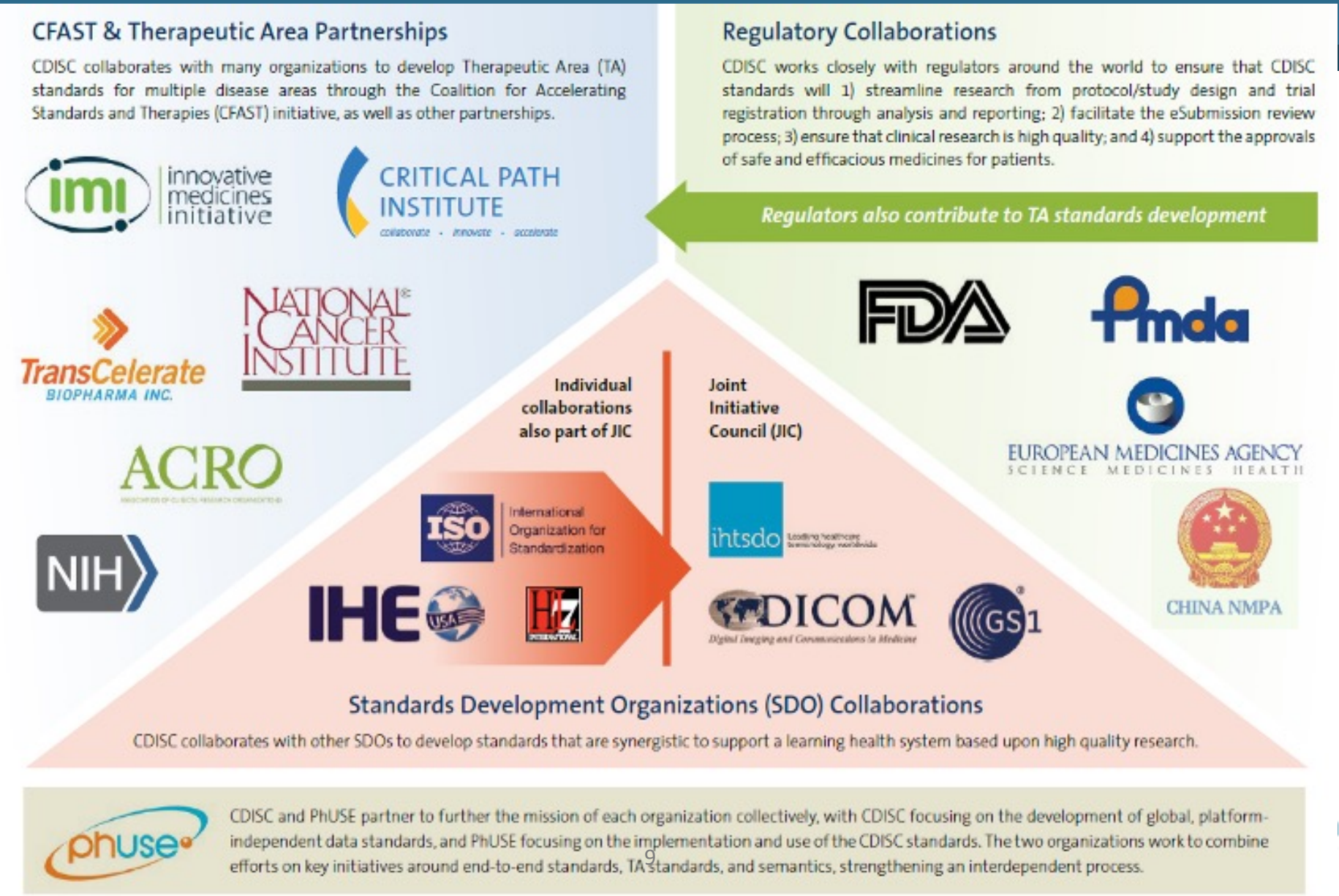
Introducing CDISC

- 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



phuse

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

TRANSFoRm

Mobile patient reported outcomes (PRO)

eTRIKS

Standards Starter Pack Curation pipeline to TransMART

CORBEL

Data sharing recommendations

EHR4CR

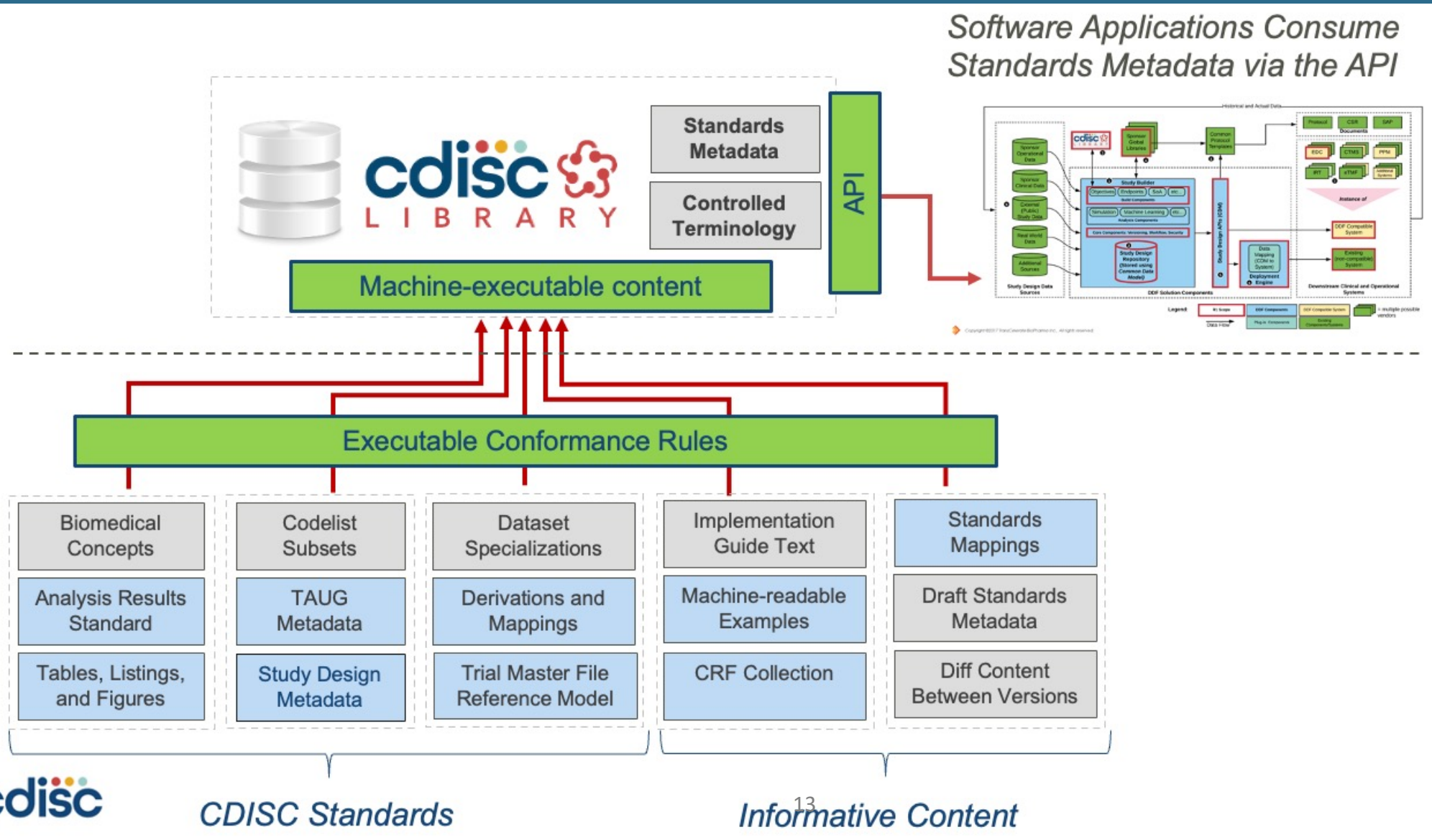
Use of standardized data for research sourced from multiple EHRs

UNIVERSITY OF OXFORD

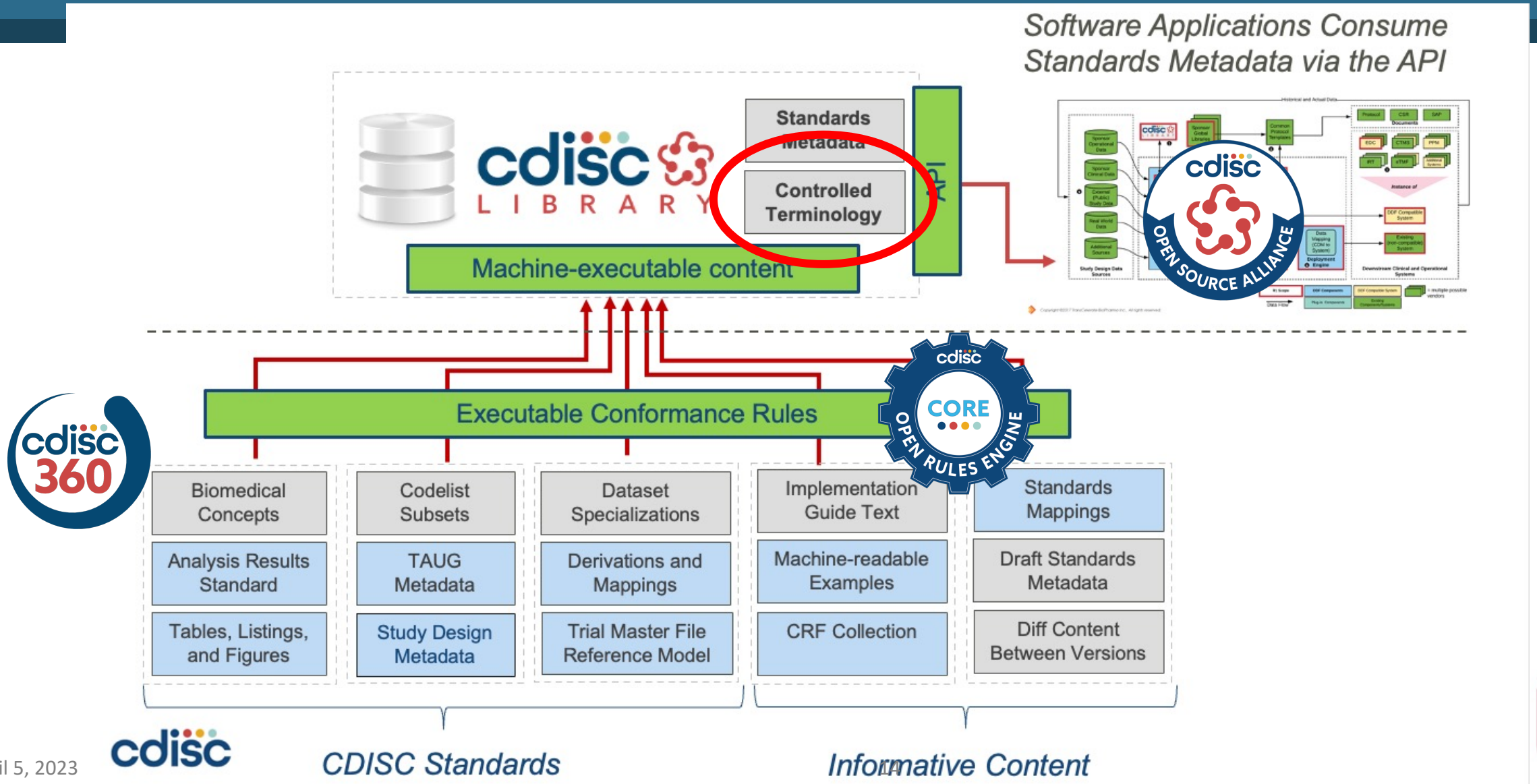
Infectious Diseases - field research data collection and aggregation support

CDISC Membership

CDISC Library Provides the Foundation



CDISC Library Provides the Foundation



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

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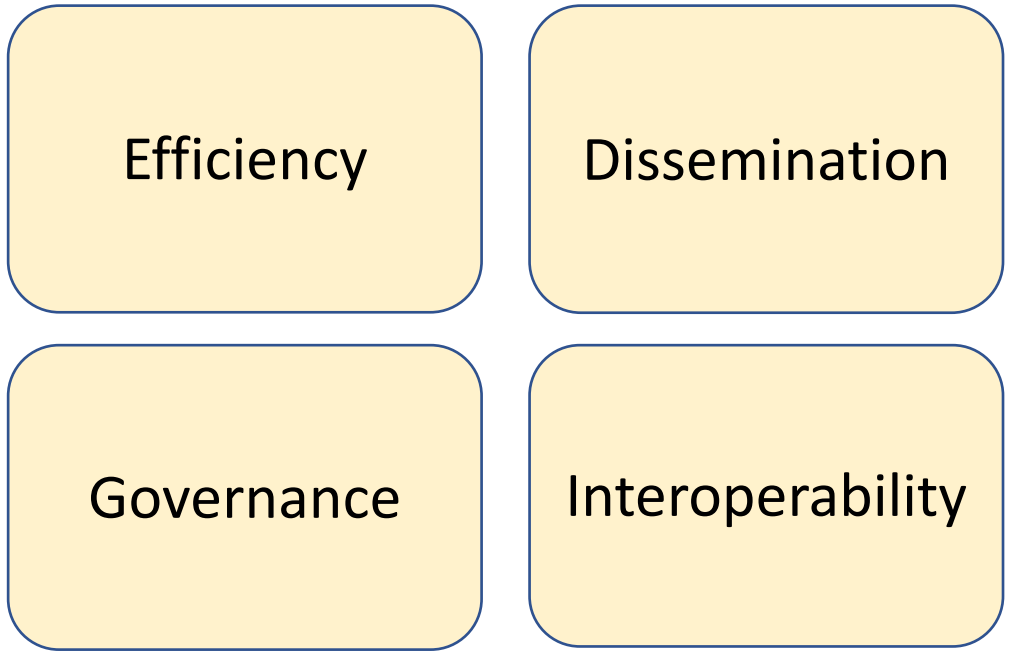
Benefits of Collaboration

- Consistency
- Accuracy
- Reliability
- Transparency
- Trustworthiness



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.

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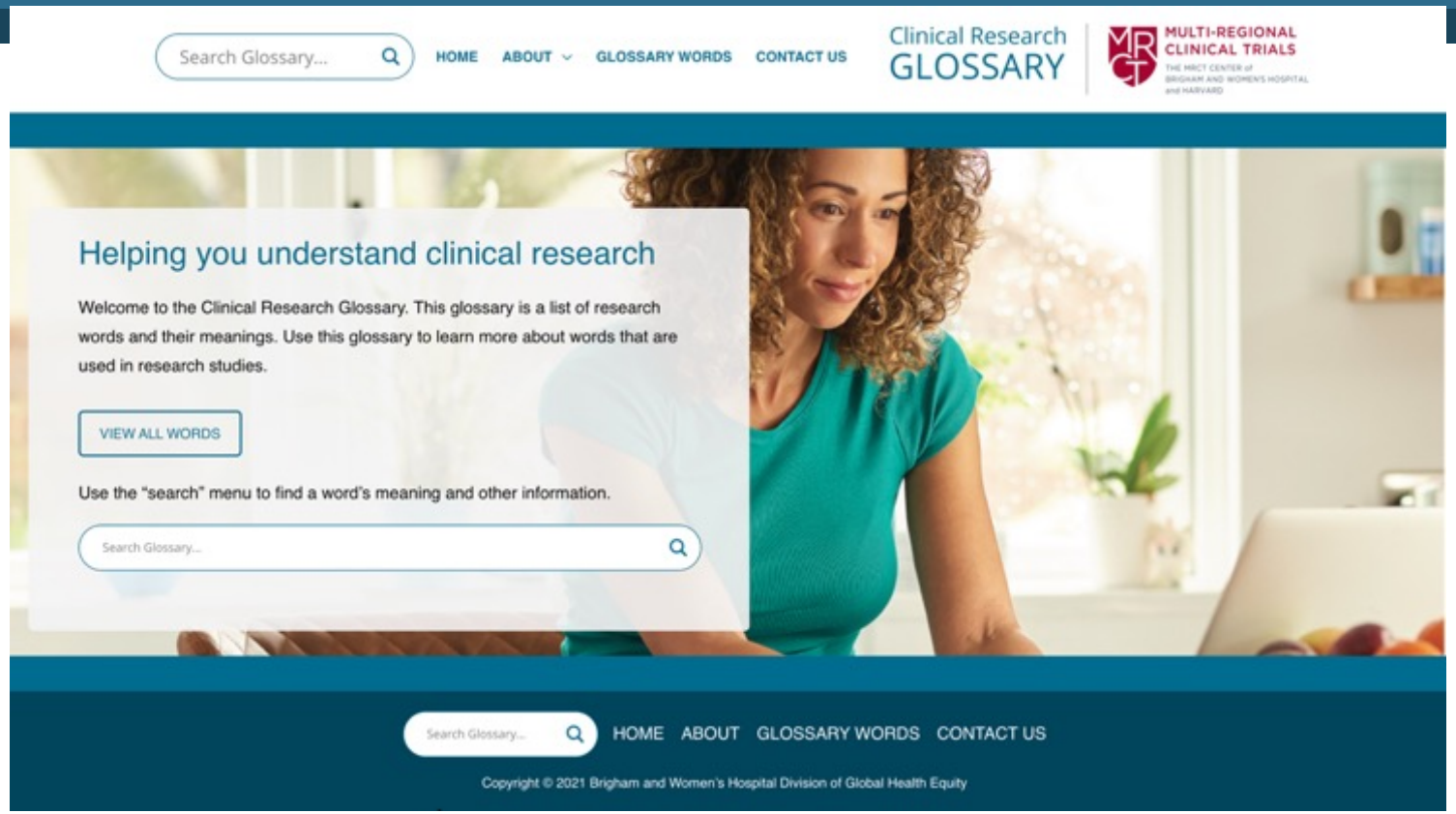
Clinical Research Glossary - Pilot

- 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

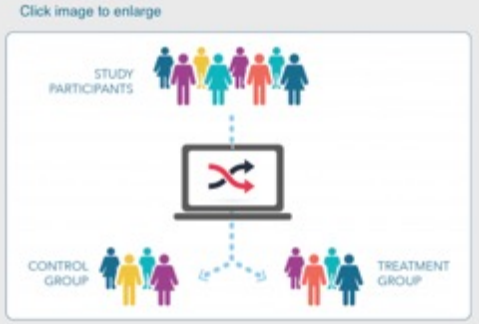
Current format for each definition:

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

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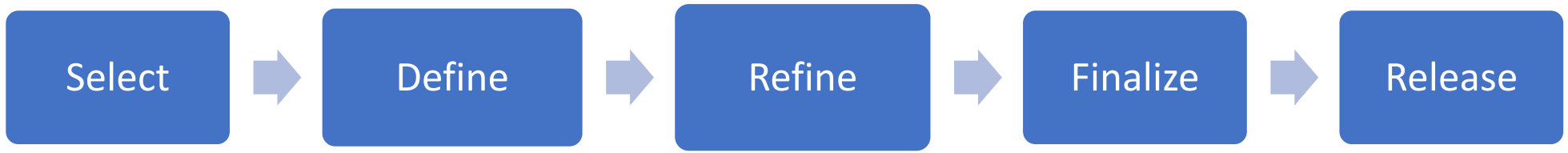
Clinical Research Glossary – Expansion Process to Date



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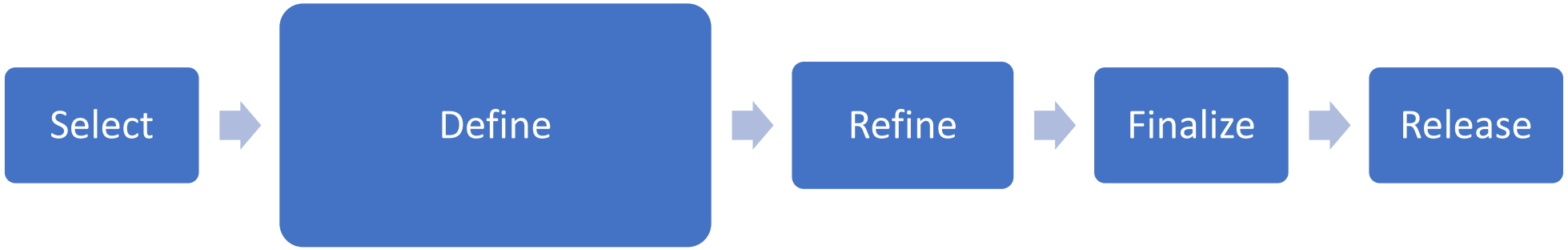
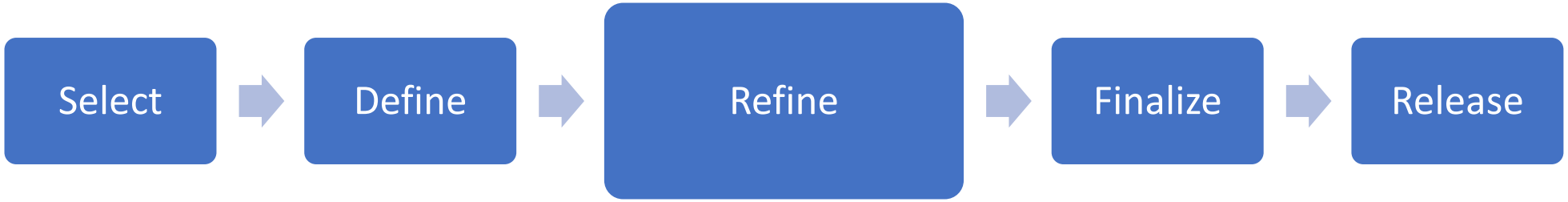
Clinical Research Glossary – How we Define



* 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

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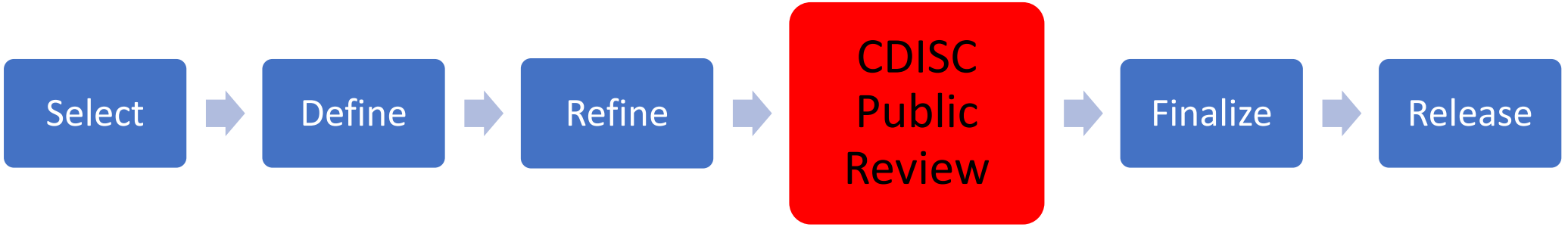
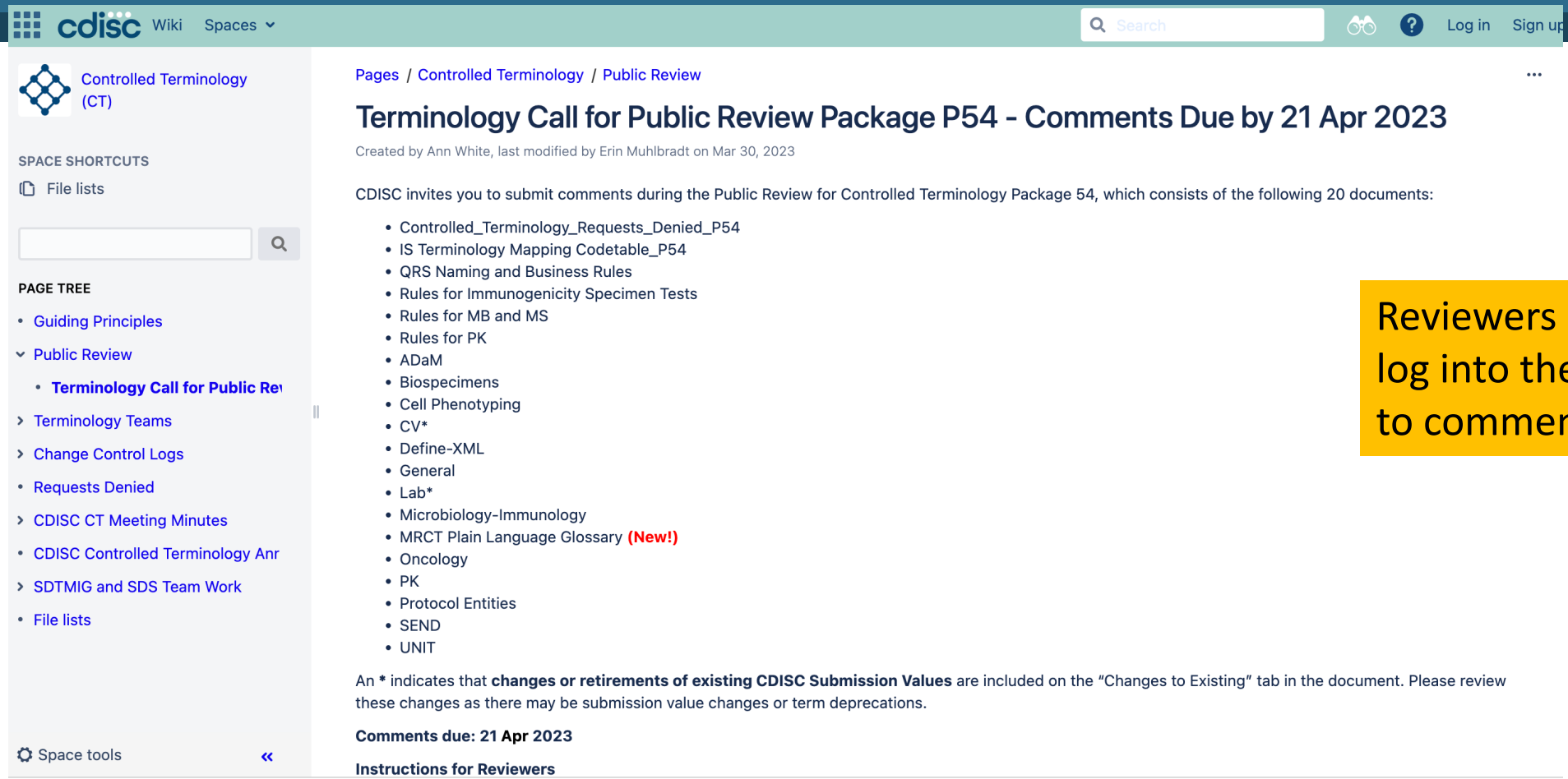
Clinical Research Glossary – New addition starting March 2023



CDISC Public Review Process



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

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3 Steps for Public Review

1)
Go to CDISC **Wiki page** for public review package P54

The **MRCT Excel workbook** will be one of the public review documents listed

2) a)
Download the MRCT Excel workbook

Review the definitions

2) b)
Do you have comments to submit?

NO

Go to Wiki page and "**like**" at the bottom so we know you've reviewed it.

3)

YES

Log into **JIRA** to enter and share comments**

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

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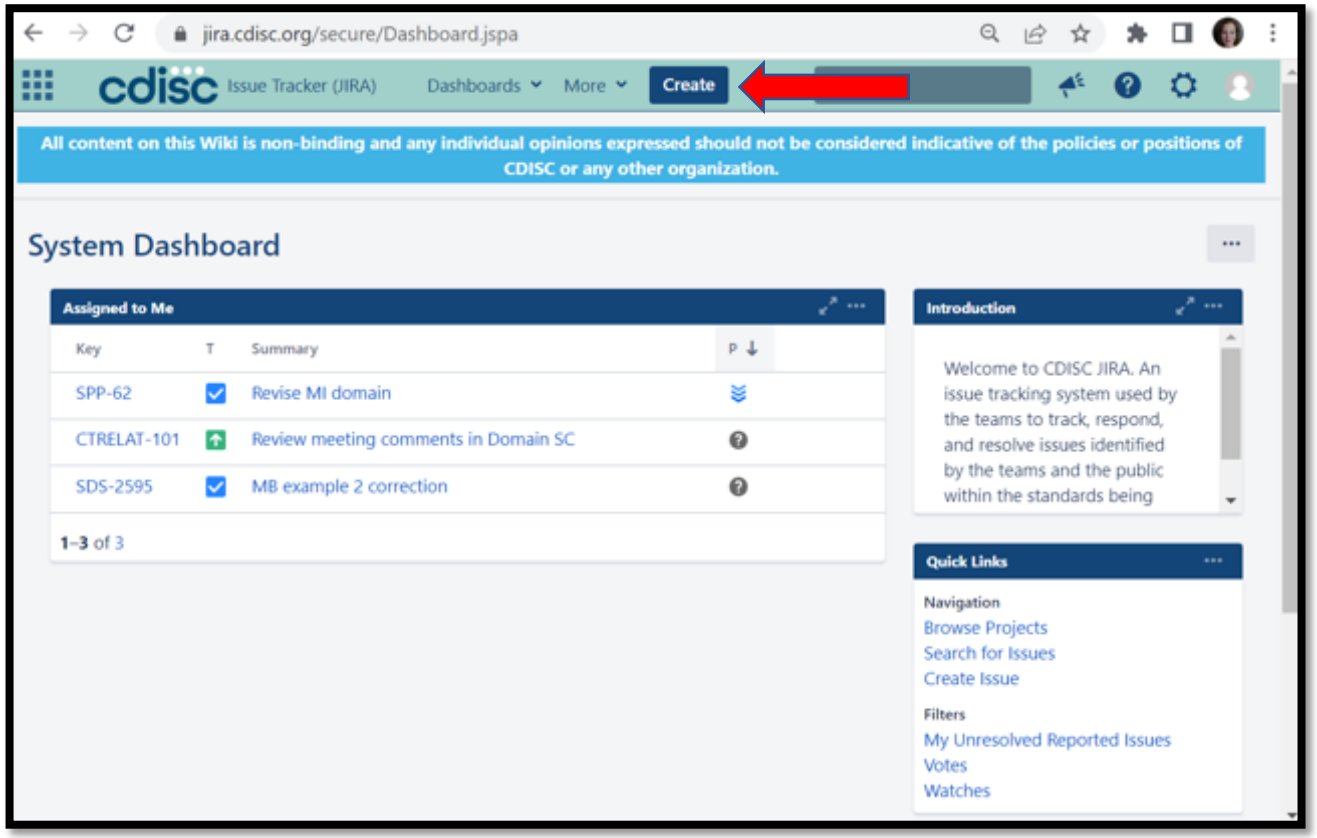
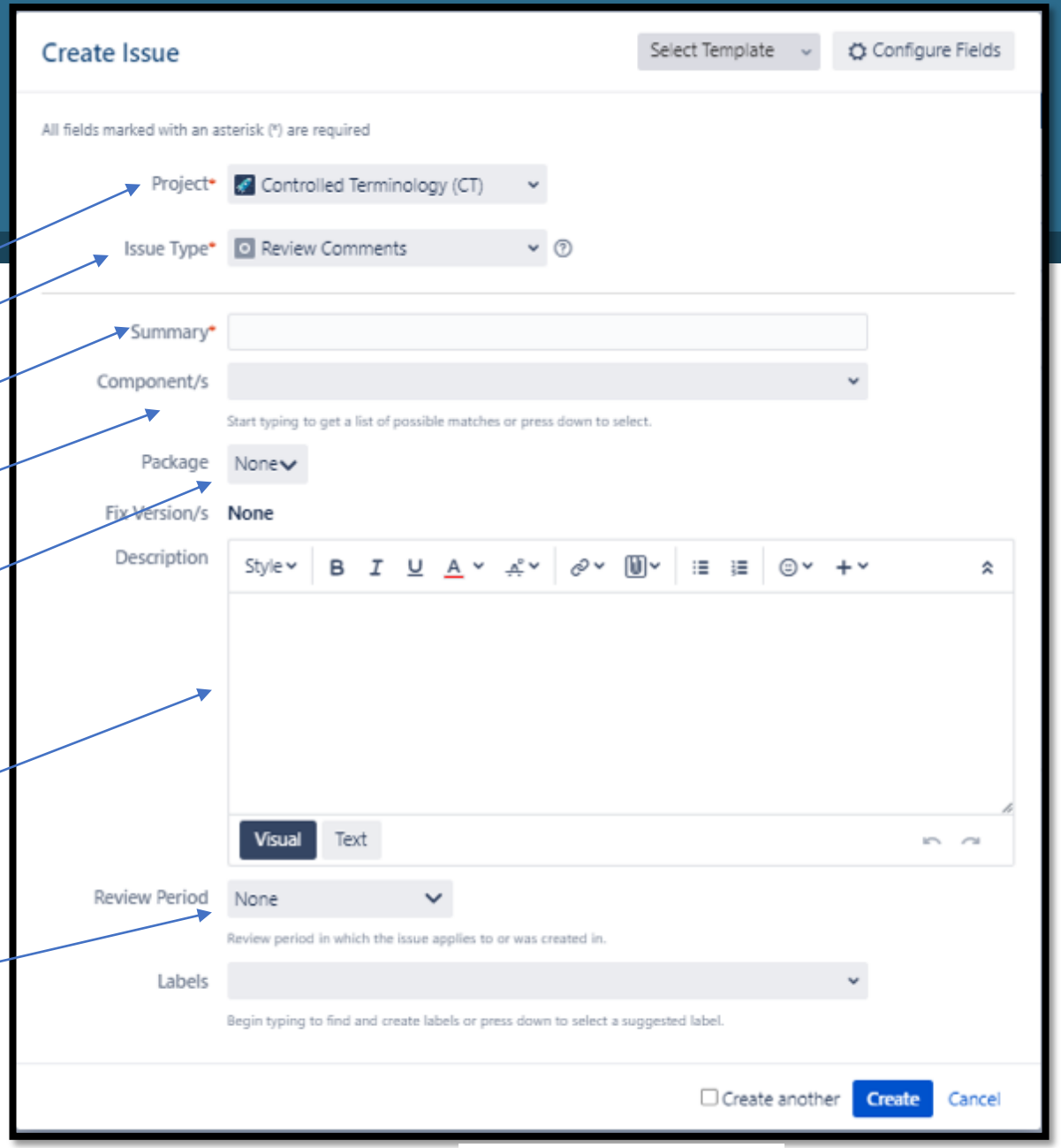
JIRA - How to Submit Comments through CDISC JIRA

- 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



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*



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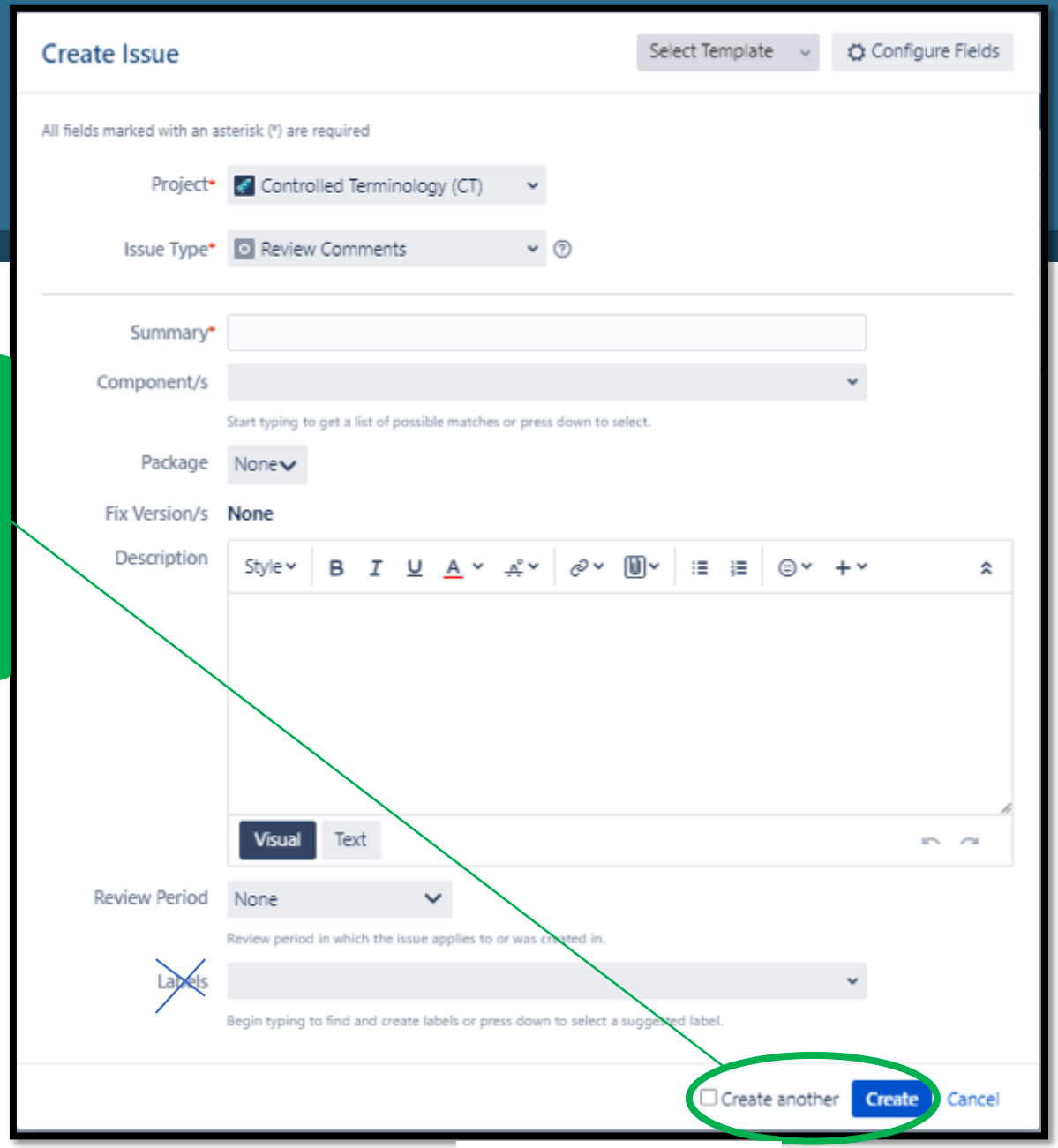
Create a JIRA Issue (2 of 2)

- 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?

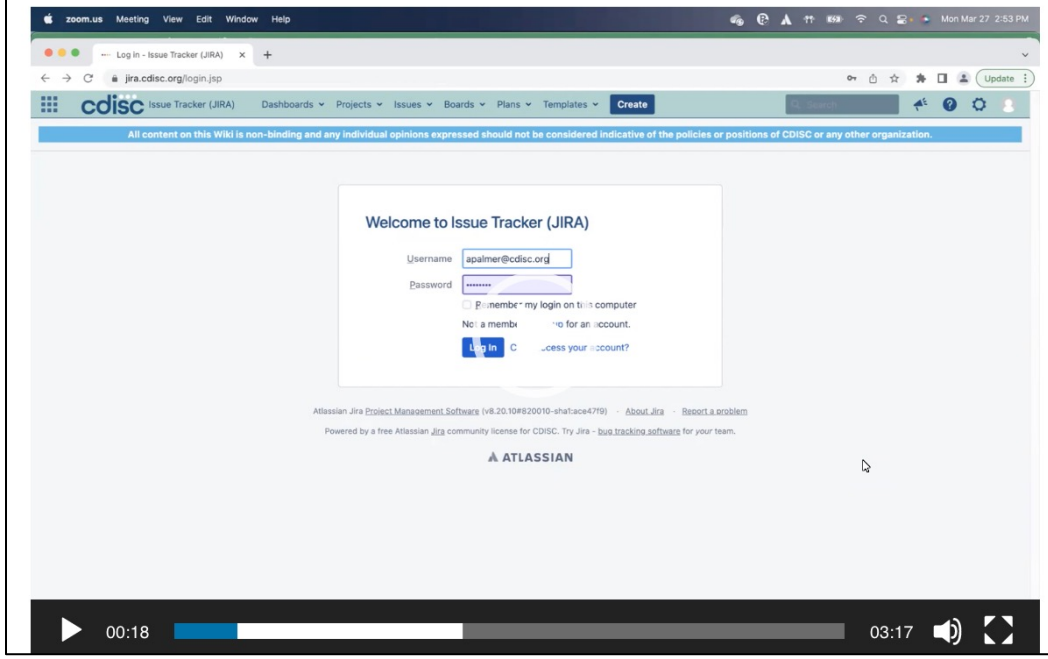
- *Please contact Dr. Erin Muhlbradt who can submit JIRAs on your behalf: muhlbradtee@mail.nih.gov*

Extra Help

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!

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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*
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Harold Silverman, *argenx*
Gloria Stone, *G Stone Connections*
Jamie Tyrone, *Advocate*
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Maura Cummings, *Advocate*
Anne Marie Mercurio, *Advocate*
Kimberly Richardson, *Advocate*
TJ Sharpe, *Advocate*
Desiree Walker (co-lead), *Advocate*

Time for questions

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Join us:

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Thank you!