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2023
US
INTERCHANGE
FALLS CHURCH, VA | 18-19 OCTOBER

Digging Deeper into CDISC's new Global Standard for Plain Language in Clinical Research

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Meet the Speaker

Sylvia Baedorf Kassis, MPH

Title: Program Director

Organization: The Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (MRCT Center)

Sylvia Baedorf Kassis, MPH is a clinical research professional with 24 years of experience in a variety of academic clinical research roles.

Over the past 6 years, she has had the privilege of focusing her career on health literacy and participant engagement efforts in the clinical research space, effectively facilitating initiatives that unite divergent perspectives into deliverables that offer harmonized and practical solutions to real-world challenges.

When Sylvia is not working, she enjoys hiking, paddle boarding, creative writing, painting, and playing the violin.

Disclaimer and Disclosures

- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC, Brigham and Women's Hospital or Harvard University.*

Agenda

1. A Quick Overview of the MRCT Center
2. Health Literacy in Clinical Research Timeline
3. Introducing the Clinical Research Glossary and Process
4. What's Next….

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.

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How it all Started – Return of Results…

2013-2017

MRCT Center led efforts to develop resources supporting the return of results and data (aggregate and individual) to participants.

In particular, EU Plain Language Summary requirements prompt conversations about health literacy.

2017 -

The guidance document, and related toolkit, was released:

http://mrctcenter.org/wp-content/uploads/2017/03/2017-03-20-MRCT-Return-of-Aggregate-Results-Guidance-Document-3.0.pdf

http://mrctcenter.org/wp-content/uploads/2017/03/2017-03-13-MRCT-Return-of-Aggregate-Results-Toolkit-3.0.pdf

… Inspired a Commitment to Health Literacy…

2018-2019 - Developed a publicly available Health Literacy in Clinical Research website

www.mrctcenter.org/health-literacy

2019 (to present) – Started designing and delivering health literacy trainings

2020 - Developed COVID-19 research pamphlets

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

2020-2021 – Developed and launched the pilot version of the Clinical Research Glossary through an agile iterative process with stakeholders, including patients and their allies

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

2022 – Clinical Research Glossary expansion efforts began

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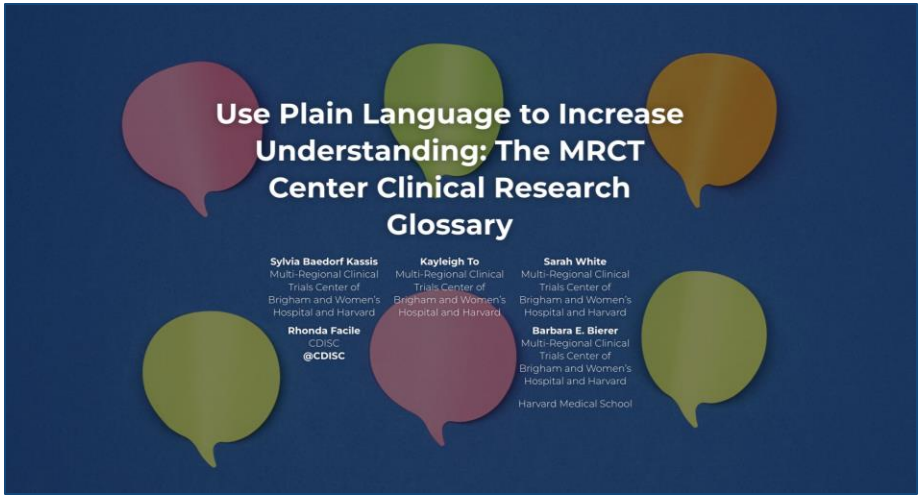
…Leading to a New Collaboration being Forged

2022 – Collaboration with CDISC began.

2023 – CDISC & MRCT Center partnership officially launched.



https://globalforum.diaglobal.org/issue/april-2023/use-plain-language-to-increase-understanding-the-mrct-center-clinical-research-glossary/

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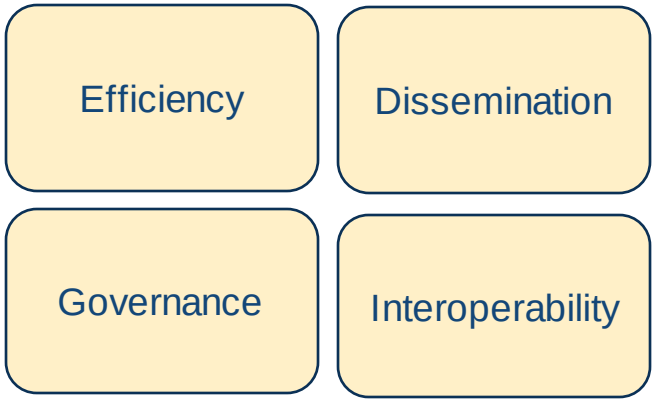
Specific Benefits of Collaboration

The MRCT Center Clinical Research Glossary provides:

- Consistency
- Accuracy
- Reliability
- Transparency
- Trustworthiness

CDISC, specifically, offers:



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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.
- A need for a unified approach that best supports patients, participants, and their caregivers was identified.

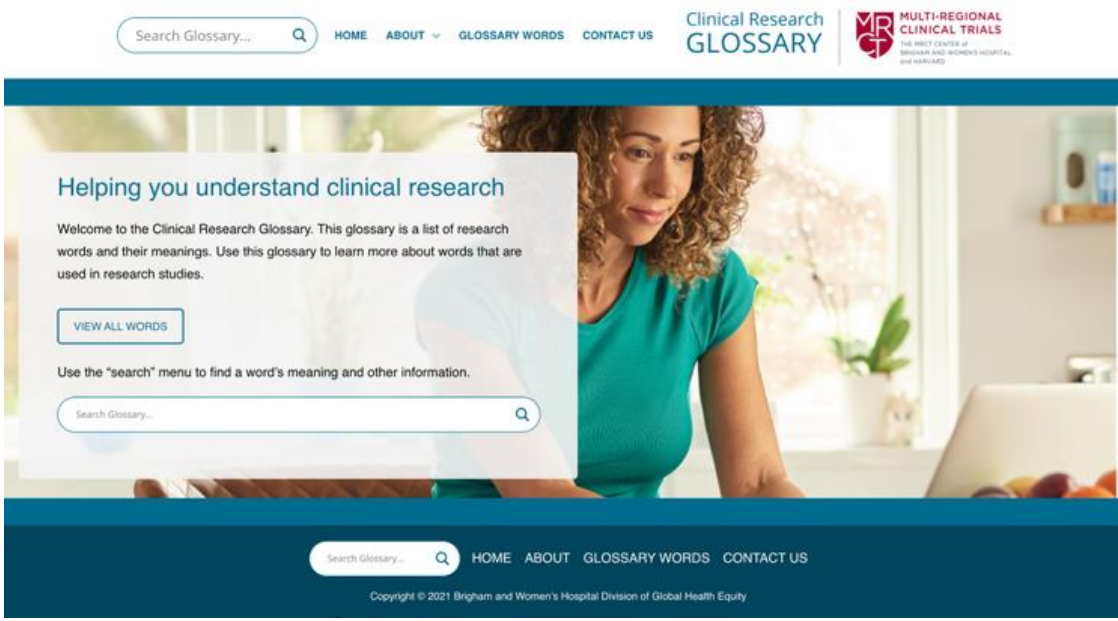
MISSION

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,
- Used to facilitate clear communication about 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

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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

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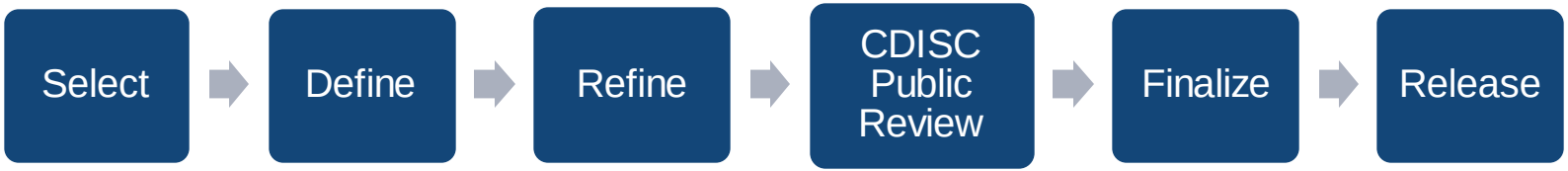
Clinical Research Glossary - Expansion Activities

- ~125 new definitions developed this year, plus additional features:
  - Updated, shareable illustrations
  - New section to support participant conversations with study team members
- 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 collection and virtual consensus sessions

Clinical Research Glossary – Development Process



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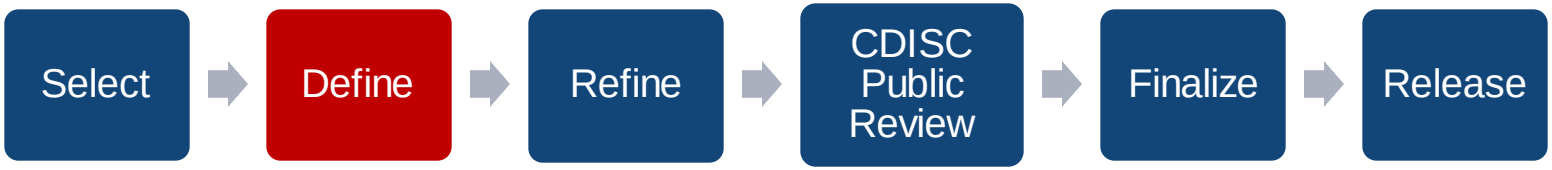
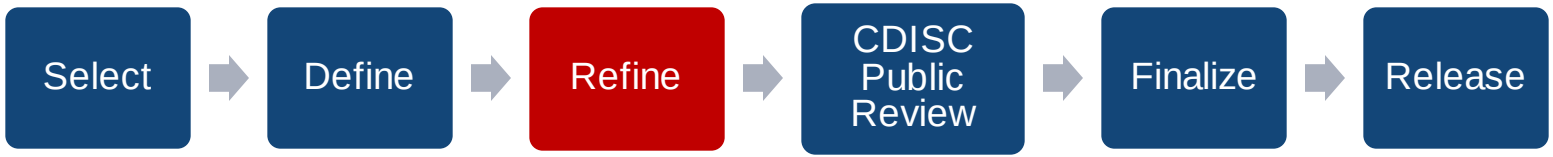
Clinical Research Glossary – Development Process



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

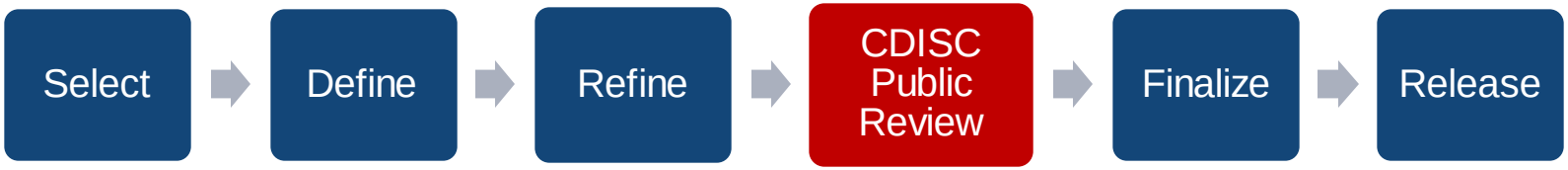
Clinical Research Glossary – Development Process



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?

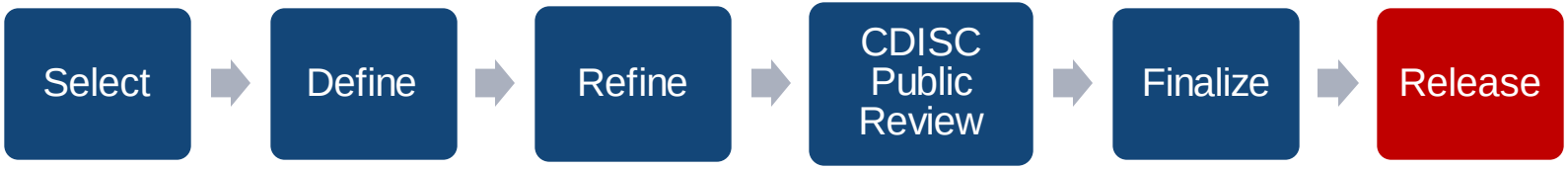
Can I accept this definition?

Clinical Research Glossary – Development Process



Definitions only
Expanded participation: youth, patients

Clinical Research Glossary – Development Process



CDISC Glossary:
- Definition only

MRCT Center website:
- Definition and all additional content

Cross-referenced

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An Advocate's Reflections on the MRCT Center Process

R. Bernard Coley
Care Partner Advocate

What makes this process work	Robust consideration of usage context Respect for patient 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 – What's Next

- Ongoing relationship building with CDISC
- Continued development of definitions and content.
- Creation of a new glossary website with improved search functionality and usability.
- Launch of the updated MRCT Center Clinical Research Glossary with the CDISC plain language standard in the first half of 2024.
- Exploration of ways to expand the reach of the public review process.
- 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 are working together to meet the goal of releasing a new website with all our defined words, plus all the definitions available as a CDISC standard, in 2024.
- New content will continue to be developed and added into the foreseeable future.
- We encourage you and members of your network to take part in the Public Review periods.
- We hope you will use and share the Clinical Research 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, Novartis
- Christopher Trudeau, University of Arkansas
- Tianna Umann, Equideum Health
- Robert Weker, Patient Advocate

And a special 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*

Maureen Kashuba, *Merck & Co.*

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*

Cornelia Weiss-Haljiti, *Boehringer-Ingelheim*

Review Team

Roberta Albany, *Advocate*

Jessica Chaikof, *Advocate*

Maura Cummings, *Advocate*

John Ghidiu, *Advocate*

Anne Marie Mercurio, *Advocate*

TJ Sharpe, *Advocate*

Desiree Walker (co-lead), *Advocate*

Thank you to the workgroup members who worked on the pilot

Behtash Bahador
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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

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Thank You!

Contact me at sbaedorfkassis@bwh.harvard.edu

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