



2023

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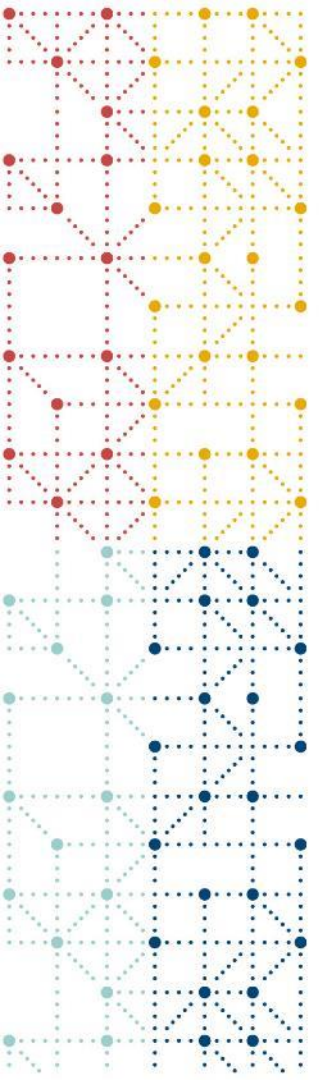
INTERCHANGE

FALLS CHURCH, VA | 18-19 OCTOBER



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

Sylvia Baedorf Kassis, MPH  
MRCT Center  
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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.



# 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>



## Return of Aggregate Results to Participants Principles

The Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (MRCT Center) Return of Results workgroup developed a practical guidance document for all sponsors (e.g., industry, non-profit, government, academic) to address in detail key challenges in returning results and potential solutions. The purpose of creating and disseminating general clinical trial result summaries to clinical trial participants is to ensure that study participants are informed about the trial results, that they know that their participation is and has been respected and appreciated, and that they understand the value of their contribution to science and public health. The foundation of returning aggregate results to participants has been summarized in 8 principles:

1. Participants or their designees should be the recipients of research results summaries.
2. Returning results to trial participants respects their volunteerism and their partnership in research; we recommend, therefore, that sponsors offer to provide results to study participants for all clinical studies.



# ... Inspired a Commitment to Health Literacy...

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

[www.mrctcenter.org/health-literacy](http://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

**Health Literacy in Clinical Research: IRB Checklist**

HEALTH LITERACY IN CLINICAL RESEARCH

“ Tell me what I need to know and make sure I understand. Tell me again tomorrow. ”

A research participant reflecting on their study experience

READ THE HEALTH LITERACY PRINCIPLES >>

Clear communication promotes health literacy and leads to a more positive patient experience

Sponsors and funders, investigators and other institutional review boards, and others bear responsibility to ensure research materials are understood and act upon.

**I AM HEALTHY: Should I Join a COVID-19 Research Study?**

People who do not have COVID-19 can help researchers learn more about the disease.

**A research study:**

- collects new information about health and disease.
- tries to answer new questions that researchers learn.
- needs volunteers to sign up.

**COVID-19:**

- is a new disease caused by a type of virus called coronavirus.
- may cause some people to have symptoms like cough, fever, weakness, muscle and other pains, and breathing problems.

**Why are there research studies about COVID-19 right now?**

COVID-19 is a new disease, so it is important to understand more about:

- How the virus spreads.
- Why some people get very sick, and some people do not.
- Which treatments work best, and if they work for everyone.

Being in a COVID-19 research study is your choice.

More can be learned

**MRCT CENTER WEBINAR**

June 30, 2021  
11:00AM - 12:00PM EDT

**The Promise of Plain Language: Launching a Glossary to Support Participant Understanding of Clinical Research**

Sylvia Baedorf Kassir, MPH  
Program Manager,  
MRCT Center

Julie Holtzopfe  
Head of Clinical Transparency  
and Data Sharing,  
AstraZeneca

Ivy Tillman  
IRB Office Director,  
Augusta University

Desiree Walker  
Patient Advocate and  
Health Educator

# ...Leading to a New Collaboration being Forged

2022 – Collaboration with CDISC began.

2023 – CDISC & MRCT Center partnership officially launched.



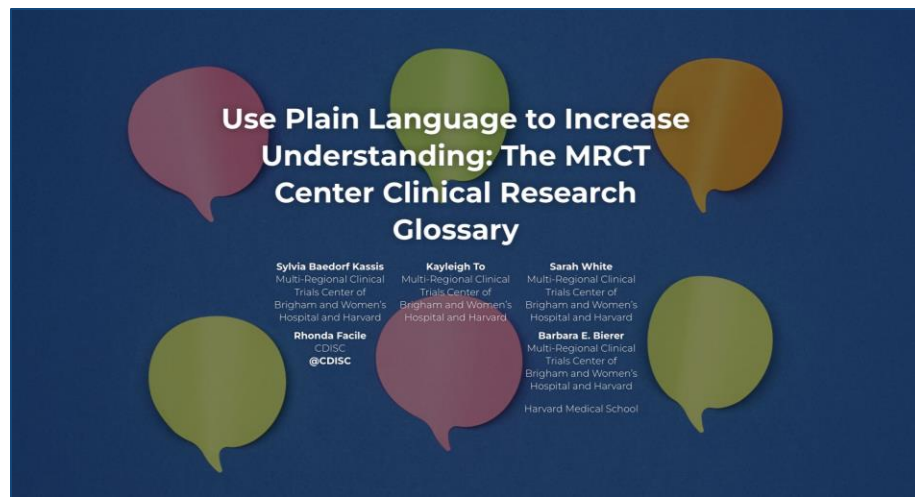
**Announcing a Global Standard for Plain Language in Clinical Research**

**REGISTER**

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





**Use Plain Language to Increase Understanding: The MRCT Center Clinical Research Glossary**

**Sylvia Baedorf Kassib**  
Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard

**Kayleigh To**  
Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard

**Sarah White**  
Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard

**Rhonda Facile**  
CDISC  
@CDISC

**Barbara E. Bierer**  
Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard  
Harvard Medical School

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



# Specific Benefits of Collaboration

The MRCT Center Clinical Research Glossary provides:

- Consistency
- Accuracy
- Reliability
- Transparency
- Trustworthiness

CDISC, specifically, offers:

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

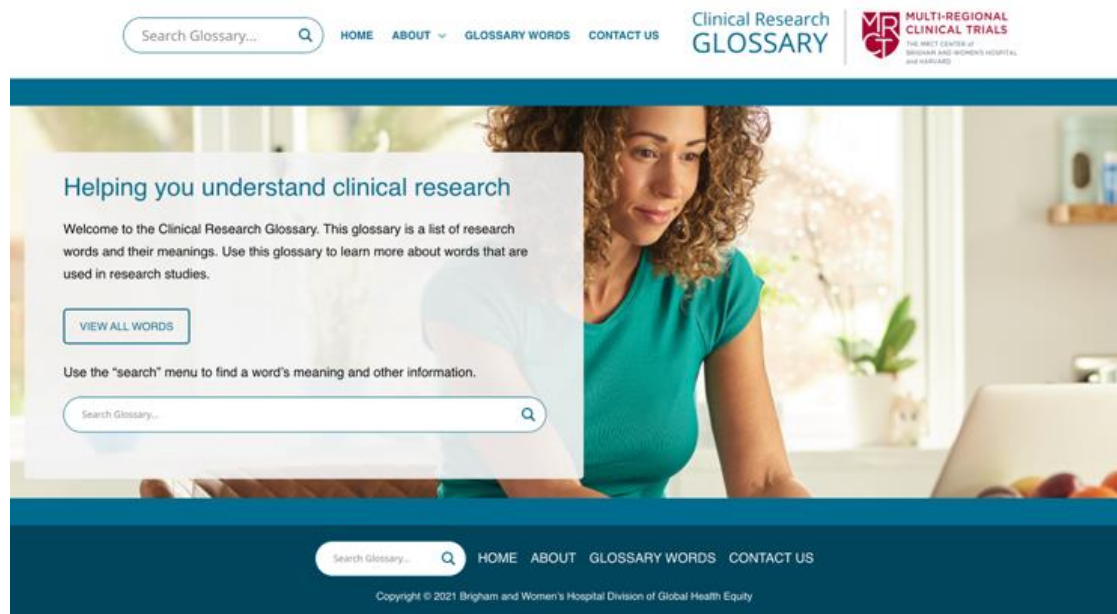
## MISSION

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](http://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

- ~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



# Clinical Research Glossary – Development Process



Single sentence definition

No complex sentences

No long sentences

No parentheses, symbols, or abbreviations

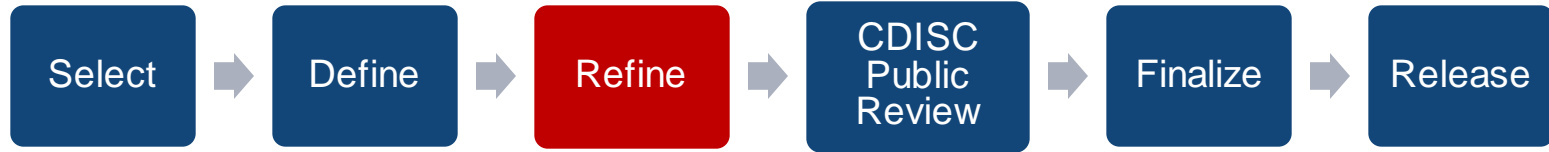
Short, simple words

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?

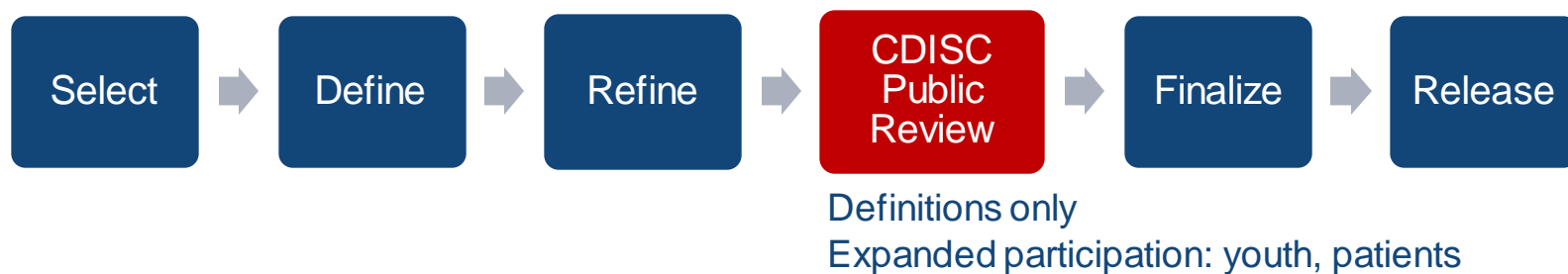
**Context** – can the content be used across research contexts?

**Other** – are there any other concerns not noted above?

Can I accept this definition?



# Clinical Research Glossary – Development Process



# Clinical Research Glossary – Development Process



CDISC Glossary:  
- Definition only

MRCT Center website:  
- Definition and all  
additional content

Cross-referenced

# 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.

# 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

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



## Learn more and follow us:



**MULTI-REGIONAL  
CLINICAL TRIALS**

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



[MRCTcenter.org](https://MRCTcenter.org)





# Thank You!

Contact me at [sbaedorfkassis@bwh.harvard.edu](mailto:sbaedorfkassis@bwh.harvard.edu)



Clinical Research  
**GLOSSARY**

