



MULTI-REGIONAL CLINICAL TRIALS

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

The MRCT Center Clinical Research Glossary – Public Review of Plain Language Definitions

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Clinical Research
GLOSSARY

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Helping you understand clinical research

Welcome to the Clinical Research Glossary. This glossary is a list of research words and their meanings. Use this glossary to learn more about words that are used in research studies.

[VIEW ALL WORDS](#)

Use the "search" menu to find a word's meaning and other information.

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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/>

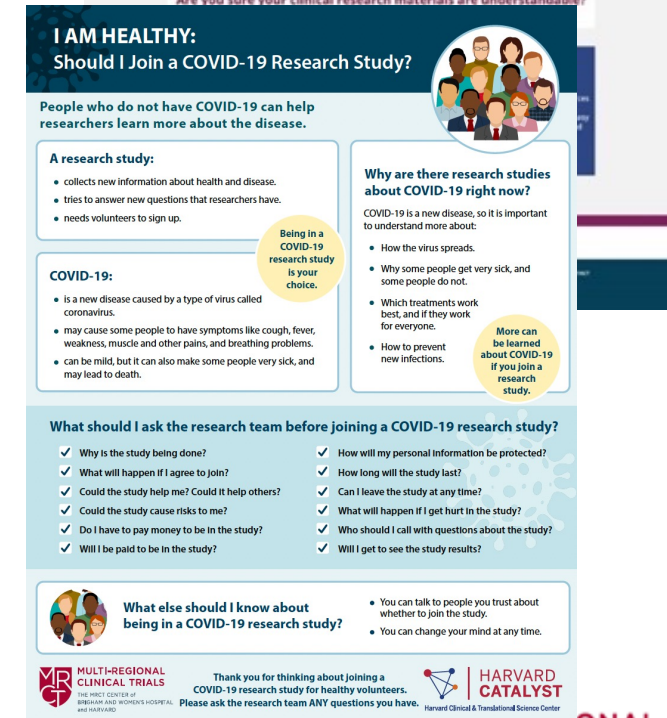
2019 to present - Design and deliver health literacy trainings

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



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.

Key features of the Clinical Research Glossary

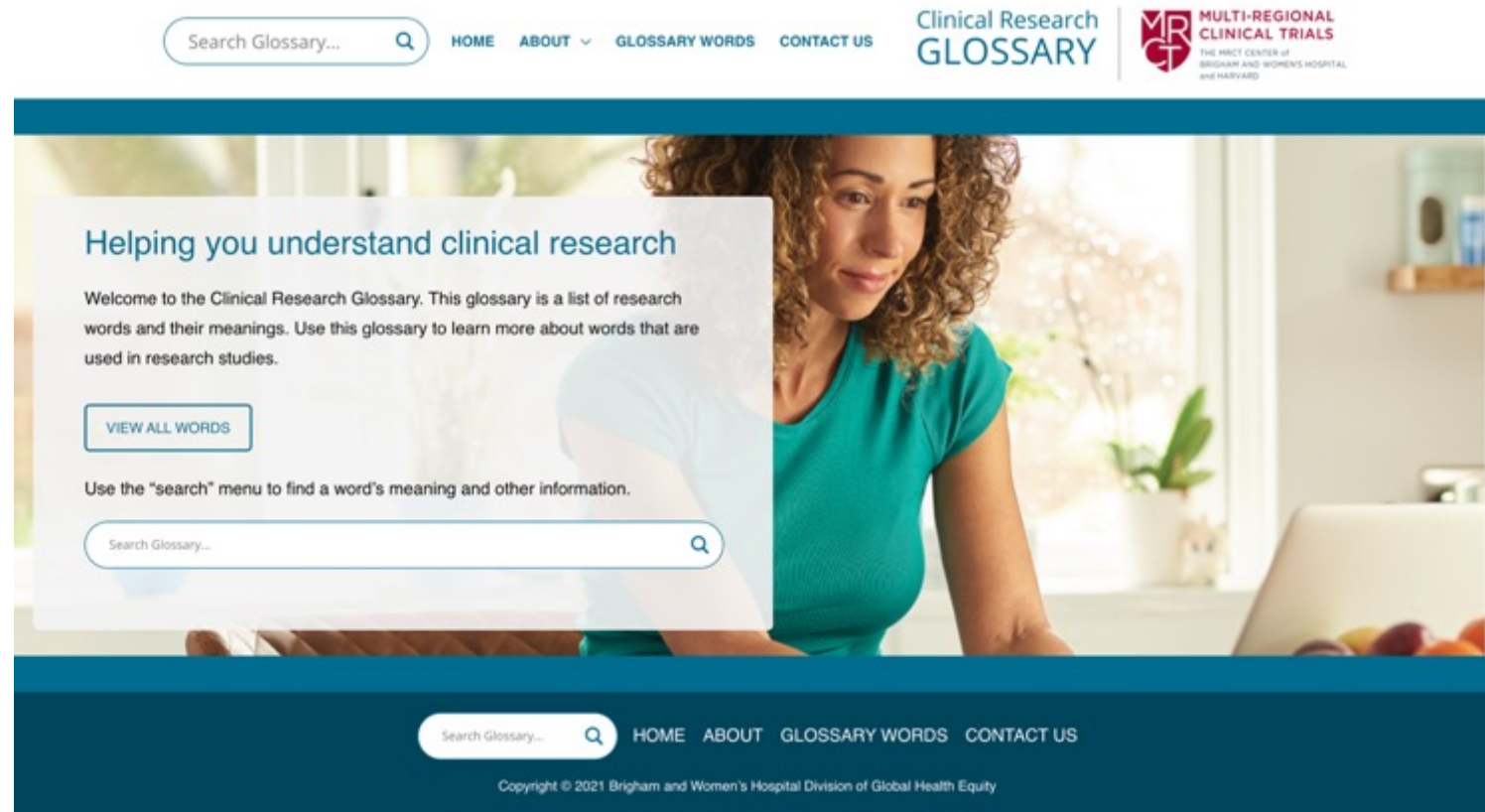
- Focus on clinical research
- Diverse workgroup (~25-30 people)
- Monthly consensus conversations
- Plain language definitions
- Additional supportive information, graphics, and other resources as applicable.

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

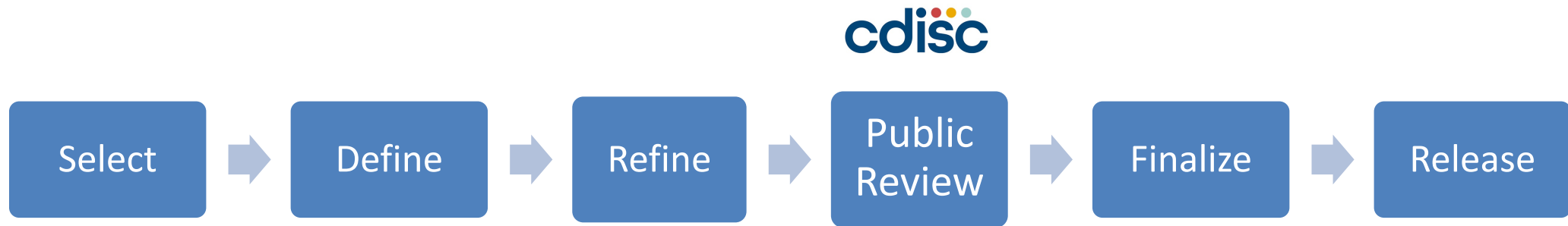
Clinical Research Glossary

- Piloted in 2020*
- 53 definitions released in 2021:
www.mrctcenter.org/clinical-research-glossary
- Adopted as CDISC standard and first public review of definitions completed in Mar/Apr 2023

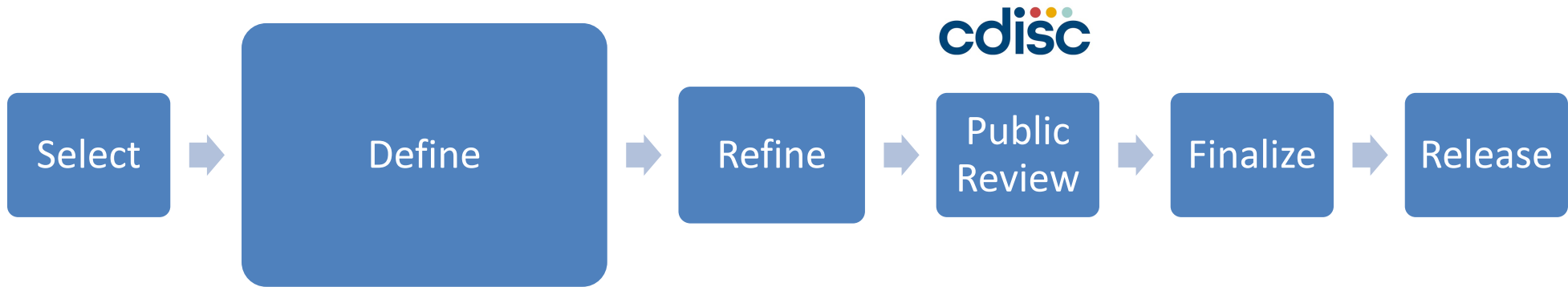


*Baedorf Kassis S, White S, & Bierer B. (2022). [Developing a consensus-driven, plain-language clinical research glossary for study participants and the clinical research community](#). *Journal of Clinical and Translational Science*, 1-20. doi:10.1017/cts.2022.12

Clinical Research Glossary Process

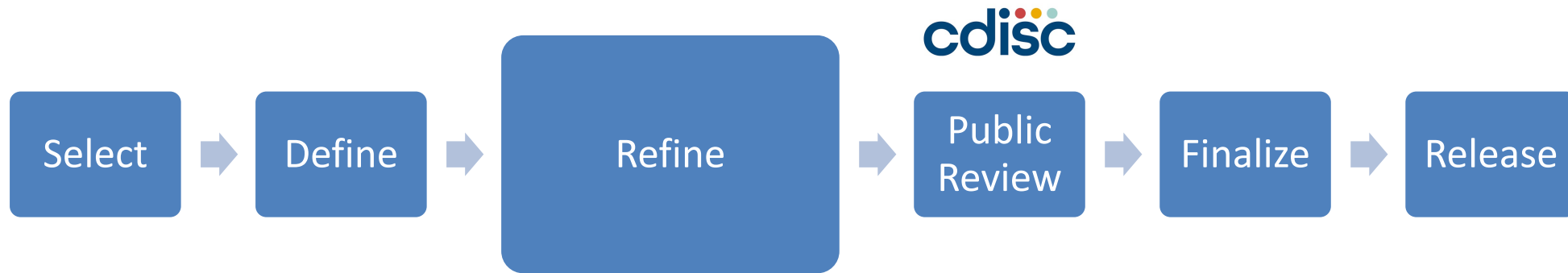


Clinical Research Glossary – How we define



- * single sentence definition
- * no complex sentences
- * no long sentences
- * no parentheses, symbols, or abbreviations
- * short, simple words
- * tone that is conversational
- * 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?

Clinical Research Glossary – Public Review Considerations



- * Definitions for non-technical communications
- * Must be plain language
- * Additional supportive information is included for each term (on the website)
- * Is the requested change absolutely necessary for this plain language definition?

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 let us know what other words we should define.
 - Also, please use the glossary and share widely!

Questions and Comments

Thank you!