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.

• The MRCT Center is supported by voluntary contributions from foundations, corporations, international organizations, academic institutions and government entities (see www.MRCTCenter.org), as well as by grants.

• We are committed to autonomy in our research and to transparency in our relationships. The MRCT Center—and its directors—retain responsibility and final control of the content of any products, results, and deliverables.
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.
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
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

Clinical Research Glossary Process

Select → Define → Refine → Public Review → Finalize → Release
Clinical Research Glossary – How we define

Select → Define → Refine → Public Review → Finalize → Release

* 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?
* 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!
Thank you!