Introducing the MRCT Center Clinical Research Glossary

We will begin shortly.
MRCT CENTER WEBINAR
The Promise of Plain Language: Launching a Glossary to Support Participant Understanding of Clinical Research

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

Sylvia Baedorf Kassis, MPH
Program Manager,
MRCT Center

Julie Holtzople
Head of Clinical Transparency
and Data Sharing,
AstraZeneca

Ivy Tillman
IRB Office Director,
Augusta University

Desiree Walker
Patient Advocate and
Health Educator
Session Format and Objectives

Format

• MRCT Center Introduction
• Overview of the Clinical Research Glossary pilot project
• Sneak peek of the Clinical Research Glossary website
• Panel Discussion
• Q&A

(Please note – the slides and webinar recording will be available by next week)

Objectives

• Describe the Clinical Research Glossary pilot project.
• Understand the importance of using plain language terminology in clinical research and having a common harmonized resource.
• Explain the benefits that understandable clinical research information offer the entire research enterprise.
• Identify opportunities to integrate the Clinical Research Glossary into organizational processes.
The MRCT Center is a research and policy center focused on addressing the conduct, oversight, ethics and regulatory environment for clinical trials.
Introduction to The MRCT Center

Our Vision

Improve the integrity, safety, and rigor of global clinical trials.

Our Mission

We engage diverse stakeholders in the research enterprise to define emerging issues in global clinical trials and to create and implement ethical, actionable, and practical solutions.
Our Ongoing Commitment to Health Literacy

Since 2019, the MRCT Center:

- Completed a multi-stakeholder initiative focused on health literacy.
- Launched a publicly available website on Health Literacy in Clinical Research www.mrctcenter.org/health-literacy
- Designed and delivered clinical-research focused health literacy trainings for several organizations and groups.
The Need for a Common Clinical Research Glossary

• The Health Literacy in Clinical Research Workgroup identified a need for a widely accessible plain language participant-friendly research glossary.

• A common clinical research glossary to support consistent and accurate use of simplified definitions across the research industry did not exist.

• Harmonizing definitions across the industry promotes a unified approach to best support patients, participants and their caregivers.
To pilot the development of a plain language glossary that includes definitions that are:
- Co-created with patients
- Designed for public understanding
- Acceptable to industry and academic stakeholders across the clinical research ecosystem.

https://journal.emwa.org/writing-for-patients/promoting-equity-in-understanding-a-cross-organisational-plain-language-glossary-for-clinical-research/
### The Clinical Research Glossary Pilot: Workgroup Members

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<th>Name</th>
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<td>Behtash Bahador</td>
<td>CISCRP</td>
<td>Lukasz Kniola</td>
<td>Biogen/PhUSE</td>
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<td>Sarah Balay</td>
<td>Privacy Analytics/PhUSE</td>
<td>Marilyn Neault</td>
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<td>Stephen Carr</td>
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<td>Jessica Chaikof</td>
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<td>Brandis Pickard</td>
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<td>Lisa Chamberlain James</td>
<td>Trilogy Writing and Consulting</td>
<td>Robyn Rennick</td>
<td>GlaxoSmithKline</td>
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<td>Deborah Collyar</td>
<td>PAIR/Patient Advocate</td>
<td>Marian Ryan</td>
<td>Institute for Healthcare Advancement</td>
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<td>Jean-Marc Ferran</td>
<td>Qualiance ApS/PhUSE</td>
<td>T.J. Sharpe</td>
<td>Medidata/Patient Advocate</td>
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<td>Helle Gawrylewski</td>
<td>CDISC Glossary Lead/Hawkwood Consulting LLC</td>
<td>Kamila Sroka-Saidi</td>
<td>Boehringer Ingelheim</td>
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<td>Art Gertel</td>
<td>MedSciCom, LLC</td>
<td>Mary Stober Murray</td>
<td>National Minority Quality Forum</td>
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<td>Shannon Hamill</td>
<td>Patient Advocate</td>
<td>Gloria Stone</td>
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<td>Lauren Hamill</td>
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<td>Michele Teufel</td>
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<td>Julie Holtzople</td>
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A warm thanks to this wonderful team of collaborators!

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MRCT Center Clinical Research
Glossary Launch 2021
The Clinical Research Glossary Pilot: Approach

- Selected words from various participant-facing materials
- Collected feedback on initial plain language definitions
- Held consensus conversations to finalize definitions
- Created supplemental information and web template
- Finalized website in preparation for launch

Ongoing patient advocacy engagement and iterative usability testing
Introducing: The MRCT Center Clinical Research Glossary Website

mrctcenter.org/clinical-research-glossary
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.

Use the “search” menu to find a word’s meaning and other information.
Informed consent

The process of learning and discussing the details of a research study before deciding whether to take part.

How to say: Informed consent

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Randomization

A way to use chance to place study participants into different study treatment groups.

How to say: Randomization

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USE IN A SENTENCE

Informed consent helps people understand what will happen if they become a participant and what their rights are.

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MORE INFO

Informed consent is an ongoing conversation between a participant and the research team before someone can participate in a study. It's an opportunity to learn information about the study changes.

Informed consent is a process to make participants aware of the potential study participant requirements and responsibilities.

A consent form is used as part of the informed consent process.

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WORDS RELATED TO INFORMED CONSENT

- consent
- consent form

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WORDS OPPOSITE TO INFORMED CONSENT

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WORDS RELATED TO RANDOMIZATION

- bias
- blinded
- random assignment
- randomized
- randomly assigned
- study arm

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WORDS OPPOSITE TO RANDOMIZATION

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OTHER RESOURCES

- FDA Resource for Patients: "Informed Consent for Clinical Trials"

If you know of another resource that could help explain this term, please contact us!
What’s Next?

• Urge commitment to using common definitions across the research industry.

• Explore expansion to Version 2 of the Clinical Research Glossary via a multi-stakeholder consortium.
Panelist Introductions

Julie Holtzople
Head of Clinical Transparency and Data Sharing, AstraZeneca

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