MULTI-REGIONAL CLINICAL TRIALS

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

Introducing the MRCT Center Clinical Research Glossary

We will begin shortly.

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

MRCT CENTER WEBINAR

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

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

Clinical Research
GLOSSARY

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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.

Brigham and Women's Hospital
Founding Member, Mass General Brigham

HARVARD UNIVERSITY

Clinical Research GLOSSARY

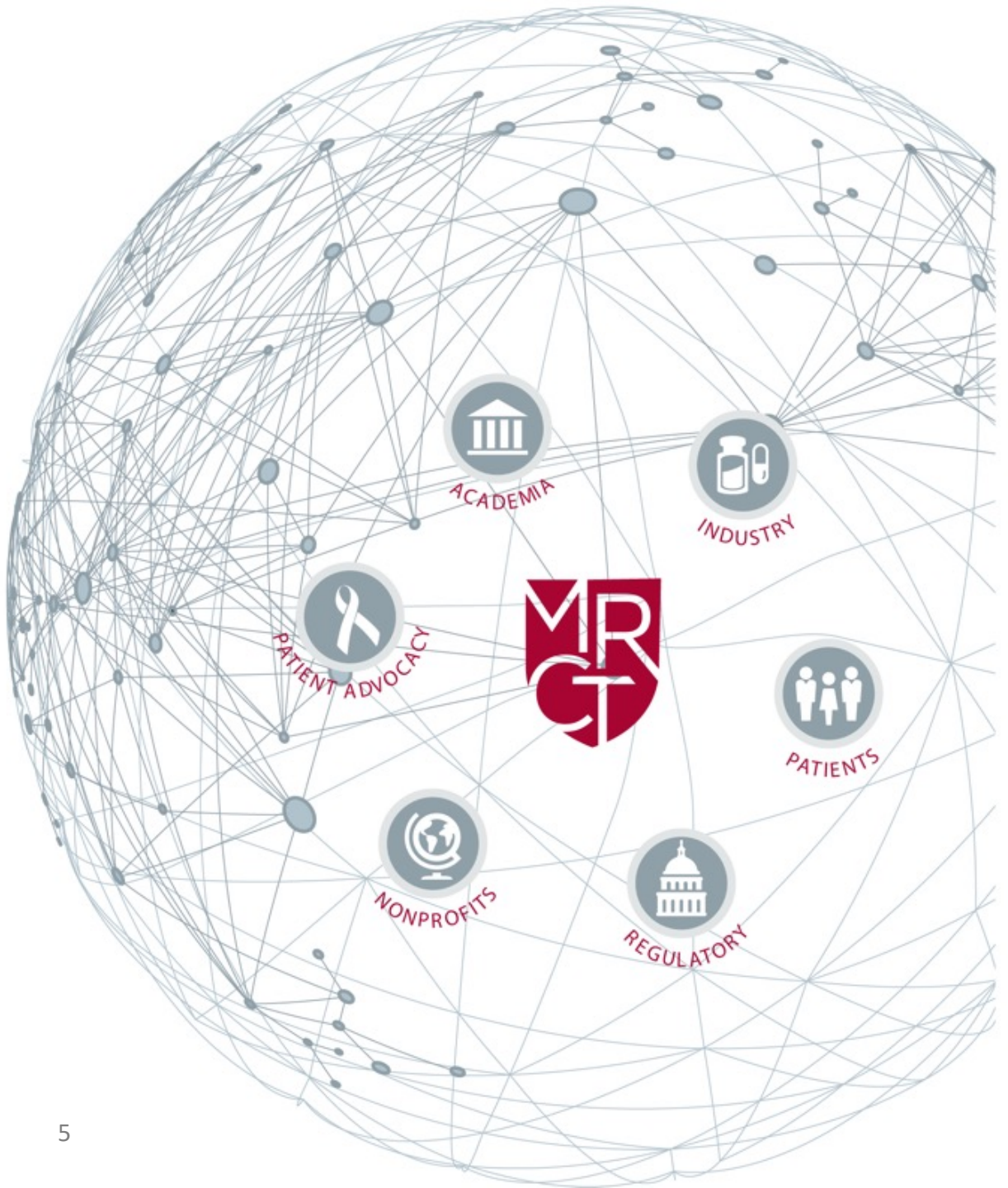
Introduction to The MRCT Center

Our Vision

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

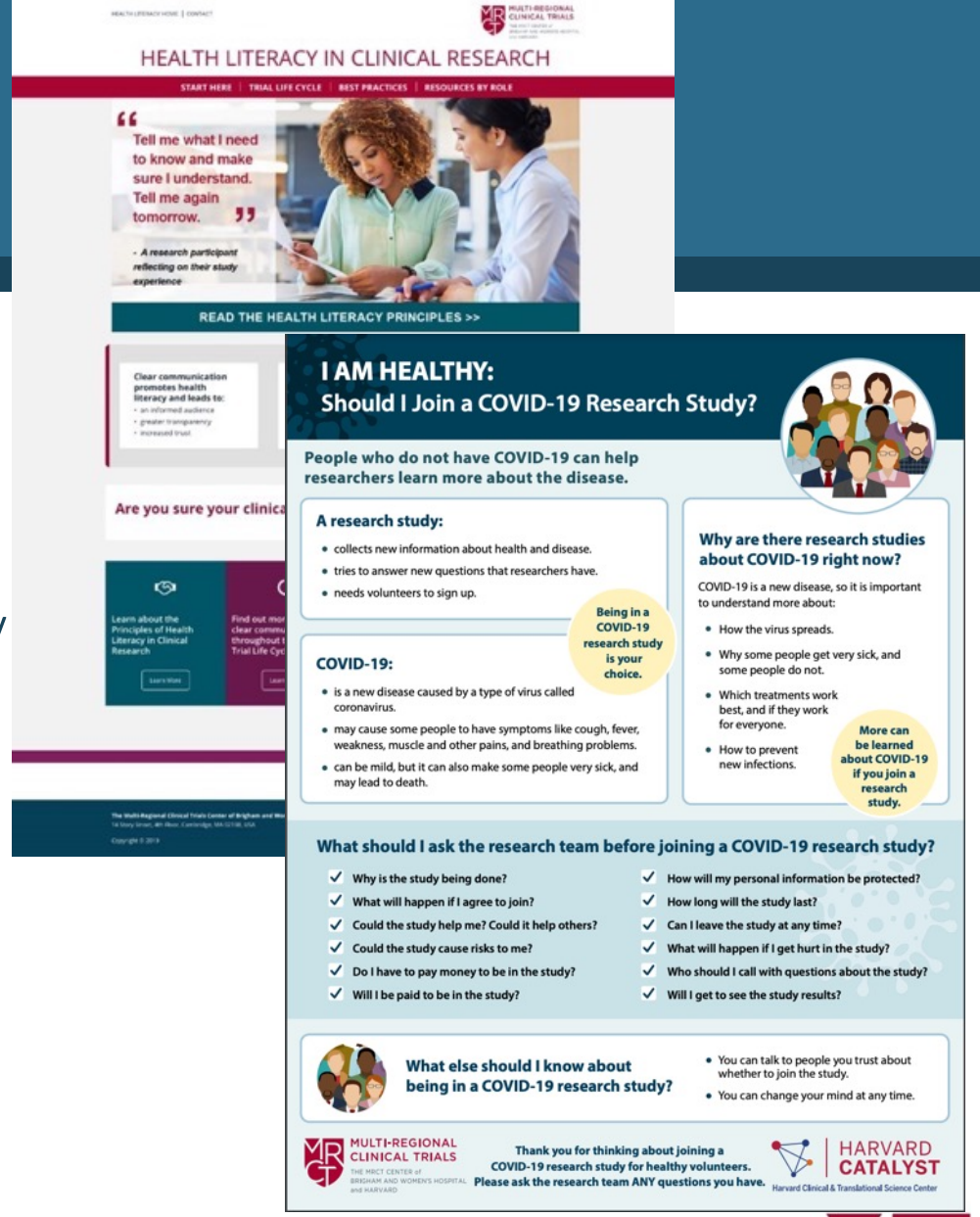
Our Mission

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
  - Developed COVID-19 pamphlets to support understanding of clinical research (in English & Spanish). https://mrctcenter.org/blog/resources/covid-19-clinical-research-flyers/
  - Designed and delivered clinical-research focused health literacy trainings for several organizations and groups.



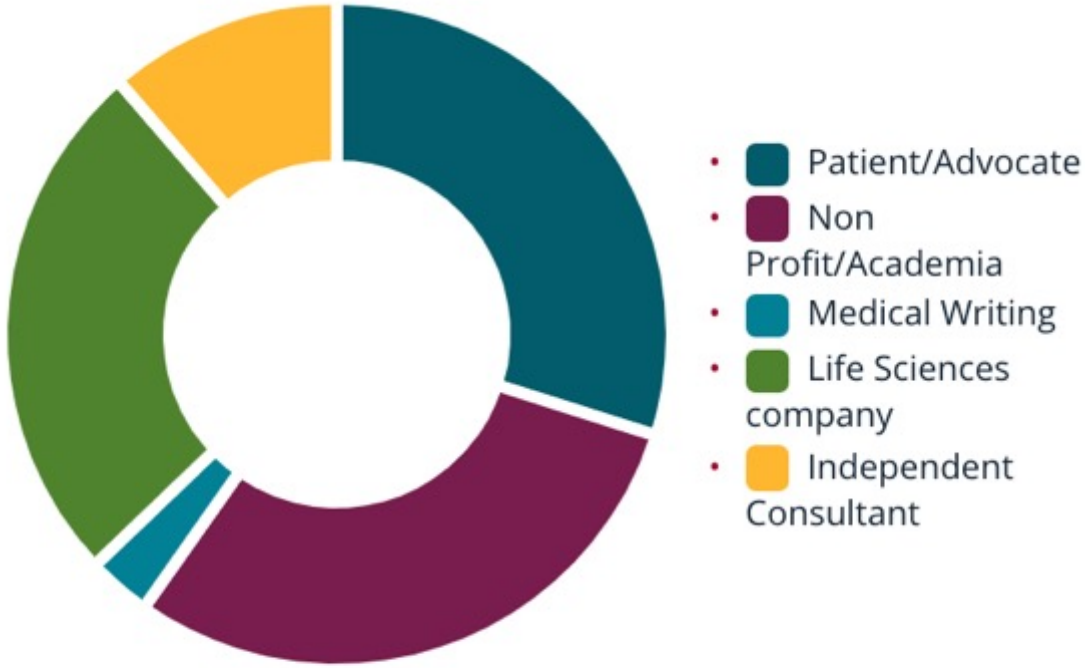
The Need for a Common Clinical Research Glossary

- 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.

The Clinical Research Glossary Pilot: Goal

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.



Categories of Glossary Workgroup Participants

https://journal.emwa.org/writing-for-patients/promoting-equity-in-understanding-a-cross-organisational-plain-language-glossary-for-clinical-research/

Clinical Research GLOSSARY

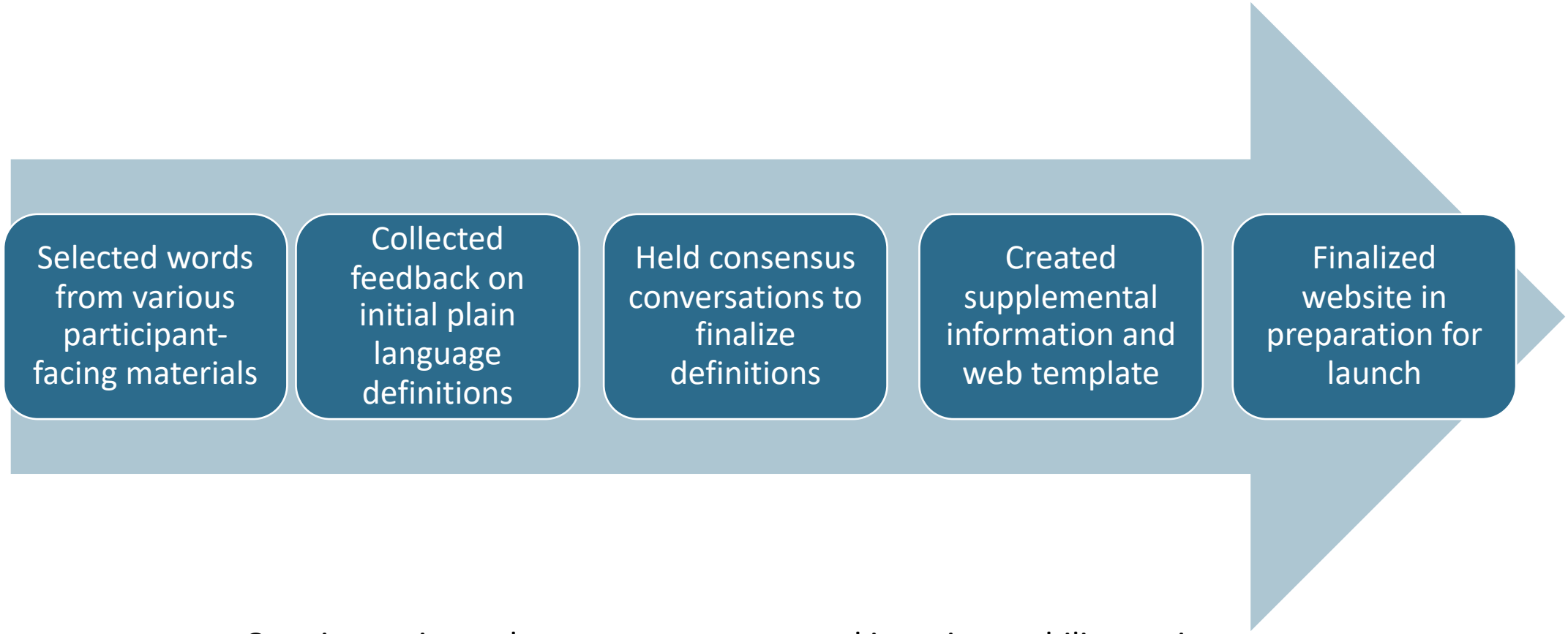
The Clinical Research Glossary Pilot: Workgroup Members

Name	Organization
Behtash Bahador	CISCRP
Sarah Balay	Privacy Analytics/PhUSE
Stephen Carr	Janssen
Jessica Chaikof	Patient Advocate
Lisa Chamberlain James	Trilogy Writing and Consulting
Deborah Collyar	PAIR/Patient Advocate
Jean-Marc Ferran	Qualiance ApS/PhUSE
Helle Gawrylewski	CDISC Glossary Lead/Hawkwood Consulting LLC
Art Gertel	MedSciCom, LLC
Shannon Hamill	Patient Advocate
Lauren Hamill	Patient Advocate
Julie Holtzople	Astra Zeneca

Name	Organization
Lukasz Kniola	Biogen/PhUSE
Marilyn Neault	Patient Advocate
Elyssa Ott	Janssen
Brandis Pickard	CISCRP
Robyn Rennick	GlaxoSmithKline
Marian Ryan	Institute for Healthcare Advancement
T.J. Sharpe	Medidata/Patient Advocate
Kamila Sroka-Saidi	Boehringer Ingelheim
Mary Stober Murray	National Minority Quality Forum
Gloria Stone	G Stone Connections
Michele Teufel	Astra Zeneca
Desiree A.H. Walker	Patient Advocate
Robert Weker	Patient Advocate

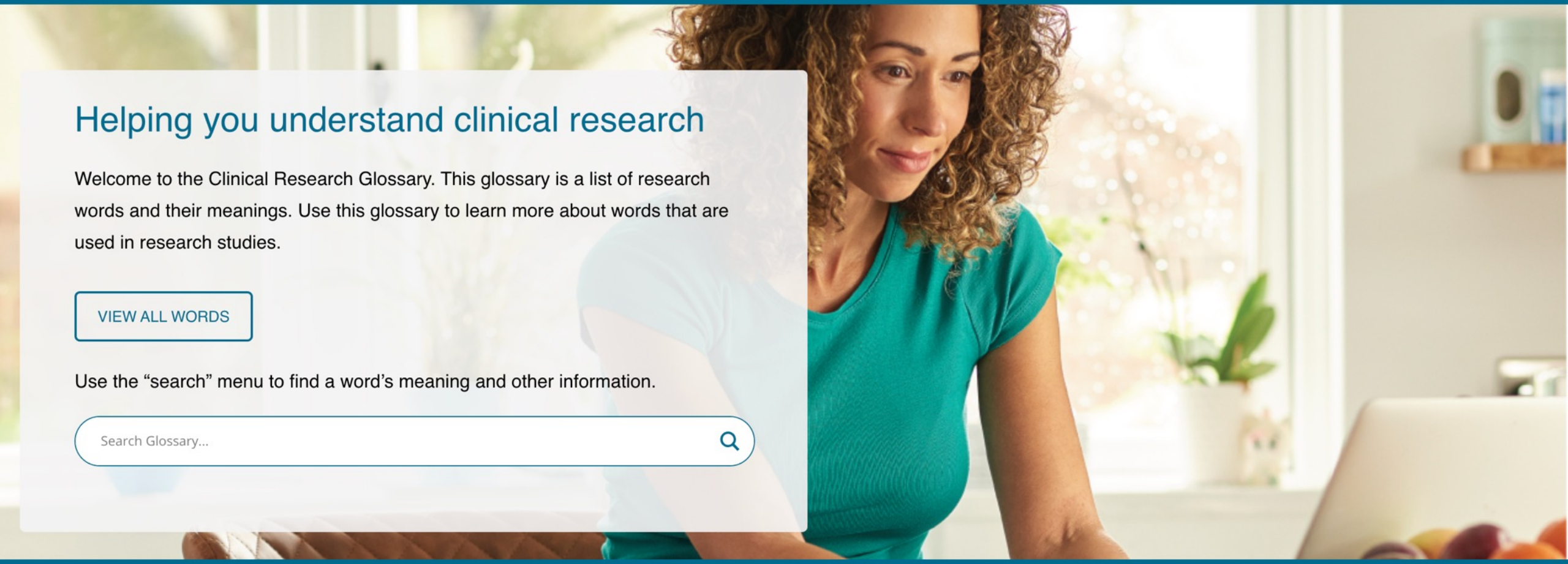
A warm thanks to this wonderful team of collaborators!

The Clinical Research Glossary Pilot: Approach



Introducing:
The MRCT Center
Clinical Research Glossary Website

mrctcenter.org/clinical-research-glossary



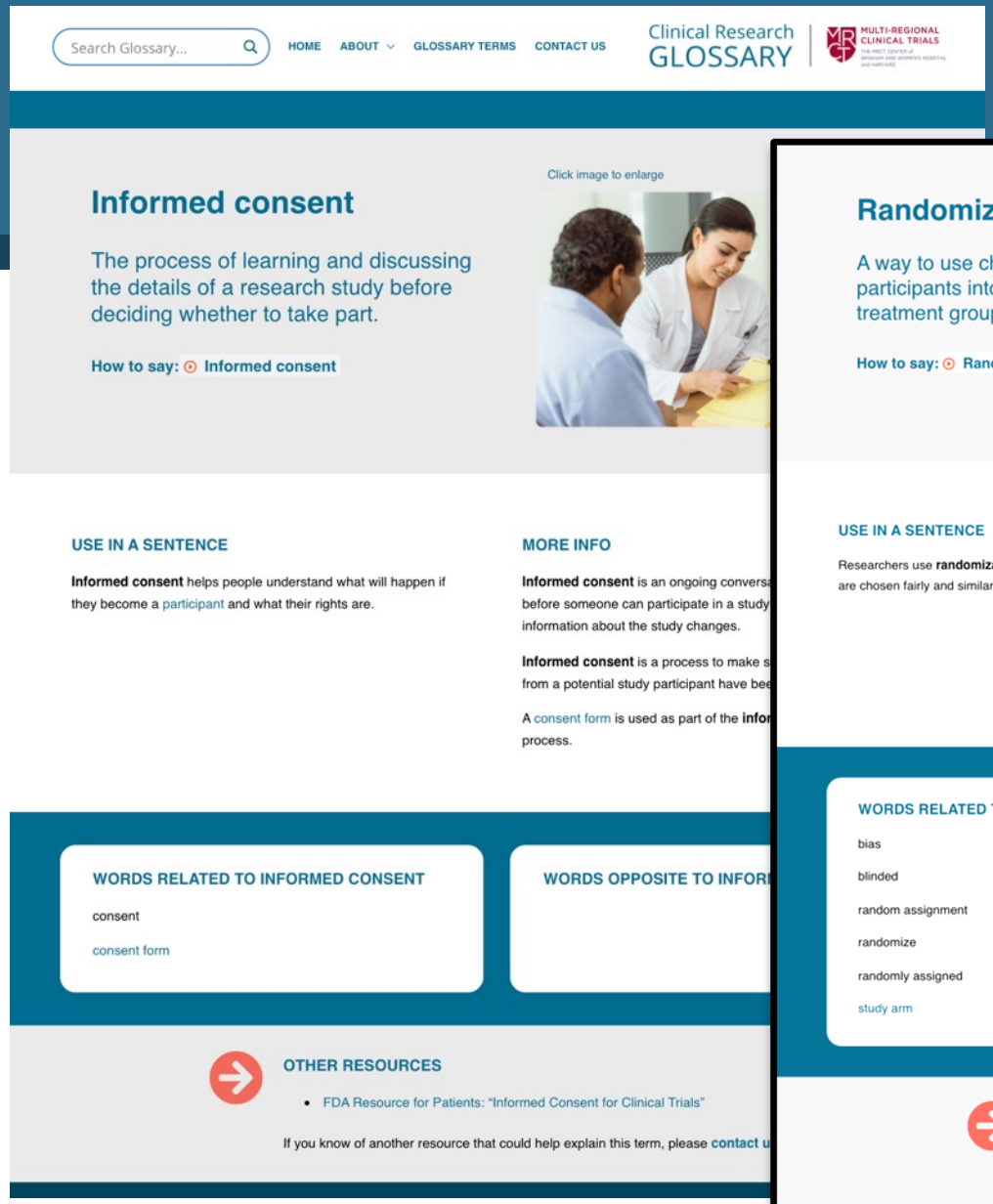
Helping you understand clinical research

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.

VIEW ALL WORDS

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

Search Glossary...


Search Glossary...
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GLOSSARY TERMS
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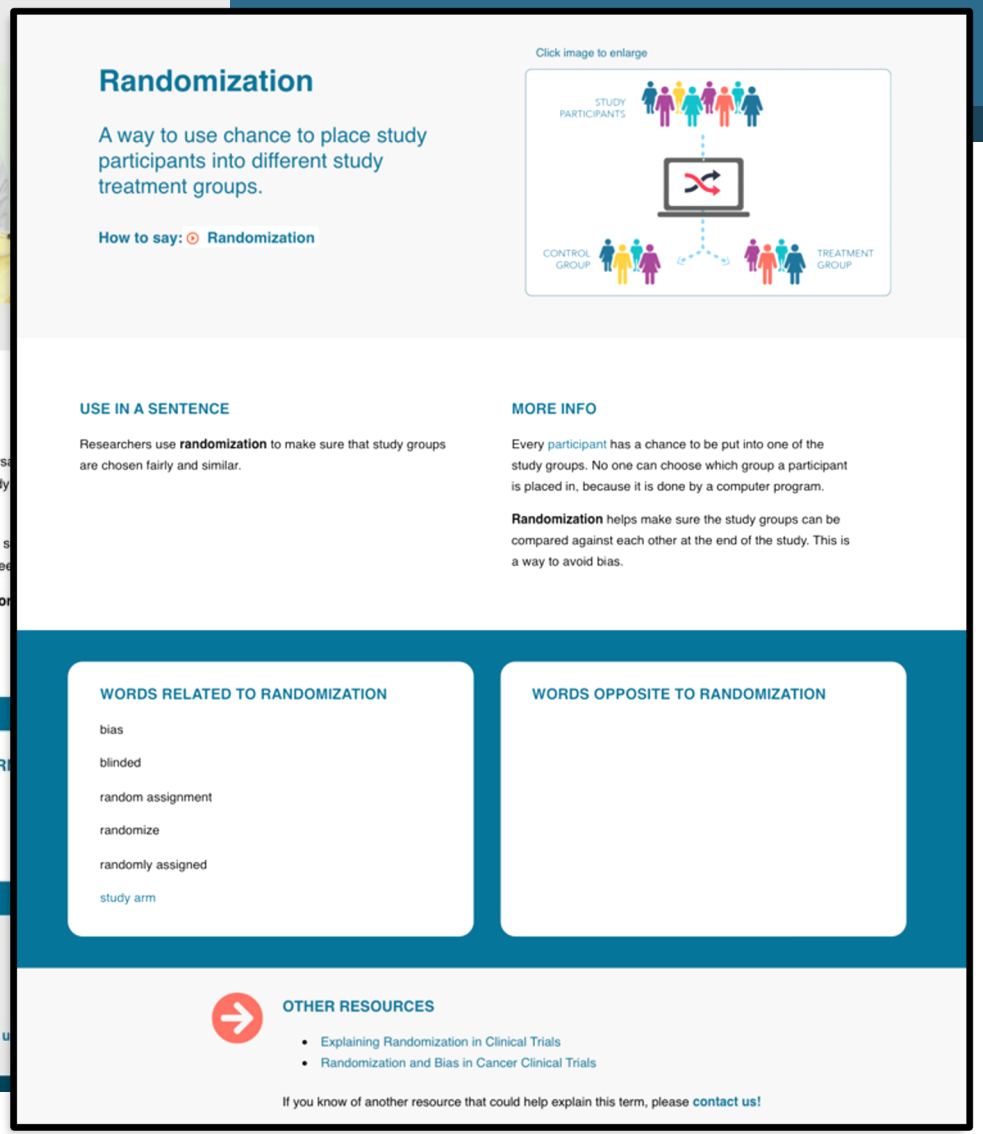
Clinical Research GLOSSARY
MULTI-REGIONAL CLINICAL TRIALS
Informed consent
The process of learning and discussing the details of a research study before deciding whether to take part.
How to say: Informed consent
Click image to enlarge
USE IN A SENTENCE
Informed consent helps people understand what will happen if they become a participant and what their rights are.
MORE INFO
Informed consent is an ongoing conversa
before someone can participate in a study
information about the study changes.
Informed consent is a process to make s
from a potential study participant have bee
A consent form is used as part of the infor
process.
WORDS RELATED TO INFORMED CONSENT
consent
consent form
WORDS OPPOSITE TO INFOR
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 u


Randomization
A way to use chance to place study participants into different study treatment groups.
How to say: Randomization
Click image to enlarge
STUDY PARTICIPANTS
CONTROL GROUP
TREATMENT GROUP
USE IN A SENTENCE
Researchers use randomization to make sure that study groups are chosen fairly and similar.
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
bias
blinded
random assignment
randomize
randomly assigned
study arm
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!

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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Join us:

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