



MULTI-REGIONAL CLINICAL TRIALS

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

Health Literacy in Clinical Research and a Common Plain Language Glossary

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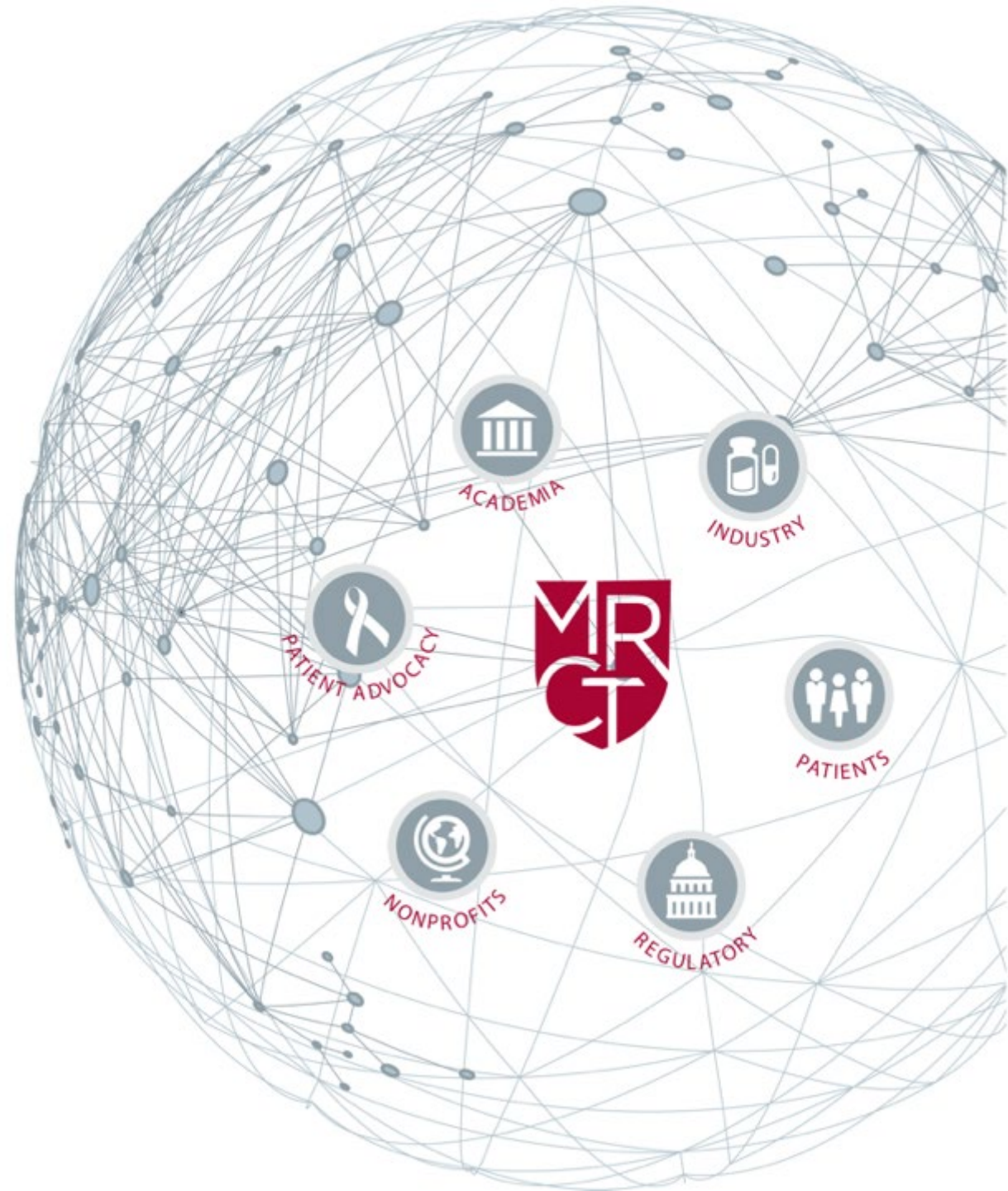
Introduction to the MRCT Center

Our Vision

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

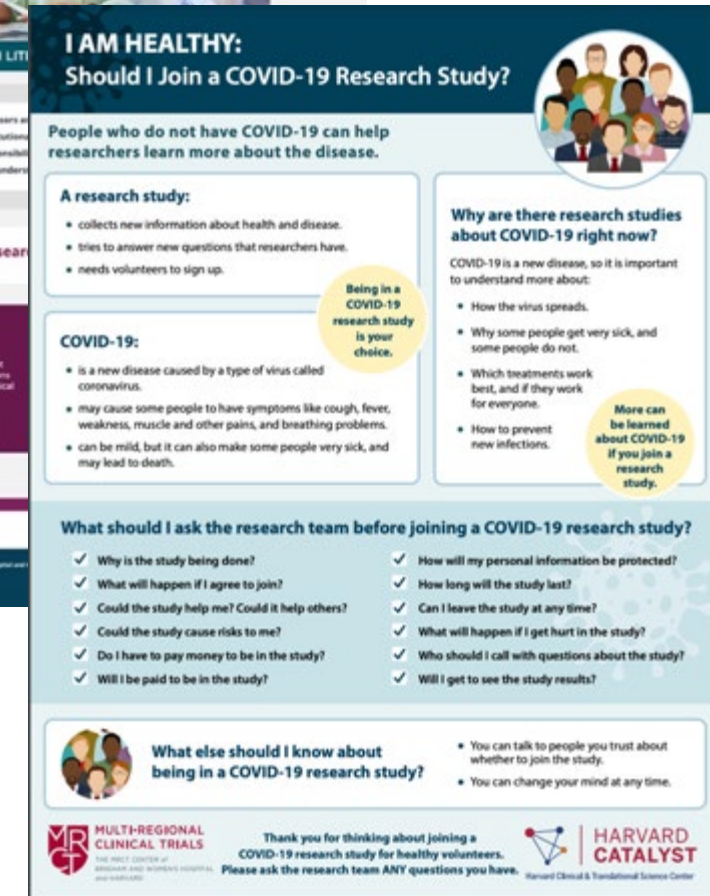
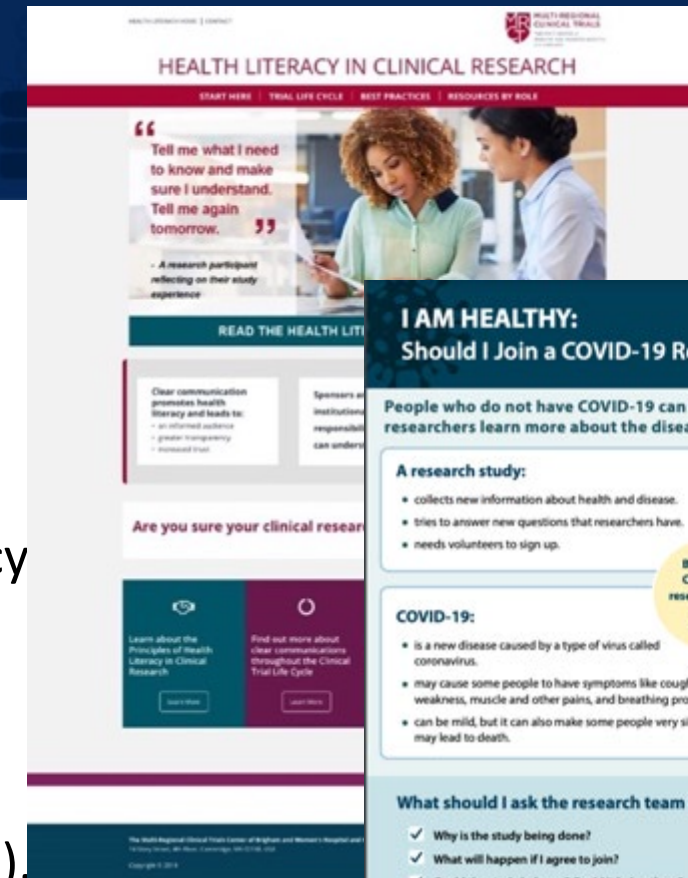
Our Mission

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.



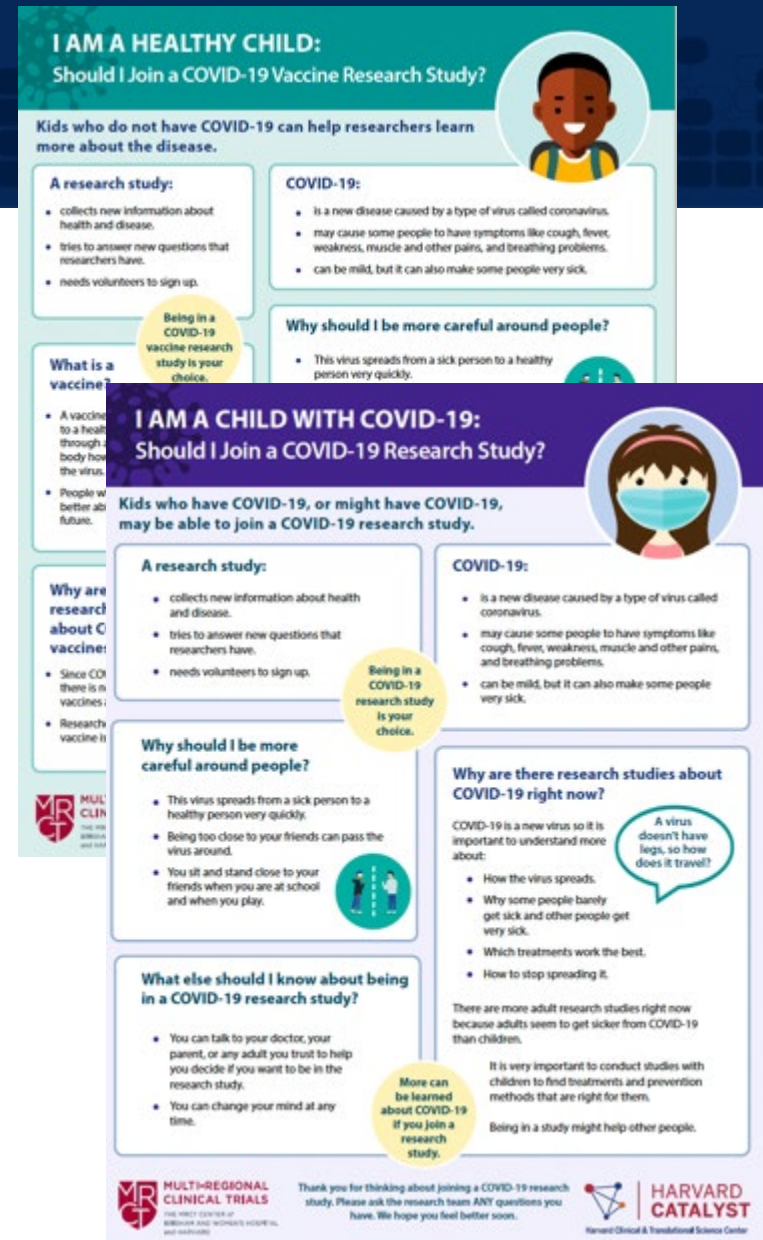
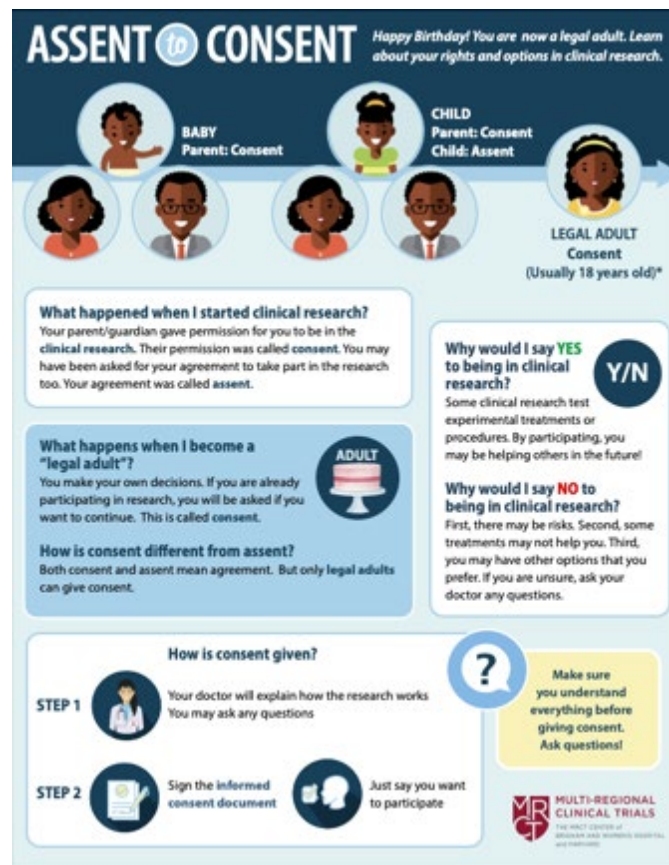
Ongoing Commitment to Health Literacy

- 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 multiple organizations and groups.



Commitment to Health Literacy Across the Age Spectrum

- The MRCT Center has also developed a suite of materials for adolescents and young adults
 - Related to COVID-19
 - Introduction to Clinical Research



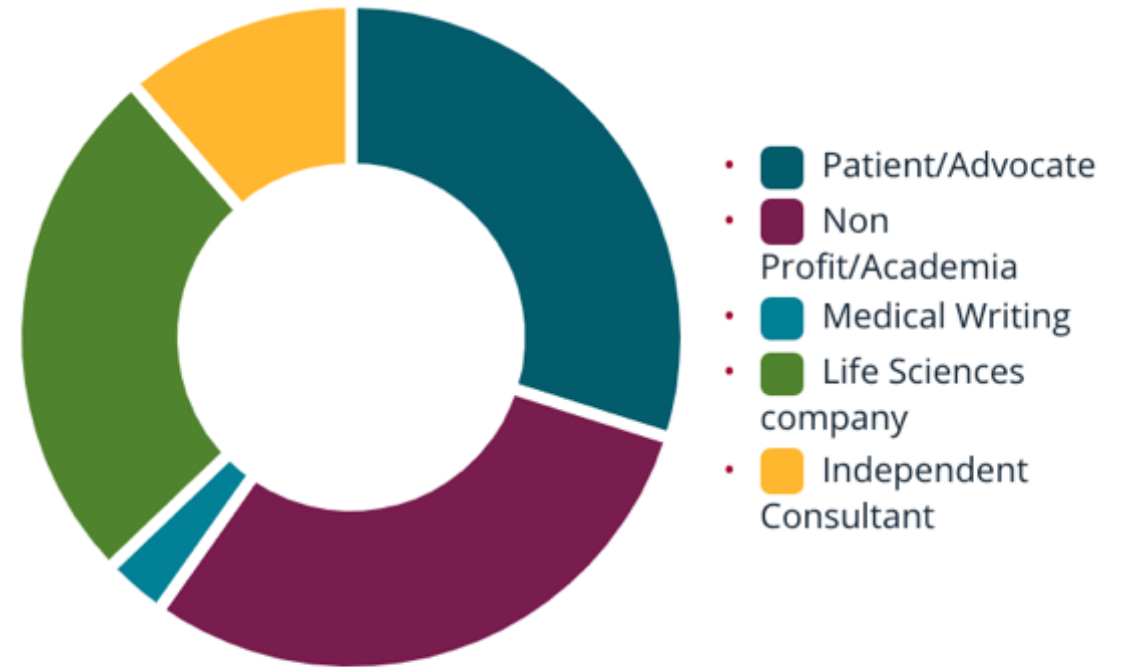
The Need for a Common Clinical Research Glossary

- A resource of consistent, accurate and simplified definitions for use 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:

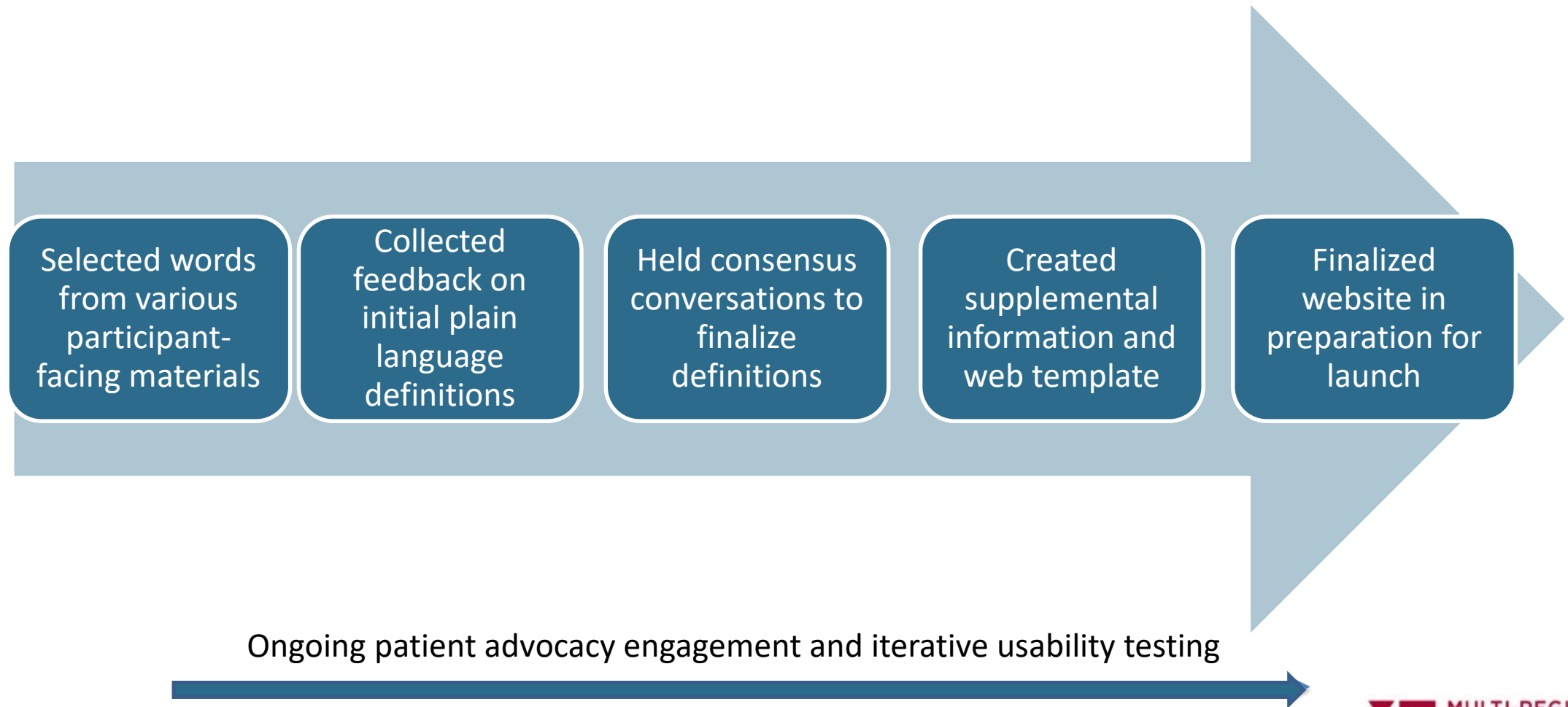
- Co-created with patients,
- Designed for public understanding,
- Acceptable to industry and academic stakeholders across the clinical research ecosystem.



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/>

The Clinical Research Glossary Pilot: Approach



The Clinical Research Glossary Pilot: Hallmarks

Creation

- Co-development with patients and participants (and user testing with patients).
- Plain language definitions and use in context.
- Addition of associated images and graphics.
- Inclusion of auditory pronunciation guide.

Dissemination

- Word of the Week social media campaign (Ongoing).
- Glossary shared on screens around hospital system (October, 2021).
- Glossary deployed in clinical trial recruitment (Planned).



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October is Health Literacy Month!

The MRCT Center of
Brigham and Women's
Hospital and Harvard has
created a

Clinical Research Glossary

to explain words that are
commonly used in
research studies.

VISIT
NOW

mrctcenter.org/glossary



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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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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 option before someone can participate in information about the study.

Informed consent is a process from a potential study participant.

A consent form is used as part of the process.

WORDS RELATED TO INFORMED CONSENT

consent
consent form

WORDS OPPOSITE TO INFORMED CONSENT



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!

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 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!



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What's Next?

- Commitment to using common definitions across the research industry.
- Expansion of the Clinical Research Glossary (version 2)
 - Addition of new words,
 - “Just in time” terminology to be included,
 - Considerations for translation,
 - Diverse and downloadable image library.

Thank you!

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