

16th Annual Meeting of ISMPP

The Evolving Role of the
Scientific Communications
Professional in an Open World



June 17, 2020 | Virtual Meeting



MULTI-REGIONAL CLINICAL TRIALS

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

A horizontal row of colorful silhouettes representing a diverse group of people. Above each silhouette is a speech bubble of a matching color. The colors transition from purple on the left, through red, orange, yellow, green, and finally blue on the right.

Advancing Health Literacy in Clinical Research

Sylvia Baedorf Kassis, MPH
Program Manager

Disclaimer

- The opinions contained herein 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) and 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.
- I have no personal conflicts of interests relevant to this presentation.

Objectives

- Recognize the importance of health literacy across the clinical research spectrum.
- Advocate for health literacy integration in your work and at your organization.
- Identify ways to apply health literacy to clinical research materials for patients and study participants.

The MRCT Center

Our Vision

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



The MRCT Center

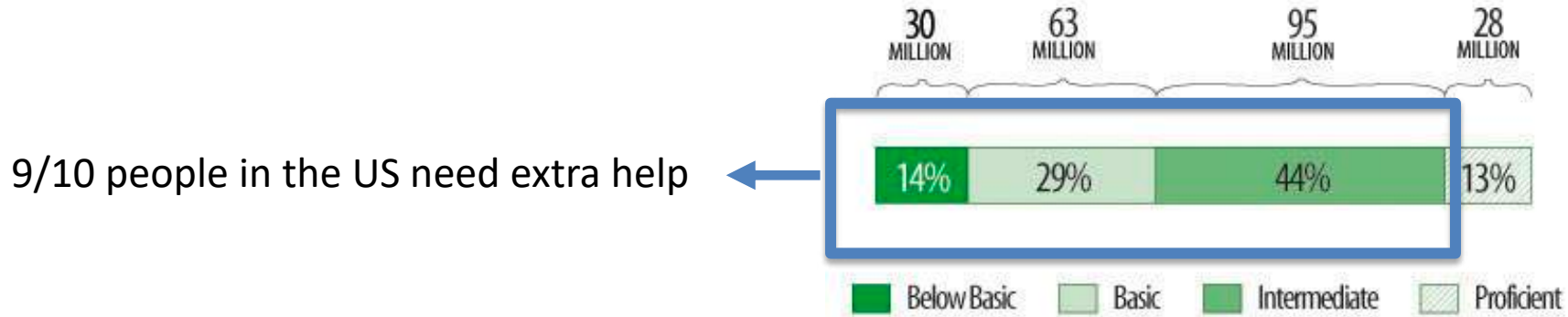
Our Mission

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.



The Health Literacy Opportunity

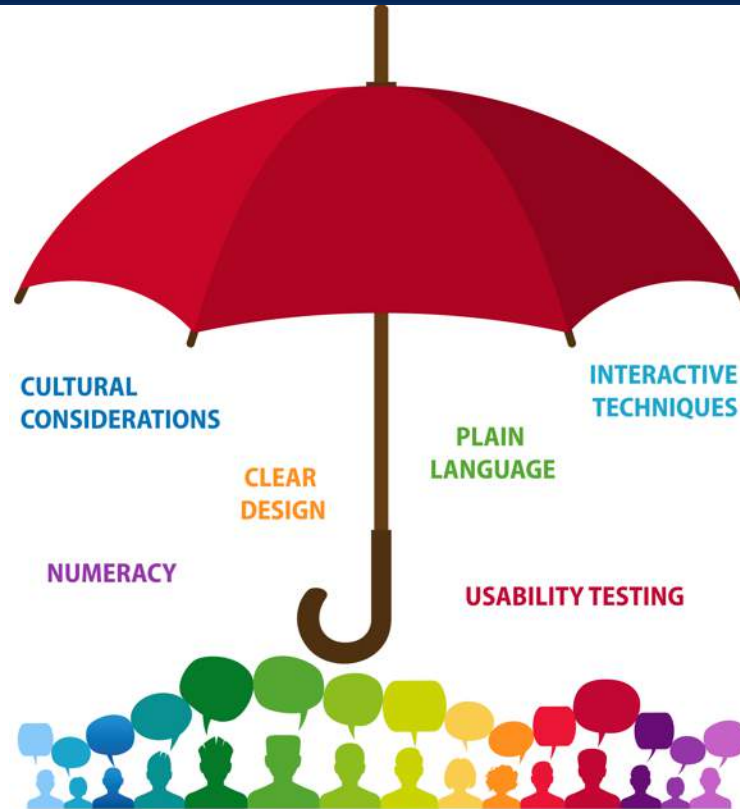
- Literacy levels are troubling around the world.



From: https://nces.ed.gov/naal/kf_demographics.asp

- Low health literacy affects a person's ability to:
 - Access services and information
 - Understand and follow health-related instructions
 - Make appropriate health-related decisions

A Broad View of Health Literacy



The Clinical Trial Life Cycle

Clear communication is essential throughout the participant's journey through the clinical trial life cycle



DISCOVERY



RECRUITMENT



CONSENT



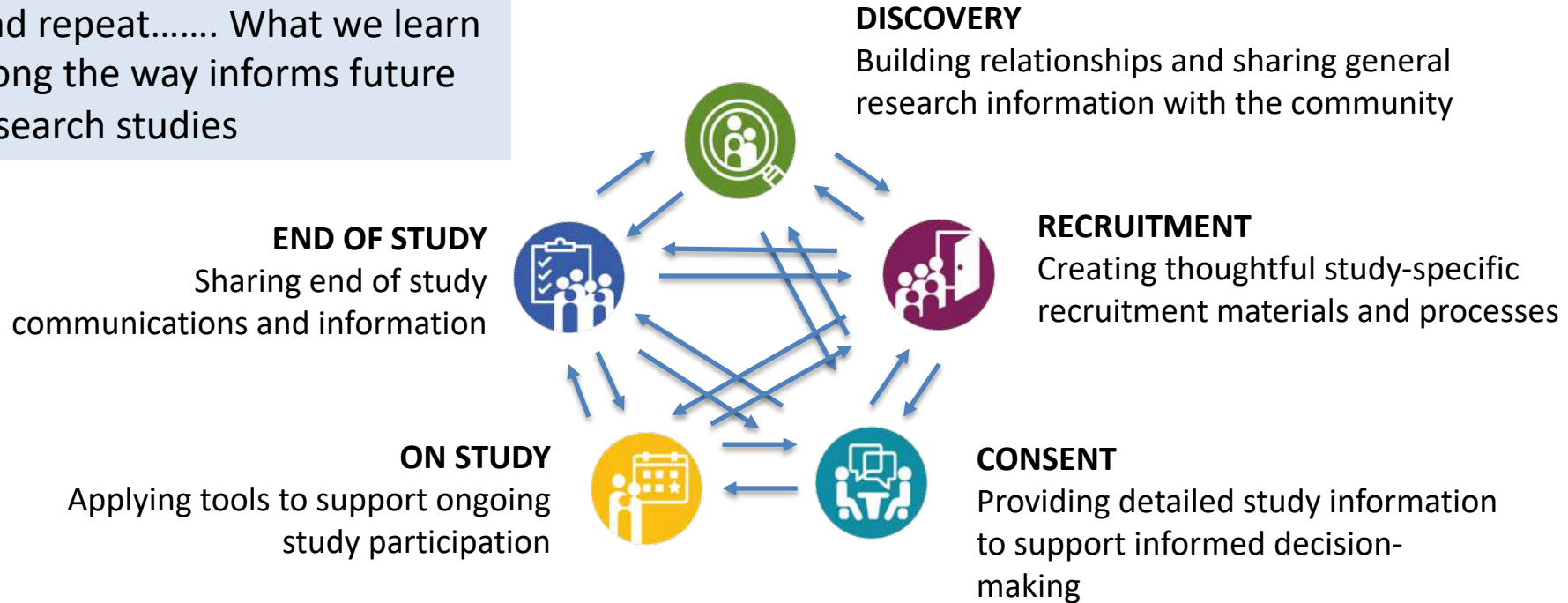
ON STUDY



END OF STUDY

Integrating Health Literacy Principles

And repeat..... What we learn along the way informs future research studies



The Potential of Applying Health Literacy Best Practices

Improved
ADHERENCE
to study procedures

Higher levels of
SATISFACTION
in the research experience

(and presumably, a better chance of
research being recommended to others)

Increased
PARTICIPATION
in studies

Greater
AWARENESS
of research

Reduced participant
ATTRITION

Clear Communications Benefit Everyone

HEALTH LITERACY HOME | CONTACT

MULTI-REGIONAL CLINICAL TRIALS CENTER

HEALTH LITERACY IN CLINICAL RESEARCH

START HERE | TRIAL LIFE CYCLE | BEST PRACTICES | RESOURCES BY ROLE

“
Tell me what I need to know and make sure I understand.
Tell me again tomorrow.”
”

- A research participant reflecting on their study experience

READ THE HEALTH LITERACY PRINCIPLES >>

Clear communication promotes health literacy and leads to:

- an informed audience
- greater transparency
- increased trust

Sponsors and funders, investigators and study teams, and institutional review boards and ethics boards all share a responsibility to create research materials that participants can understand and act upon.

Are you sure your clinical research materials are understandable?

Learn about the Principles of Health Literacy in Clinical Research

Learn More

Find out more about clear communications throughout the Clinical Trial Life Cycle

Learn More

Use tools and techniques to integrate health literacy into your clinical research role today

Learn More

View and share resources for your clinical trial participants that are easy to read and understand

Learn More

The Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard
14 Brook Street, 4th Floor, Cambridge, MA 02138, USA

CONTACT

Copyright © 2019

- The MRCT Center led the development of a dynamic web-based resource that highlights:
 - How health literacy applies throughout the clinical trial life cycle
 - Best practices to support clear research communications
 - Case studies and practical examples of how health literacy has already been integrated into research processes
 - Ways to take action in your own clinical research role

www.mrctcenter.org/health-literacy



MULTI-REGIONAL CLINICAL TRIALS

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

A horizontal illustration at the bottom of the slide shows a row of colorful silhouettes of people of various ethnicities and ages. Above each silhouette is a speech bubble of a different color, creating a rainbow gradient from purple on the left to blue on the right. A white rectangular box with a red border is superimposed over the center of the illustration, containing the text '1) Advocate at your organization'.

1) Advocate at your organization

HEALTH LITERACY IN CLINICAL RESEARCH

[START HERE](#) | [TRIAL LIFE CYCLE](#) | [BEST PRACTICES](#) | [RESOURCES BY ROLE](#)

“
 Tell me what I need
 to know and make
 sure I understand.
 Tell me again
 tomorrow.”

- A research participant
 reflecting on their study
 experience



READ THE HEALTH LITERACY PRINCIPLES

Clear communication
 promotes health
 literacy and leads to:

- an informed audience
- greater transparency
- increased trust

Sponsors and funders, investigators and study teams, and
 institutional review boards and ethics boards all share a
 responsibility to create research materials that participants
 can understand and act upon.

Are you sure your clinical research materials are understandable?



Learn about the
 Principles of Health
 Literacy in Clinical
 Research

[Learn More](#)


Find out more about
 clear communications
 throughout the Clinical
 Trial Life Cycle

[Learn More](#)


Use tools and techniques
 to integrate health
 literacy into your clinical
 research role today

[Learn More](#)


View and share resources
 for your clinical trial
 participants that are easy
 to read and understand

[Learn More](#)

HEALTH LITERACY IN CLINICAL RESEARCH

[START HERE](#) | [TRIAL LIFE CYCLE](#)

Health L

[Home](#) > [Start Here](#) > [Health Literacy Overview](#)

What is Health Literacy?

The classic definition of health literacy refers to an individual's capacity to obtain, process, and understand basic health information and services to make appropriate health decisions¹.

Yet, health literacy is in fact a dynamic process – it is a state not a trait. As such health literacy can be affected by various factors, like the stress of a new diagnosis or the setting within which information being shared.

Healthy People 2030 is proposing a new working definition of health literacy that reflects a consensus of health literacy a two-sided construct affected by both:

- an individual's capacities, and
- the abilities of those responsible for c

Health



PLAIN



Health Literacy in Clinical Research Principles

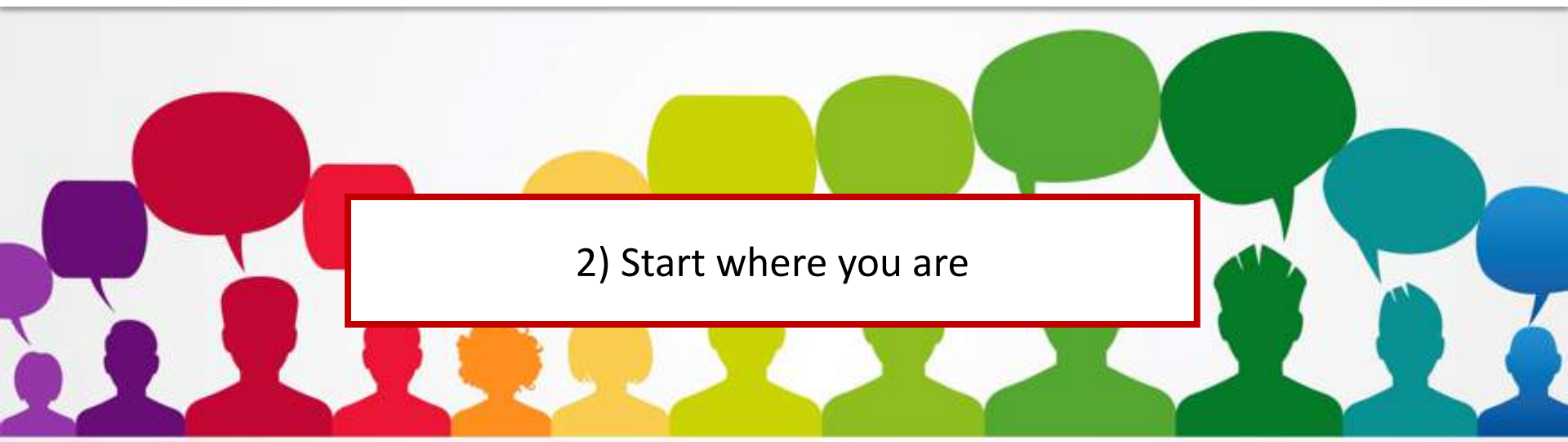
Clear communication with potential, enrolled, and past research participants supports understanding and decision-making that aligns to their values. Health literacy focuses on a person's ability to access, process, and understand health information to make informed health decisions. Clear communication, however, requires the communicator to share information in ways that the participant and their family, friends, and/or caregivers can understand and act upon. As such, clear communication is both respectful and ethically responsible, and important throughout the clinical research study life cycle - from access, recruitment, and informed consent to the end of a trial and the sharing of results. The MRCCT Center Health Literacy in Clinical Research workgroup has developed foundational principles to help guide the adoption and integration of health literacy practices into clinical research. These are intended to support sponsors and funders, investigators and study teams, and institutional review boards and ethics committees in their communications with potential, enrolled, and past participants.

1. All clinical research communications should be clear and easy to understand.
2. Clear communication is necessary throughout the clinical research life cycle.
3. All clinical research stakeholders share an ongoing responsibility for ensuring research communication is clear and easy to understand.
4. Clinical research communications should be developed by partnering with the intended audience(s).
5. Cultural respect is an integral part of communicating appropriately about clinical research.
6. Clinical research materials for participants should integrate health literacy practices, including plain language, numeracy, clear design techniques, and cultural considerations.
7. Clinical research materials for participants should be evaluated to ensure the intended audience(s) can understand the information.
8. In-person communication with the intended audience(s) should encourage dialogue and confirm understanding.
9. All clinical research stakeholders should support the development and implementation of organizational policies that integrate health literacy into clinical research.
10. Integration of health literacy into clinical research requires proactive planning to develop, test, modify, and confirm understanding of clinical research communications.



MULTI-REGIONAL CLINICAL TRIALS

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

A horizontal band at the bottom of the slide features a row of colorful silhouettes of diverse people. Above each silhouette is a speech bubble of a matching color. The colors transition from purple on the left, through red, orange, yellow, green, and finally blue on the right. A white rectangular box with a red border is superimposed over the center of this graphic.

2) Start where you are

HEALTH LITERACY IN CLINICAL RESEARCH

START HERE | TRIAL LIFE CYCLE | BEST PRACTICES | RESOURCES BY ROLE

Clinical Trial Life Cycle Overview

Home > Trial Life Cycle > Overview

Health literacy can support the participant through their clinical trial journey.



1. DISCOVERY

Public awareness of, education about, and access to clinical research



2. RECRUITMENT

Targeted, relevant, written and verbal invitations to join research



3. CONSENT

Clear written and verbal conversations about informed consent to research participation



4. ON STUDY

Clear information about ongoing research procedures, data collection and reporting



5. END OF STUDY

Plain language summaries, reports, and research publications

START HERE | TRIAL LIFE CYCLE | BEST PRACTICES | RESOURCES BY ROLE

Home > Trial Life Cycle > Overview > On Study



4. On Study

Clear information about ongoing research procedures, data collection and reporting

"On Study" is the time when the participant is enrolled into the specific research study and undergoes the research procedures outlined in the protocol.

- At this point the focus of the research team is on quality data collection, compliance with the research procedures and retention of enrolled participants.
- Ongoing clear communications about expectations and logistics are important.
- It is advised that any materials and scripts used during the ongoing study should go through **usability testing** with members of the intended audience.
- Through a process of ongoing engagement and active listening, researchers should periodically confirm participants understanding of the research and willingness to continue as the study proceeds

Click through the individual tabs to learn more about how your "On Study" research communications can be improved through plain language, numeracy, clear design and cultural considerations.

Plain Language

Numeracy

Clear Design

Cultural Considerations

Clear Design

During the "On Study" stage clear design techniques can be applied to print materials to support a participant's continued engagement in the study.

All tools and resources (such as health literate study calendars, study medication instructions, and study procedure descriptions), as well as additional materials like a regular study newsletter or results

How to give yourself the study medicine

Panel A (Days 1-5) and Panel B (Days 6-10)

Study medicine

Each bottle holds 1 mL of active drug or placebo.

The study staff will tell you how much medicine to use each time (this is called your dose). Only give yourself the dose the study staff tells you. Do not use all the medicine in the bottle.

The study staff will tell you how much to inject from each bottle.

Important safety information

- Follow the 10-step "Check Before" process.
- Only use each bottle 3 times.
- Use a new syringe and needle each time.
- Only shake the bottles when you use them.

Steps to give yourself the study medicine

Get ready

1. Gather your supplies:



PLAIN LANGUAGE Resources



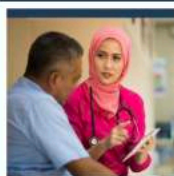
NUMERACY Resources



CLEAR DESIGN Resources



USABILITY TESTING Resources



CULTURAL CONSIDERATIONS Resources



INTERACTIVE TECHNIQUES Resources



GLOSSARY Resources



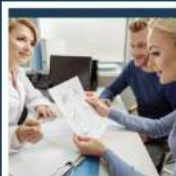
CONSENT GUIDE Resources



CASE STUDY LIBRARY Resources



EDUCATION & TRAINING Resources



RETURN OF RESULTS Resources



RESEARCH PARTICIPANTS' Resources



HEALTH LITERACY IN CLINICAL RESEARCH

Return of Results

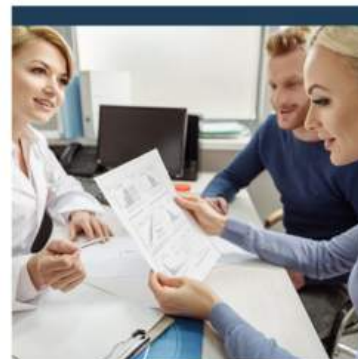
Home > Best Practices > Overview > Return of Results

Create and disseminate general clinical trial result summaries

(also known as Lay Summaries or Plain Language Summaries) so clinical trial participants:

- are informed about the trial results,
- know their participation is respected and appreciated
- understand the value of their contribution to science and public health.

More information about previous MRCT Center work on Return of Results can be [found here](#).



[Download](#) this fillable Return of Results template and adapt it to your study situation.





MULTI-REGIONAL CLINICAL TRIALS

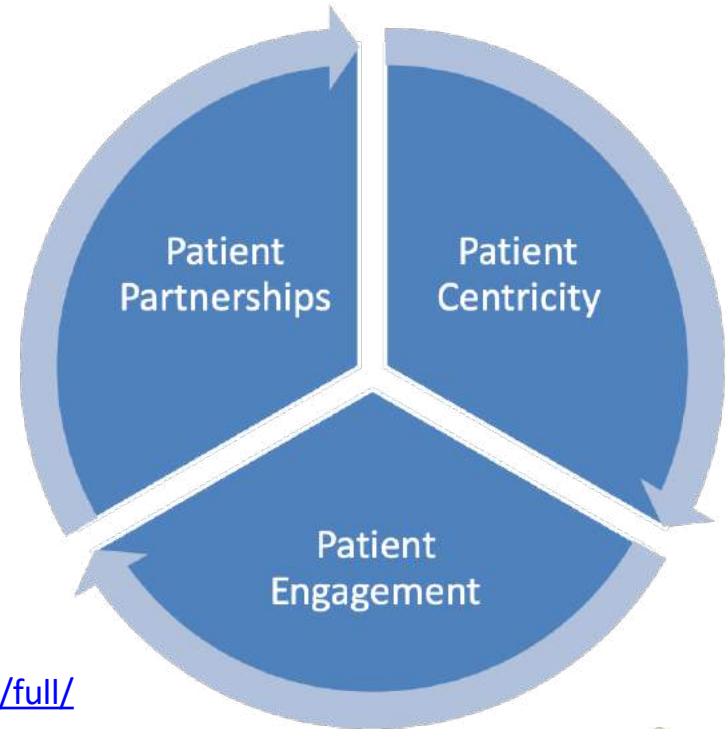
THE MRCT CENTER of
BRIGHAM AND WOMEN'S HOSPITAL
and HARVARD

A horizontal illustration at the bottom of the slide shows a row of colorful silhouettes of people of various ethnicities and ages. Above each silhouette is a speech bubble of a different color, representing patient input. A red-bordered box is overlaid on the center of the illustration, containing the text '3) Consider how to get patient input'.

3) Consider how to get patient input

Partnering with Patients

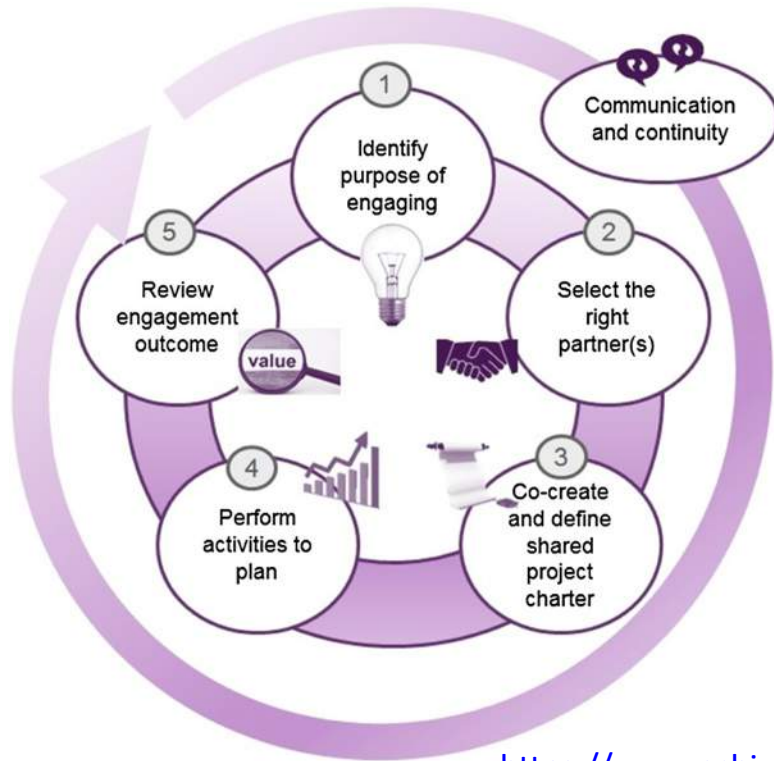
- Lessons learned from healthcare
 - People actively involved in their health and health care tend to have better outcomes.*
 - Patient decision making is *enhanced* by personal experience and *complemented* by scientific knowledge of healthcare professionals.**
 - Recognition of patients as experts fosters collaboration.**



*<https://www.healthaffairs.org/doi/10.1377/hpb20130214.898775/full/>

**<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4391791/>

Five Process Steps for Patient Group Engagement (PGE)

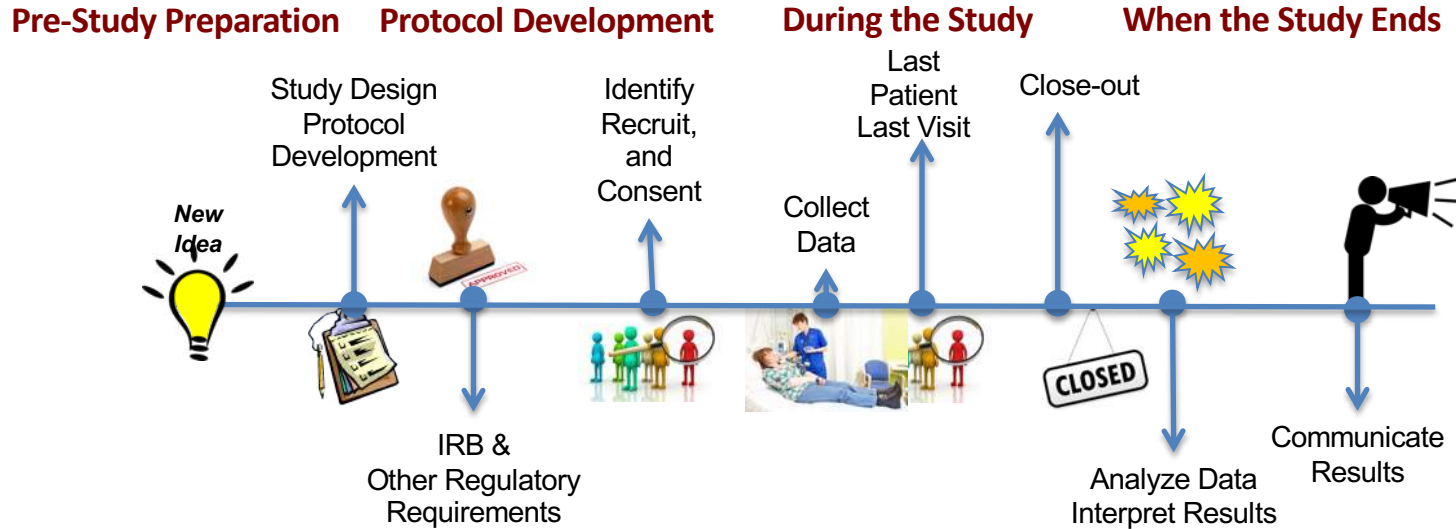


<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5766722/>

STAR Principles for PGE

- **Shared ambition**
 - Open and honest partnership focused on collaboration
- **Transparency**
 - Strategic objectives and clarity about processes
- **Accountability**
 - Key point of contact with aligned internal processes and ownership
- **Respect**
 - Maintained relationship and proactive communication

Phasing of Patient Input into the Return of End of Study Summaries



Find out early on what participants most want to learn through the research.

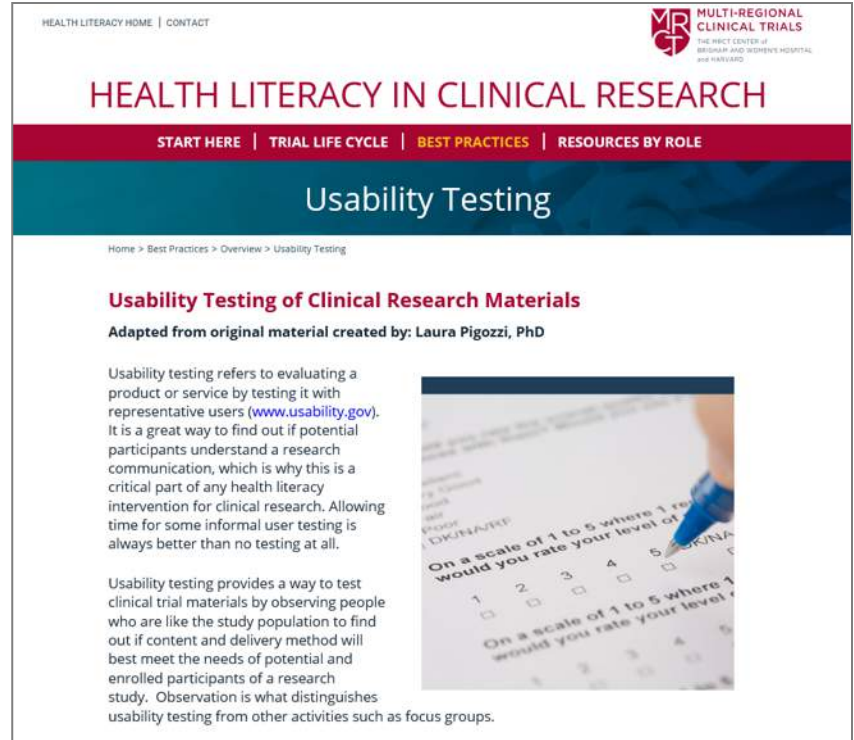
Get input on what, when and how to return results to the study population

Keep track of any study issues that may be important to address in the results summary

Collect feedback on the summary itself before it is posted/distributed widely.

Usability Testing of Clinical Research Materials

- Get input on whether research materials, documents and/or processes work as intended.
 - Can the user complete a specific task or set of tasks?
 - Can the user answer questions about what the information actually means?



HEALTH LITERACY HDME | CONTACT

MR MULTI-REGIONAL CLINICAL TRIALS
THE PRICK CENTER AT
BRIGHAM AND WOMEN'S HOSPITAL
AND HARVARD

HEALTH LITERACY IN CLINICAL RESEARCH

START HERE | TRIAL LIFE CYCLE | BEST PRACTICES | RESOURCES BY ROLE

Usability Testing


Home > Best Practices > Overview > Usability Testing

Usability Testing of Clinical Research Materials

Adapted from original material created by: Laura Pigozzi, PhD

Usability testing refers to evaluating a product or service by testing it with representative users (www.usability.gov). It is a great way to find out if potential participants understand a research communication, which is why this is a critical part of any health literacy intervention for clinical research. Allowing time for some informal user testing is always better than no testing at all.

Usability testing provides a way to test clinical trial materials by observing people who are like the study population to find out if content and delivery method will best meet the needs of potential and enrolled participants of a research study. Observation is what distinguishes usability testing from other activities such as focus groups.



Learn more at <https://mrccenter.org/health-literacy/tools/overview/usability-testing/>

Additional Resources

Patient Engagement in the Design and Conduct of Medical Device Clinical Investigations



Patient Protocol Engagement Toolkit (P-PET)



Resource Guide
Version 1

Patient-Focused Drug Development: Collecting Comprehensive and Representative Input

CTTI Prioritization Tool for Sponsors and Patient Groups

OVERVIEW

ANALYZE

VISUALIZE

This tool helps patient groups and clinical research sponsors identify high-value opportunities to work together. Using this tool, you will:



- ▶ Select engagement opportunities that are relevant to the project or collaboration you have in mind.
- ▶ Use our comprehensive list or add your own.
- ▶ Rate the benefits and investments for each opportunity.
- ▶ Review and adjust your analysis within a visual display.
- ▶ Add a partner's analysis for comparison and discussion.
- ▶ Select opportunities to pursue with your partner and get started!

The work at the MRCT Center continues....

- COVID-19 Research Flyers
- A Pilot of a Collaborative Cross-Industry Plain Language Glossary for Clinical Research
- Additional resources for specific stakeholders.

I am Healthy: Should I Join a COVID-19 Research Study?

This flyer is designed for healthy adults. It includes a 'Research study' section with bullet points on what to look for, a 'COVID-19' section explaining the virus, and a 'What should I ask the research team' section with a checklist of questions. It features the logos for the University of Michigan and the Harvard Catalyst Center.

I am a Healthy Child: Should I Join a COVID-19 Research Study?

This flyer is for healthy children and their parents. It covers 'Research study' details, 'COVID-19' information, and a 'What should I ask the research team' checklist. It includes the Harvard Catalyst logo.

I am Sick with COVID-19: Should I Join a COVID-19 Research Study?

This flyer is for individuals currently sick with COVID-19. It provides information on 'Research study' options, 'COVID-19' symptoms and testing, and a 'What should I ask the research team' checklist. It features the Harvard Catalyst logo.

My Child has COVID-19: Should they join a COVID-19 Research Study?

This flyer is for parents of children who are sick with COVID-19. It details 'Research study' information, 'COVID-19' facts, and a 'What should I ask the research team' checklist. It includes the Harvard Catalyst logo.

I am a Child with COVID-19: Should I Join a COVID-19 Research Study?

This flyer is for children who are sick with COVID-19. It covers 'Research study' details, 'COVID-19' information, and a 'What should I ask the research team' checklist. It features the Harvard Catalyst logo.

Vaccine Research: Should I Join a COVID-19 Vaccine Research Study?

This flyer is for individuals interested in COVID-19 vaccine research. It includes 'Research study' information, 'COVID-19' background, and a 'What should I ask the research team' checklist. It features the Harvard Catalyst logo.

<https://mrctcenter.org/blog/resources/covid-19-clinical-research-flyers/>

Takeaways

- We all play a critical role
 - Clear participant-facing communications are essential throughout the clinical research life cycle.
- Help break down the silos
 - Preparation and planning for clear research communications starts early in the clinical research process.
- Patients have the lived experience
 - Including the participant's input is an essential part of creating understandable study-related materials
- There is no need to re-invent the wheel
 - Resources exist on the MRCT Center website and through other groups

Please follow the MRCT Center:



Multi-Regional Clinical Trials Center of Brigham...

Research · Cambridge, Massachusetts · 224 followers

Improving the integrity, safety, and rigor of global clinical trials

[Visit website](#)



[linkedin.com/company/multi-regional-clinical-trials-center-of-brigham-and-women's-hospital-and-harvard](https://www.linkedin.com/company/multi-regional-clinical-trials-center-of-brigham-and-women's-hospital-and-harvard)



twitter.com/MRCTCenter



[Edit profile](#)

Multi-Regional Clinical Trials Center

@MRCTCenter

The MRCT Center of Brigham and Women's & Harvard is a research and policy center that aims to improve the integrity, safety and rigor of global clinical trials.

mrcrcenter.org Joined December 2015

Thank you!

Sylvia Baedorf Kassis, MPH

Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard

sbaedorfkassis@bwh.harvard.edu