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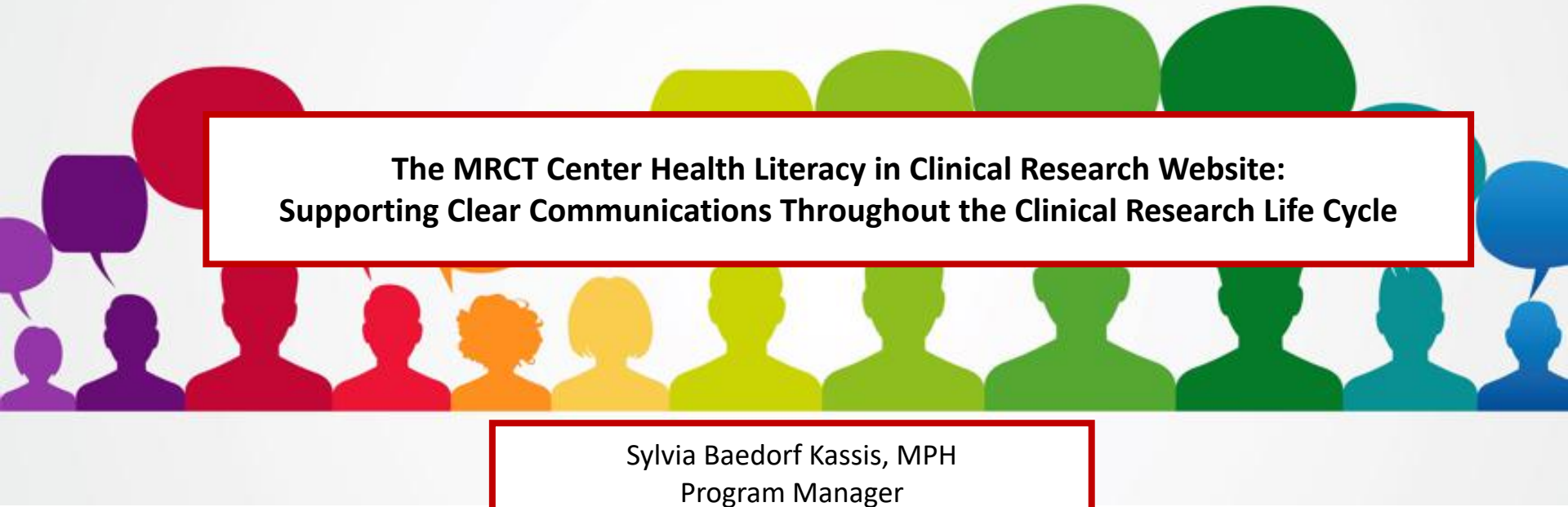

The MRCT Center Health Literacy in Clinical Research Website: Supporting Clear Communications Throughout the Clinical Research Life Cycle

Sylvia Baedorf Kassis, MPH
Program Manager

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- I have no personal conflicts of interests relevant to this presentation.

Objectives

- At the end of the session, attendees will be able to:
  - Describe the application of health literacy principles throughout the clinical research life cycle.
  - Access and use resources on the MRCT Center's *Health Literacy in Clinical Research* website to develop participant-facing materials and processes that support participant understanding.
  - Share best practices with their colleagues and team members to promote greater integration of health literacy best practices into their clinical research processes.

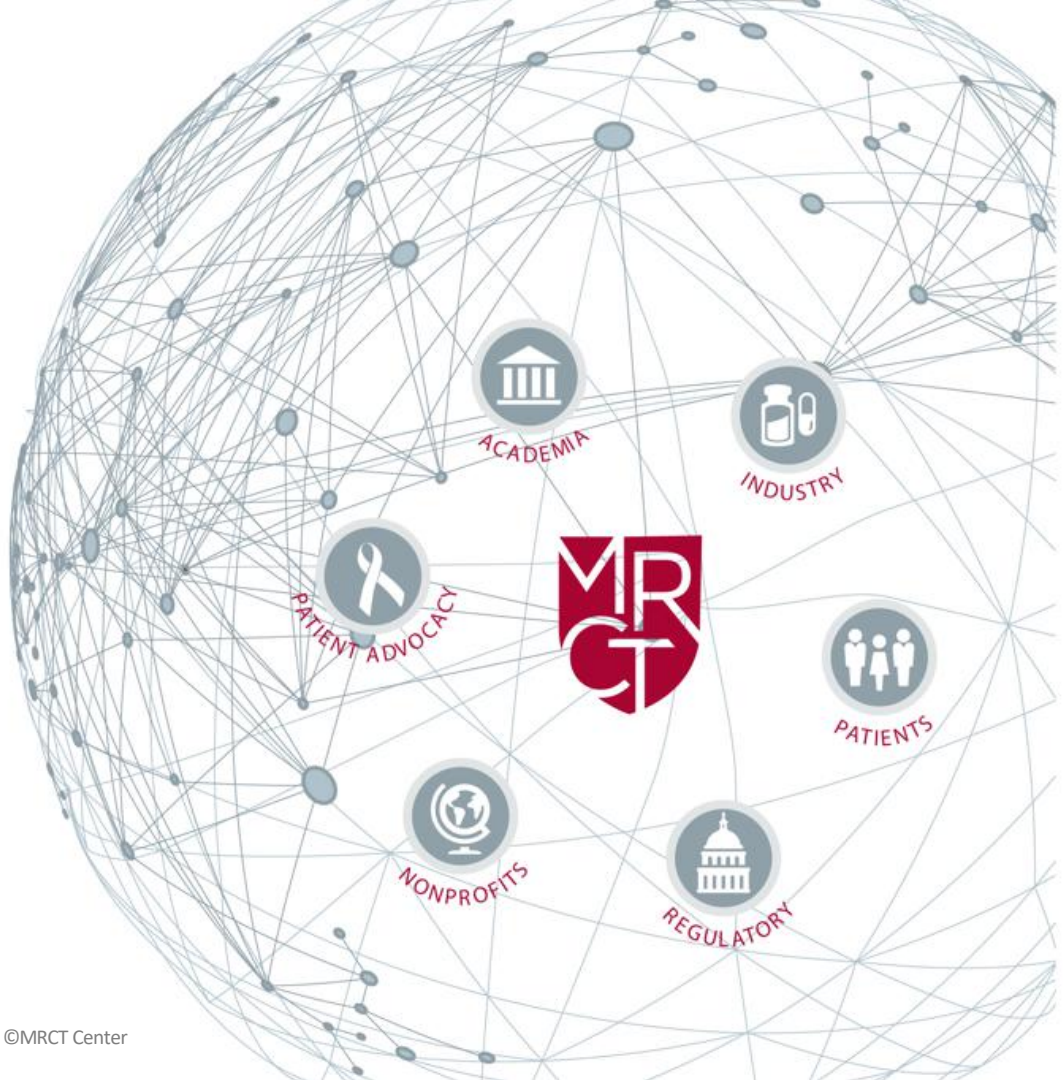
The MRCT Center

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.



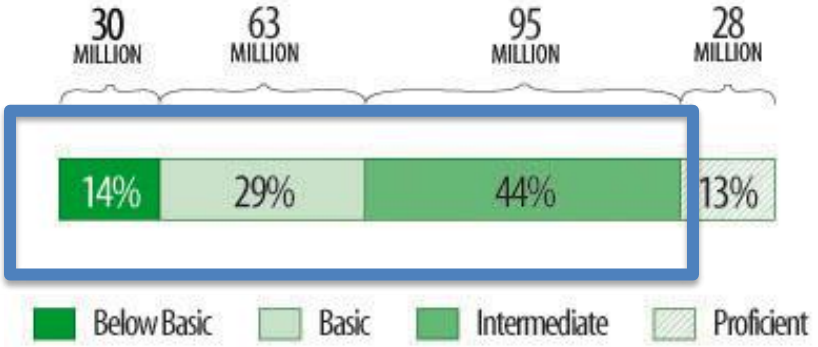
Prior MRCT Center Work

https://mrctcenter.org/blog/projects/return-of-individual-results/
https://mrctcenter.org/blog/projects/return-of-results-to-participants/

The Health Literacy Opportunity

- Literacy levels are troubling around the world.

9/10 people in the US need extra help



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

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

A Broad View of Health Literacy

…and a shared responsibility.

The Clinical Trial Life Cycle

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

Integrating Health Literacy Principles

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

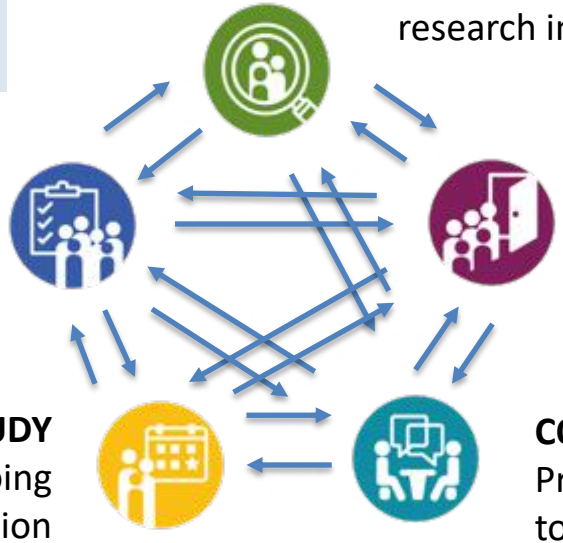
DISCOVERY
Building relationships and sharing general research information with the community

RECRUITMENT
Creating thoughtful study-specific recruitment materials and processes

CONSENT
Providing detailed study information to support informed decision-making

ON STUDY
Applying tools to support ongoing study participation

END OF STUDY
Sharing end of study communications and information



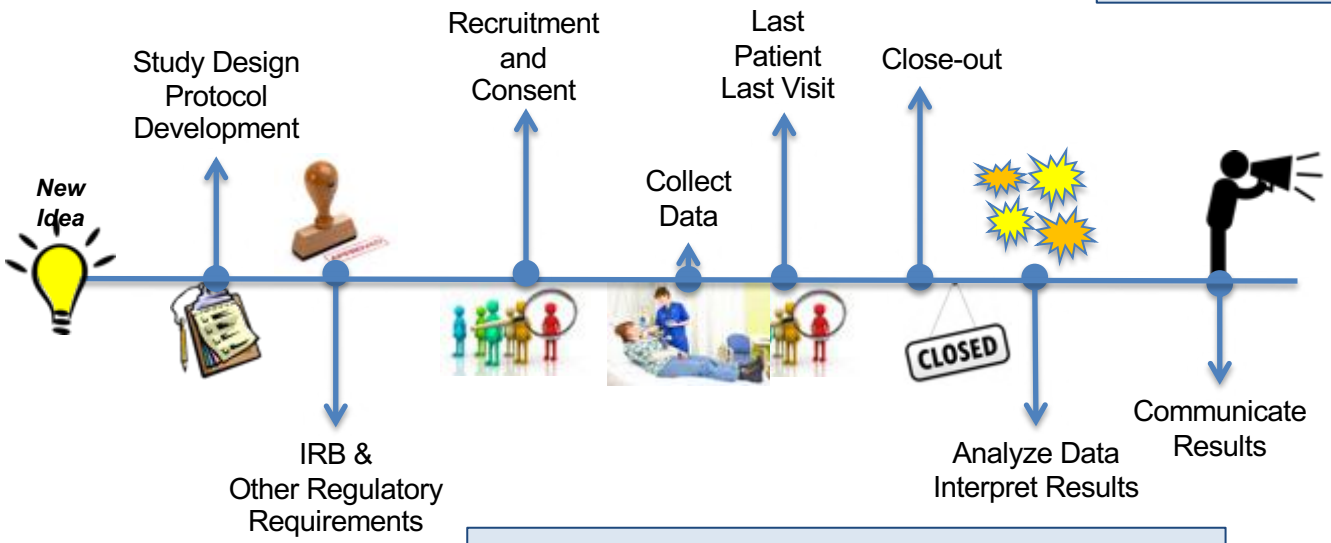
Integrate Health Literacy into the Trajectory of a Research Study

Get to know about the study population

Ask members of the study population for feedback

Explain end of study processes

Report findings to participants



Provide additional information to support participation

Develop recruitment materials and consent forms using health literacy best practices

Stage of Journey through the Life Cycle	Examples of Clear Communication Opportunities
 **Discovery**	- Research awareness campaigns - Outreach and engagement efforts to solicit patient input into study design and development
 **Recruitment**	- Advertisements - Recruitment scripts
 **Consent**	- Consent scripts - Consent forms - Study schedules/calendars
 **On Study**	- Study medication/intervention instructions - Study commitment contract - Adverse event reporting information - Participant satisfaction survey
 **End of Study**	- Instructions for coming off trial - Information on maintaining access to treatment options - Study results/summaries

The Potential of Applying Health Literacy Best Practices

Clear Communications Benefit Everyone

- 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

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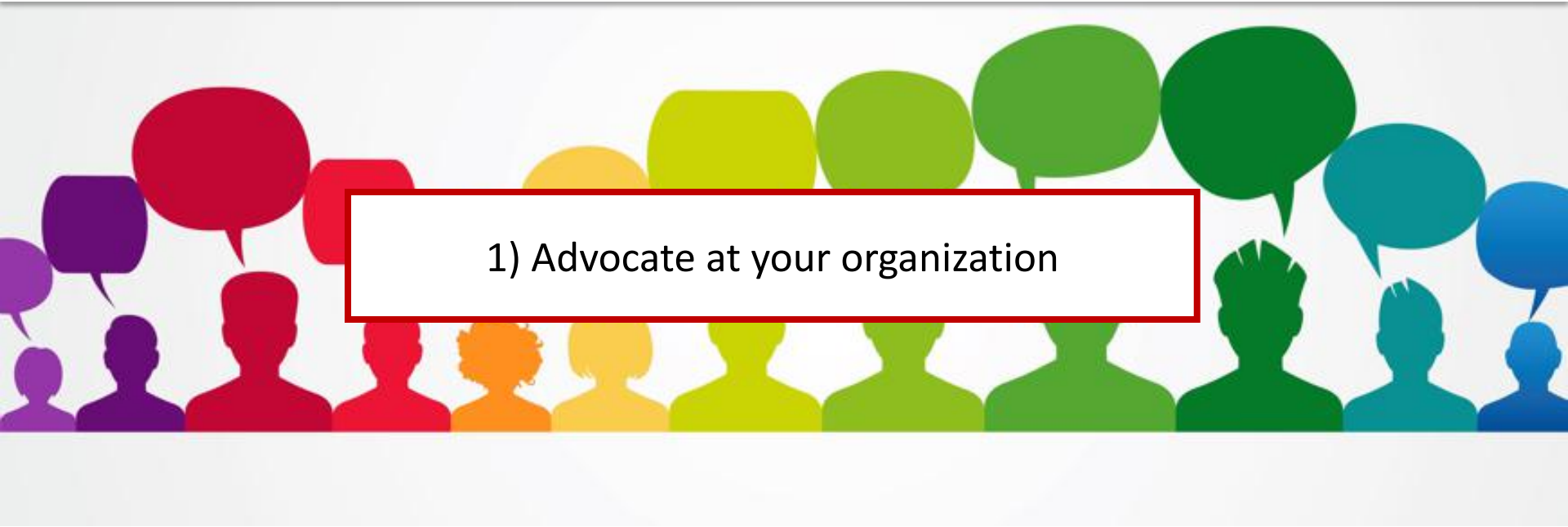

1) Advocate at your organization

HEALTH LITERACY HOME | CONTACT

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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	Find out more about clear communications throughout the Clinical Trial Life Cycle	Use tools and techniques to integrate health literacy into your clinical research role today	View and share resources for your clinical trial participants that are easy to read and understand
Learn More	Learn More	Learn More	Learn More

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CONTACT

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HEALTH LITERACY IN CLINICAL RESEARCH

START HERE | TRIAL LIFE CY

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 obt process, and understand basic health information and services to make appropriate health decisions [1].

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

Healthy People 2030 is proposing a nev working definition of health literacy tha 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

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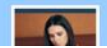

PLAIN

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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 MRCT 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.

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For more information about the MRCT Center's work on health literacy in clinical research, visit: https://mrctcenter.org/health-literacy/

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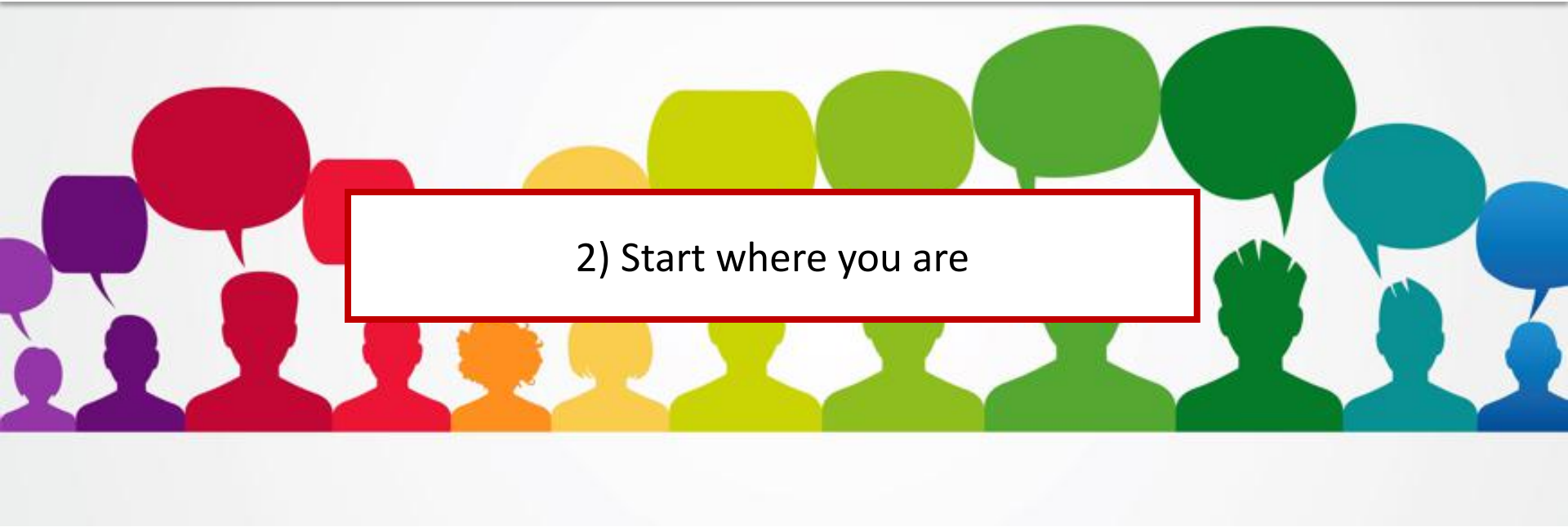

2) Start where you are

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HEALTH LITERACY IN CLINICAL RESEARCH

Clinical 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, results 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 told 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

- Refrigerate the kit box – Do not freeze.
- Only use each bottle 1 time.
- Use a new syringe and needle each time.
- Only uncap the bottles when you use them.

Steps to give yourself the study medicine

Get ready

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

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 HOME | CONTACT

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HEALTH LITERACY IN CLINICAL RESEARCH

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

Return of Results

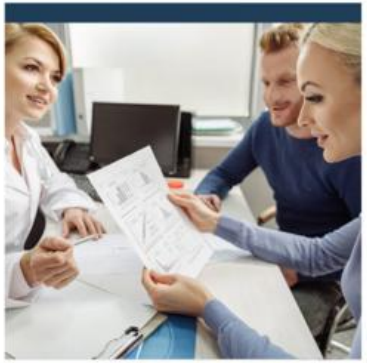
Home > Best Practices > Overview > Return of Results

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.

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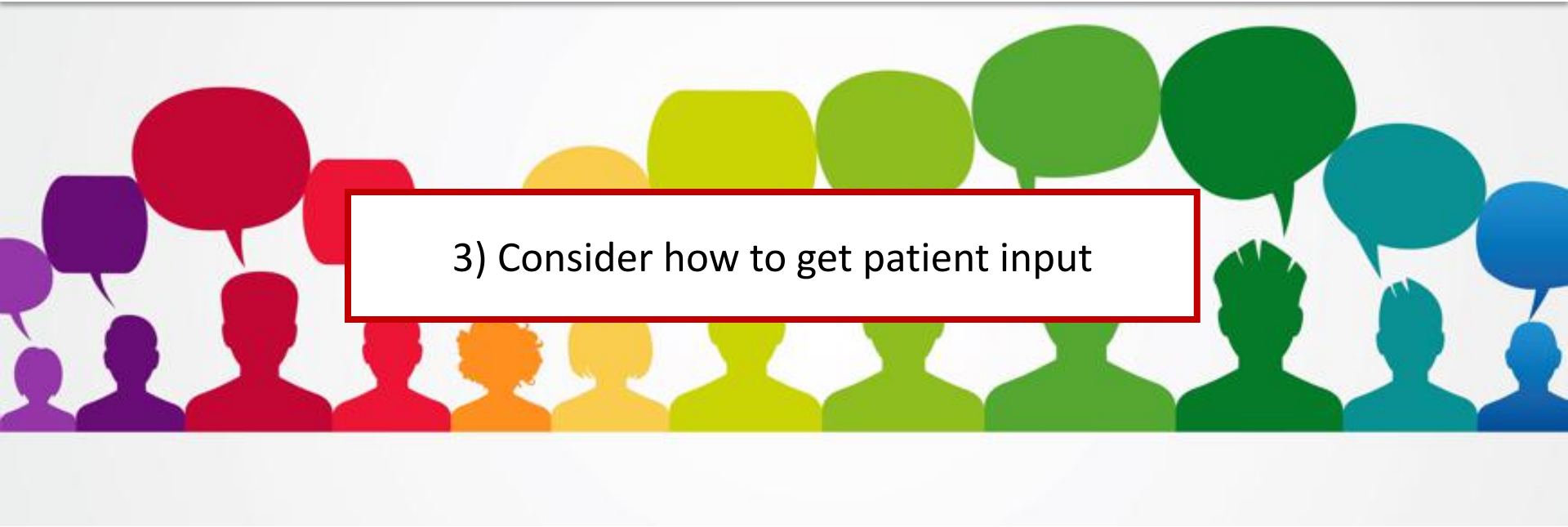
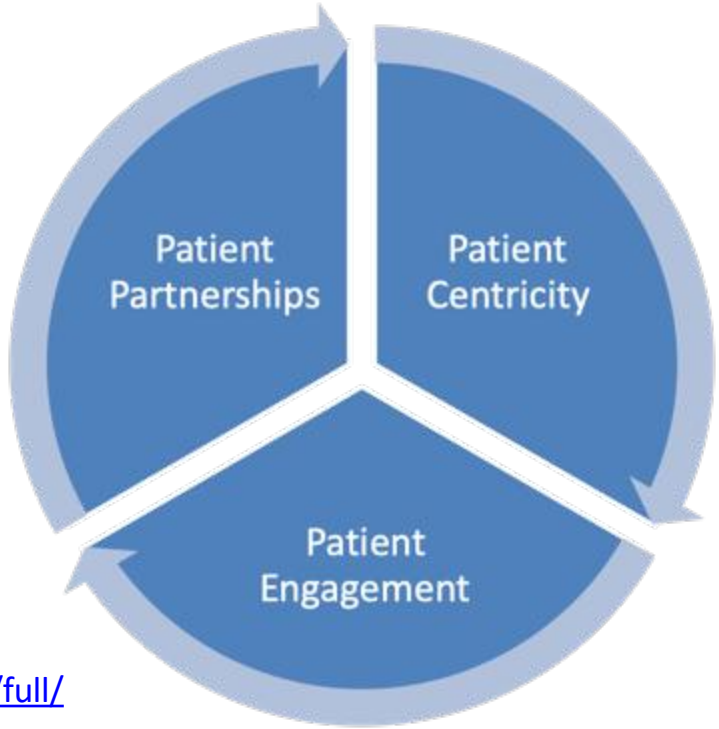


3) Consider how to get patient input

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.**

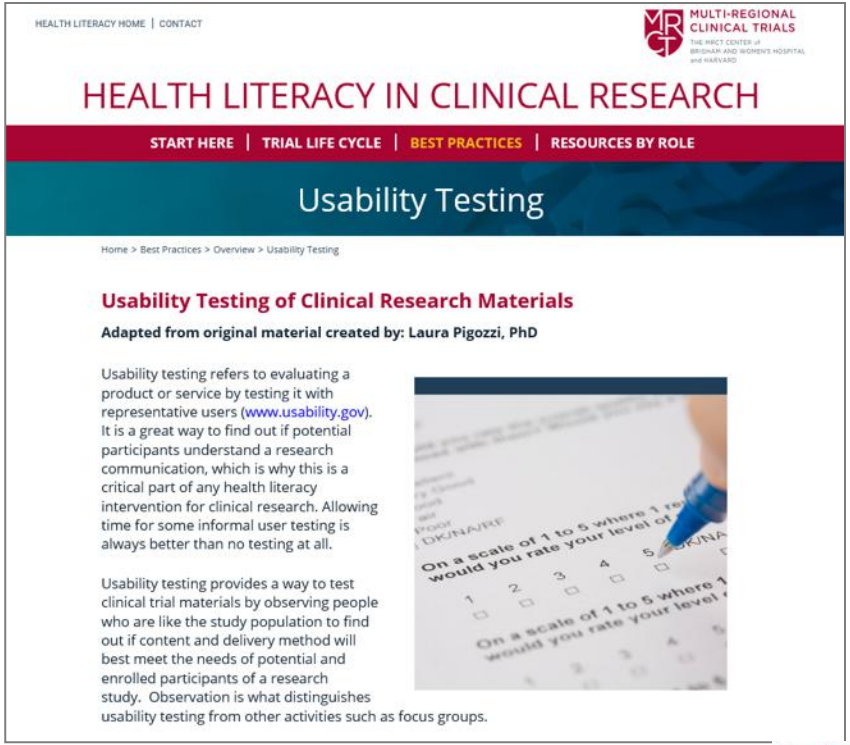


*https://www.healthaffairs.org/do/10.1377/hpb20130214.898775/full/

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

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?



Learn more at https://mrctcenter.org/health-literacy/tools/overview/usability-testing/

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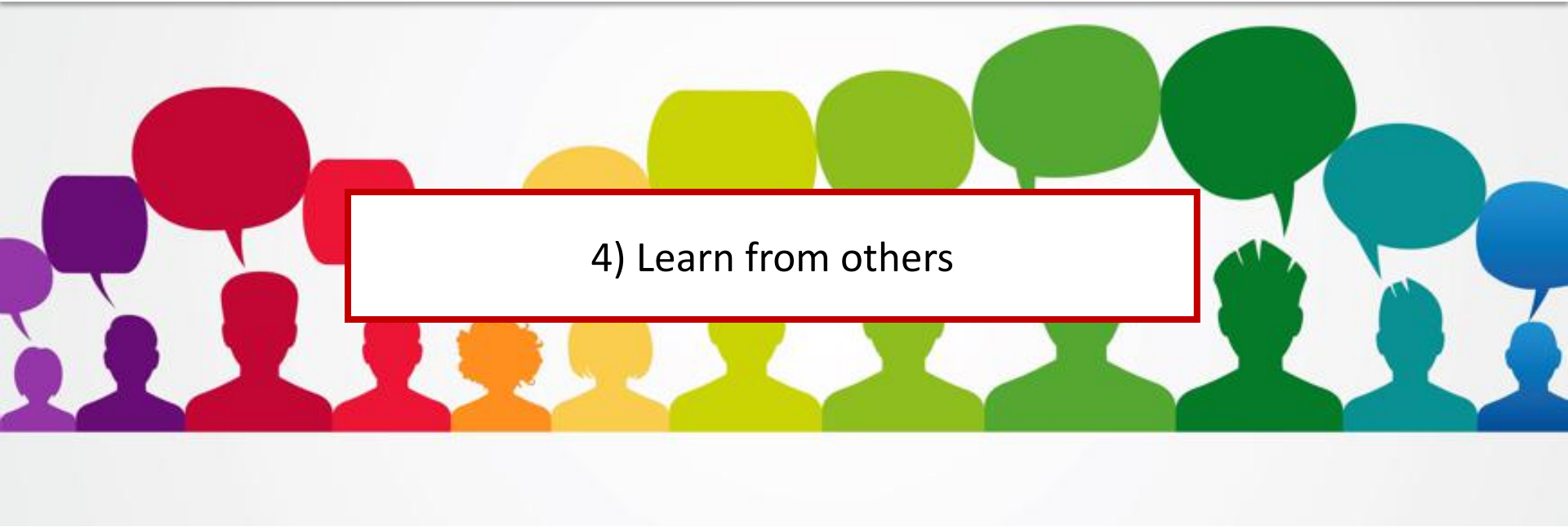


4) Learn from others

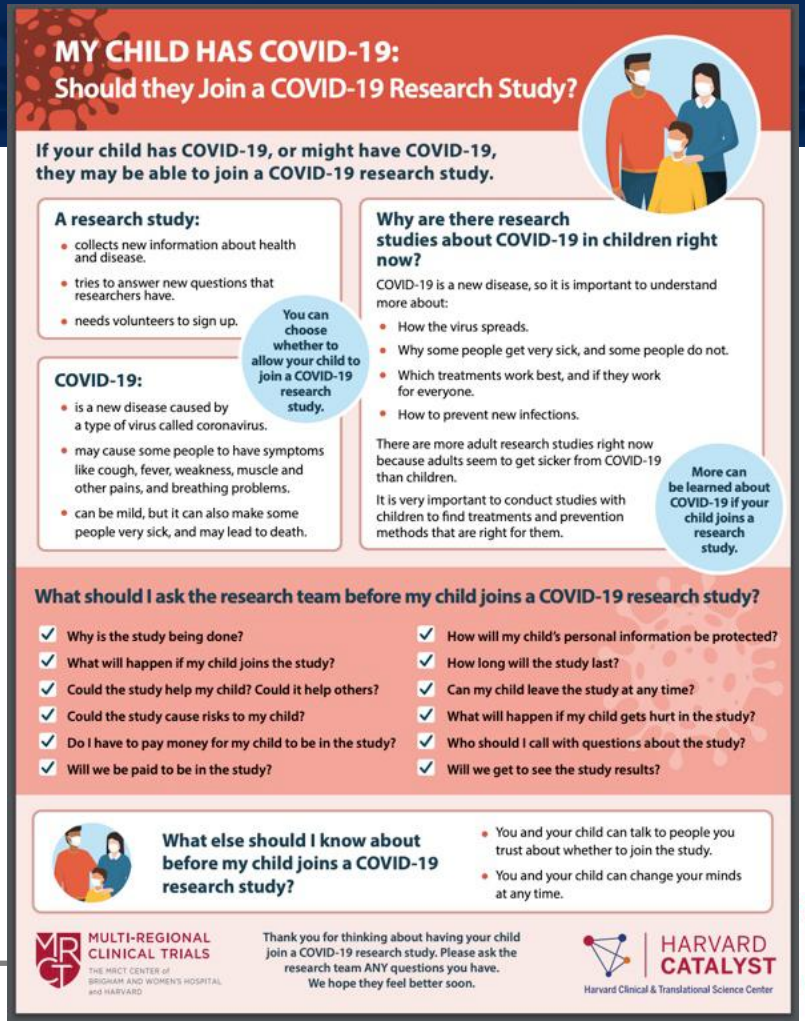
Research Teams are Applying Health Literacy Best Practice

- Case Studies are a great way to learn more about what others are doing.
- Cases include:
  - Creating pediatric assent forms
  - Supporting participant retention
  - Developing informed consent templates
  - Implementing implicit bias exercises into staff training
- Do you have a case to share?

Learn more at https://mrctcenter.org/health-literacy/tools/overview/casestudies/

Example Recruitment Flyer

- Introductory research information can help people be better able to understand the details of your study
- Health literacy best practices were applied to develop introductory information like in this one on joining COVID-19 trials



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

Study Medication Instructions

- Study-specific instructions can help participants follow the requirements of the study

- Use health literacy best practices to develop instructions like this one on how to give yourself the study medicine

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 told you. Do not use all the medicine in the bottle.

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

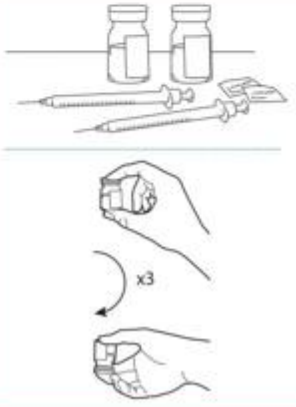
Important safety information

- Refrigerate the kit box – Do not freeze.
- Only use each bottle 1 time.
- Use a new syringe and needle each time.
- Only uncap the bottles when you use them.

Steps to give yourself the study medicine

Get ready

1. Gather your supplies:
   - 2 syringes
   - 2 bottles of medicine
   - 2 alcohol swabs
2. Take out 2 bottles from the kit box and put the kit box back in the refrigerator.
   - Let the bottles sit on the counter for at least 15 minutes to get to room temperature.
   - Turn the bottles upside down and then right side up at least 3 times.
3. Wash your hands with soap and water.



Merck & Co., Inc. example with input from Health Literacy Media

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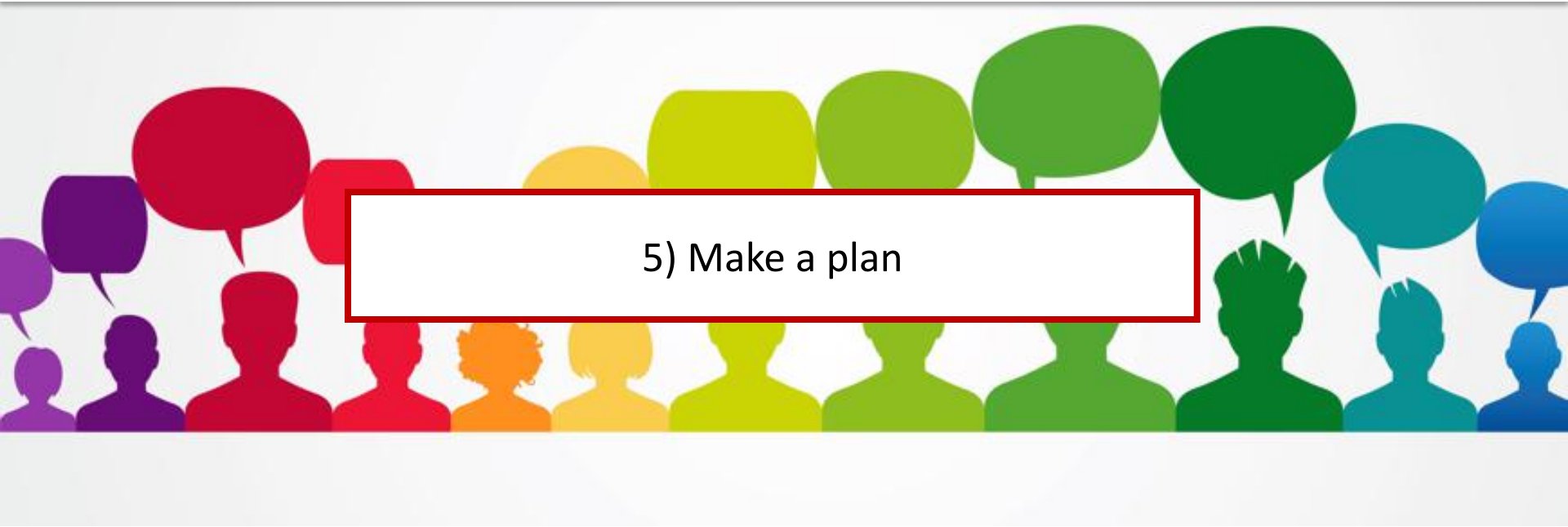

5) Make a plan

What is one thing your learned that you you plan to share with your colleagues?

Key Takeaways

- Each of us can play a role in creating more understandable research materials
  - Clear participant-facing communications are essential throughout the clinical research life cycle.
- Consider health literacy best practices in your research study planning
  - Preparation and planning for clear research communications starts early in the process.
- Engage patients and participants with the lived experience to co-create
  - Including the participant's input is an essential part of developing understandable study-related materials.
- There is no need to re-invent the wheel
  - Resources exist on the MRCT Center website!

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MRCTcenter.org

Contact me at: sbaedorfkassis@bwh.harvard.edu

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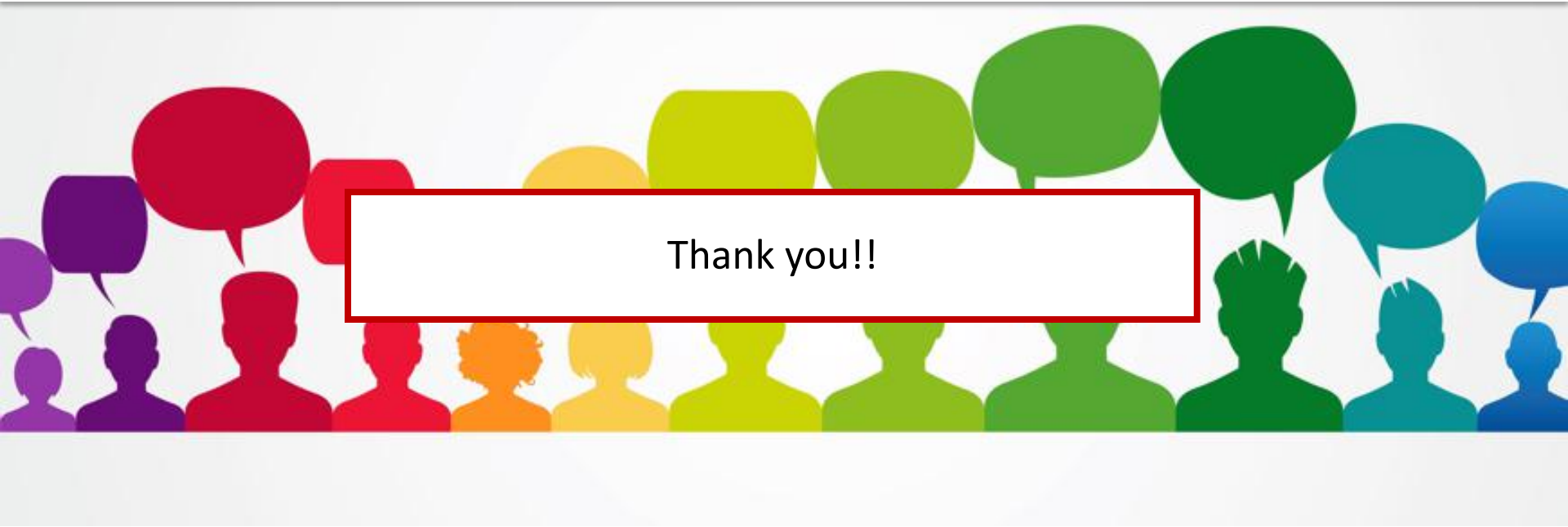

Thank you!!