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

Advancing Health Literacy in Clinical Research

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- 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

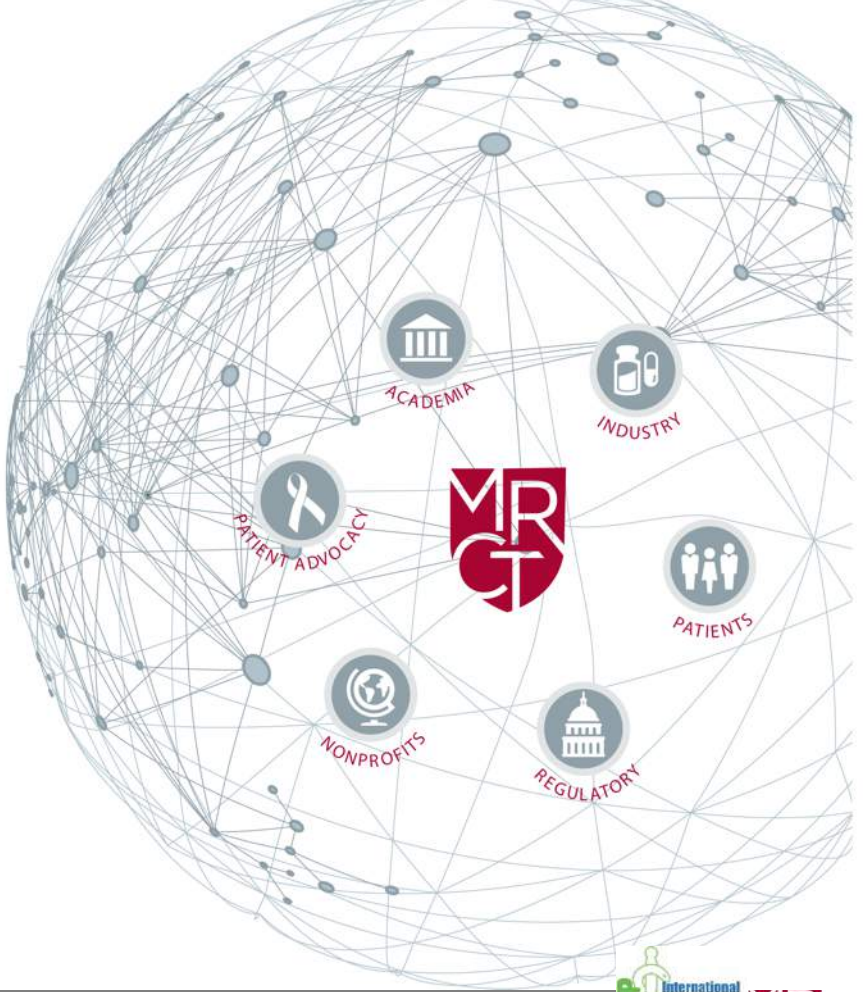
Our Vision

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.

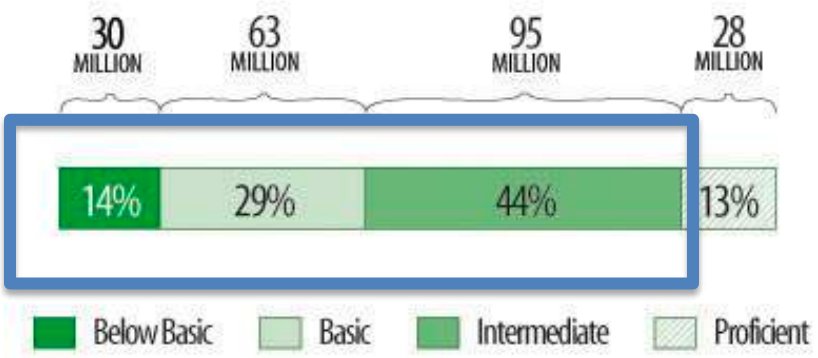


ISMPP International Society for Medical Publication Professionals

The Health Literacy Opportunity

- Literacy levels are troubling around the world.

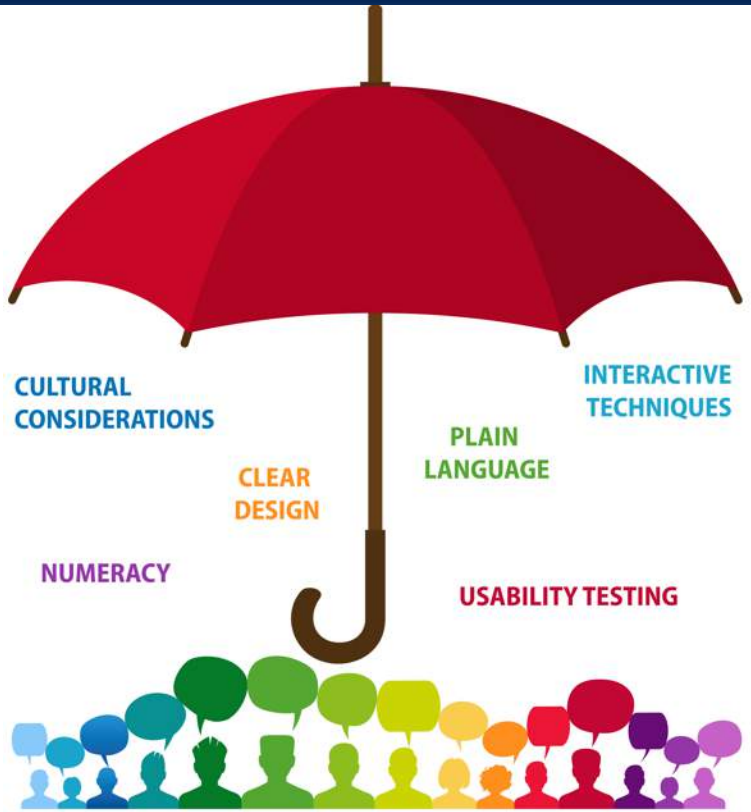
9/10 people in the US need extra help



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

- 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



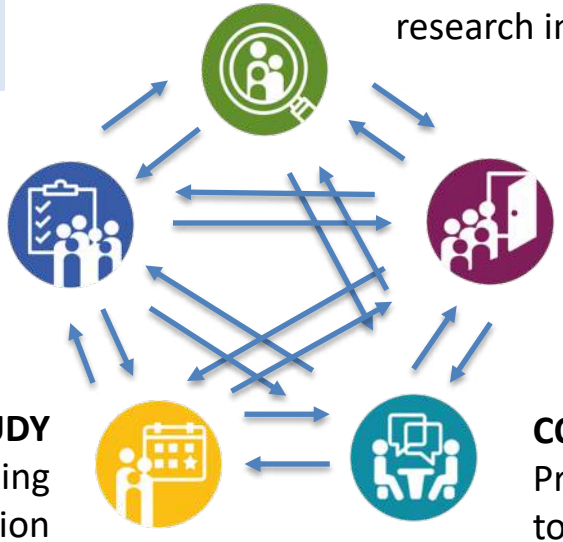
The Clinical Trial Life Cycle

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

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



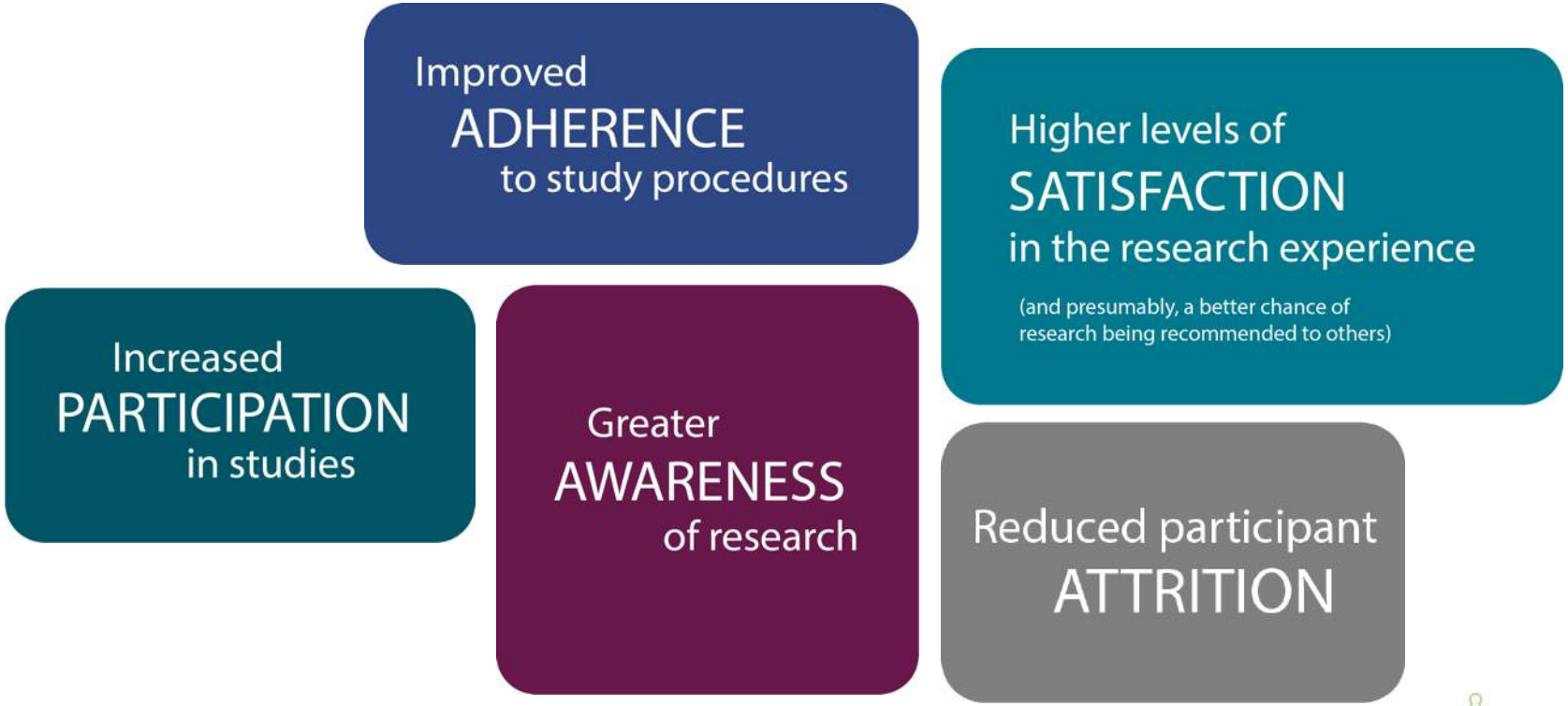
RECRUITMENT
Creating thoughtful study-specific recruitment materials and processes

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

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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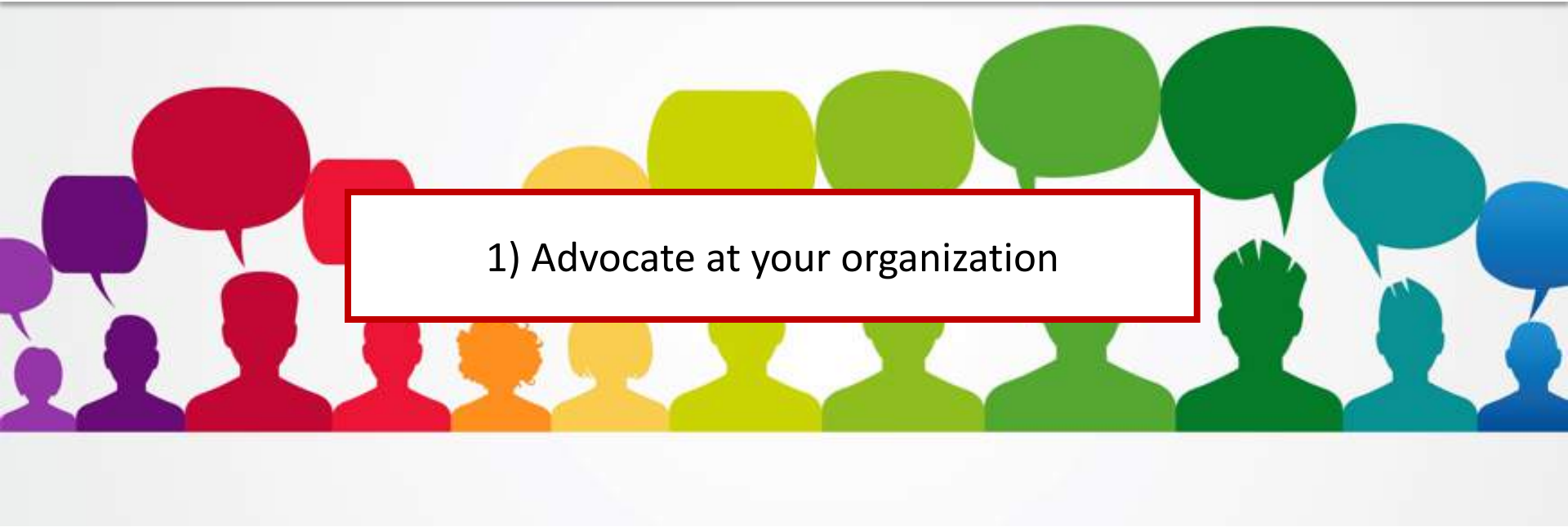
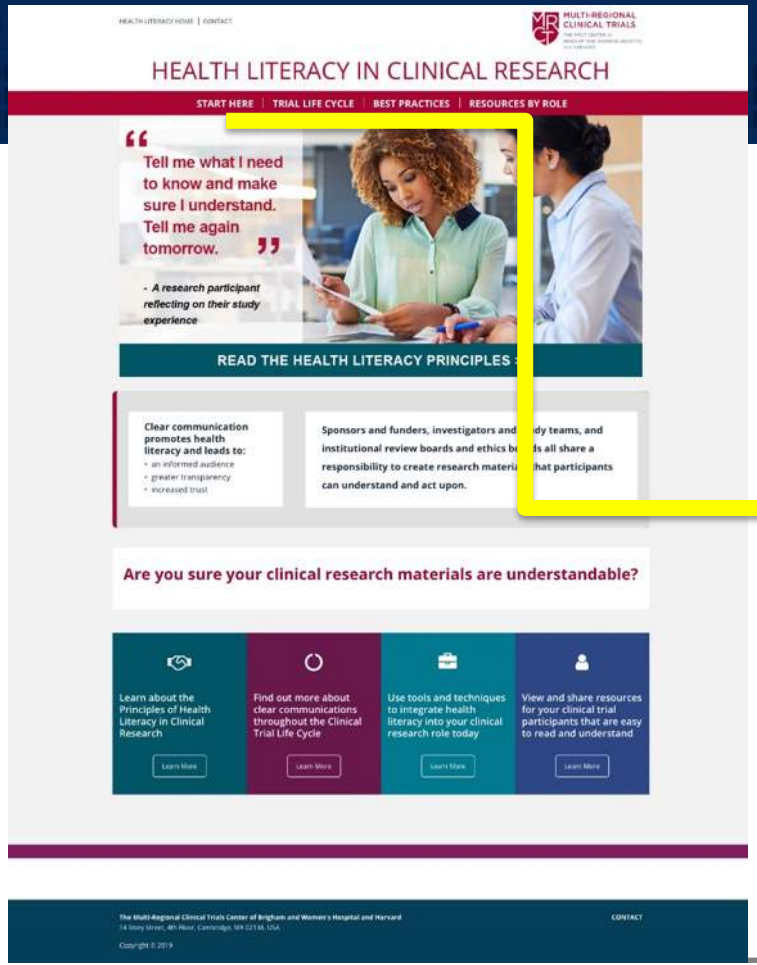
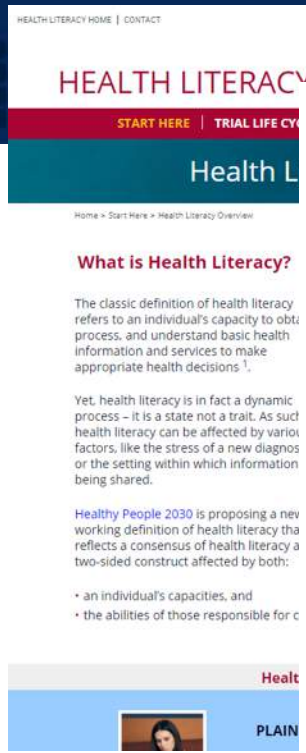


1) Advocate at your organization





Health Literacy 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

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.

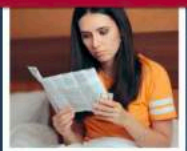
Plain Language | Numeracy | Clear Design | Cultural Considerations

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

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



PLAIN LANGUAGE Resources

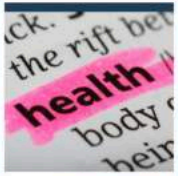
NUMERACY Resources

CLEAR DESIGN Resources

USABILITY TESTING Resources

CULTURAL CONSIDERATIONS Resources

INTERACTIVE TECHNIQUES Resources

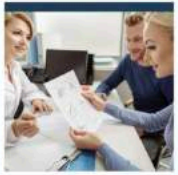


GLOSSARY Resources

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

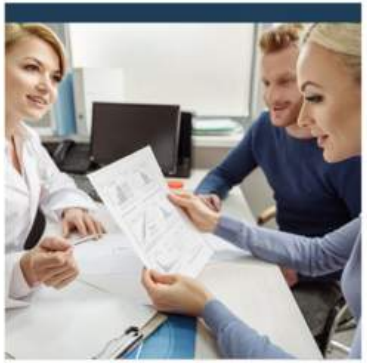
Home > Best Practices > Overview > Return of Results

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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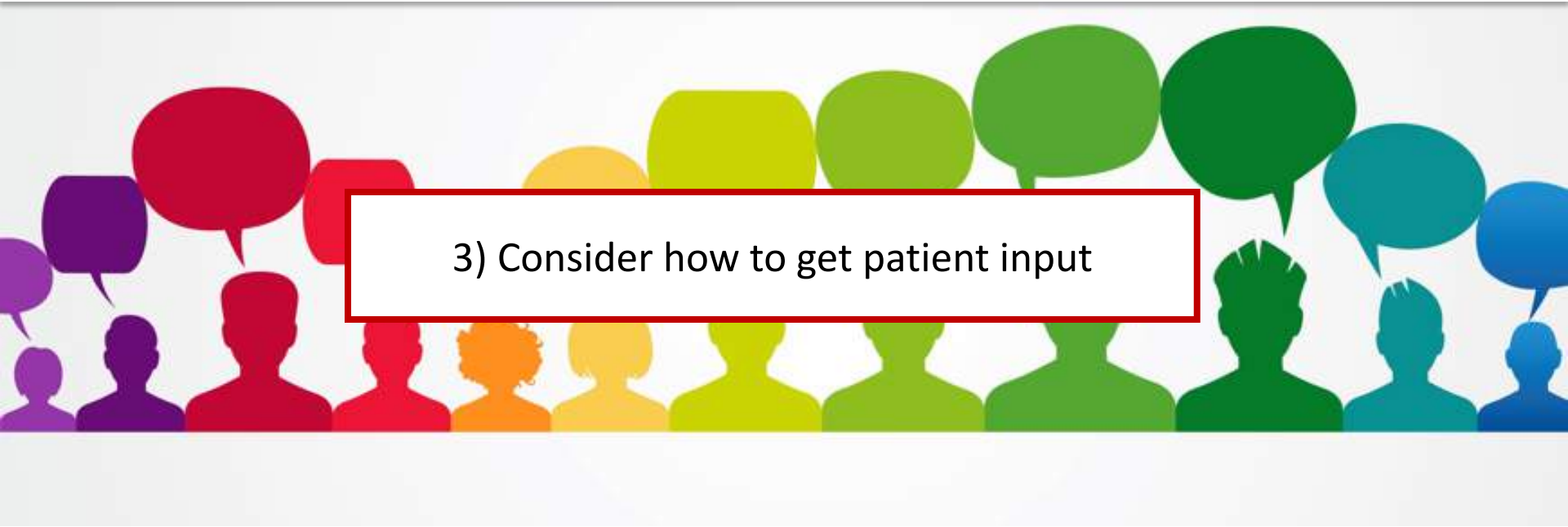
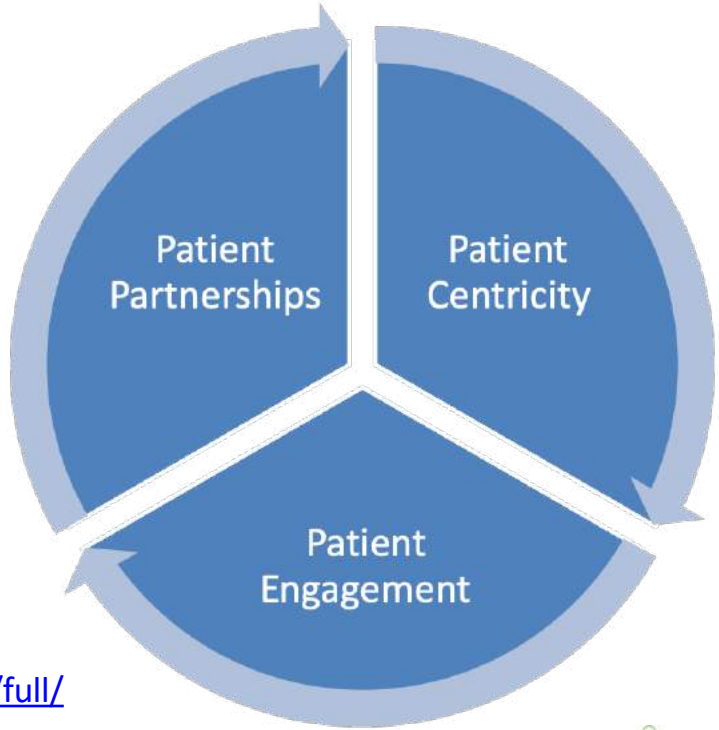


3) Consider how to get patient input

Partnering with Patients

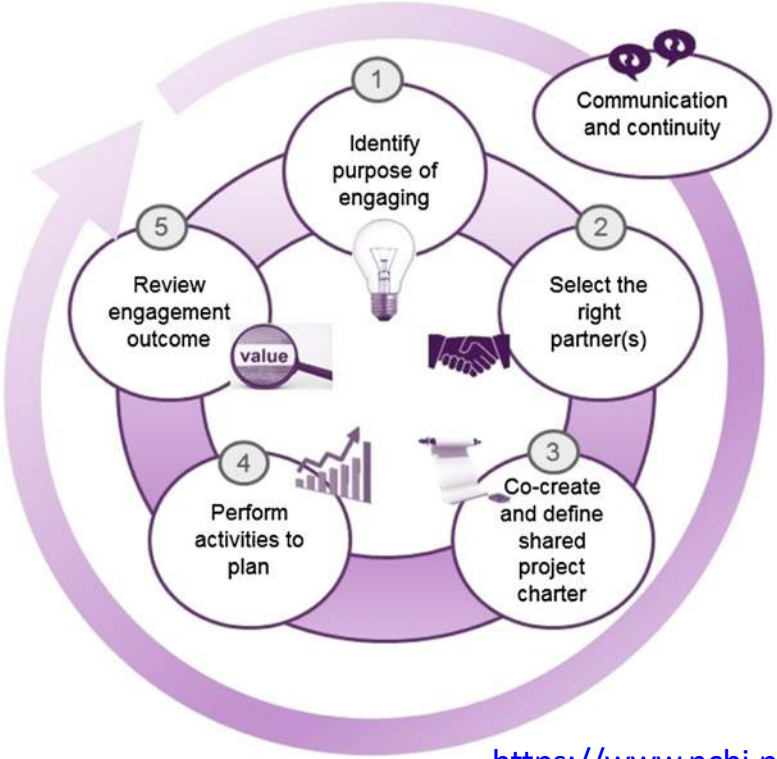
- Lessons learned from healthcare
  - People actively involved in their health and health care tend to have better outcomes.*
  - Patient decision making is *enhanced* by personal experience and *complemented* by scientific knowledge of healthcare professionals.**
  - Recognition of patients as experts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



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

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

Five Process Steps for Patient Group Engagement (PGE)

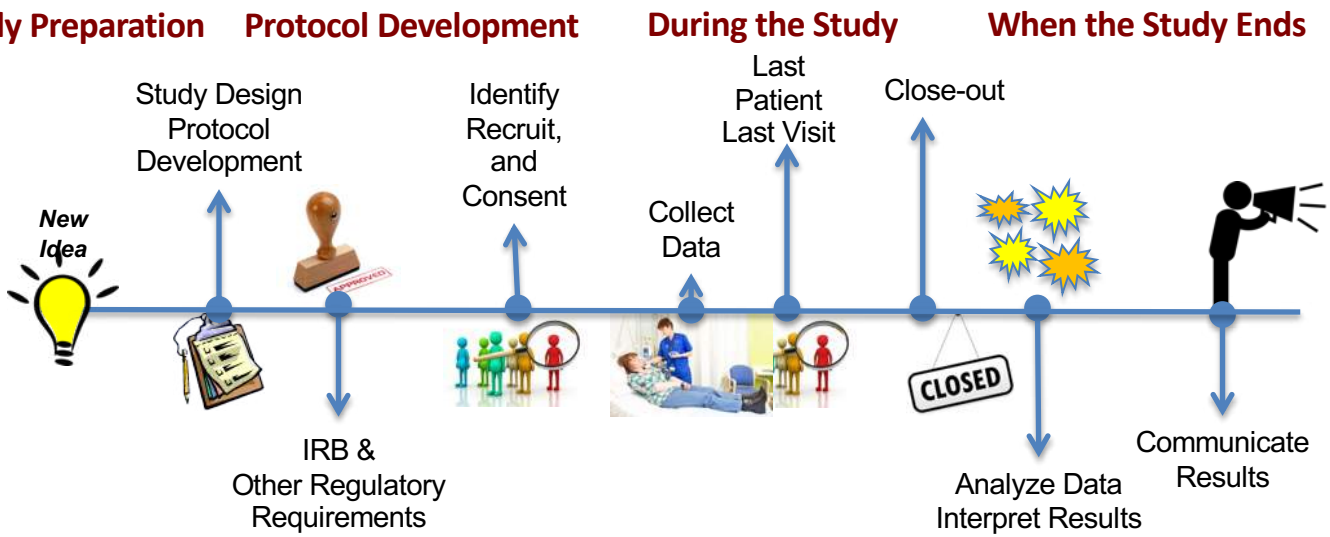


STAR Principles for PGE

- **S**hared ambition
  - Open and honest partnership focused on collaboration
- **T**ransparency
  - Strategic objectives and clarity about processes
- **A**ccountability
  - Key point of contact with aligned internal processes and ownership
- **R**espect
  - Maintained relationship and proactive communication

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

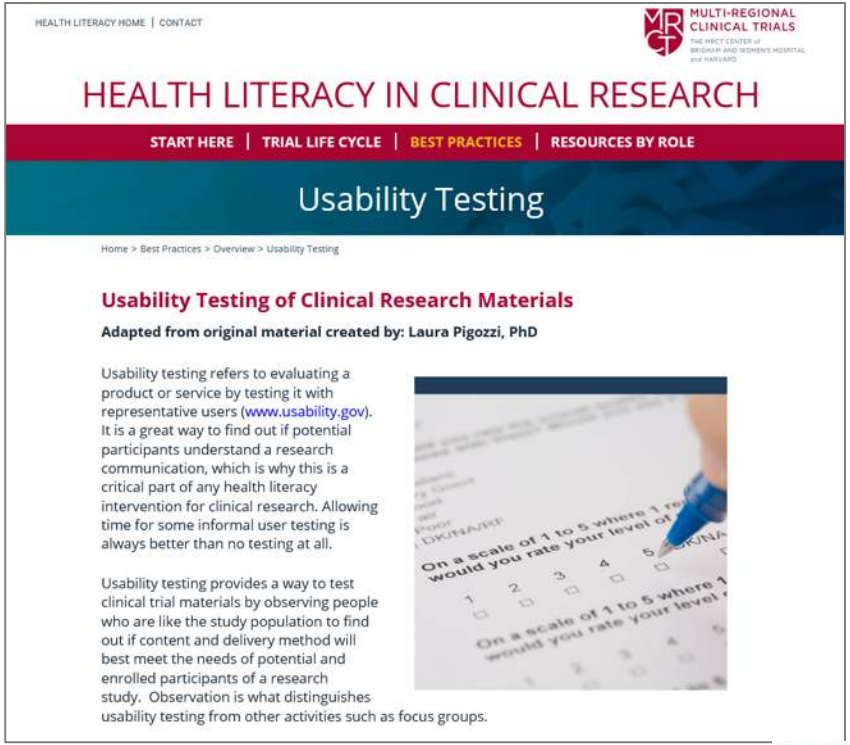
Phasing of Patient Input into the Return of End of Study Summaries



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.

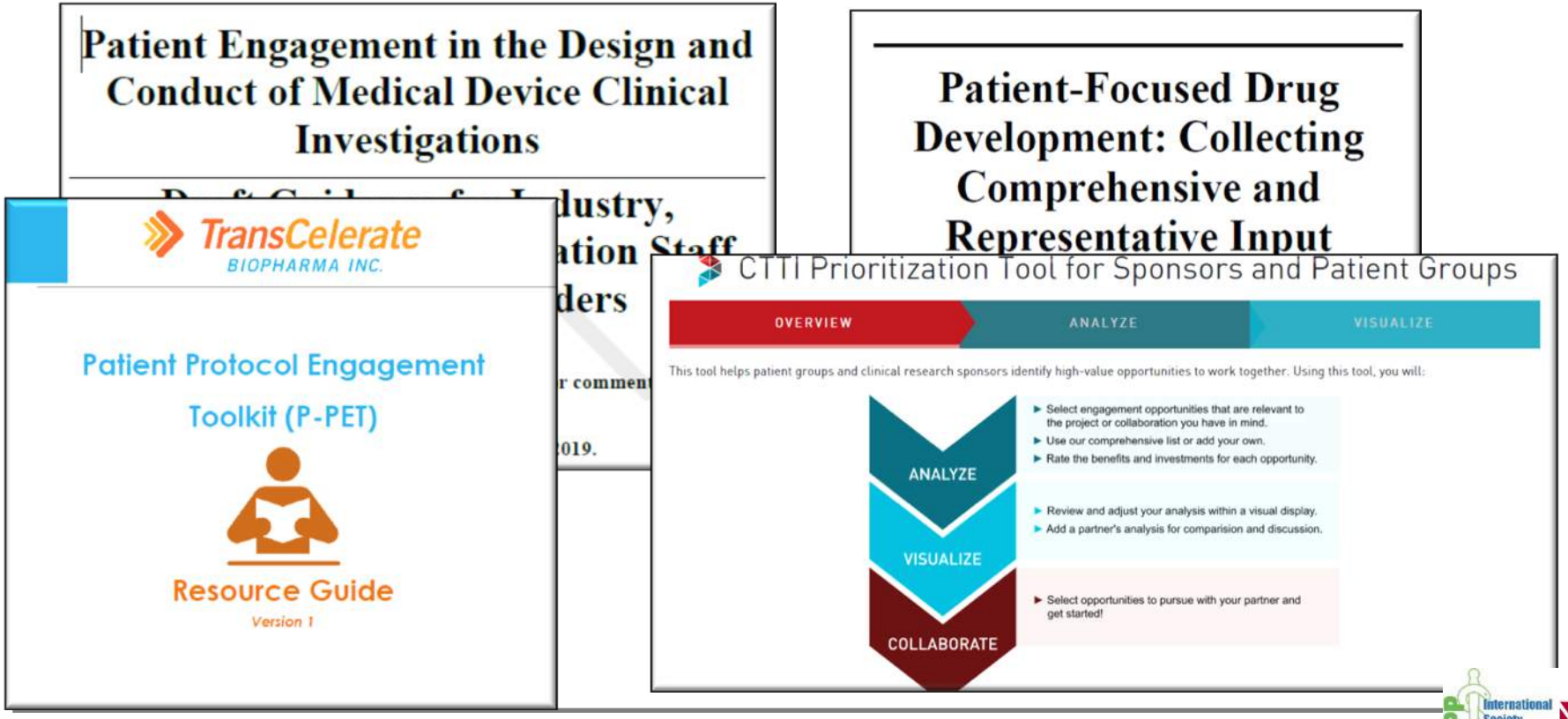
Usability Testing of Clinical Research Materials

- 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?



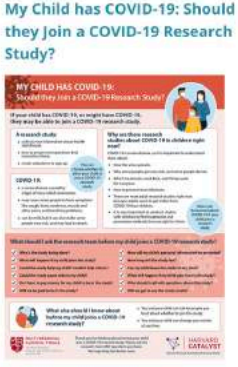
Learn more at https://mrctcenter.org/health-literacy/tools/overview/usability-testing/

Additional Resources



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.

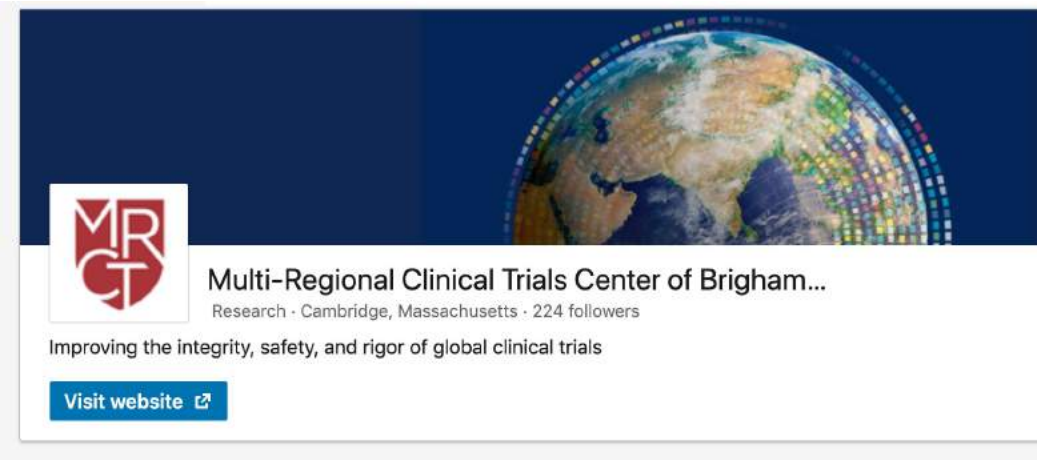


https://mrctcenter.org/blog/resources/covid-19-clinical-research-flyers/

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:



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Thank you!

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