MULTI-REGIONAL CLINICAL TRIALS

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

Partnering with Patients and Participants to Develop Clinical Research Materials and Plain Language Summaries

Sylvia Baedorf Kassis, MPH

Program Manager, MRCT Center

CBI Clinical Data Disclosure, Transparency and Plain Language Summaries

Coral Gables, FL

January 24, 2020

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

- Identify opportunities for participant input throughout the clinical research process;
- Describe how co-development can elevate document quality and impact;
- Discuss compliance concerns in partnering with patients and advocates to develop participant-facing materials;
- Apply best practices to establishing partnerships with patients and participants;
- Review case studies and examples of patient and participant input being integrated into clinical research materials.

The MRCT Center

The MRCT Center

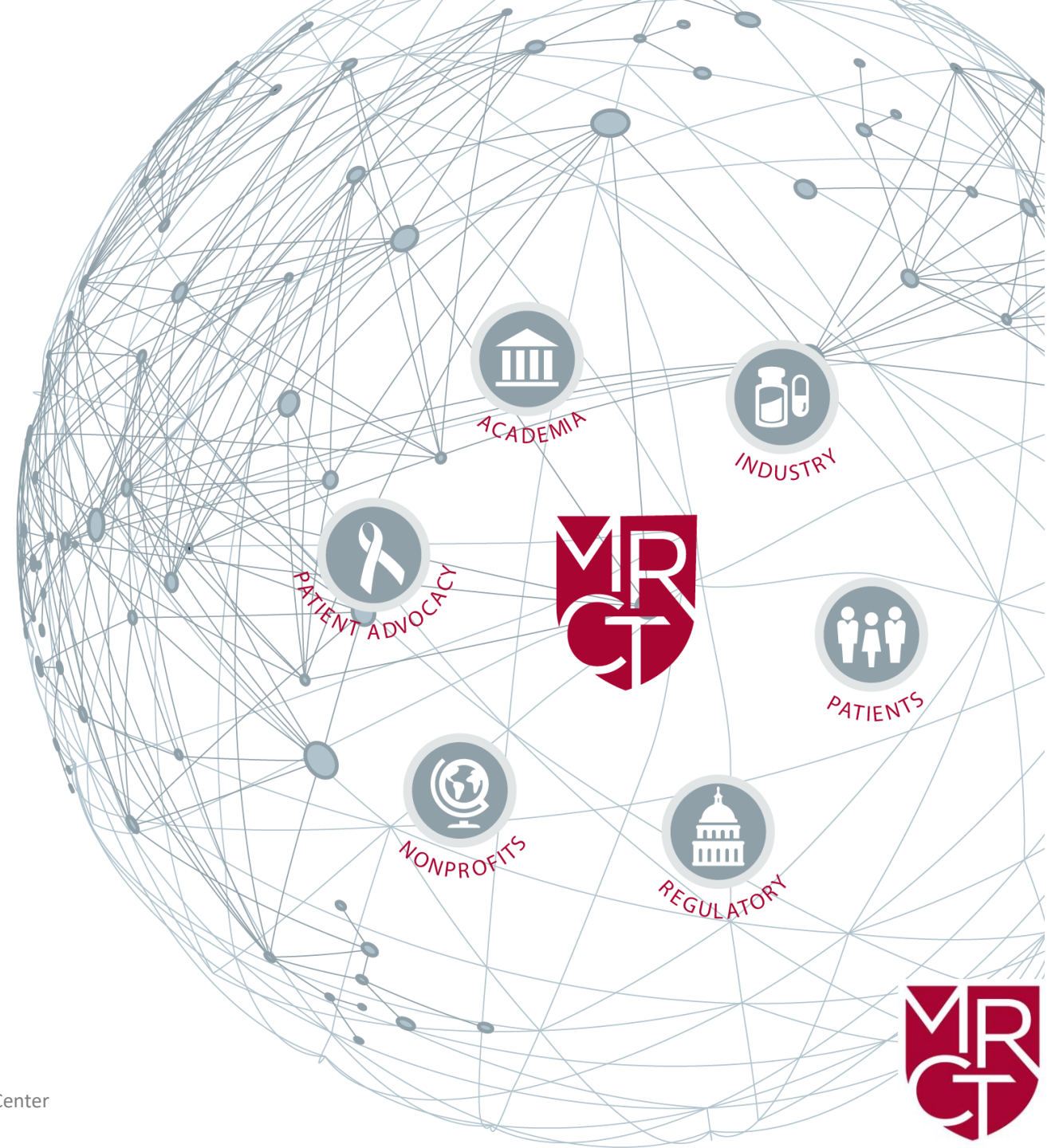
Our Vision

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.



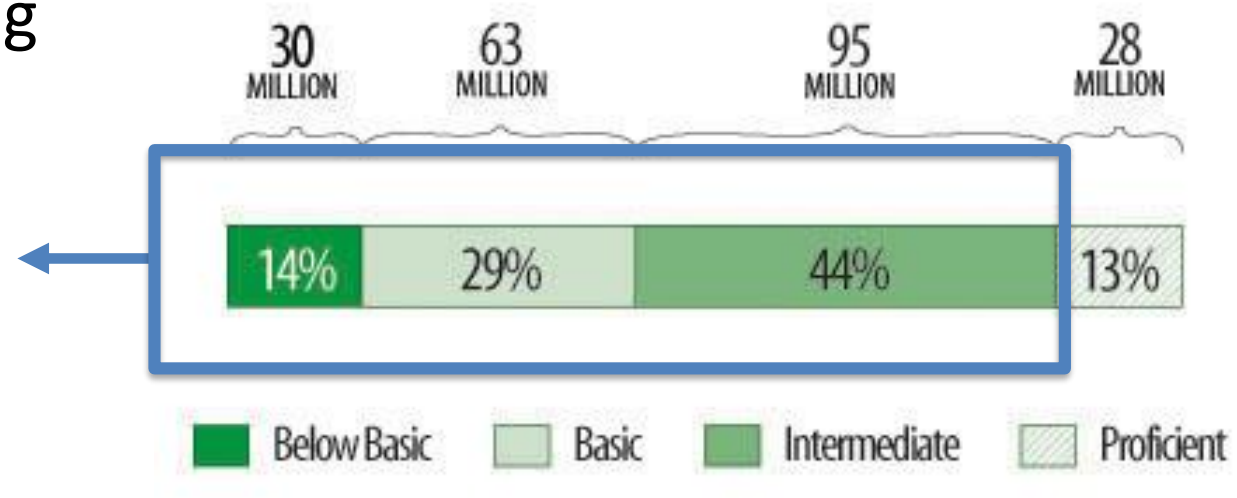
Health Literacy and Clear Communications in Clinical Research

January 24, 2020

Why are clear communications so important in clinical research?

- Literacy levels in the US are troubling

9/10 people 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

Clear communication is a shared responsibility

- Anyone can struggle with low health literacy, depending on the content and context.
- It is not just the responsibility of the person receiving information to try to make sense of it.
- The communicator is responsible for sharing information in a clear, respectful way, confirming understanding and inviting questions.
- Systems also play an important role
  - processes and accountability support clear communication with potential, enrolled, and past research participants

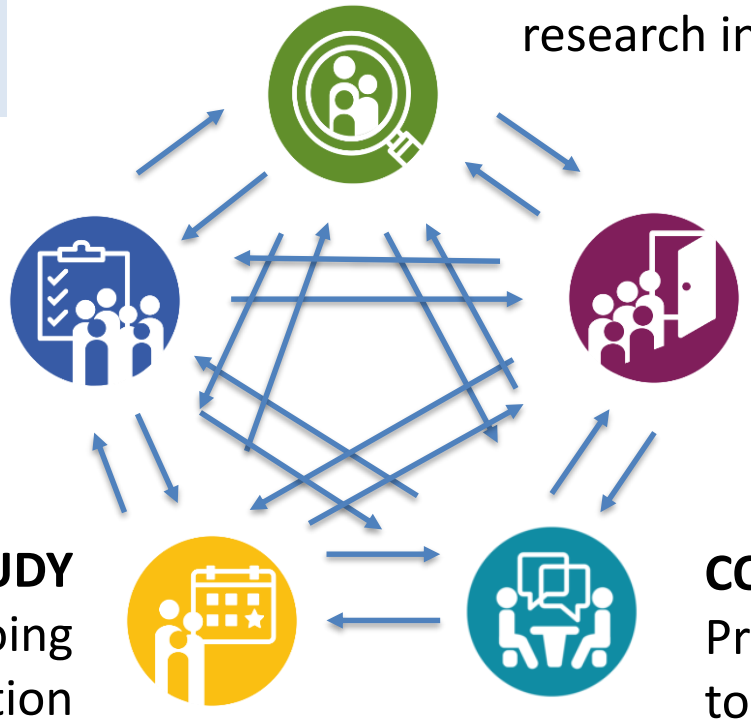
Clear communication is a need in clinical research

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

What does clinical research that integrates health literacy principles look like?

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

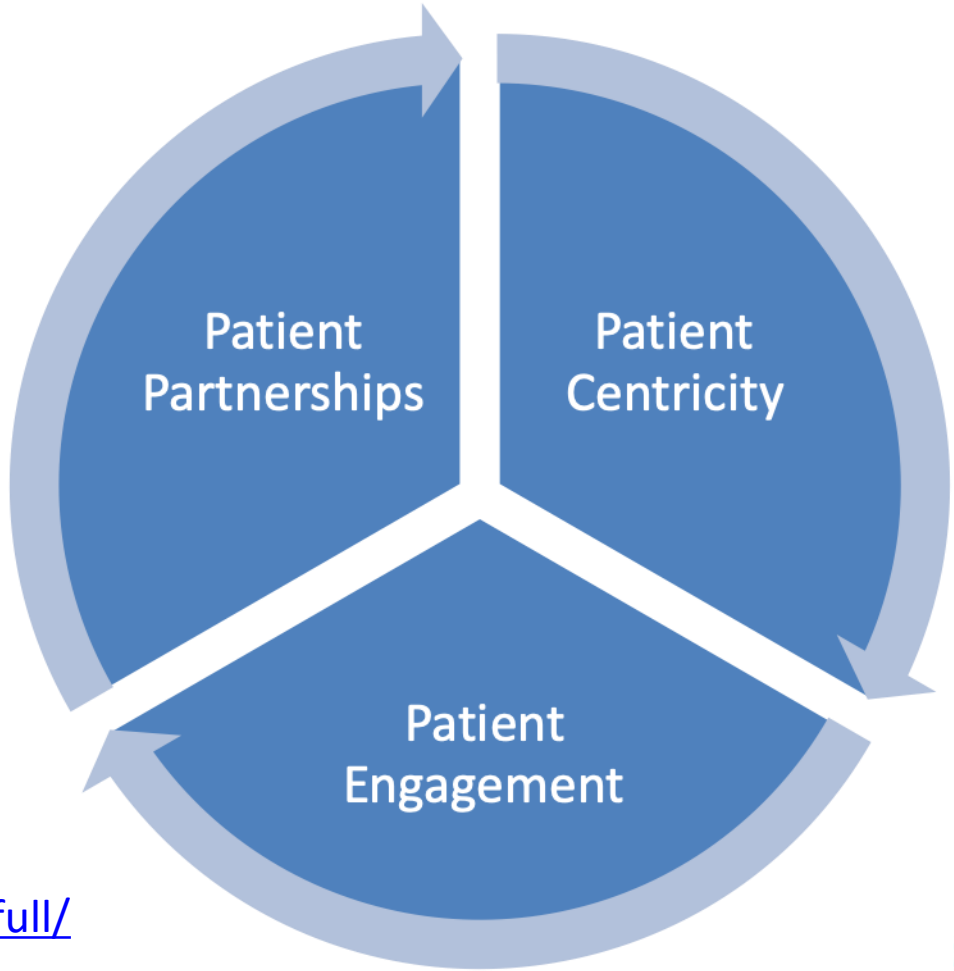
Bilateral engagement and partnerships are always of benefit

Partnering with Patients to (Co-)Develop Clear Communications Throughout the Clinical Trial Life Cycle

January 24, 2020

Why partner 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/

What do patient partnerships mean for research?

Improved
ADHERENCE
to study procedures

Higher levels of
SATISFACTION
in the research experience

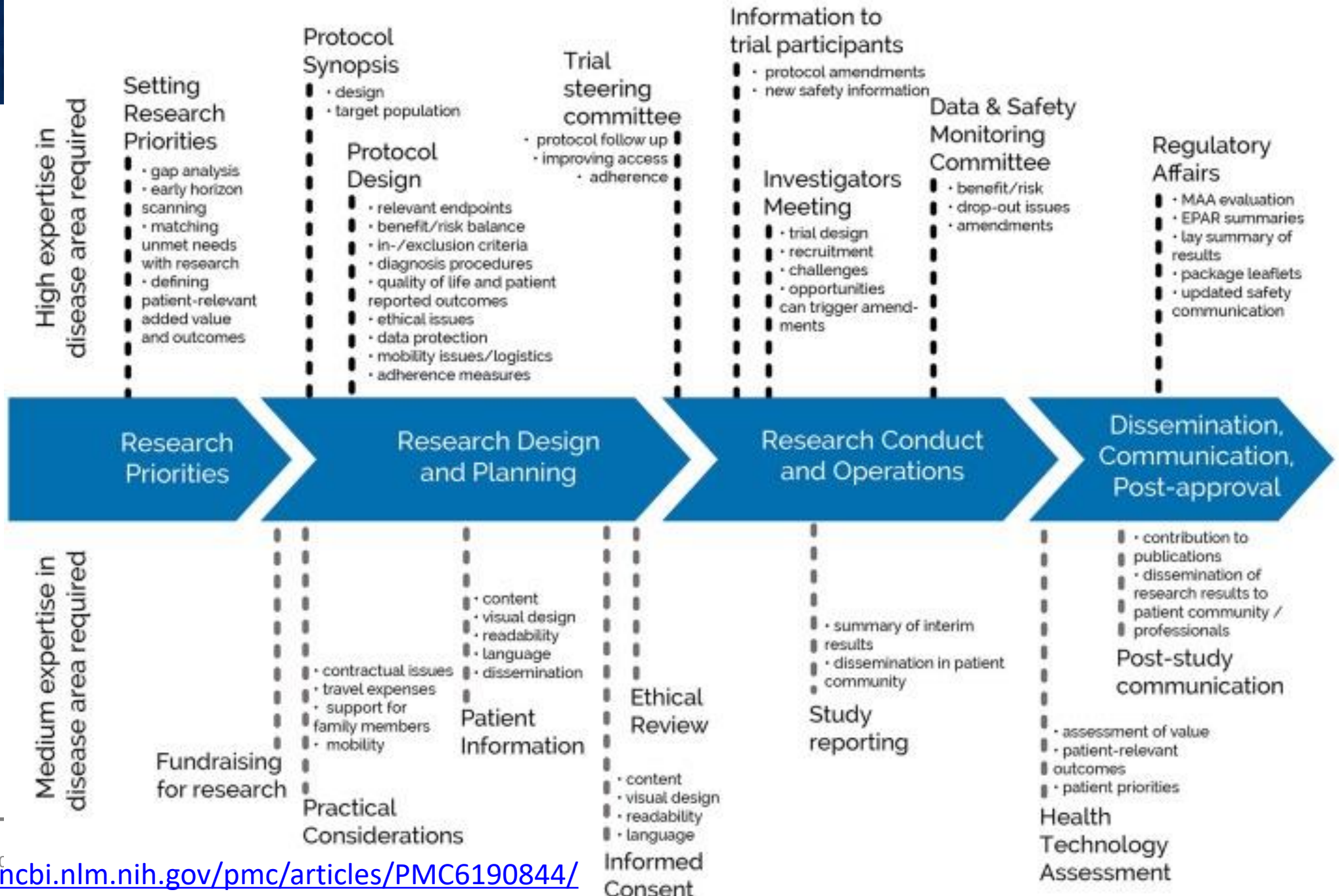
(and presumably, a better chance of research being recommended to others)

Increased
PARTICIPATION
in studies

Greater
AWARENESS
of research

Reduced participant
ATTRITION

Patient involvement in medicines R&D



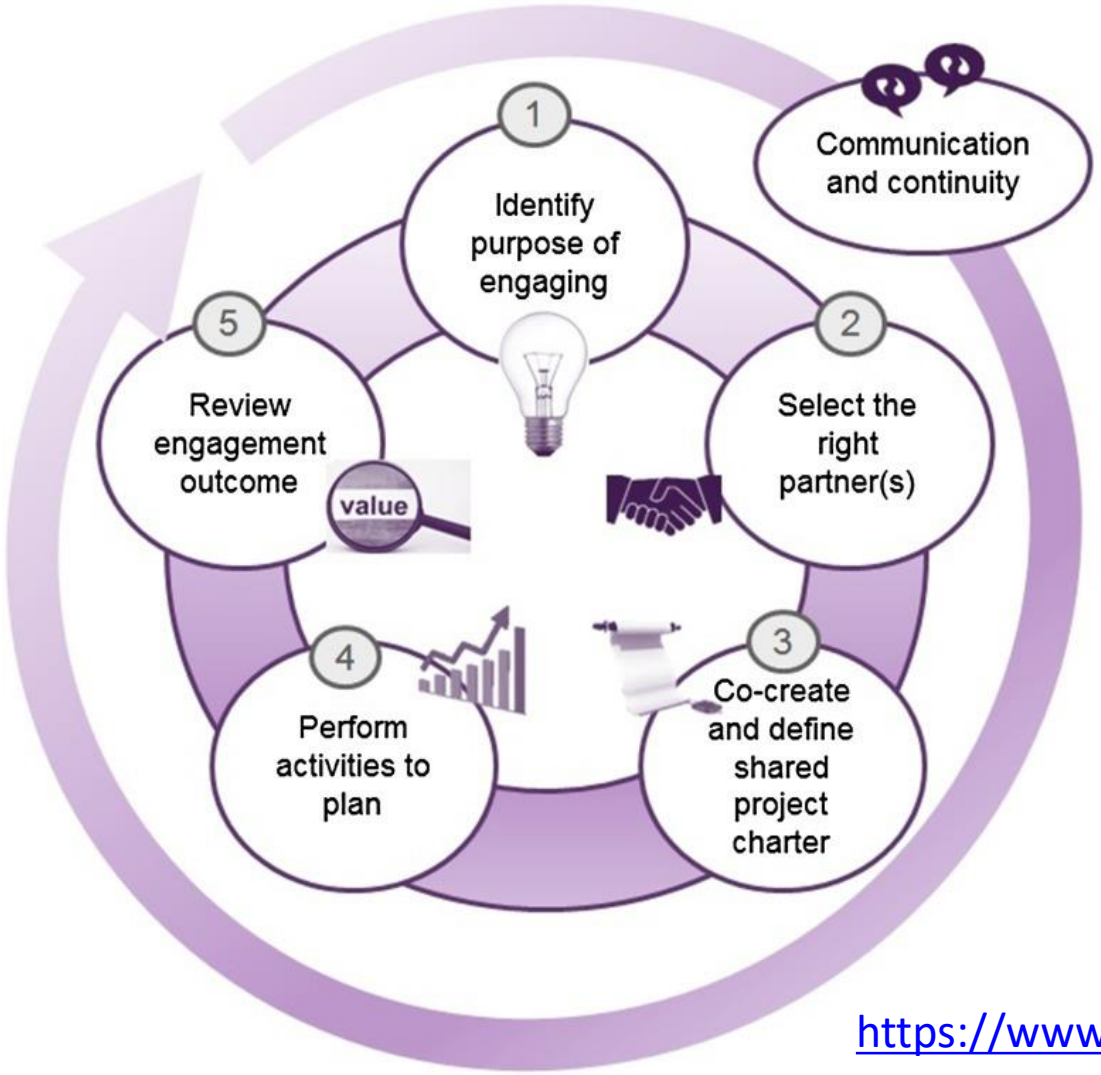
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6190844/

What are some of the concerns raised about partnering with patients?

- Extra time needed to involve patients in the process;
- “Tokenism” or a false appearance of inclusiveness by involving patients;
- A fear of “scope creep” whereby potentially irrelevant patient concerns and issues might decrease the feasibility of the study;
- Regulatory compliance concerns about direct contact between industry and patients.

Adapted from: https://www.ncbi.nlm.nih.gov/pubmed/24568690 and https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6193089/

Five Process Steps for Patient Group Engagement (PGE)



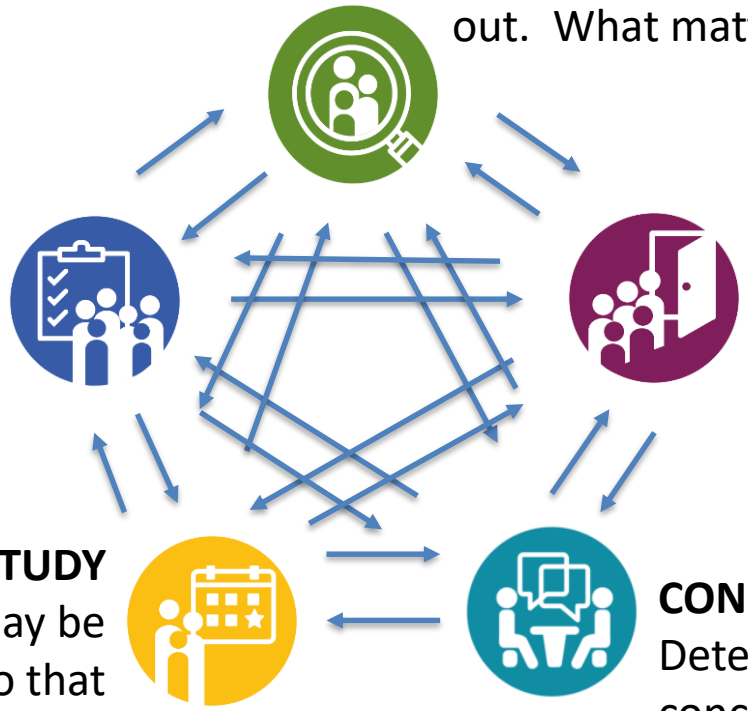
STAR Principles for PGE

- **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/

How can patient partnerships be incorporated into the clinical research process?

DISCOVERY
Get input from patients on what they already know about the research topic and what more they really hope to find out. What matters most to them?



RECRUITMENT
Identify how patients learn about health related initiatives and where they are likely to feel comfortable having initial study-related conversations.

CONSENT
Determine what the biggest questions and concerns about the research are so that consent processes can adequately address them.

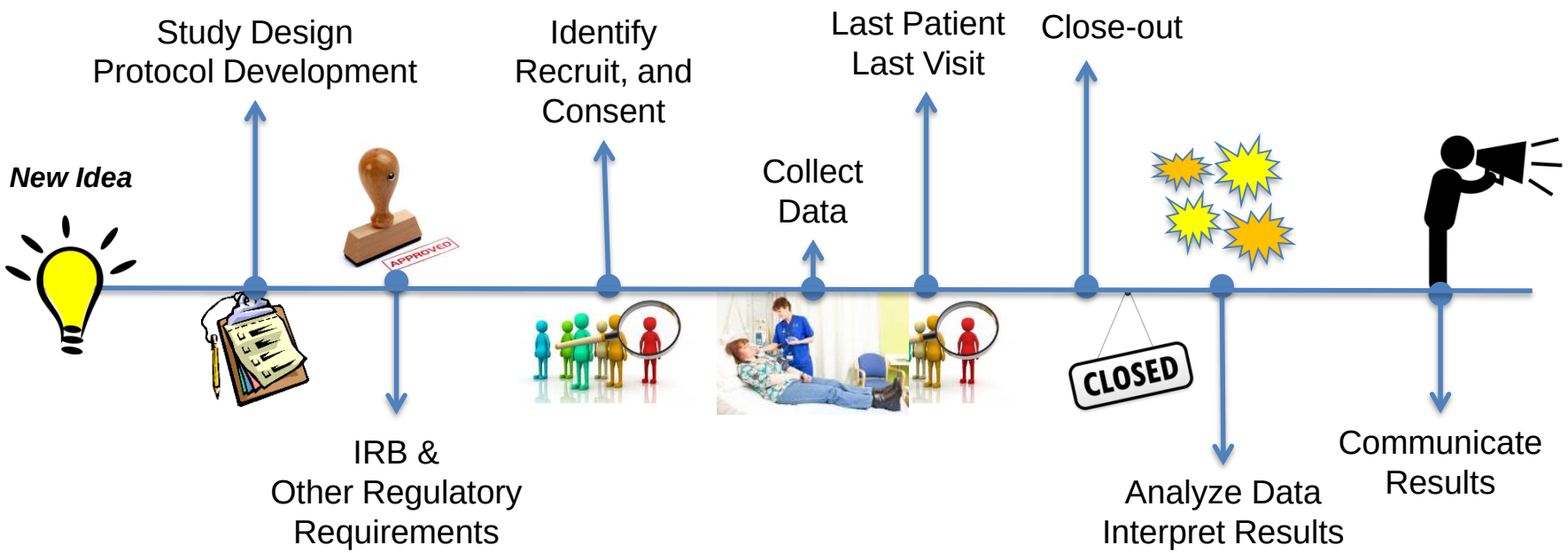
ON STUDY
Find out early where there may be challenges with study adherence so that supportive processes can be implemented

END OF STUDY
Incorporate patient information priorities identified throughout the study into a meaningful research results summary

Patient Partnerships in Action

Patient Partnership Example :
Phasing of Patient Input into the Return of End of Study Summaries

Pre-Study Preparation **Protocol Development** **During the Study** **When the Study Ends**



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	Find out if there were 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.

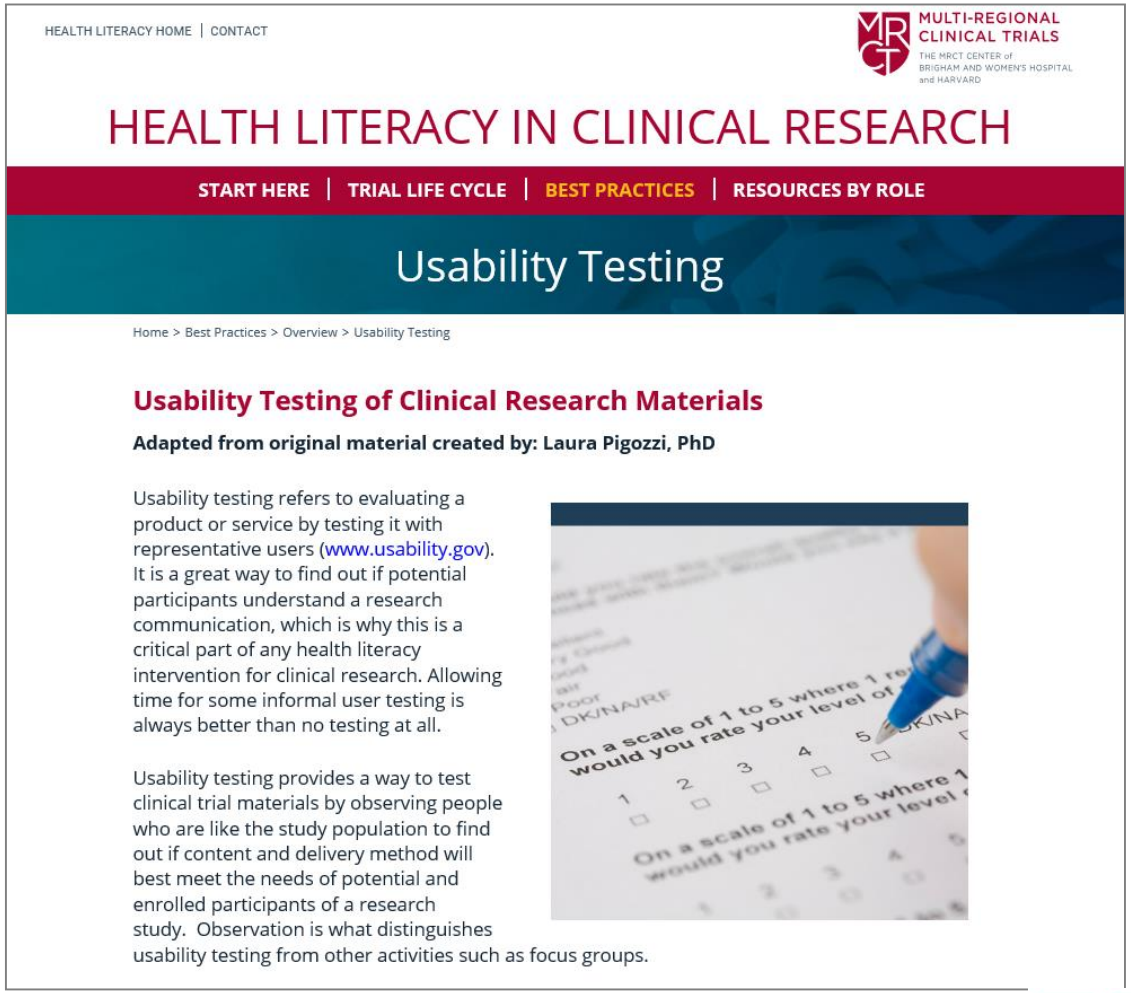
Patient Partnership Case Study:
How one company has started to incorporate patient input into R&D

- Pharmaceutical companies are starting to include patient engagement in their activities
  - Sanofi Genzyme, for example:
    - Included the “Patient Perspective” in their 2019 Research & Development priorities
    - Integrated Patient Advisory Panels into their processes to:
      - Develop recruitment materials and methods targeted to the desired patient population
      - Provide patients with clinical trial education in order to make an informed decision to participate or not
      - Design study-specific materials to engage and support the patient throughout the clinical trial

https://mrctcenter.org/health-literacy/tools/overview/casestudies/#sanofi

Patient Partnership Best Practice: 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 HOME | CONTACT

MULTI-REGIONAL CLINICAL TRIALS
THE MRCT CENTER of 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://mrctcenter.org/health-literacy/tools/overview/usability-testing/

A Few Additional Patient Engagement Resources

Clear communications benefit everyone in the clinical research process

- 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

HEALTH LITERACY HOME | CONTACT

MULTI-REGIONAL CLINICAL TRIALS
THE MRCT CENTER of BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

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 Story Street, 4th Floor, Cambridge, MA 02138, USA

CONTACT

Copyright © 2019

HEALTH LITERACY HOME | CONTACT

MULTI-REGIONAL CLINICAL TRIALS
THE MRCT CENTER of BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

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 obta 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 such health literacy can be affected by variou factors, like the stress of a new diagnos or the setting within which information being shared.

Healthy People 2030 is proposing a new 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

Healt

PLAIN

MRCT

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.

MULTI-REGIONAL CLINICAL TRIALS
THE MRCT CENTER of BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

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

HEALTH LITERACY HOME | CONTACT

MULTI-REGIONAL CLINICAL TRIALS
THE MRCT CENTER of BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

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, 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

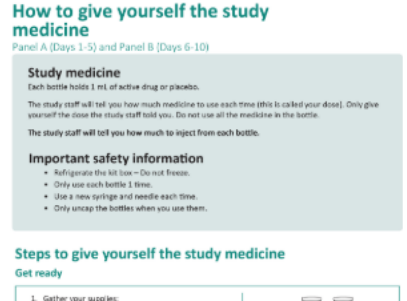
Click through the individual tabs to learn more about how your "On Study" research communications can be improved through plain language, numeracy, clear design and cultural considerations.

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

HEALTH LITERACY HOME | CONTACT

MULTI-REGIONAL CLINICAL TRIALS
THE MRCT CENTER of BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

HEALTH LITERACY IN CLINICAL RESEARCH

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

Cultural Considerations

Home > Best Practices > Overview > Cultural Considerations

Cultural Considerations in Clinical Resear

Culture is defined as the shared ideas, meanings, and values acquired by individuals as members of society (from: Health Literacy: A prescription to end confusion). Broadly, then, culture is a way of life for a group of people. At the same time, culture can mean different things to different people and can be challenging to generalize – especially since a single person can belong to and identify with many different cultures (race, ethnicity, gender identity, sexual orientation, language, profession, etc).

Members of the clinical research enterprise are often used to thinking in categories while seeking definitive answers to pre-defined questions. Yet the complexities of culturally appropriate materials and interactions often require a more nuanced appro

HEALTH LITERACY HOME | CONTACT

MULTI-REGIONAL CLINICAL TRIALS
THE MRCT CENTER of BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

HEALTH LITERACY IN CLINICAL RESEARCH

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

Interactive Techniques

Home > Best Practices > Overview > Interactive Techniques

Clinical research communications are enhanced through person, verbal interactions.

Research has shown that providing both written and verbal information is more effective than written or verbal information alone (Al-Harthy et al, 2016).

Interactive techniques are particularly important and helpful in the clinical research environment, as they facilitate conversations that can lead potential and enrolled participants to greater clarity about research and their decision to participate. Thus, reviewing plain language materials and effectively using verbal teach-back to check for participant understanding are essential to determining understanding

Anyone presenting information can take on the role of a supportive teacher when sharing information so that potential and enr

HEALTH LITERACY HOME | CONTACT

MULTI-REGIONAL CLINICAL TRIALS
THE MRCT CENTER of BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

HEALTH LITERACY IN CLINICAL RESEARCH

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

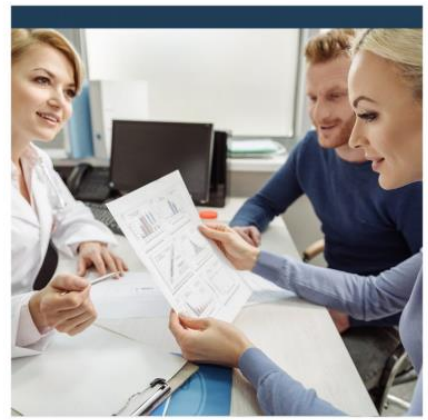
Return of Results

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.

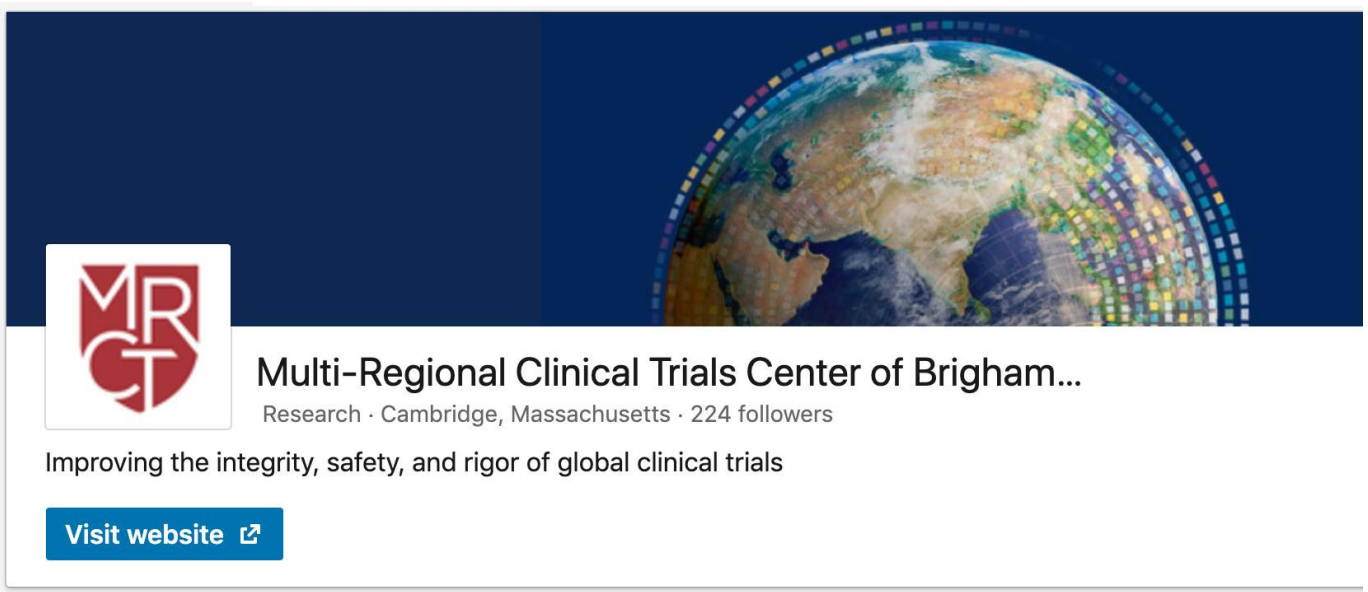
Takeaways

- Clear participant-facing communications are essential throughout the clinical research journey
- Preparation and planning for clear research communications, including plain language summaries, starts early in the clinical research process. Break down the silos!
- Including the participant's input is a critical part of creating understandable study-related materials, including plain language summaries
- Free resources exist on the MRCT Center website and through other groups

Special thanks to the MRCT Center Health Literacy in Clinical Research Workgroup

Jessica S Ancker, MPH, PhD
May-Lynn Andresen, DNP, RN
Maria Apostolaros, JD, PharmD, FASCP, CCEP
Sylvia Baedorf Kassis, MPH (PM)
Behtash Bahador, MS
Suzanne Bakken, RN, PhD, FAAN, FACMI
Teal Benevides, PhD, MS, OTR/L
Amy Ben Arieh, JD, MPH
Barbara E. Bierer, MD (Co-Chair)
Poorvi Chablani
Reetu Dandora, JD
Theresa R. Devins, DrPH
James (Jay) Duhig, PhD
Diana Fisher, MS, MPH, CPH
Claire Foster
Valery Gordon, MPH, PhD
Lori Hall, RN, BSN
Zachary Hallinan
Tara Hastings
Renee Jenkins
Rebecca Johnson
David Leventhal, MBA
Becca Lory, CAS, BCCS
Newell McEllwee, PharmD, MSPH
Jill McNair, MBA
JoAnn Muir
Laurie Myers, MBA (Co-Chair)
Marilyn Neault, PhD
Catina O'Leary, PhD, LMSW
Michael K. Paasche-Orlow, MD, MA, MPH
Lisa Palladino Kim, MS
Laura Pigozzi, PhD
Margaret Rankovic, BA, MEd
Mary Roary, PhD
Dominic (Nik) Roberts
Erin Rothwell, PhD
Anirban Roy Chowdhury, M.Pharm, MBA
Rima Rudd, ScD
Jennifer Scanlon
Louise Scott, LSW
Vanessa Simonds, ScD
Rhonda Smith, MBA
Kathy Spiegel, PhD, MWC
Christopher Trudeau, JD (Co-Chair)
Jessica Valencia, PhD
Michael Villaire, MSLM
Desirée Walker
Michele Weitz, MA
Sarah White, MPH, CIP (Co-Chair)
Earnestine Willis, MD, MPH
Robert Winn, MD

Please follow the MRCT Center:



linkedin.com/company/multi-regional-clinical-trials-center-of-brigham-and-women's-hospital-and-harvard

twitter.com/MRCTCenter

Questions and Discussion