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

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CBI Clinical Data Disclosure, Transparency and Plain Language Summaries
Coral Gables, FL
January 24, 2020
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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.
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.
Health Literacy and Clear Communications in Clinical Research
Why are clear communications so important in clinical research?

- Literacy levels in the US are troubling
  - 9/10 people need extra help

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

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

**CONSSENT**
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

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Partnering with Patients to
(Co-)Develop Clear Communications Throughout the Clinical Trial Life Cycle
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
- Increased **PARTICIPATION** in studies
- Greater **AWARENESS** of research
- Reduced participant **ATTRITION**
- Higher levels of **SATISFACTION** in the research experience (and presumably, a better chance of research being recommended to others)
Patient involvement in medicines R&D

Research Priorities
- Setting Research Priorities
  - gap analysis
  - early horizon scanning
  - matching unmet needs with research
  - defining patient-relevant added value and outcomes
- High expertise in disease area required

Research Design and Planning
- Protocol Synopsis
  - design
  - target population
- Protocol Design
  - relevant endpoints
  - benefit/risk balance
  - in-/exclusion criteria
  - diagnosis procedures
  - quality of life and patient reported outcomes
  - ethical issues
  - data protection
  - mobility issues/logistics
  - adherence measures

Research Conduct and Operations
- Information to trial participants
  - protocol amendments
  - new safety information
- Data & Safety Monitoring Committee
  - benefit/risk
  - drop-out issues
  - amendments

Dissemination, Communication, Post-approval
- Regulatory Affairs
  - MAA evaluation
  - EPAR summaries
  - lay summary of results
  - package leaflets
  - updated safety communication

Fundraising for research
- Practical Considerations
  - contractual issues
  - travel expenses
  - support for family members
  - mobility

Patient Information
- Ethical Review
  - content
  - visual design
  - readability
  - language
  - dissemination
- Study Reporting
  - summary of interim results
  - dissemination in patient community

Post-study communication
- assessment of value
  - patient-relevant outcomes
  - patient priorities
- Health Technology Assessment

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.

Five Process Steps for Patient Group Engagement (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

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
- Study Design
- Protocol Development

Protocol Development
- Identify
- Recruit, and
- Consent

During the Study
- Last Patient
- Last Visit
- Collect
- Data

When the Study Ends
- Close-out
- Analyze Data
- Interpret Results
- Communicate Results

New Idea

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.

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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
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/
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
What is Health Literacy?

The classic definition of health literacy refers to an individual’s capacity 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, clearer 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.
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

   - Plain language summaries, results reports, and research publications

   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.

   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 updates, can be improved through plain language and clear design.

   Numeracy

   Numeracy is the ability to interpret and use numbers in practical situations. It is important to ensure that study data is presented in a clear and comprehensible manner.

   Plain Language

   Using clear and straightforward language helps participants understand and process information more easily.

   Cultural Considerations

   Cultural considerations involve understanding and respecting the cultural background of participants, ensuring that all communication is inclusive and relevant to their cultural context.

   How to give yourself the study medicine

   - Study medicine
   - Study guide
   - Study brochure
   - Study flyer

   Important safety information:
   - Study guidelines
   - Study volunteer
   - Study study
   - Study code of conduct
   - Study confidentiality

   Steps to give yourself the study medicine

   Get ready:
   - Read the study guidelines
   - Review the study volunteer
   - Understand the study code of conduct
   - Ensure confidentiality

   Follow the study code of conduct:
   - Study guidelines
   - Study volunteer
   - Study confidentiality
   - Study code of conduct
   - Study study

   Regards:
   - Study guidelines
   - Study volunteer
   - Study confidentiality
   - Study code of conduct
   - Study study
Cultural Considerations in Clinical Research

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 approach.

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-Harthi 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 is essential to determining understanding.

Anyone presenting information can take on the role of a communication facilitator, sharing information in that potential and unpersuasive way.

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.
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

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January 24, 2020
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