Communicate and co-create with patients across the medicines development lifecycle: Principles and best practices

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Patient engagement opportunities exist throughout the medicines development lifecycle.
Session overview

Research priorities
Research design and planning
Research conduct and operations
Dissemination, communication, post-approval

1. Integrating health literacy into the clinical trial lifecycle: Benefits and challenges
Sylvia Baedorf Kassis
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Research design and planning

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1. Integrating health literacy into the clinical trial lifecycle: Benefits and challenges
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2. Using key audience insights to create accessible health materials
   Catina O'Leary
## Session overview

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Integrating health literacy into the clinical trial lifecycle: Benefits and challenges

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Multi-Regional Clinical Trials Center of Brigham and Women’s Hospital and Harvard
• 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.
The Health Literacy Opportunity

• Literacy levels are troubling around the world.

9/10 people in the US 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
The 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
A Broad View of Health Literacy
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
• 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/
Why partner with patients?

- 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
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

STAR Principles for PGE

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

TransCelerate
BIOPHARMA INC.

Patient Protocol Engagement
Toolkit (P-PET)

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

Draft Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders

DRAFT GUIDANCE
This draft guidance document is being distributed for comment purposes only.
Document issued on September 24, 2019.

CTTI Prioritization Tool for Sponsors and Patient Groups

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.

Patient-Focused Drug Development: Collecting Comprehensive and Representative Input

Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders

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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
Takeaways

• You play a critical role
  – Clear participant-facing communications are essential throughout the clinical research journey.

• 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

• No need to re-invent the wheel
  – Free resources exist on the MRCT Center website and through other groups
Using key audience insights to create accessible health materials

Catina O’Leary
President and CEO
Health Literacy Media
About HLM

St. Louis-based nonprofit communication organization founded in 2009

Focus on helping partner organizations better communicate with their stakeholders

Interdisciplinary team of thought leaders in health literacy

More than 100 years of combined experience in health literacy, public health, clinical science, education, public policy, and plain language
A tangle of challenges

- Complex topic
- Alarm fatigue
- Nonquantifiable
- No reference
- Communicator
- Audience
- False sources
- Health literacy
- Uncertain timing
- Abstract concept

Health literacy

Abstract concept
Health literacy through the clinical trial process

Recruitment

- Effective and useful recruitment materials
  - Printed media
  - Social media
  - Website design
  - News releases

Consent

- Engaging retention materials
  - Patient information
  - Helpful reminders
  - Data collection forms

Retention

- Improving all materials and processes via rigorous evaluation
  - Formative
  - User testing
  - Multimedia

Results

- Truly informed consent
  - Effective, understandable, and legal informed consent forms

Evaluation

- Health-literate summaries
  - Clinical trial results
  - Journal articles

Communication

- Collaborative communication between trial staff and participants
  - Effective, valid, and reliable frameworks for best practice adoption
Health literacy is a set of tools and processes

- Understand the science
- Apply clear communication principles
- Test materials with target audience
- Revise content and design

Plain language summary
Standards for clinical research communication

Requirements and guidelines
- Accurate, factual, objective
- Understandable
- Balanced risk information
- Actionable and applicable

Health literacy principles
- Plain, clear language
- Information organization
- Numeracy principles
- Behavior focus

Clear and accurate content that addresses all requirements
A phase II study of RO4929097 in metastatic colorectal cancer

CONCLUSION:
In this study of RO4929097 in patients with refractory metastatic colorectal cancer, no radiographic responses were seen and time to progression was short, which suggests that RO4929097 at the study dose and schedule has minimal single agent activity in this malignancy.
Evaluating communication clarity

- Technical language
- Everyday language

More clear

Less clear
Measuring communication clarity

Audience Testing

- Technical language
- Everyday language

Less clear → More clear
Best practices for audience testing

Focus groups
• Best for general impressions
• Useful for broad audiences
• Requires less staff time
• Requires moderator expertise: vulnerable to groupthink, domineering

One-on-one interviews
• Best for gauging clarity or usability
• Useful for sensitive topics and low-literacy populations
• Requires more staff time per person
• Remote interviews can reduce staff time and expand recruitment pool
Best practices for audience testing

Match your testing audience to the intended audience as closely as possible.

Ensure your questions or prompts align with your testing goals.

Avoid words that imply a value or judgement, such as “Did you understand this?”, “Is this eye-catching?”

Instead ask:

• “In your own words, can you walk me through this graphic?”
• “What parts of this graphic draw your attention?”
What patients and the public want to know

Will (or did) the treatment work?

Is it safe?

What happens (or happened) during the trial?

Will (or did) the trial include people like me?
<table>
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<tr>
<th>Word</th>
<th>Scientific perspective</th>
<th>Non-scientific perspective</th>
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<tbody>
<tr>
<td>Inflammation</td>
<td>The body’s complex biological response to harmful stimuli, such as infections or injury</td>
<td>Swelling, redness, pain</td>
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<tr>
<td>Dose</td>
<td>A precisely measured quantity of a medicine delivered as a unit</td>
<td>A pill or capful of a medicine; taking a medicine</td>
</tr>
<tr>
<td>Tolerability</td>
<td>A measure of how well a drug performs compared to its safety results</td>
<td>How much medicine a person can take without being bothered by unpleasant effects</td>
</tr>
<tr>
<td>Anterior</td>
<td>Towards the front of the body</td>
<td>Inside (?)</td>
</tr>
<tr>
<td>(or other location terms)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Effective</td>
<td>A measure of a drug’s performance on key indicators</td>
<td>It worked well to treat a disease or condition</td>
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Case study: One-on-one testing

• What we tested: 3 informational videos for clinical trials and an accompanying brochure

• When: March-April 2020

• Who we interviewed: 10 people (5 men, 5 women) who we recruited through HLM’s social media and community contacts. We recruited a sample audience that reflected diversity in race, gender, education, geographical location, and clinical trial experience.

• How we conducted the interviews: 1-hour, virtual one-on-one interviews through Zoom. We used screen sharing to show the videos and brochure and gathered opinions on the style and content of the materials.
Case study: Findings

People desire representation
- People noted that all 3 characters were female and young, and 2 of 3 reflected people of color
- Older men said that they didn’t see anyone who looked like them

Content and tone was inappropriate for certain clinical trials
3 of 10 participants were older cancer survivors with clinical trial experience. These participants expressed significant concerns with:
- The use of animated videos with light-hearted tone
- Characters that were too young, healthy, and happy to reflect their experience
- The concept that trial staff keep participants safe
- The use of the term “placebo”

‘images are not reflective of the people who might participate in a trial.’

Characters ‘brought the information to life’ and ‘help me remember’ the content

‘trials are life or death” and people are not excited to be joining’
I’ve been to countless doctors all telling me what to do or what to take…I never really understood what my condition was, what was going on with my body, until I read this summary.

- Clinical trial summary user interview
Thank you

Catina O’Leary
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Health Literacy Media
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Join the conversation #DIA2020
Patient engagement in plain language summaries (PLS) of publications: Co-creation principles and best practices

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Overview

What are plain language summaries (PLS) of publications?

Why are PLS needed?

A practical framework for PLS development
What are PLS of publications?

- Clear, accessible summaries of peer-reviewed journal articles and congress presentations for non-specialist audiences

- What they are **not**: lay summaries of clinical study results (mandated by EU CTR 536/2014)
Why are PLS needed?

Patients and the public are seeking to access and understand the latest scientific research – but this isn’t always easy\textsuperscript{1–3}

PLS can:

\begin{enumerate}
\item Help patients to engage with original research and gain up-to-date medical knowledge\textsuperscript{2–4}
\item Empower patients in their discussions with healthcare professionals\textsuperscript{2,4,5}
\item Enhance communication pathways between scientists and broader audiences\textsuperscript{6}
\end{enumerate}

A practical framework for PLS development

A multi-stakeholder Patient Focused Medicines Development Working Group are co-creating a ‘How to’ module for PLS of publications

- Patients
- Journal editors
- Pharma
- Publication professionals

Identifies key steps in PLS development and practical considerations for patient engagement at each step
Stepwise approach for PLS development

1. Scope & prioritisation
2. Identify your target audience
3. PLS development & co-creation
4. Dissemination
5. Evaluation
Guiding principles for PLS

PLS should:

1. Reflect the content of the original publication in an accurate, balanced way

2. Be neutral and non-promotional

3. Be approved by (as a minimum) the lead author of the original publication

4. Declare funding sources for the study and any writing support

5. Be inclusive of all genders and nationalities, and be translated accurately
Which publications to do PLS for
- Objective, transparent, prospective criteria needed

Resource planning

Journal or congress selection

Dissemination planning
- Journal or congress requirements
- Format
Quality of patient engagement

1. Scope & prioritisation

2. Identify your target audience

3. PLS development & co-creation

4. Dissemination

5. Evaluation

Who will use the PLS?
What are their needs & priorities?
Quality of patient engagement

1. Scope & prioritisation
2. Identify your target audience
3. PLS development & co-creation
4. Dissemination
5. Evaluation

Consider language, numeracy, structure and design

Readability tools

Suitability tools
A freely available, evidence-based, co-created resource

- PLS template
- QC checklist
- Cover sheets for patient and sponsor reviewers
- Glossary guide
- Evidence bibliography

https://www.envisionthepatient.com/plstoolkit/
Involving key stakeholders from your target audience can help to ensure the PLS is relevant & understandable.

Potential co-creation activities:
- Selecting which publications are most suitable for PLS development
- Planning the content of PLS
- Writing the PLS
- Reviewing the PLS

Different skill sets needed for each activity.
1. Scope & prioritisation
2. Identify your target audience
3. PLS development & co-creation
4. Dissemination
5. Evaluation

Who can share the PLS?
Where will it be shared?
Quality of patient engagement

1. Scope & prioritisation

2. Identify your target audience

3. PLS development & co-creation

4. Dissemination

5. Evaluation

Potential sources of metrics:
- Journal tracking & Altmetrics
- Repositories

Evaluate – and publish! – your experience of patient engagement
Key takeaways

PLS of publications are an important channel to share the latest research with broad audiences.

Co-creation can help to ensure that PLS are suitable for the target audience.

Practical guidance is available to guide you to develop PLS of publications.
Thank You

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