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

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Sylvia Baedorf Kassis

Catina O'Leary

Antony Chuter



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Meet our speakers

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Program Manager,
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Patient Champion



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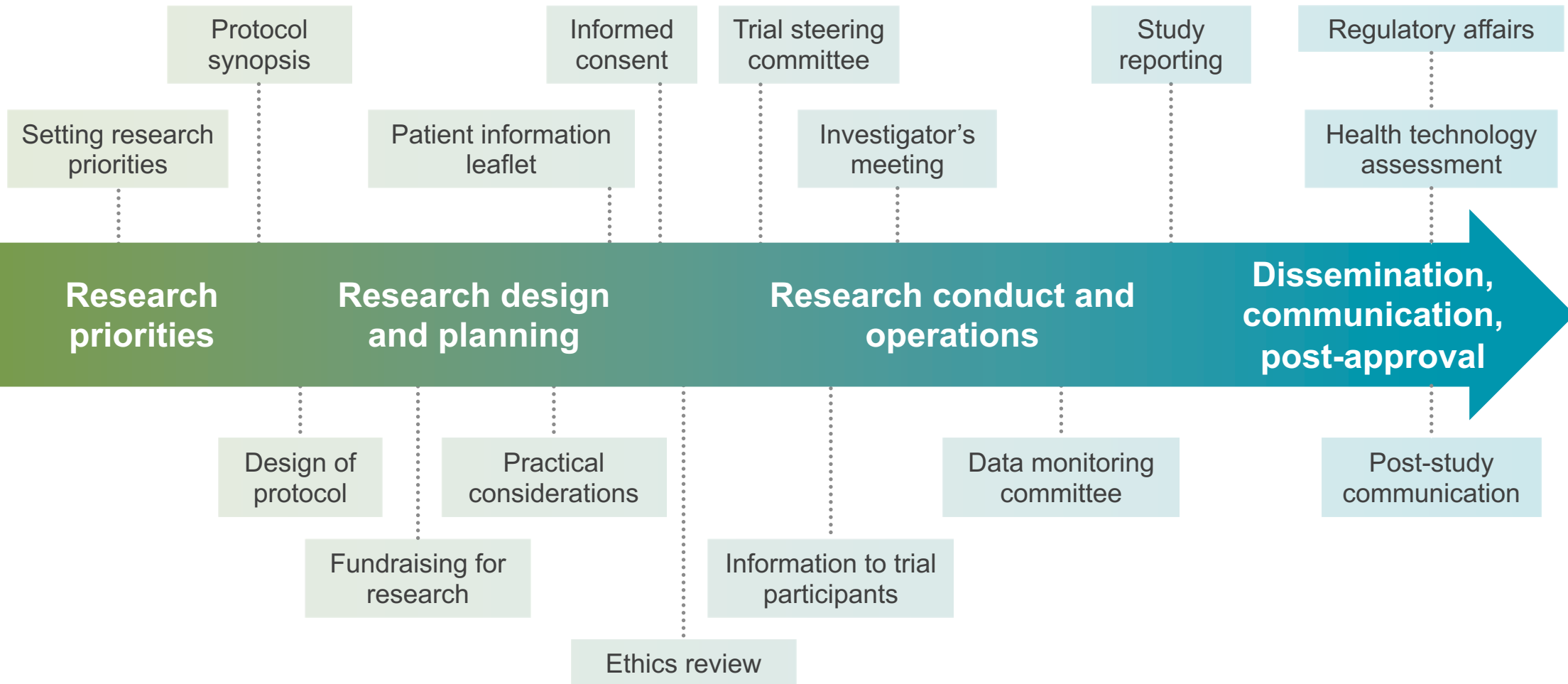
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Patient engagement opportunities exist throughout the medicines development lifecycle



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Session overview



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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

Session overview



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1 Integrating health literacy into the clinical trial
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2 Using key audience insights to
create accessible health materials
Catina O'Leary

Session overview



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1 Integrating health literacy into the clinical trial
lifecycle: **Benefits and challenges**
Sylvia Baedorf Kassis

2 Using key audience insights to
create accessible health materials
Catina O'Leary

3 Patient engagement in plain language
summaries (PLS) of publications:
Co-creation principles and best practices
Lauri Arnstein & Antony Chuter



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

Sylvia Baedorf Kassis, MPH

Program Manager

Multi-Regional Clinical Trials Center of
Brigham and Women's Hospital and Harvard

@MRCTcenter





MULTI-REGIONAL CLINICAL TRIALS

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

A horizontal band of colorful silhouettes representing a diverse group of people. The silhouettes are in various colors including purple, red, orange, yellow, green, and blue. Above each silhouette is a speech bubble of a matching color, suggesting communication or shared experiences.

Health Literacy in Clinical Research

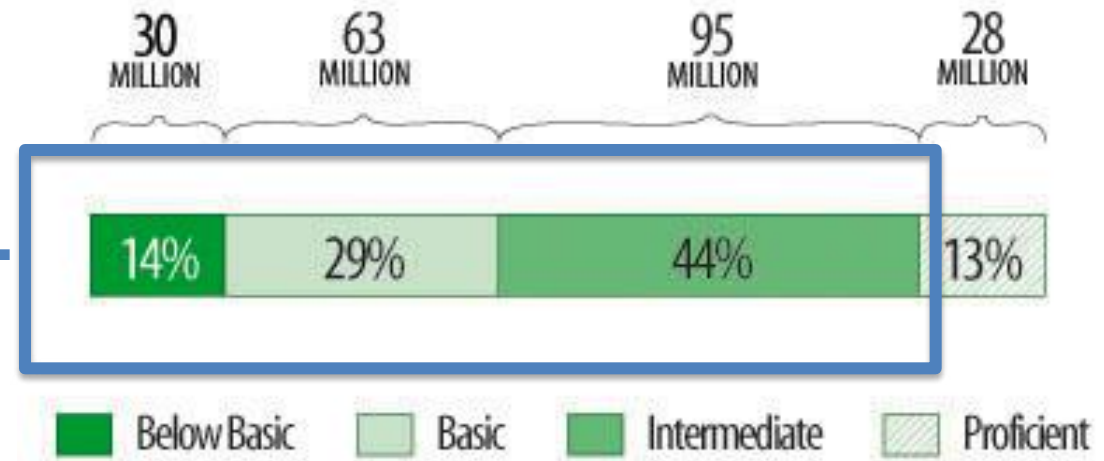
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- The opinions contained herein are those of the authors and are not intended to represent the position of Brigham and Women's Hospital or Harvard University.
- The MRCT Center is supported by voluntary contributions from foundations, corporations, 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



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

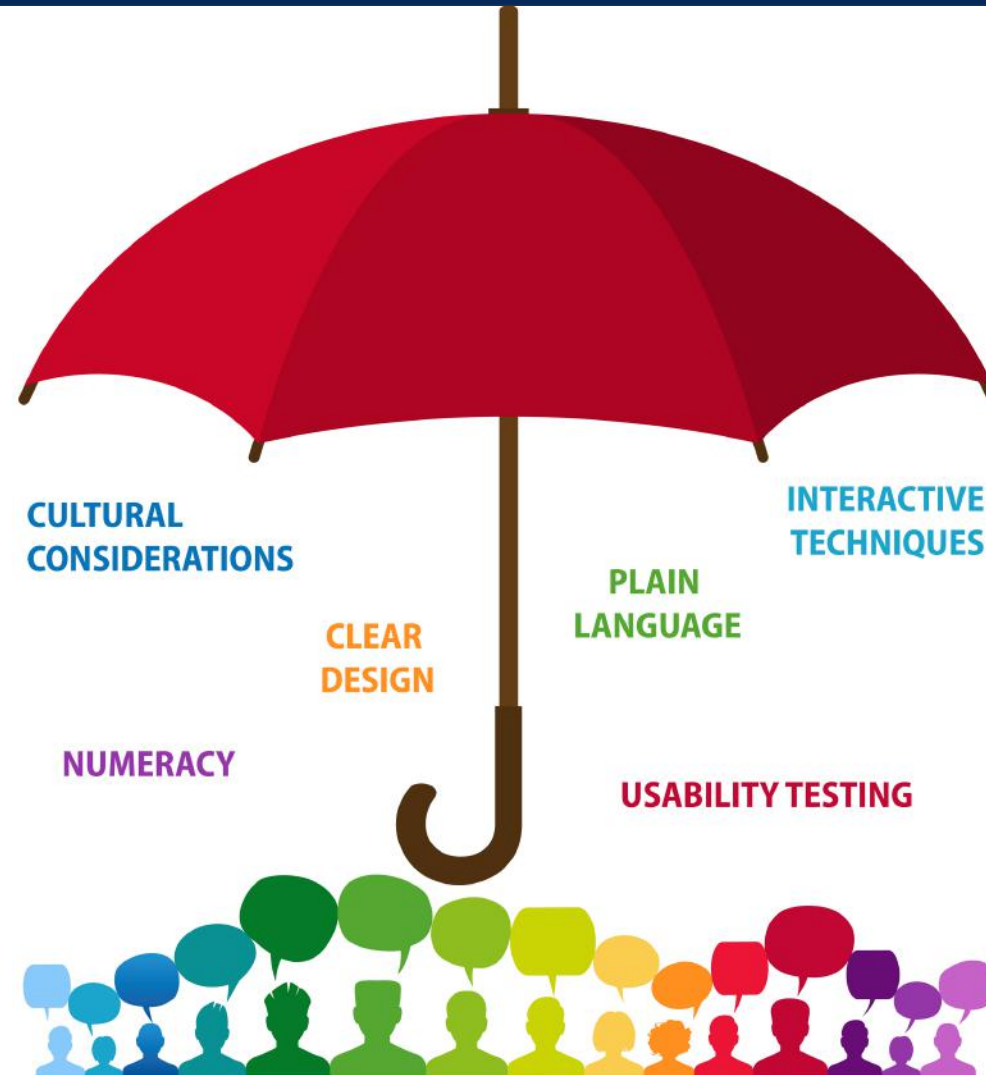
- Low health literacy affects a person's ability to:
 - Access services and information
 - Understand and follow health-related instructions
 - Make appropriate health-related decisions

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



The Clinical Trial Life Cycle

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



DISCOVERY



RECRUITMENT



CONSENT



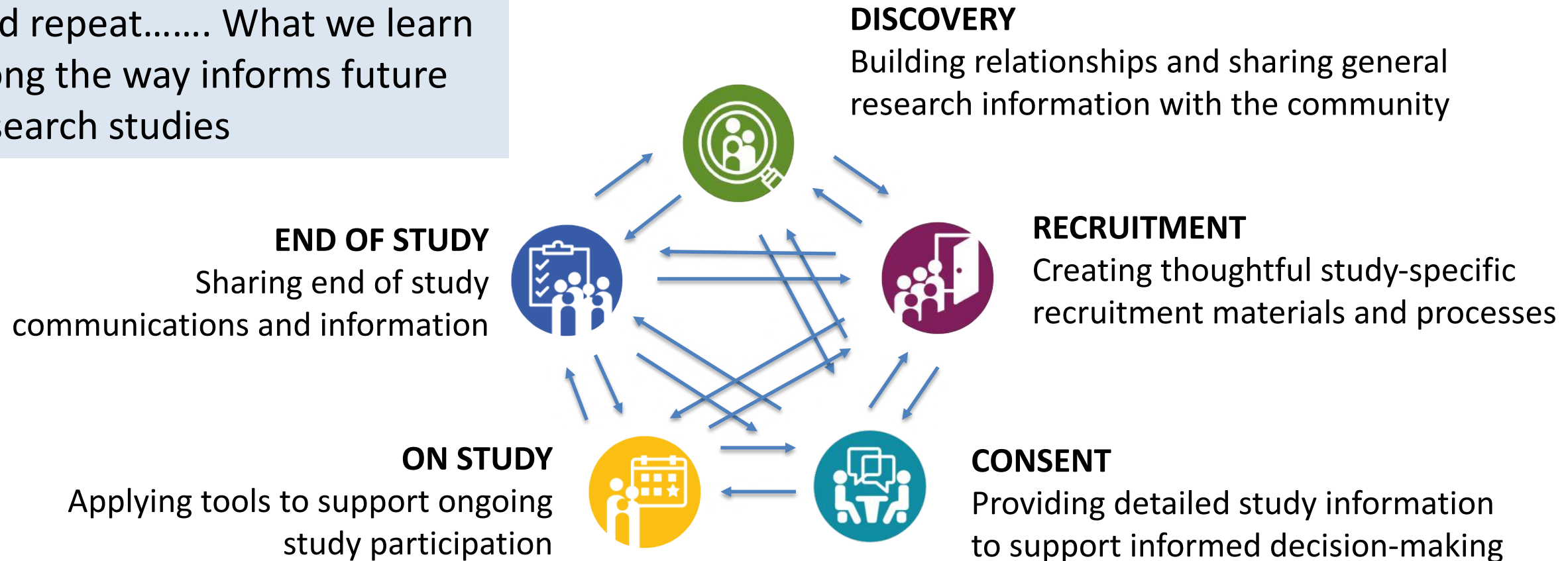
ON STUDY



END OF STUDY

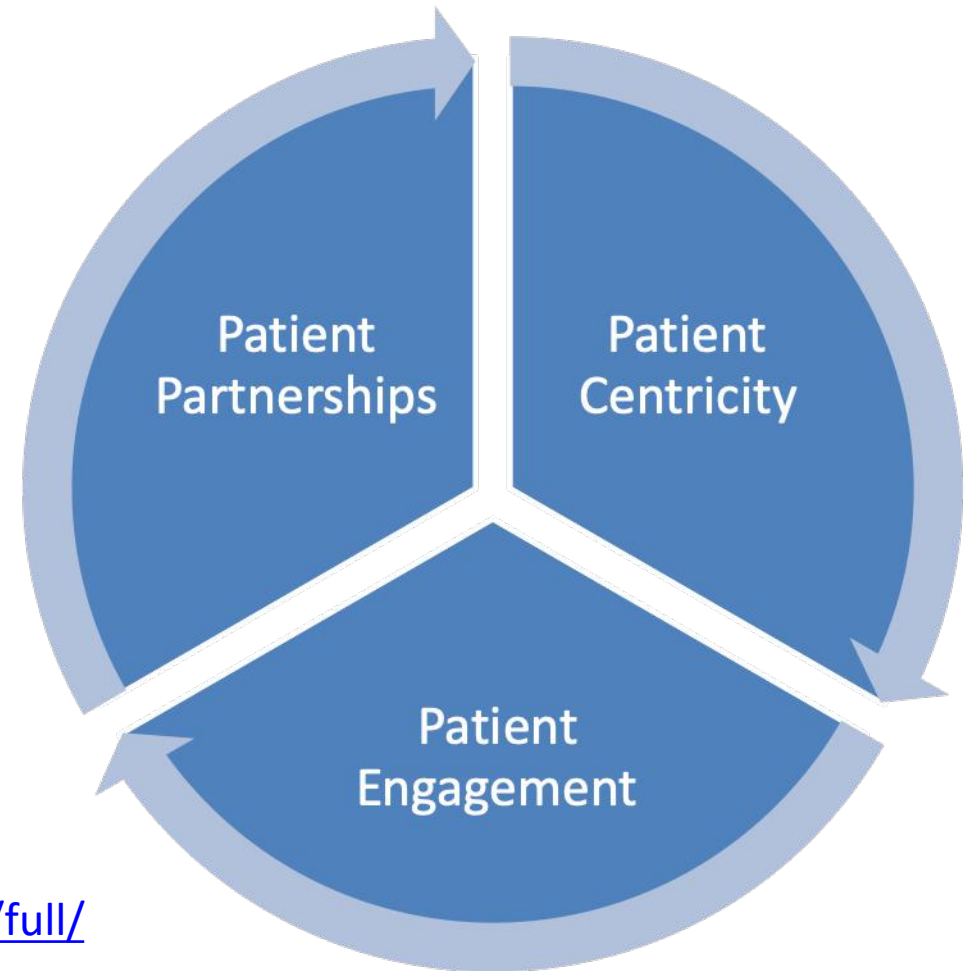
What does clinical research that integrates health literacy principles look like?

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



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/doi/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

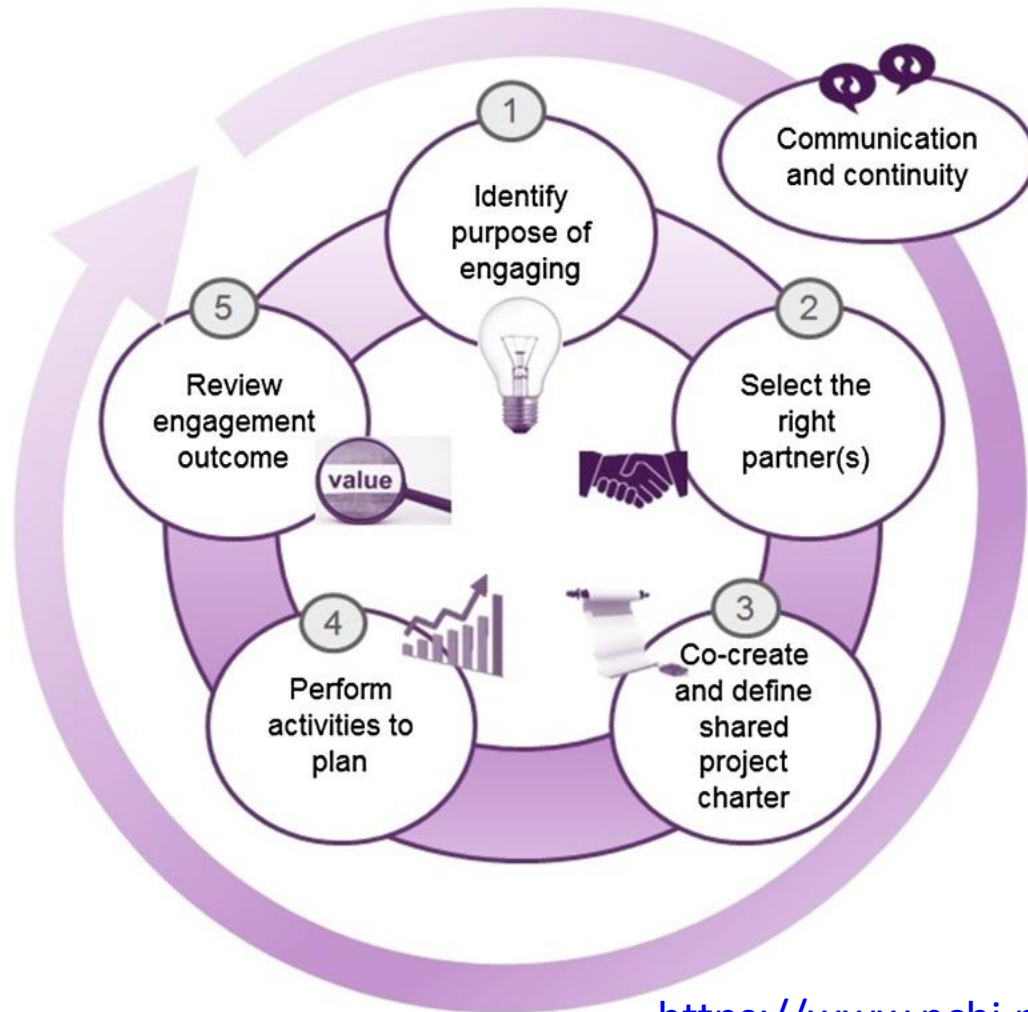
Reduced participant
ATTRITION

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.

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)



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

STAR Principles for 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

Additional Resources



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

OVERVIEW

ANALYZE

VISUALIZE

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

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Clear communications benefit everyone in the clinical research process

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
- 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

- 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



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Using key audience insights to create accessible health materials

Catina O'Leary

President and CEO

Health Literacy Media

@HealthLitMedia



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



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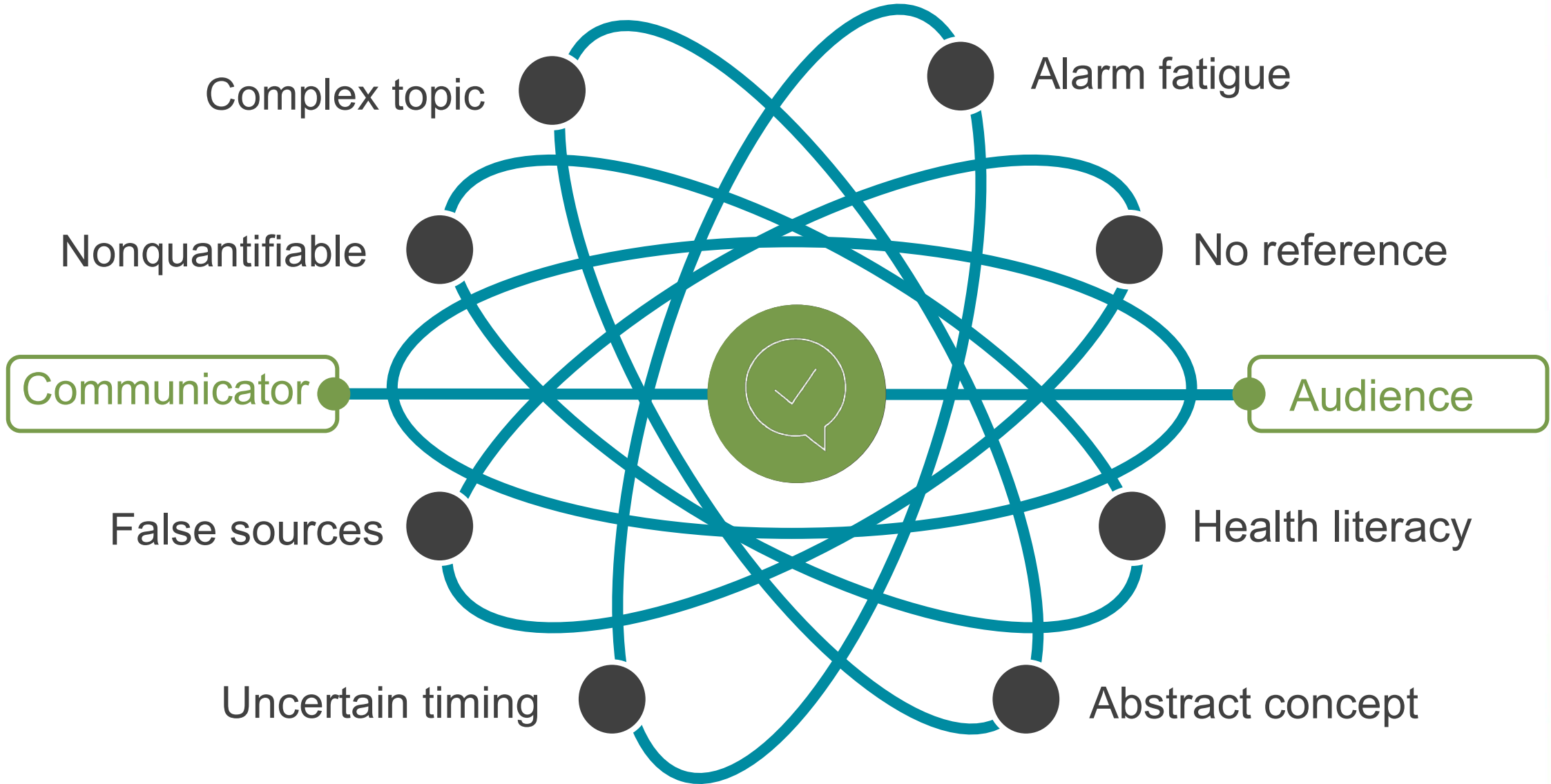
A tangle of challenges



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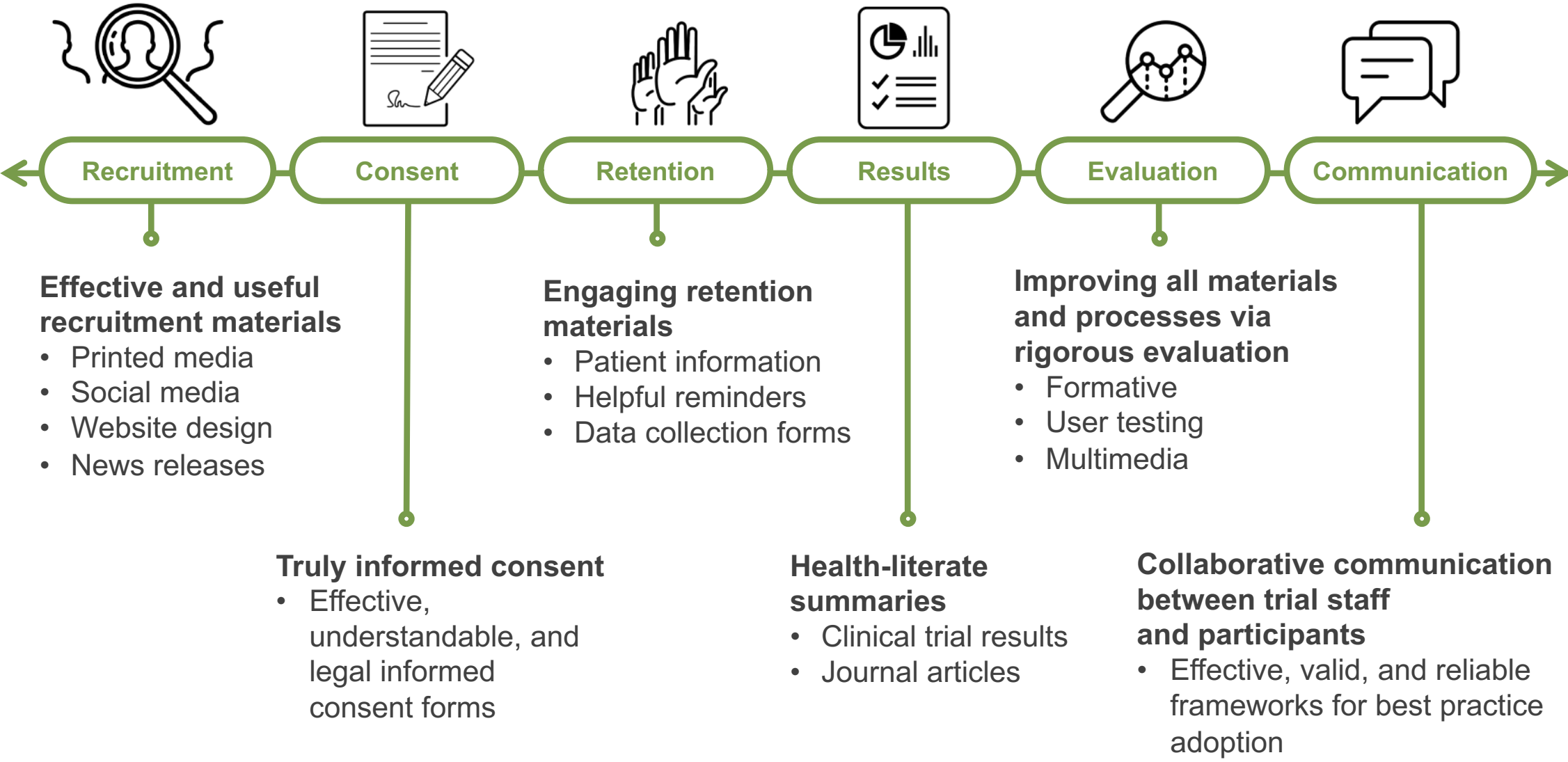
Health literacy through the clinical trial process



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Health literacy is a set of tools and processes



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Plain language summary



Understand the science



Apply clear communication principles



Test materials with target audience



Revise content and design

Standards for clinical research communication



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Health literacy principles

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

Clear and accurate content that addresses all requirements

Requirements and guidelines

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



A communication continuum



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MISSOURI DEPARTMENT OF SOCIAL SERVICES
FAMILY SUPPORT DIVISION
Provider Attestation of Physician's Order of Medical Necessity

ATTENTION: All fields on this document are required to be completed.

Patient Name (Print): _____ MO HealthNet Number: _____
Provider Name: _____
Certifying Physician Name: _____ Telephone: _____
Physician's Address: _____
Care Plan Begin Date: _____ Care Plan End Date: _____

By signing this form, you are attesting there is a physician's diagnosis of a condition which specifically requires the services provided and billed for this patient. A copy of the physician's order must be made available to the Family Support Division upon request. You attest all services provided and billed are within the scope of the physician's order and are necessary for the treatment of the diagnosed medical condition of this patient.
Anyone who knowingly and willfully makes or causes to be made, a false statement or representation of this statement may be prosecuted under applicable federal or state laws.

↑
Technical language



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.

← Less clear

More clear →



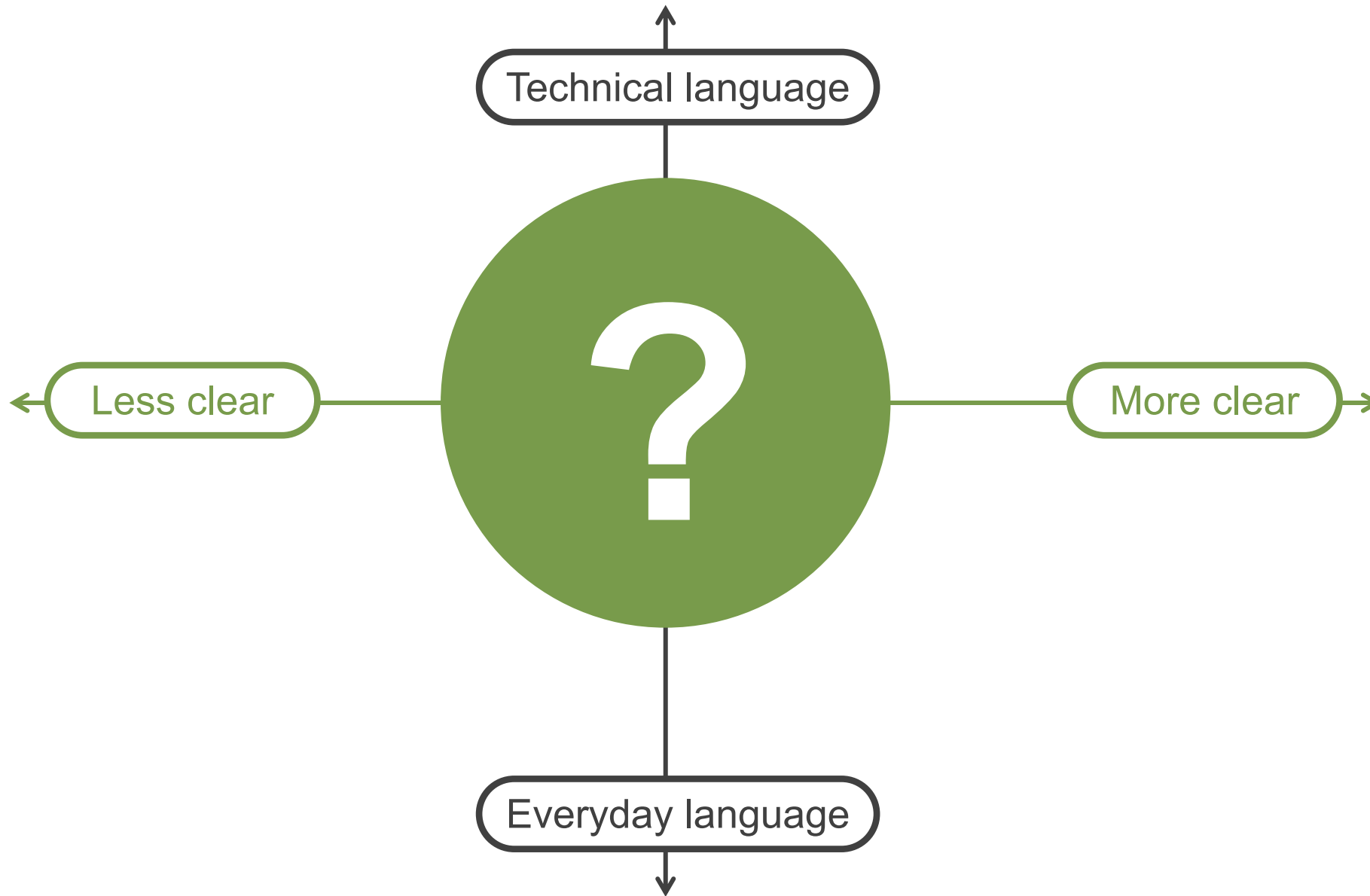
↓
Everyday language

A clinical trial that tested the trial drug RO4929097 in patients with colorectal cancer

What were the main results?

- 📄 Researchers found that RO4929097 did not work to treat colorectal cancer when taken alone.
- 👥 Most patients in this clinical trial had their cancer grow or spread further.
- ✗ Researchers do not recommend further testing of this trial drug when taken alone as a treatment for colorectal cancer.

Evaluating communication clarity

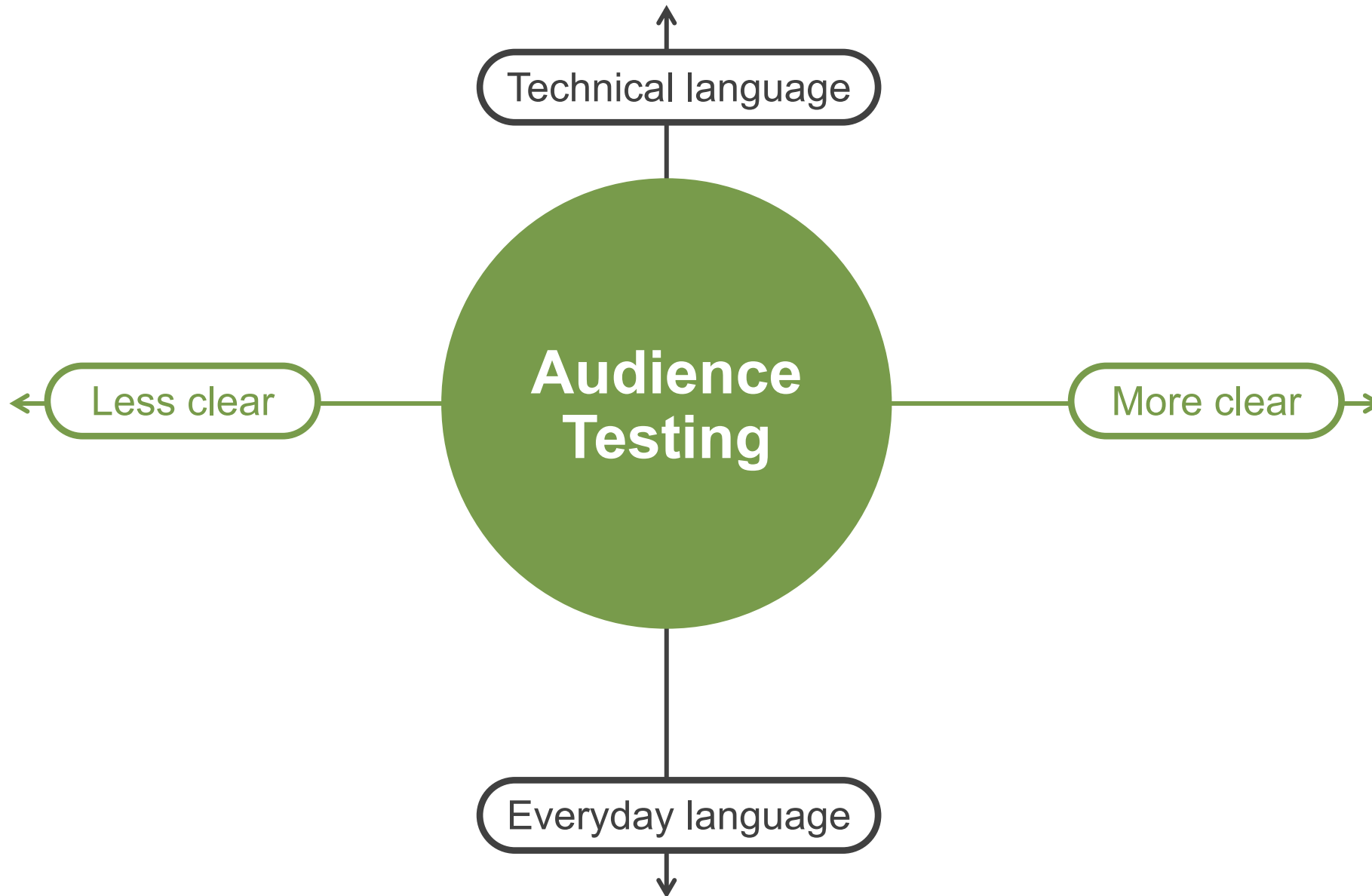


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Measuring communication clarity



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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



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Best practices for audience testing



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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?”

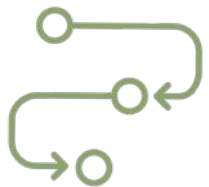
What patients and the public want to know



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?



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Test materials with your intended audience



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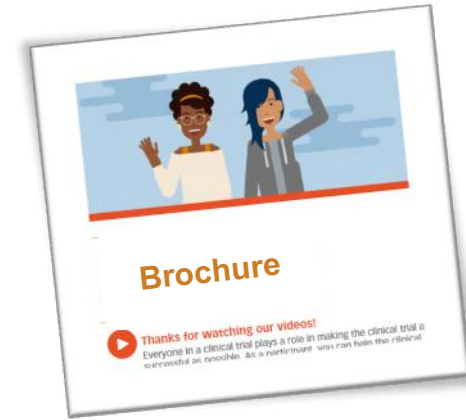
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Word	Scientific perspective	Non-scientific perspective
Inflammation	The body's complex biological response to harmful stimuli, such as infections or injury	Swelling, redness, pain
Dose	A precisely measured quantity of a medicine delivered as a unit	A pill or capful of a medicine; taking a medicine
Tolerability	A measure of how well a drug performs compared to its safety results	How much medicine a person can take without being bothered by unpleasant effects
Anterior (or other location terms)	Towards the front of the body	Inside (?)
Effective	A measure of a drug's performance on key indicators	It worked well to treat a disease or condition

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.



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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'



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”

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

President and CEO

Health Literacy Media

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Patient engagement in plain language summaries (PLS) of publications: Co-creation principles and best practices

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Antony Chuter, RCGP (Hon)

Patient Champion



@Tallbloke1971

Overview



What are plain language summaries (PLS) of publications?



Why are PLS needed?



A practical framework for PLS development



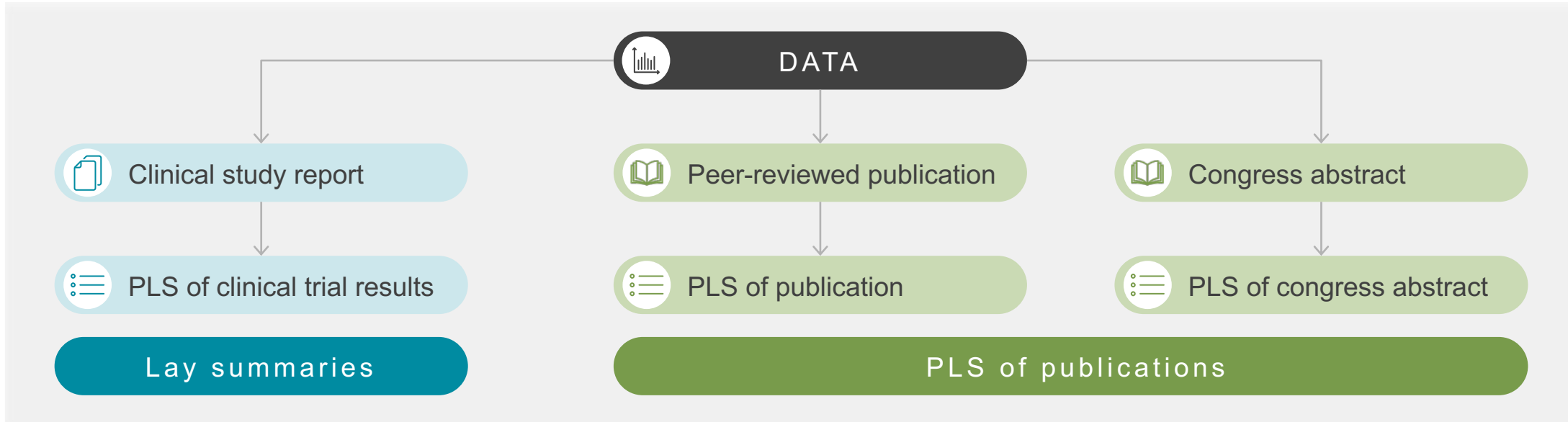
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What are PLS of publications?

- ▶ 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^{1–3}

PLS can:

- 1 Help patients to engage with original research and gain up-to-date medical knowledge^{2–4}
- 2 Empower patients in their discussions with healthcare professionals^{2,4,5}
- 3 Enhance communication pathways between scientists and broader audiences⁶

1. Amelot V, et al. *Pharm Med.* 2017;21:329–37; 2. Georgieva A, et al. Poster presentation at ISMPP EU Meeting 2018; 3. Fisher G, et al. Poster presentation at the ISMPP EU meeting 2020; 4. McKinnon VE. Poster presentation at EMBLIVE 2019; 5. Pushparajah DS, et al. *Ther Innov Regul Sci.* 2017; <https://doi.org/10.1177/2168479017738723>; 6. Kuehne LM, Olden JD. *PNAS.* 2015;112(12):3585–6.



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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



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Stepwise approach for PLS development



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Quality of patient engagement

- 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



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1

Scope & prioritisation



2

Identify your target audience



3

PLS development & co-creation



4

Dissemination



5

Evaluation

Which publications to do PLS for

- Objective, transparent, prospective criteria needed

Resource planning

Journal or congress selection

Dissemination planning

- Journal or congress requirements
- Format



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Who will use the PLS?
What are their needs & priorities?



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Consider language, numeracy, structure and design

Readability tools

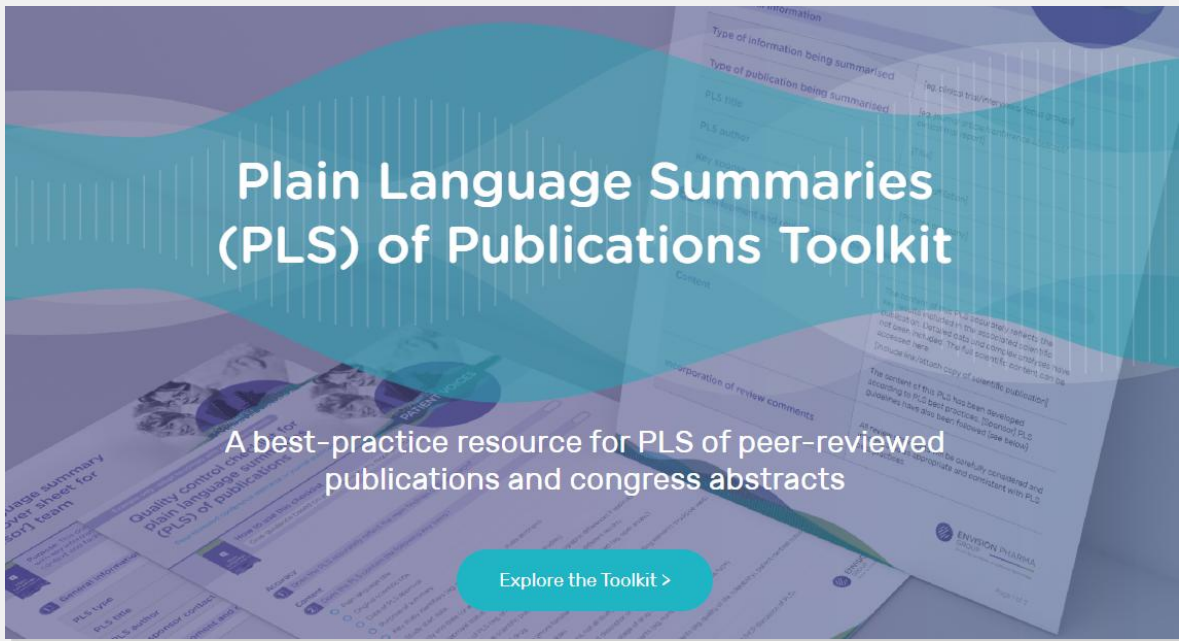
Suitability tools



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

PLS template

QC checklist

Cover sheets for patient and sponsor reviewers

Glossary guide

Evidence bibliography



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





Who can share the PLS?

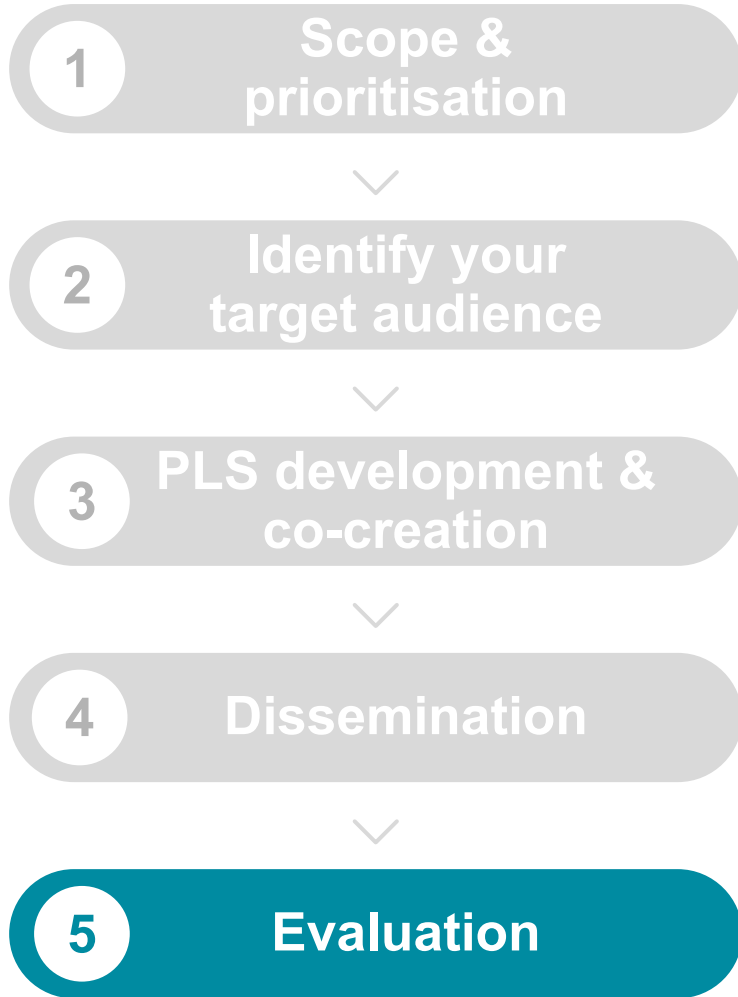
Where will it be shared?



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Potential sources of metrics:

- Journal tracking & Altmetrics
- Repositories

Evaluate – and publish! – your experience of patient engagement



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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



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Thank You

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