

Update on the National Institutes of Health ENGAGE Initiative



Christin Veasley, BS

Co-founder & Director, Chronic Pain Research Alliance

Co-chair, NIH ENGAGE Working Group (10/2023-9/2025)

Co-chair, PWLE Committee, HEAL K12 Clinical Pain Career Development Award Program

Co-chair, PWLE Engagement Committee, US Association for the Study of Pain

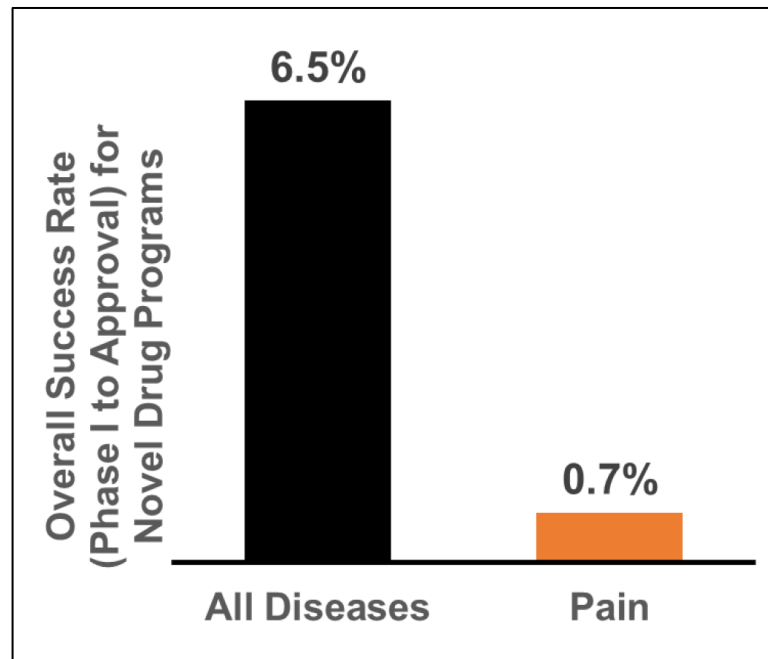


Traditional Research Model & Team Members



What's Wrong with This Model?

- Problem #1: Success rates for new therapeutics very low (<7% get FDA-approval)
- Problem #2: It takes 17 years for research findings to reach clinical practice!



Challenging the Traditional Research Model

“ ... used to give voice to the idea that those who are affected by [medical] research have a right to influence *what* is researched and *how* this is done...

... Given that medical research is often funded through public resources ... consumers should have a say ...



... The involvement of consumers can play an important role in the ownership and dissemination of research findings.”



Challenging the Traditional Research Model

UNBIASED


BIASED


Trisha Greenhalgh #FBPE 
@trishgreenhalgh 


Doctor: Don't confuse your Google search with my 6y at medical school.

Patient: Don't confuse the 1-hour lecture you had on my condition with my 20y of living with it.

6:30 AM - 26 May 2018

11,439 Retweets 35,155 Likes 

535 11K 35K 

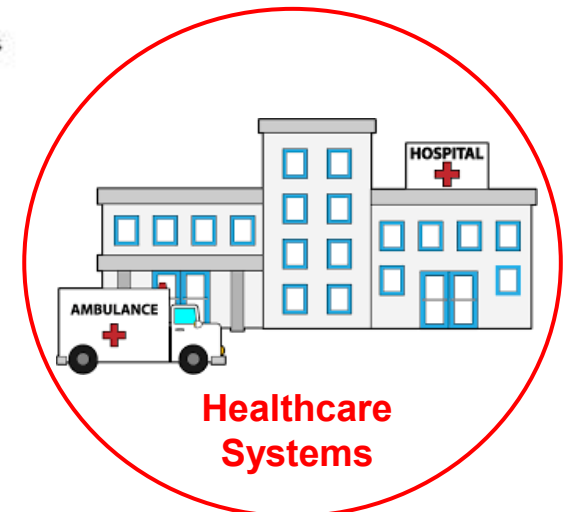


“Expertise” comes in different forms – lived experience is just as valuable as scientific experience – can be complementary if both are valued and respected.

We all come to the table with bias.
We all have valuable perspectives & important contributions.
The issue is how you manage the bias.

The “New” Model – Expanded Research Team

“End-Users of the Study Findings”



Patient Research Engagement *aka “PWLE Engagement” (Persons with Lived Experience)*



“Engagement is when individuals [patients, caregivers] ... partner with researchers to plan, design, and/or conduct research so that the research and its outcomes are meaningful and actionable.”

“The ultimate goal is for people and communities to guide the direction of, and partner in, research that is relevant and impactful to them.”
(NIH, 2025)

Just Some Benefits of PWLE Engagement



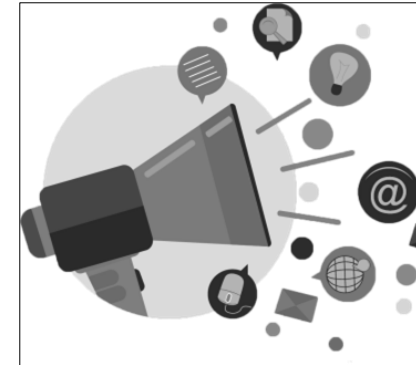
↑ **Enrollment & Retention**
(including diverse populations)



↓ **Time to Study Completion**



↓ **Cost**



↑ **Dissemination of Study Findings**



↑ **Trust**

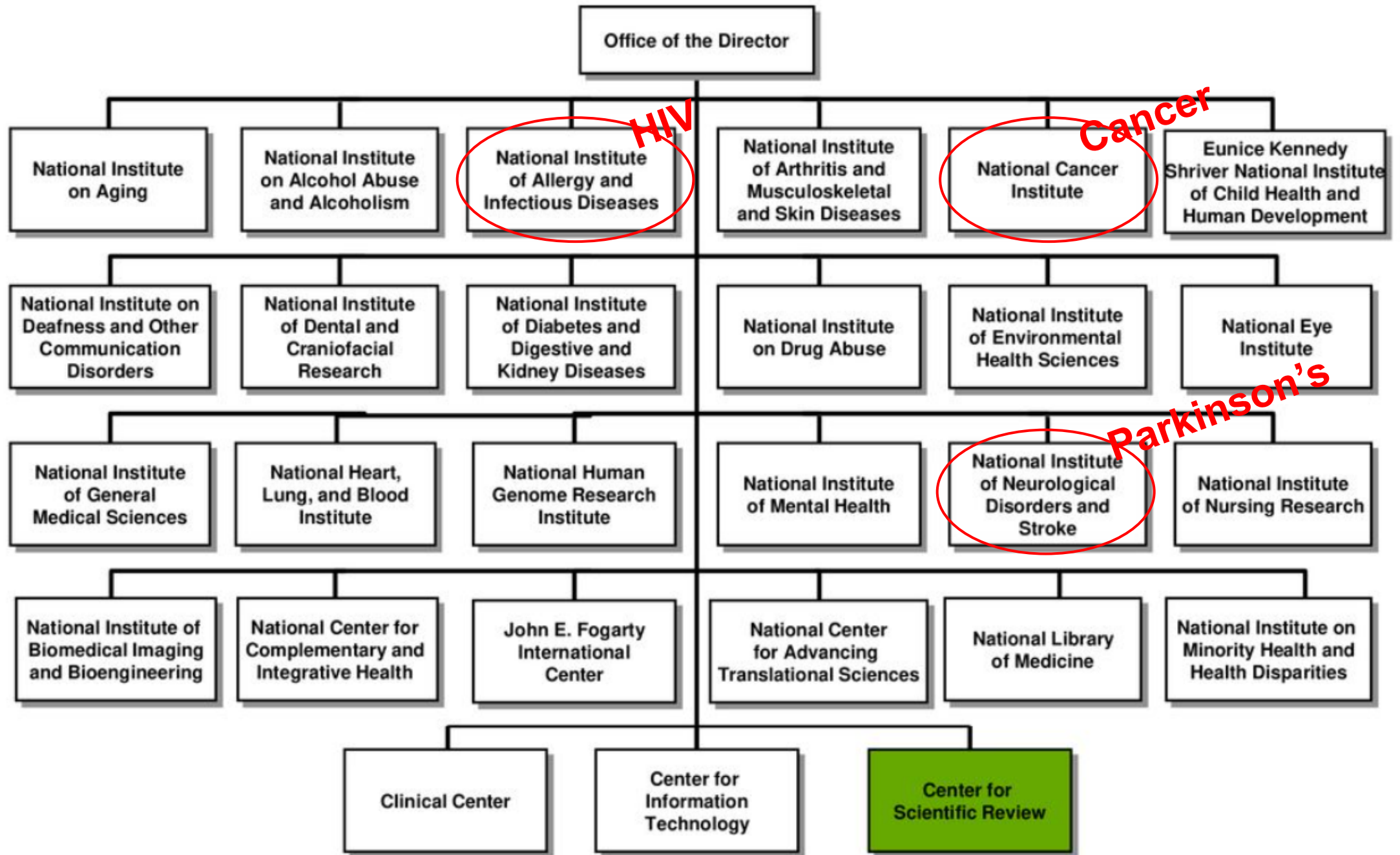
Domecq JP, et al. Patient engagement in research: a systematic review. BMC Health Serv Res. 2014 Feb 26;14:89.

Levitan B, et al. Assessing the Financial Value of Patient Engagement. Ther Innov Regul Sci. 2018 Mar;52(2):220-229.

Cargo M, Mercer SL. The value and challenges of participatory research: strengthening its practice. Annu Rev Public Health. 2008;29:325-50.

Additional Problems

- Even though benefits of PWLE/community engagement have been widely demonstrated, engagement is not standard practice in research
- Engagement is increasingly being required by research funders, but few scientists receive education/training on how to incorporate engagement into their studies
- The National Institutes of Health (NIH) does not have an agency-wide policy, guidance or approach to PWLE/community engagement, even though it is the largest funder of biomedical research (funding ~\$45B in research in FY25)



NIH ENGAGE Initiative

- In October 2023, NIH launched the ENGAGE (Engaging the Public as Partners in Clinical Research) Initiative to address this problem
- ENGAGE was charged with the task of developing an agency-wide vision, goal and framework for incorporating patient/public engagement in all phases and types of NIH-funded clinical research



NIH Working Group Members

- Working Group members represented a broad range of patients, advocates, researchers, clinicians, and non-profit representatives



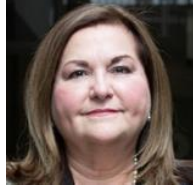
Suzanne Bakken
(Co-Chair)
Researcher,
Clinician



Christin Veasley
(Co-Chair)
Patient Advocate



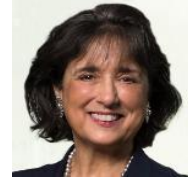
Jessica Ancker
Researcher



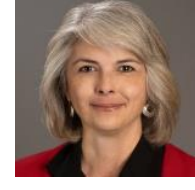
María Aranda
Researcher



Cinnamon Bloss,
Researcher



Roberta Diaz Brinton
Researcher



Karen Gaindec
Non-Profit



Kristin Garman
Non-Profit



Venus Ginés
Patient Advocate



Tiffany Haynes
Researcher



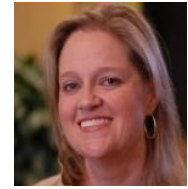
Sally Hodder
Researcher



Jonathan Jackson
Researcher



**Lance Jasper
Jones**
Patient Advocate



Annie Kennedy
Non-Profit



Kent Key
Researcher



Alexa Kimball
Clinician



Esther Krofah
Non-Profit



Doug Lindsay
Patient Advocate



Marjorie Mau
Researcher



Kenneth Oye
Researcher



Somava Saha
Clinician, Non-Profit



Judy Stecker
Patient Advocate

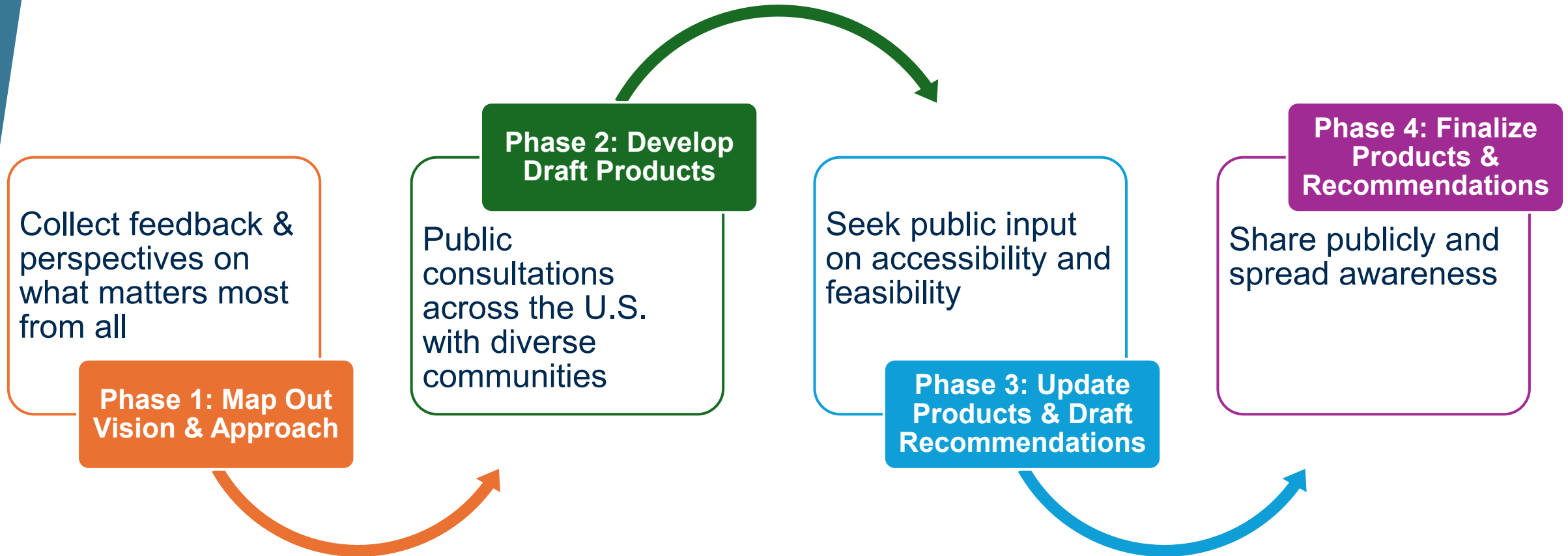


Maria Trent
Clinician,
Researcher



Michelle Sie Whitten
Patient Advocate

Process



Community Conversations



In-Person CCs planned but not held:

- Los Angeles, CA
- Honolulu, HI
- Houston, TX
- Wichita, KS

Virtual CCs planned but not held:

- Researchers,
academic orgs
- Leaders of
organizations
serving American
Indian & Alaska
Native communities

Community Conversation

COMMUNITY INPUT



COMMUNITY PARTNERSHIPS



THE FRAMEWORK



By JULIA BAKAY!

Vision and Goal for Clinical Research Engagement @ NIH

VISION

A future where clinical research engagement is standard practice, promoting responsiveness to community needs, accountability, and transparency while helping turn discoveries into improved health

GOAL

For people and communities to influence the agenda and direction of, as well as have meaningful input into, research that is relevant and impactful to them

Framework for Clinical Research Engagement





ACTION STEPS

- 1** Ongoing and consistent collection and assessment of community health needs by researchers and communities
- 2** Develop understanding of the importance of the community health need(s)



ACTION STEPS

- 1 Execute a shared priority-setting process that includes both researcher and community participation
- 2 Clarify evidence gaps and possibilities for research
- 3 Craft the research question(s) and identify potential funding opportunities

STEP 2:
Co-Develop the
Research
Question



What are the Key Activities?

1. Shared Priority Setting

- Identify and compare top concerns from PWLE
- Decide together which topics rise to the highest level of importance

2. Reviewing Evidence and Knowledge Gaps

- Look at what is already known and where unanswered questions remain
- Create a shared understanding of why certain questions are timely and relevant

3. Joint Assessment of Funding Opportunities

- Review active or upcoming funding announcements
- Discuss which priorities align with current funder interests and how to frame the study to meet funder requirements

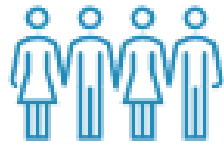
4. Draft Research Questions and Aims

- Transform priorities that align with current/future funding opportunities into structured research questions (clear, specific, feasible)
- Identify short-term, fundable questions and longer-term aspirational questions for future development

5. Reach Group Consensus

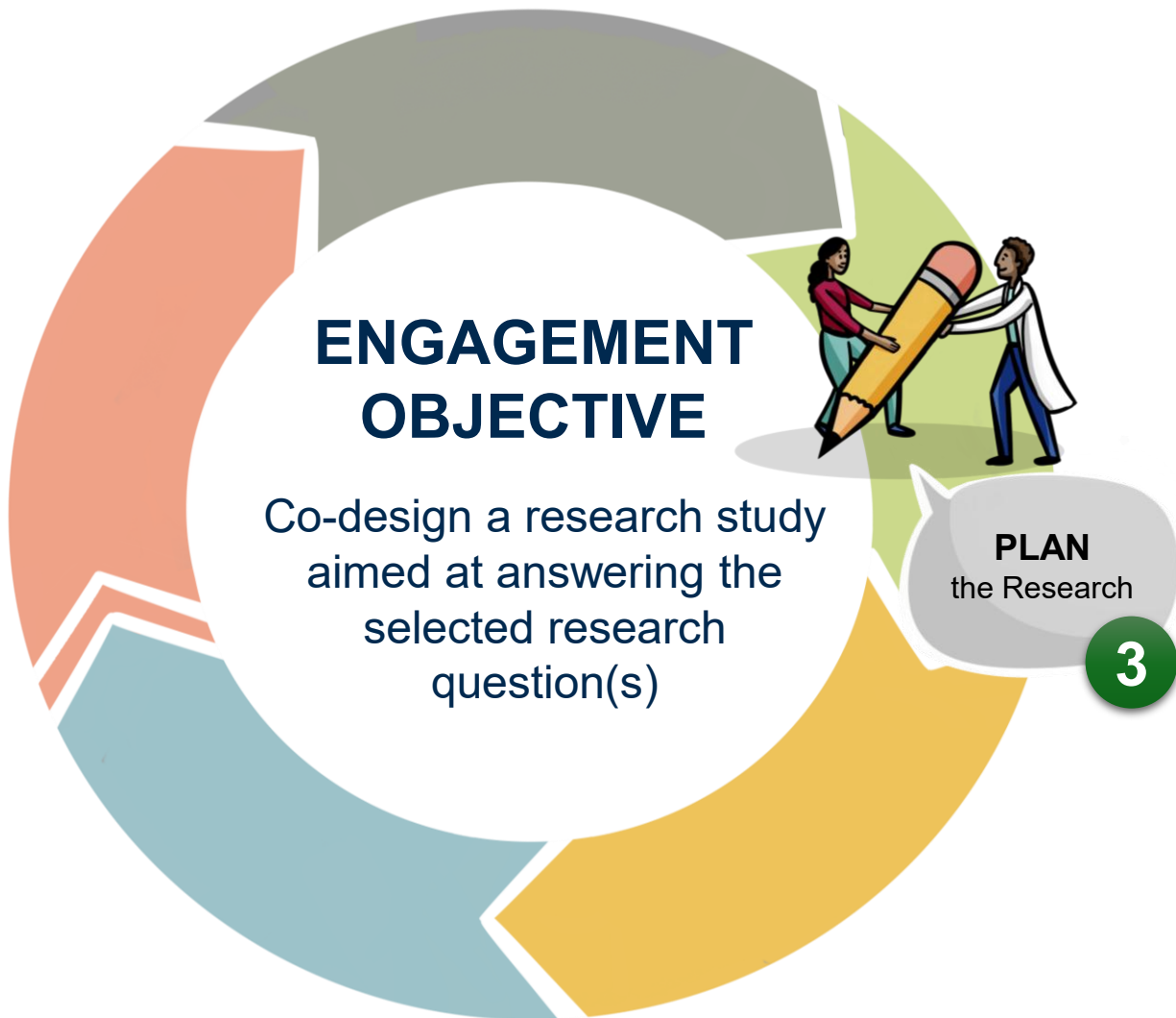
- Use transparent, fair decision-making processes to finalize research questions

STEP 2:
Co-Develop the
Research
Question



What are the Methods?

Method	What It Is	Format	Who Participates	Best For
Town Halls / Community Forums	Public meetings for broad input and transparency	Large group; presentation + Q&A	Broad community, PWLE, caregivers, clinicians, public	Awareness, diverse views, trust- building
Digital Feedback Tools	Online input collection at scale	Surveys, polls, crowdsourcing	Broad community, PWLE, caregivers, stakeholders	Quick reach, quantitative/general feedback
Listening Sessions	Open conversations to understand needs & priorities	Moderated discussion; minimal presentation	PWLE, caregivers, community members	Early discovery of concerns & themes
Storytelling Sessions	Guided sharing of lived experience	1:1 or small group; narrative-driven	PWLE with deep experience	Understanding challenges, shaping meaningful outcomes
Engagement Studios	Structured sessions for actionable research feedback	Small group (6–10 PWLE); facilitated; focused questions	PWLE, facilitators, research team	Refining research questions, study design, materials, procedures



ACTION STEPS

- 1 Reach agreement on community and researcher roles, responsibilities, and decision-making processes
- 2 Deliver study- or role-specific training to prepare community partners and researchers for collaborative design
- 3 Incorporate community expertise into study design to improve quality and feasibility



ACTION STEPS

- 1** Monitor study progress to ensure community-centeredness and fulfillment of responsibilities
- 2** Implement community-informed study modifications to address obstacles
- 3** Co-interpret study results with input from both community partners and researchers

ENGAGEMENT OBJECTIVE

Collaboratively return research results to study participants, community of focus, scientific audiences, and the broader public

5

Share the FINDINGS



ACTION STEPS

1

Co-design tailored plans for returning results to participants, community(ies), scientists, and the public

2

Co-create the dissemination products

3

Co-communicate dissemination products through multiple channels

Preparing for Engagement



Establish Partnerships

Create relationship in which all partners contribute knowledge, share decision-making, and collaborate to design and conduct research

1



Compensation & Resources

All partners should be offered fair and equitable compensation that is based on their role, expected contributions, and preferences.

2



Establish Expectations

All partners should create baseline expectations for how they will work together, make decisions, and manage disagreements.

3



Deliver Training

Teams should identify what each partner already knows, where there are gaps, and deliver appropriate education and training to meet those needs.

4

Recommendations to NIH

RECOMMENDATION

1

NIH should require and support the integration of the *Framework for Clinical Research Engagement* into its funded clinical research by providing financial and training resources

RECOMMENDATION

2

NIH should actively foster an environment in which bi-directional researcher-community partnerships are standard practice

RECOMMENDATION

3

NIH should create a process to ensure robust community input on NIH initiatives from a broad range of community organizations and advocates

RECOMMENDATION

4

NIH should invest in the continuous evolution and improvement of its clinical research engagement methods and processes

What's Next?

- Presented the final draft report to NIH Director, Dr. Bhattacharya (9/29/25) - government shutdown began 2 days later
- NIH finalized report and sent to NIH Director in early December 2025
- Dr. Bhattacharya endorsed the ENGAGE report & recommendations in his NIH Director's Statement (December 19, 2025): <https://www.nih.gov/about-nih/nih-director/statements/roadmap-engaging-public-partners-clinical-research>
 - *"I am pleased to endorse these recommendations ... NIH is eager to begin implementing this roadmap, starting in 2026."*
- To read report: https://osp.od.nih.gov/wp-content/uploads/2025/12/NExTRACs-ENGAGE-Report_FINAL.pdf
- To watch the presentation: <https://osp.od.nih.gov/events/novel-and-exceptional-technology-and-research-advisory-committee-meeting-3/>
- Stay tuned:
 - [Contact me: CVeasley@CPRAlliance.org](mailto:CVeasley@CPRAlliance.org)
 - <https://partnersinresearch.nih.gov>

Questions?

Group Activity – Early Engagement

How many in the group have experience collaborating with researchers in the early engagement phase?



Group Activity – Early Engagement

- Imagine a group of researchers wants to work with your community AND they're coming to you before they've chosen a research question or written a grant!
 - **1: Starting the Relationship**
 - What would researchers need to do to earn trust and show they're serious about listening? What would feel respectful vs. extractive?
 - **2: Deciding What Matters**
 - How should a community and researchers work together to decide which health concerns and related research questions are most important to focus on?
 - **3. From Priorities to a Grant**
 - If funding limits mean only one or two priorities can move forward, how should that decision be made fairly? What transparency would you expect from researchers?