

Update from the Working Group on Engaging the Public as Partners in Clinical Research

Suzanne Bakken, RN, PhD, FAAN, FACMI, FIAHSI
*Alumni Professor of the School of Nursing & Professor of Biomedical
Informatics, Vagelos College of Physicians & Surgeons, Columbia University*

Christin Veasley
Co-Founder & Director, Chronic Pain Research Alliance

June 17, 2024

NExTRAC
Novel & Exceptional Technology
and Research Advisory Committee

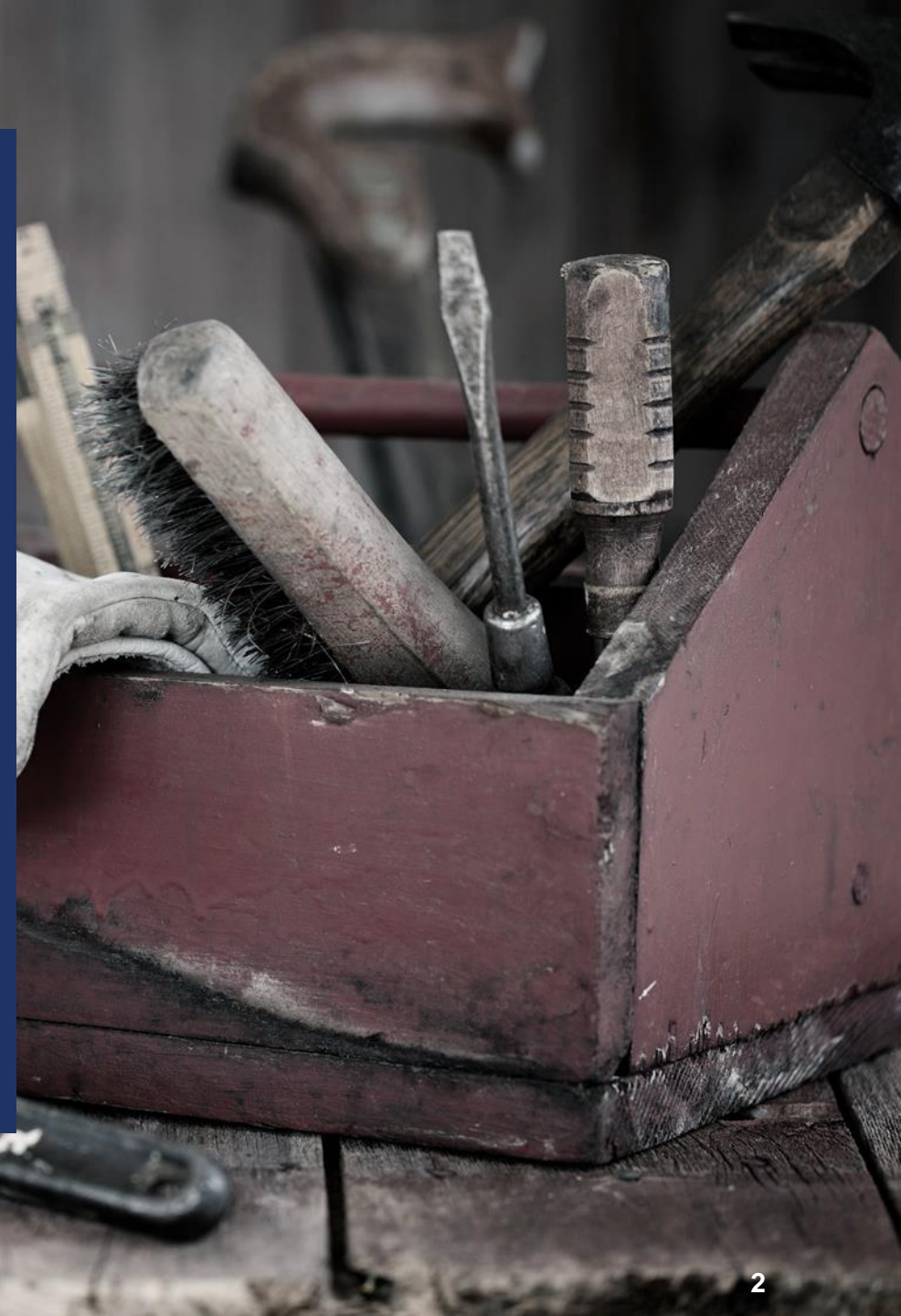
Building a Toolkit for Public Engagement

FOR RESEARCHERS: A practical set of options for meaningful engagement that can be tailored to the objectives, design/scale of the study

FOR SCIENCE: Increased representation and understanding of factors affecting successful study design, implementation, and dissemination

FOR PARTICIPANTS: A vision and framework for how members of the public can contribute to the scientific enterprise

FOR THE PUBLIC: A roadmap for building understanding of and trust in NIH and scientific research



Working Group Members



Jessica Ancker,
Vanderbilt University
Medical Center



María Aranda,
University of
Southern California



Suzanne Bakken,
Columbia University



Cinnamon Bloss,
University of
California, San
Diego



**Roberta Diaz
Brinton,**
University of Arizona



Karen Caindec,
Southcentral
Foundation



Kristin Carman,
Patient-Centered
Outcomes Research
Institute



Venus Ginés,
Día de la Mujer
Latina



Tiffany Haynes,
University of
Arkansas for Medical
Sciences



Sally Hodder,
West Virginia
University



Jonathan Jackson,
CRESCENT
Advising, LLC,
Harvard Medical
School



**Lance Jasper
Jones,**
Jasper House
Warriors



Annie Kennedy,
EveryLife
Foundation for Rare
Diseases



Kent Key,
Community Based
Organization Partners
& Michigan State
University



Alexa Kimball,
Harvard Medical Faculty
Physicians, Beth Israel
Deaconess Medical
Center



Esther Krofah,
FasterCures, Milken
Institute



Doug Lindsay,
The Lindsay Center
LLC, Doug Says
LLC



Marjorie Mau,
University of Hawai'i
at Mānoa



Kenneth Oye,
Massachusetts
Institute of
Technology



Somava Saha,
Well-being and
Equity (WE) in the
World



Judy Stecker,
Hill+Knowlton
Strategies



Maria Trent,
Johns Hopkins
University

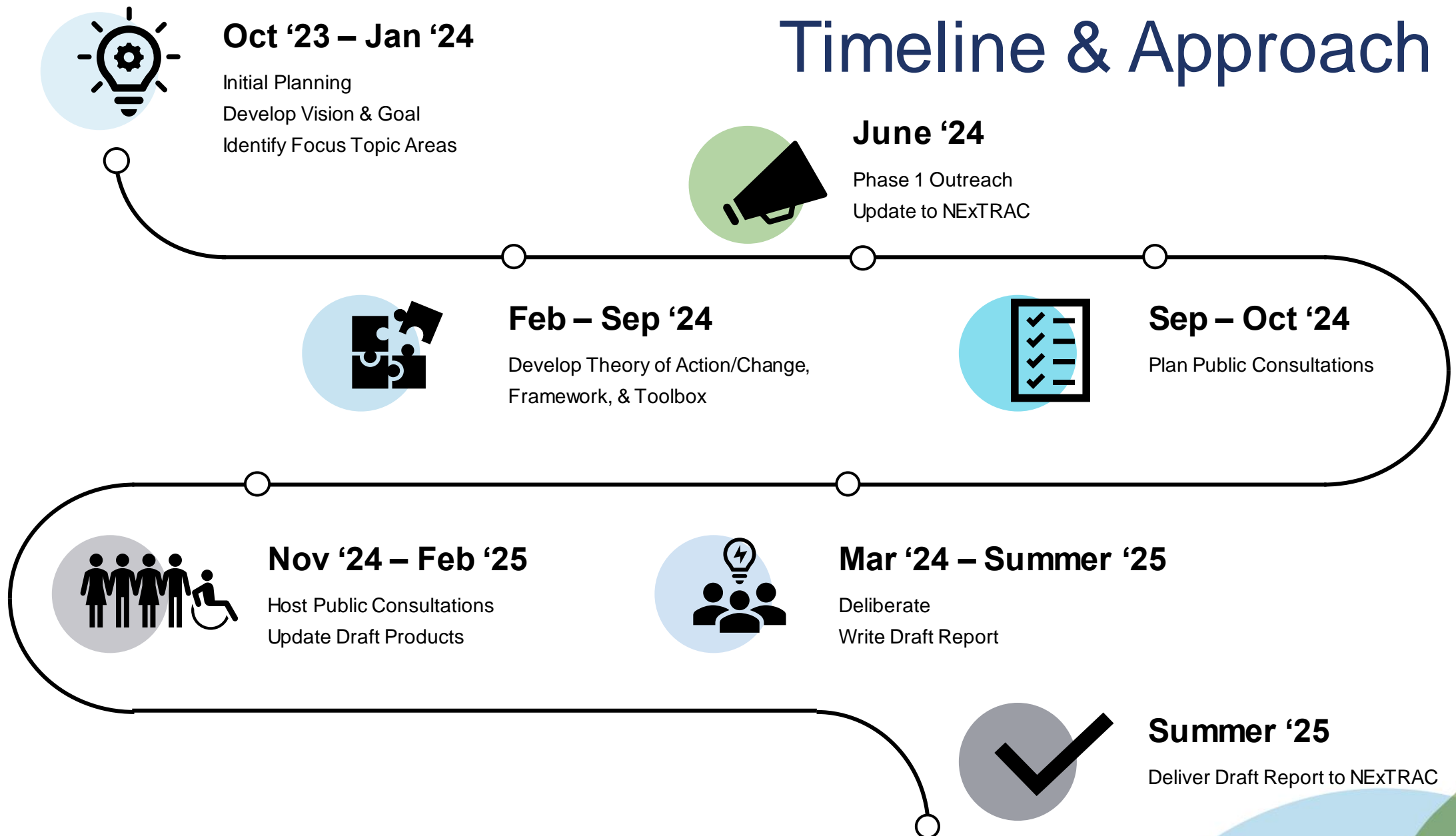


Christin Veasley,
Chronic Pain
Research Alliance



Michelle Sie Whitten,
Global Down
Syndrome Foundation

Timeline & Approach



Timeline & Approach



Oct '23 – Jan '24

Initial Planning
Develop Vision & Goal
Identify Focus Topic Areas



June '24

Phase 1 Outreach
Update to NExTRAC



Feb – Sep '24

Develop Theory of Action/Change,
Framework, & Toolbox



Sep – Oct '24

Plan Public Consultations



Nov '24 – Feb '25

Host Public Consultations
Update Draft Products



Mar '24 – Summer '25

Deliberate
Write Draft Report



Summer '25

Deliver Draft Report to NExTRAC

ENGAGE Progress: Initial Draft Definition

Clinical Research Engagement: involvement that varies by level and type depending on research and community needs, with individuals, groups of people, communities, and/or organizations across the various stages of clinical research so that the research and its outcomes are meaningful and actionable to relevant partners.



Various Stages of Clinical Research



Relevant Partners

ENGAGE Progress: Initial Draft Vision & Goal

Vision: Engagement in clinical research is a standard practice to promote responsiveness to community needs, accountability, and transparency while helping turn discoveries into improved health of people.

Goal: People and communities have a say in the agenda and direction of research that is relevant and impactful to them.

ENGAGE Progress: Cross-Cutting Themes

Leveraging Emerging Technology

- Artificial intelligence & machine learning (AI/ML)
- Utilizing informatics approaches

Building Partnerships

- Should be patient/community driven
- Reframe paradigm to focus on trustworthiness, accountability, and empowerment

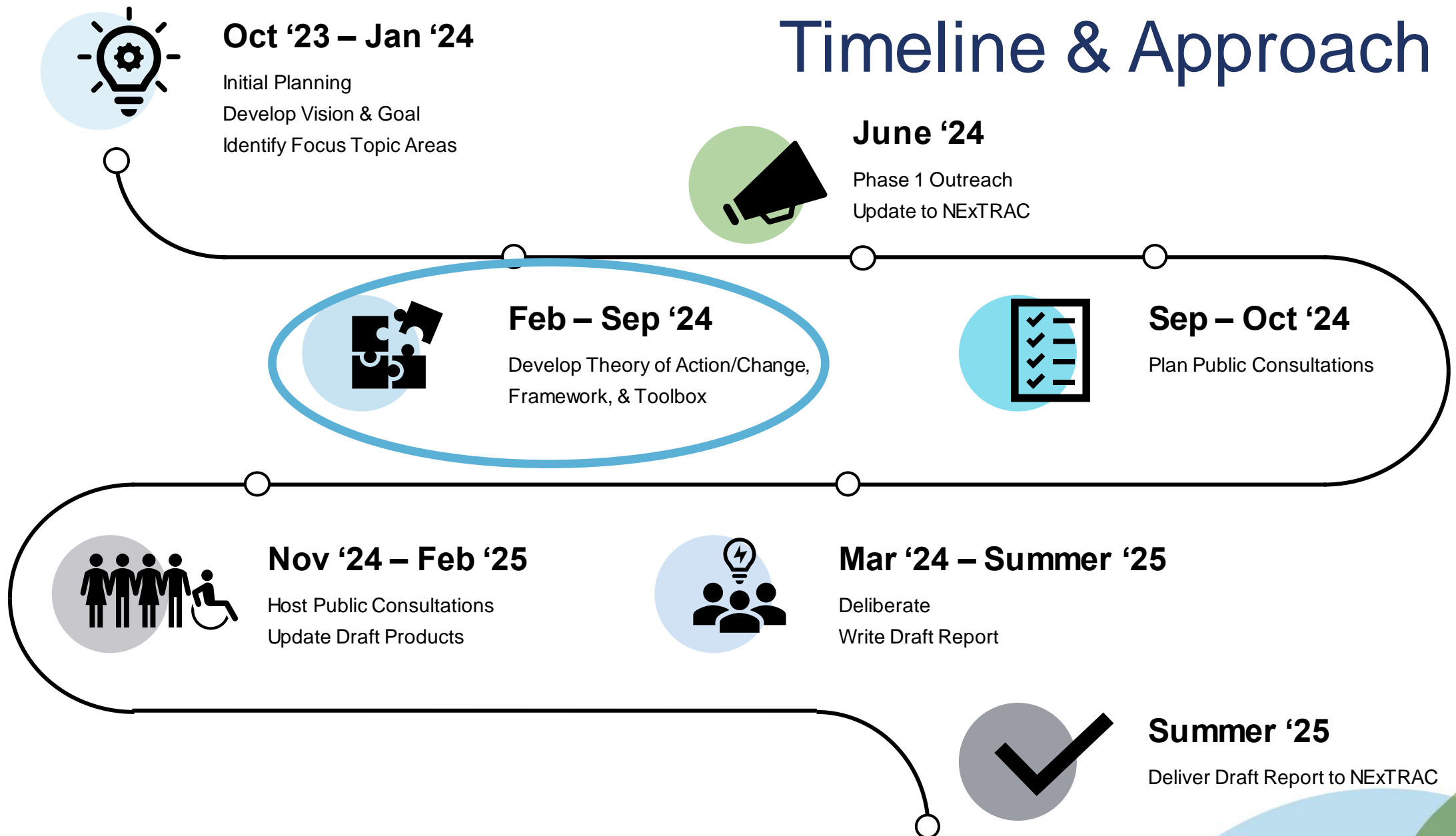
Promoting Access & Transparency

- Promote access and dissemination of publications and data (considering data sovereignty)
- Focus on transparency and accountability throughout research process

Advancing Justice & Equity

- Balancing local, regional, and global needs and perspectives
- Utilizing a decolonized approach

Timeline & Approach



Focus Topic Areas

Developing **Theory of Action/Change**



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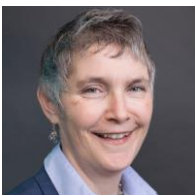
Reviewing Existing Frameworks & Developing **ENGAGE Framework**



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Kenneth Oye



Somava Saha

Identifying, Collecting, and Recommending a **Resource Toolbox**



Jessica Ancker



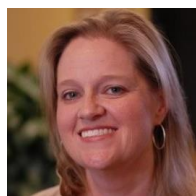
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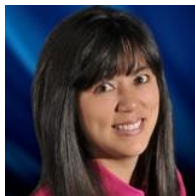
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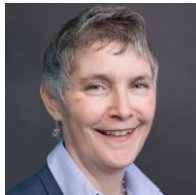
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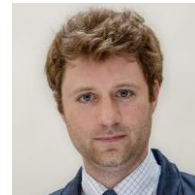
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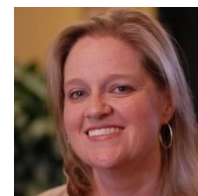
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What is a Theory of Change/Action?

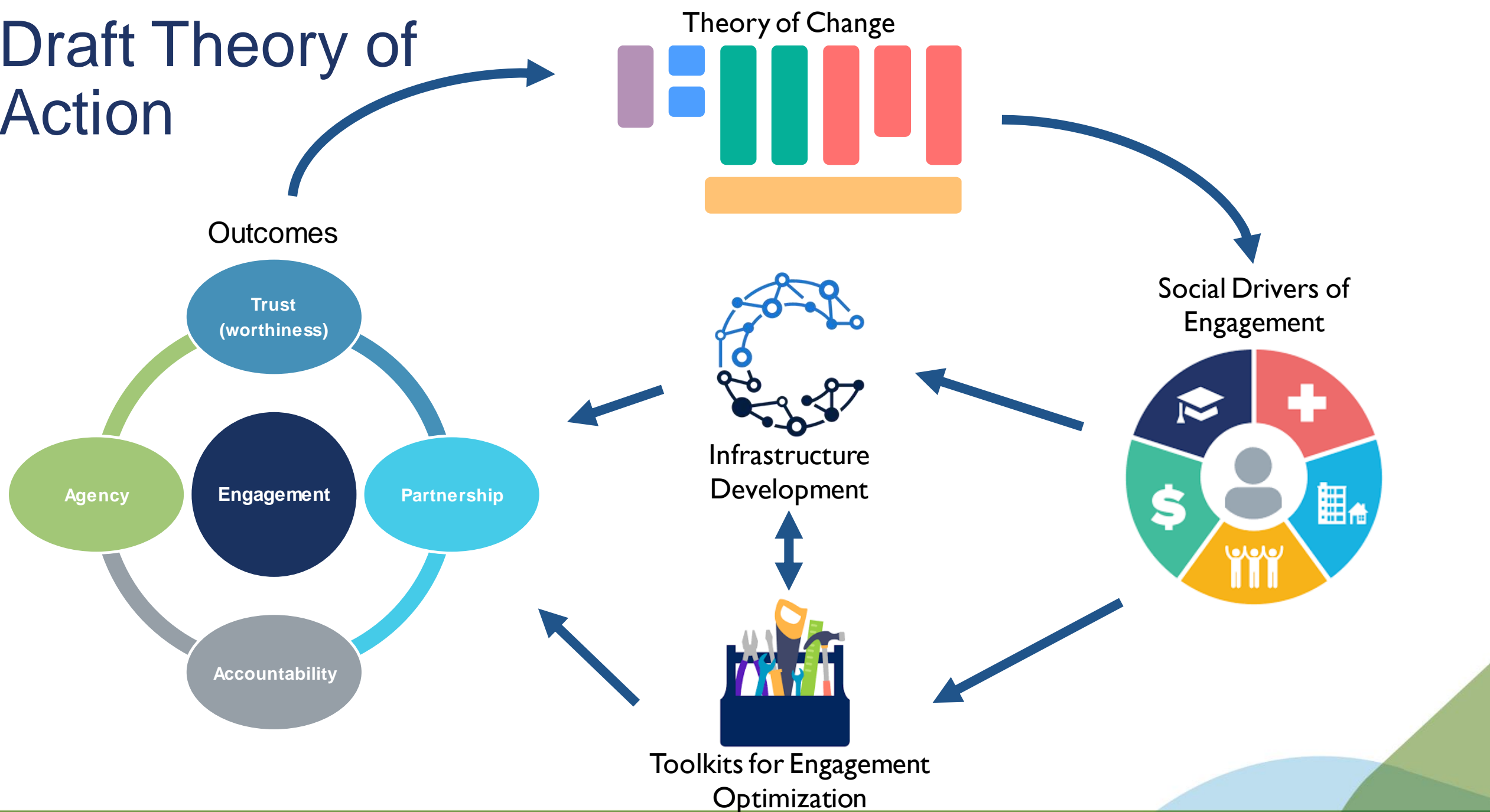
Theory of Change:

- Model of early stages of internal ENGAGE work
 - Maps out different moving pieces
 - Governs internal processes
- Helps us understand who we're trying to impact and what's achievable
- Focuses on what's achievable in the short-term, using what we have

Theory of Action:

- Visual of late stages of ENGAGE work and implementation
- Highlights ways to act on and communicate the recommendations to the larger public
 - If we can't reach everyone, we need to understand why and provide our reasoning
- Focuses on capacity-building for long-term goals, identifying gaps and responsible change agents

Draft Theory of Action



Focus Topic Areas

Developing **Theory of Action/Change**



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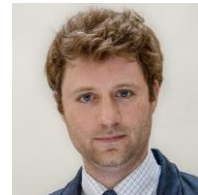
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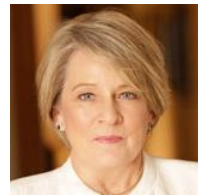
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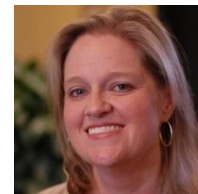
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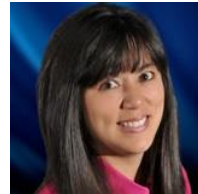
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ENGAGE Framework

A Roadmap for Engagement

- Targeting a broad audience
- Actionable Domains
- Complementary Maturity Model
- Case Studies and Examples

Draft Guiding Principles

1. Effective and equitable research design requires bi-directional engagement among everyone involved in the research enterprise, including individuals, communities, grassroots/community/faith-based organizations, institutions, funders, and policy makers.
2. Engagement is not one-size-fits-all, and opportunities for tailoring and growth need to be integrated throughout the research endeavor.
3. Engagement efforts must understand the context of existing societal values and work to shift these values to be more equitable and inclusive.
4. Engagement requires investment in resources and infrastructure that reduce barriers, are culturally-tailored to the needs of diverse communities, and allow for long-term, sustainable efforts.
5. While people and communities have the right to either agree or decline to engage with researchers and the research process, it is still the obligation of researchers to equitably include the communities affected by the research in all stages of the process.

Draft Guiding Principles *(cont.)*

6. Tokenistic engagement that is only a symbolic attempt at including the community's voice rather than developing a meaningful and equitable partnership cannot be tolerated.
7. The goal of engagement is to improve research accountability, bring agency to community voices in the research process, and restore, rebuild, and advance trust between scientists and the public.
8. Equitable health outcomes result from engagement efforts that consistently and equitably partner with people, communities, grassroots/community/faith-based organizations, and institutions involved in clinical research.
9. Engagement strengthens the research enterprise and improves the quality of research by refining the questions being studied, expanding the analysis of the data generated, and sharpening the focus on outcomes that are most relevant and useful to the people who will use them.

Focus Topic Areas

Developing **Theory of Action/Change**



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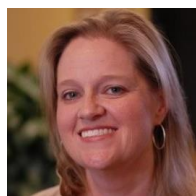
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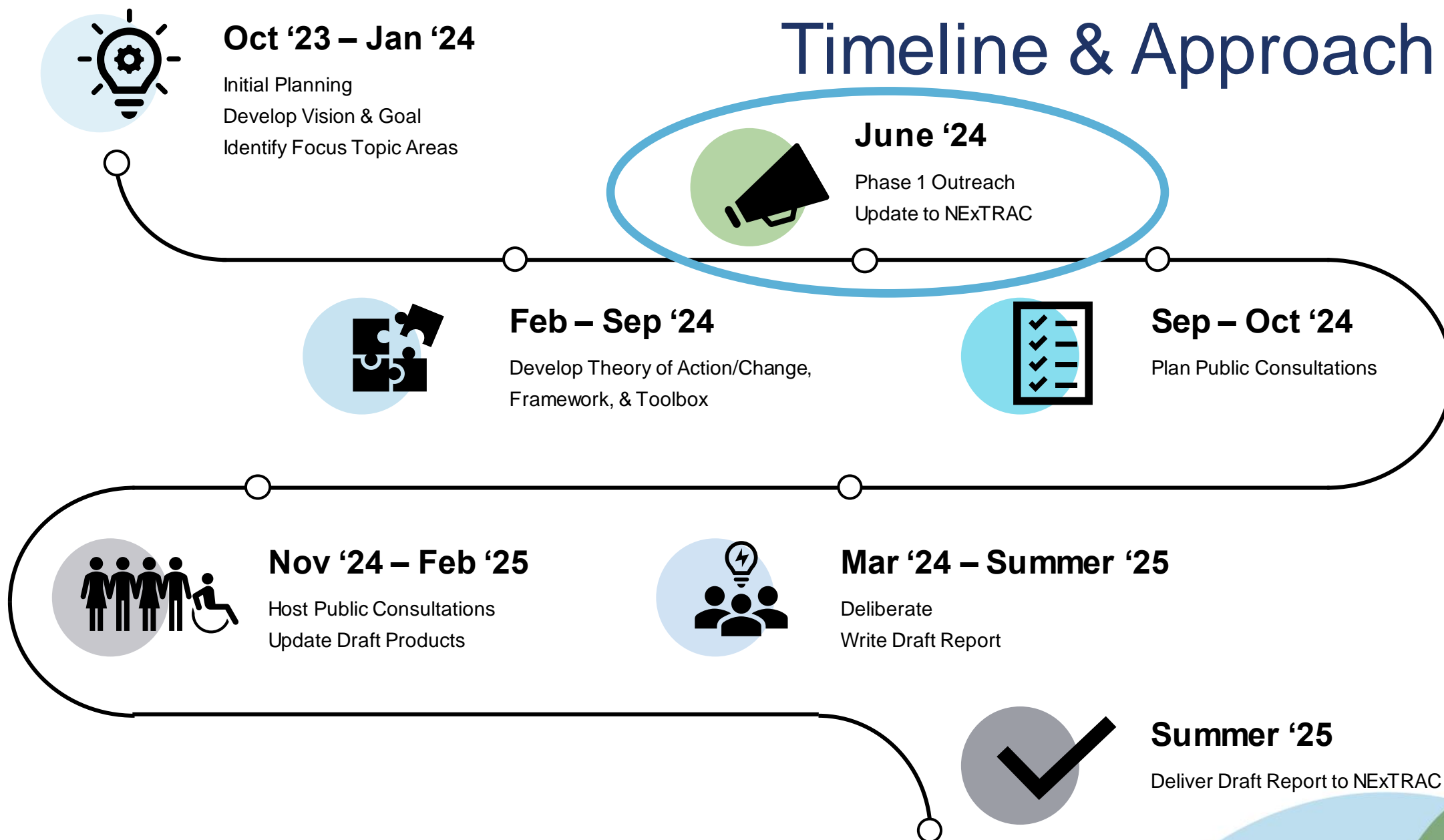
ENGAGE Progress: Toolbox

- Identified four goals:
 - Develop a framework outlining the types of tools and resources that could be used to support engagement in clinical research
 - Identify and collect existing tools and resources in this domain
 - Identify recommended new tools and resources for NIH to develop as well as existing tools and resources that should be updated
 - Identify potential barriers (at multiple levels) to using these tools and resources to their greatest potential

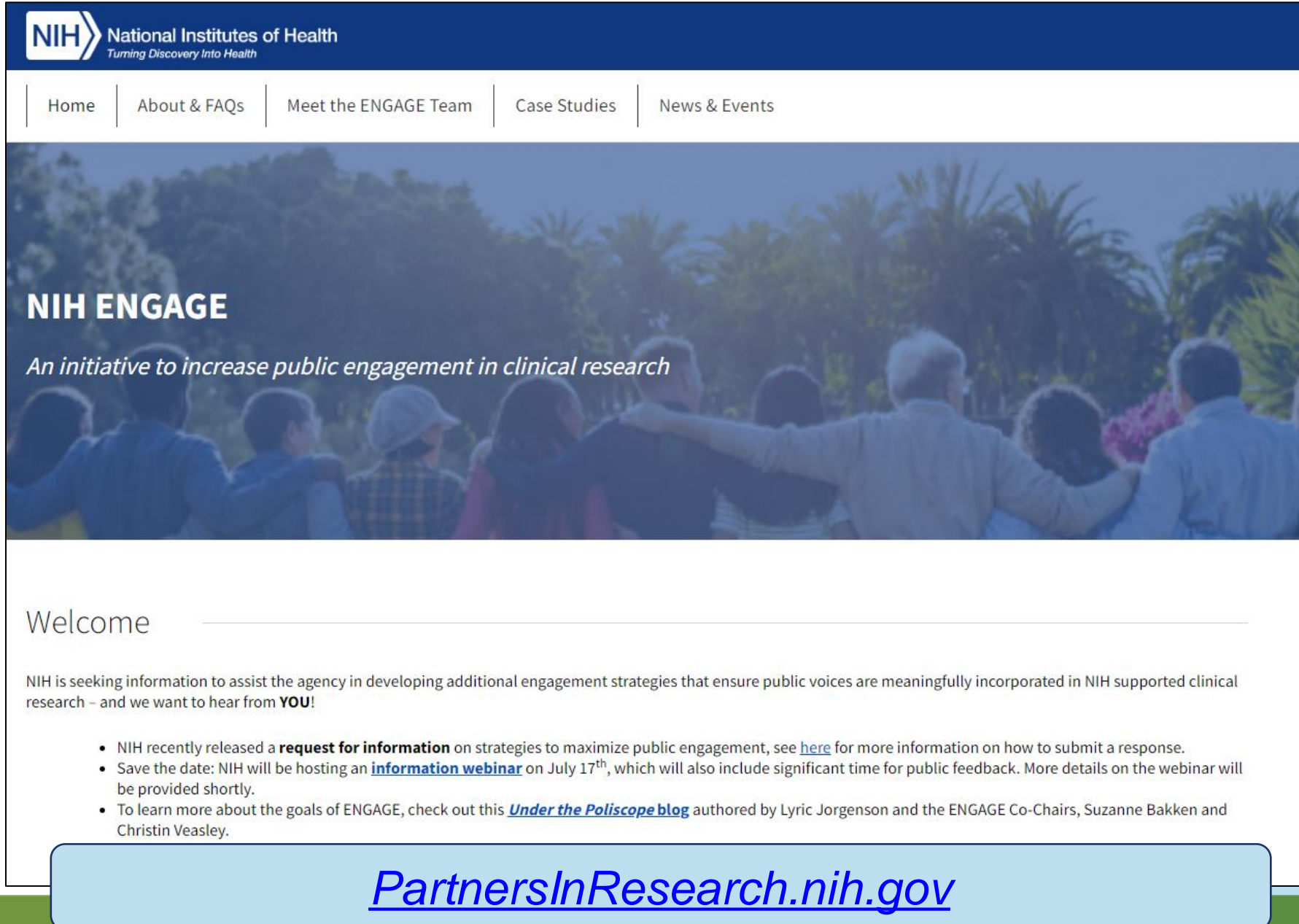
ENGAGE Progress: Toolbox *(cont.)*

- Developed 7 domains to filter resources:
 - Resource user
 - Target audience
 - When (*research stage*)
 - How (*engagement method*)
 - Novel technology
 - Resource format
 - Resource type
- Working to stress test domains with sample resources

Timeline & Approach



Phase 1 Outreach: New ENGAGE Website



NIH National Institutes of Health
Turning Discovery Into Health

Home | About & FAQs | Meet the ENGAGE Team | Case Studies | News & Events

NIH ENGAGE

An initiative to increase public engagement in clinical research

Welcome

NIH is seeking information to assist the agency in developing additional engagement strategies that ensure public voices are meaningfully incorporated in NIH supported clinical research – and we want to hear from **YOU!**

- NIH recently released a **request for information** on strategies to maximize public engagement, see [here](#) for more information on how to submit a response.
- Save the date: NIH will be hosting an [information webinar](#) on July 17th, which will also include significant time for public feedback. More details on the webinar will be provided shortly.
- To learn more about the goals of ENGAGE, check out this [Under the Poliscope blog](#) authored by Lyric Jorgenson and the ENGAGE Co-Chairs, Suzanne Bakken and Christin Veasley.

PartnersInResearch.nih.gov

What is ENGAGE?



Engaging the Public as Partners in Clinical Research (ENGAGE) is an initiative of the National Institutes of Health (NIH) which is working to develop a vision and framework for incorporating public voices in all phases and types of clinical research. To accomplish this, NIH asked the Novel and Exceptional Technology and Research Advisory Committee (NExTRAC) to form the ENGAGE Working Group. This Working Group includes patients, advocates, researchers, clinicians, non-profit representatives, and more (see [Meet the Team](#) page for more information).

Co-Chairs' Corner

As the Co-Chairs of the ENGAGE Working Group, we are excited to help NIH promote engagement in research. We come from different backgrounds – one of us a patient advocate and one a researcher – but we share the same goal of ensuring NIH-funded research and its outcomes are meaningful and actionable (especially for those who could benefit from or be affected by the research).

We believe, and the Working Group agrees, that engagement should happen early and often throughout the research process. And by that same thought, frequent public engagement should also be a key component of the ENGAGE Initiative. Therefore, we are very excited to release an update on our Phase 1 efforts and seek public input on preferences, experiences, and recommendations relating to increasing public engagement in all phases of clinical research. We look forward to hearing from you!

– Suzanne Bakken and Christin Veasley



Vision & Charge

Patients, communities, and members of the public are essential partners to the success of clinical research. However, meaningfully engaging people and communities is not a one-size-fits-all approach. NIH believes that engagement should be tailored to the needs and experiences of people and communities, and that they should guide the direction of research that is impactful to them. This engagement should be done on an ongoing basis so that members of the public can become active leaders in all stages of the research process.

To accomplish this, NIH asked the Novel and Exceptional Technology and Research Advisory Committee ([NExTRAC](#)) to form the ENGAGE Working Group. This Working Group will identify gaps in current NIH engagement processes and ways to promote the principles of accountability, transparency, and responsiveness to community needs. See [here](#) for the Working Group's full charge.



FAQs

What does the NIH do? NIH is the nation's biomedical research agency, which funds research across the U.S. to make important discoveries that improve health and save lives.

What is clinical research? Clinical research is medical research that involves people to learn more about disease and improve health. Clinical research relies on research participants, who are people who voluntarily join research studies across the Globe. Participants participate in clinical research so that more can be learned about how certain diseases affect people, how to prevent diseases, and to help ensure new drugs, devices, and intervention are safe and effective. See [here](#) for more information.

What is research engagement? Engagement is when individuals, such as patients, groups of people, communities, and/or organizations partner with researchers to plan, design, and/or conduct research so that the research and its outcomes are meaningful and actionable (especially for those who could benefit from or be affected by the research). The ultimate goal is for people and communities to guide the direction of, and partner in, research that is relevant and impactful to them.

When does research engagement happen? The inclusion of individuals and community members can be important during all stages of research, including planning and carrying out studies, analyzing results, and sharing study findings so they can be useful for real people in real communities.

Phase 1 Outreach: Request for Information

Request for Information: Strategies for Maximizing Public Engagement in NIH Supported Clinical Research

NIH is seeking information to assist the agency in developing additional engagement strategies that ensure public voices are meaningfully incorporated in NIH supported clinical research studies.

NIH is the nation's biomedical research agency, which funds research across the U.S. to make important discoveries that improve health and save lives. To accomplish this goal, NIH supports the conduct of [clinical research](#) to learn more about disease and improve health.

Patients, communities, and members of the public are essential partners to the success of clinical research. However, meaningfully engaging people and communities is not a one-size-fits-all approach. NIH believes that engagement should be tailored to the needs and experiences of people and communities, and that they should guide the direction of research that is impactful to them. This engagement should be done on an ongoing basis so that members of the public can become active leaders in all stages of the research process.

This request for information (RFI) is part of a larger NIH effort to develop a vision and framework for incorporating public voices in all phases and types of clinical research. To accomplish this, NIH asked the Novel and Exceptional Technology and Research Advisory Committee ([NExTRAC](#)) to form the ENGAGE Working Group. This Working Group includes patients, advocates, researchers, clinicians, non-profit representatives, and more.

For the purposes of this RFI, NIH is specifically seeking input about engaging the public throughout all stages of clinical research and not focused solely on recruitment or participation in clinical research and trials. The responses NIH receives to this request will help inform the development of the NExTRAC's recommendations on incorporating public perspectives in clinical research.

Phase 1 Outreach: Request for Information Questions

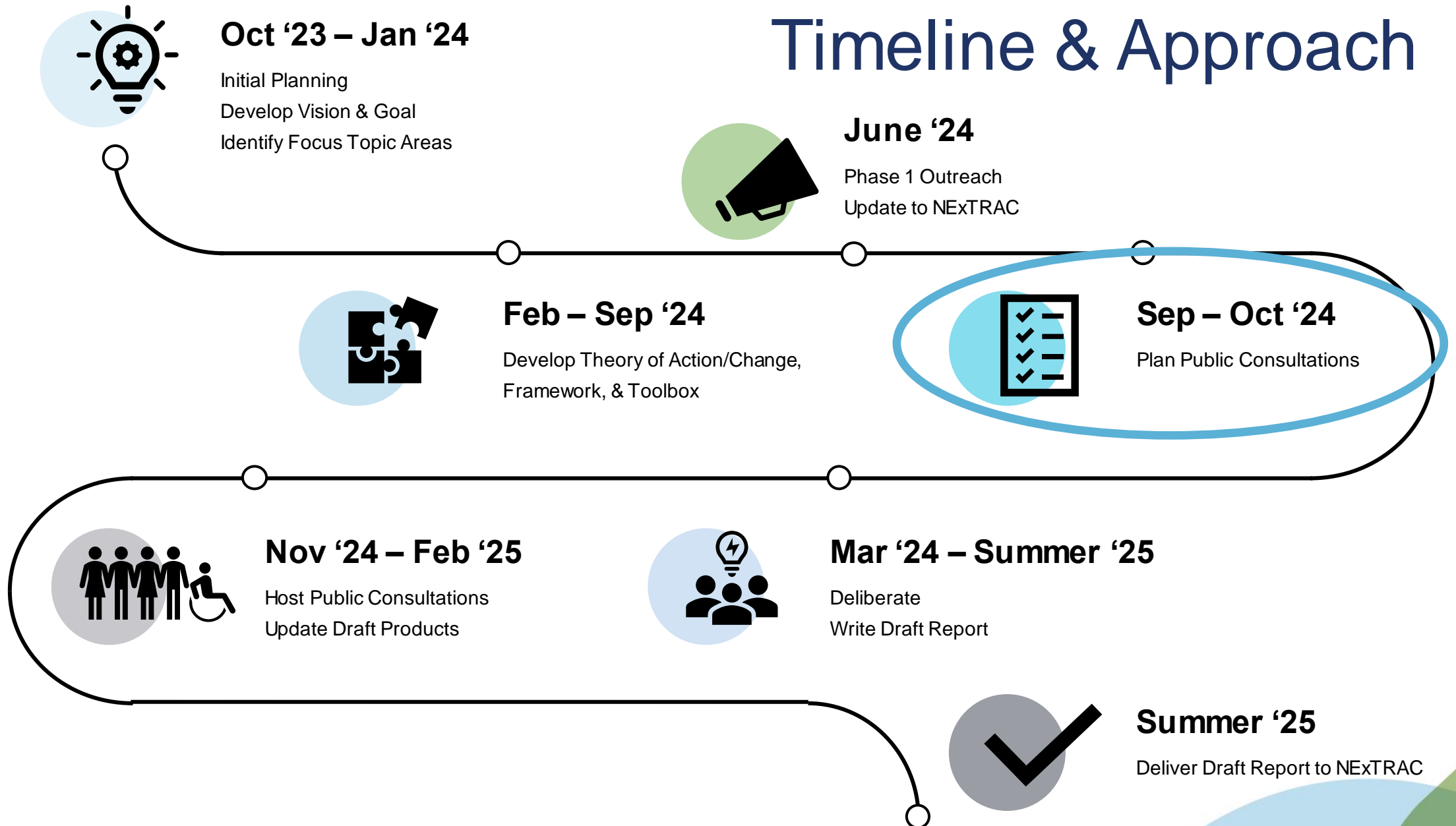
- 1. Strategies for researchers to best partner and work with people and communities.** *For example, developing resources respectful of different cultures, facilitating open dialogues for decision-making, sharing results in a way that is valuable, etc.*
- 2. Ways for institutions performing research** (e.g., academic medical centers, universities, health systems, primary care providers) **to support and incentivize active, bi-directional partnerships between researchers and people/communities.** *Examples may include encouraging people/community members to establish shared decision-making on project milestones, prioritizing local community review of research questions and research proposals, specific research design factors, leveraging existing patient-clinician relationships, etc.*
- 3. Approaches for research funders** (e.g., government agencies, non-profits, companies) **to incorporate partnerships between people, communities, and researchers into their programs and priorities.**

Phase 1 Outreach: Request for Information Questions *(cont.)*

4. **Specific examples of things that may make people and communities more likely to want to engage with researchers and research institutions.** *Examples may include specific technologies to reduce the burden of research participation, opportunities, fair compensation, cultural competence training and/or culturally competent research models, etc.*
5. **Specific examples of things that may make people and communities less likely to want to engage with researchers and research institutions.** *Examples may include no/unfair compensation, participation opportunities only happening during typical work hours, lack of awareness of opportunities, etc.*

Save the date! [NIH webinar/listening session](#) on July 17th!

Timeline & Approach



Recap: Previous Community Conversations

to inform NExTRAC WG on Data Science and Emerging Technology

- Discussions with scientists & developers
 - *What topics are pushing frontiers in data science in biomedical research?*
- 9 Community Conversations with ~160 people
 - *How do you feel about the use of your data in biomedical research?*



Harlem, NY



Bronx, NY
En Español



Alamosa, CO



Jackson, MS



Dearborn, MI



Rural & Rare
Disease Orgs
Virtual Webinar



Santa Clara, CA



AI/AN Advocates
Virtual Webinar

Overall Goals for Public Outreach

- Respectfully communicate and engage with the public early and often throughout the ENGAGE process
- Seek diverse perspectives across the U.S.
 - Including, but not limited to, patient partners, caretakers, community representatives, research participants, patient advocacy organizations, clinical researchers, and local health providers
- Use mixed methods to gather input (e.g., case studies, open-ended questions, collecting stories)
 - Collect feedback on draft WG products throughout the process

NExTRAC Discussion

- Any comments on draft products to date or next steps?
- What elements of the previous *Community Conversations* should be preserved? What other goals or elements should be added?
- Any suggestions for novel approaches to future *Community Conversations* and public engagements?
- Are there specific communities and/or populations we should include in future public engagements?