

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

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NExTRAC

Novel & Exceptional Technology
and Research Advisory Committee

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Agenda



Foundational principles of ENGAGE initiative



Working group's progress to date



Community conversations and other avenues for public input



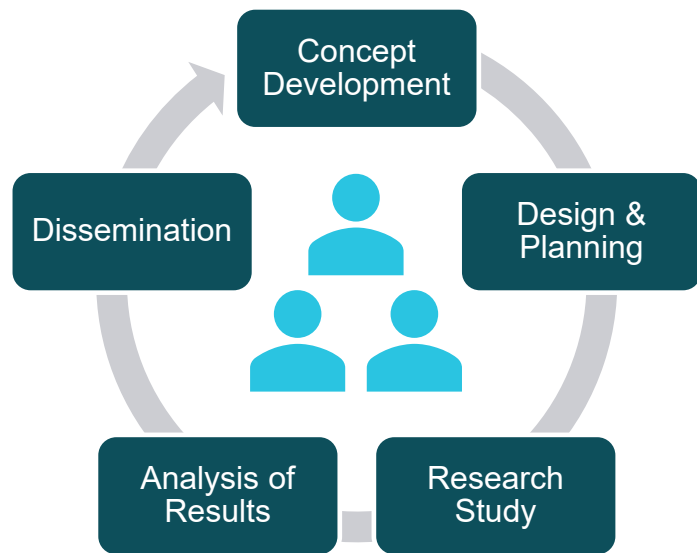
Next steps and plan of action

Foundational Principles of ENGAGE

What is guiding our work?

What is Clinical Research Engagement?

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.

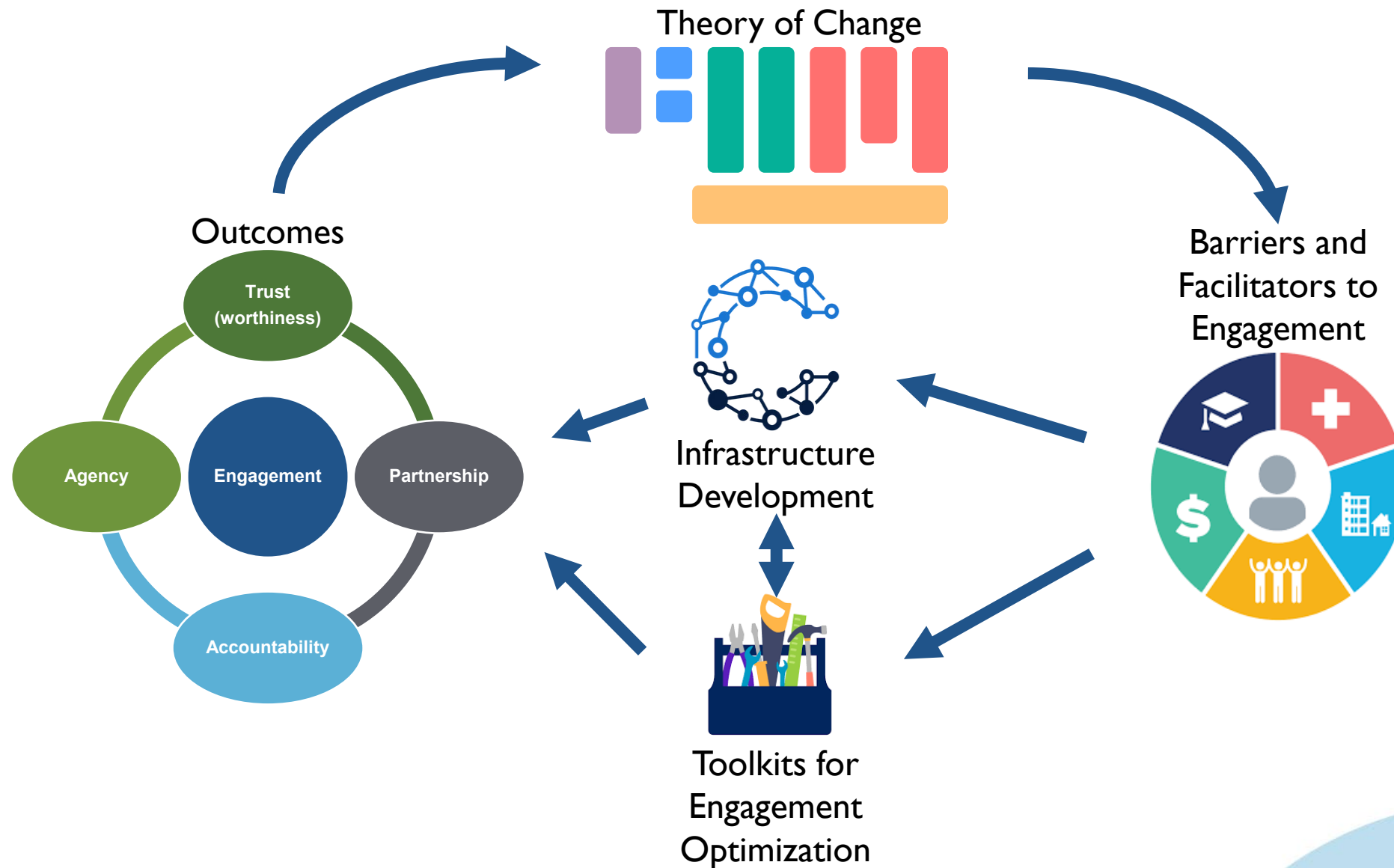


Various Stages of Clinical Research

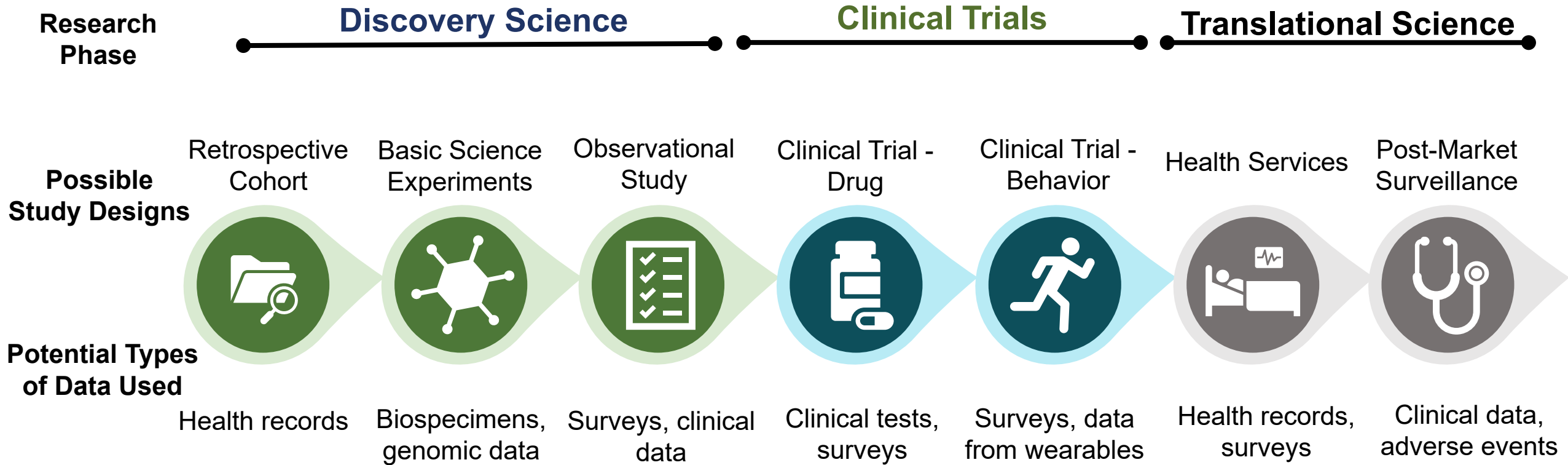


Relevant Partners

How Are We Approaching Our Work?



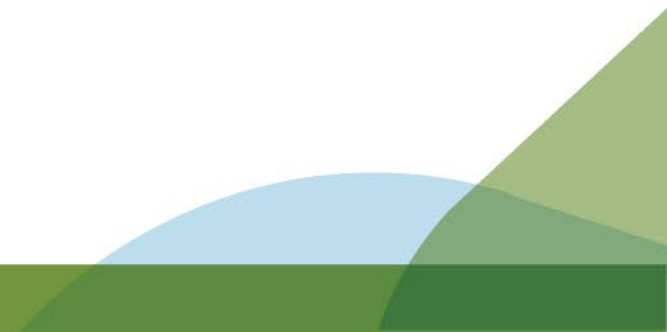
Utilizing a Broad Definition of Clinical Research



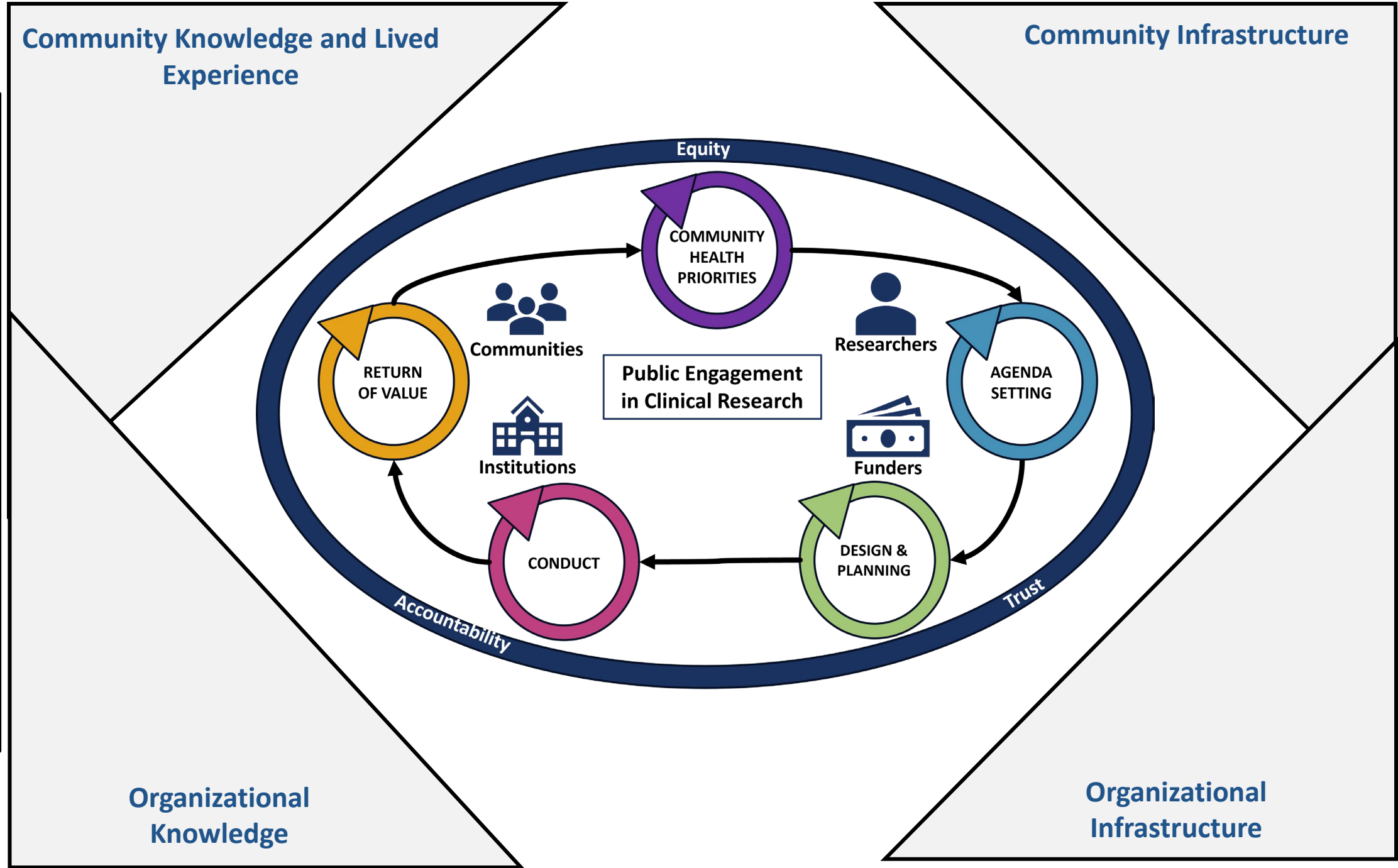
Working Group's Progress

What have we been up to?

Framework Focused Topic Area

- Roadmap for engagement
 - Suitable for a broad audience
 - Actionable Domains
 - Complementary Maturity Model
- 
- A decorative graphic in the bottom right corner of the slide. It consists of several overlapping semi-circular and triangular shapes in shades of green and blue, creating a modern, abstract design.

Building Long-Term Partnerships

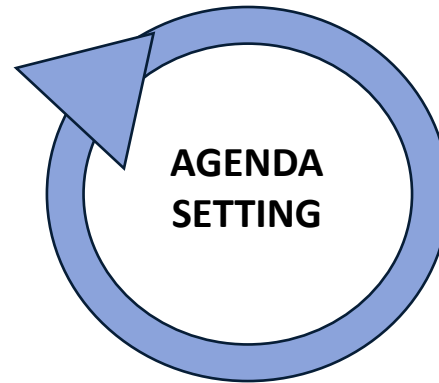


Mitigating Social Determinants of Health

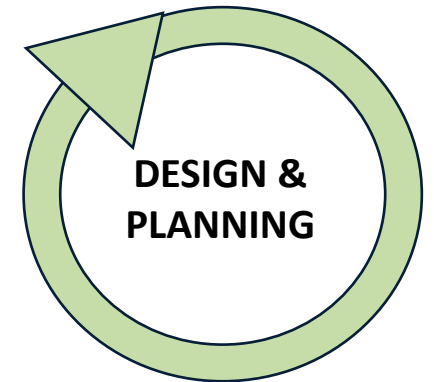
Draft Objectives



Research question or research study is informed and driven by community health needs and priorities.

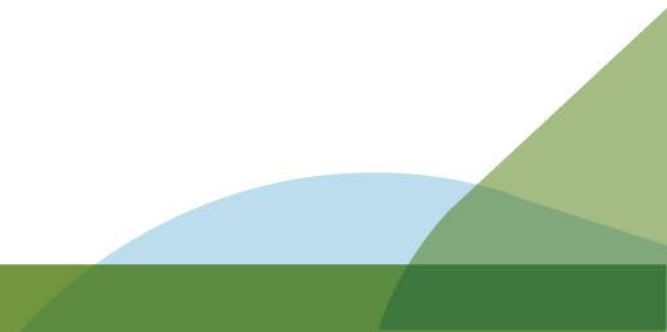


Shared, equitable priority setting process where community needs are matched to the research questions.



Ensure that the research question or research study is co-designed with community members.

Toolbox Topic Area

- Creating a preliminary library of engagement resources
 - Tagging system to improve ease of searching
 - Align resources with framework
 - Variety of resource types
- 

Resource Tagging System



- Patients or advocacy groups
- Community
- Researcher
- Institution
- Funder

Resource User



- Patients or advocacy groups
- Community
- Researcher
- Institution
- Funder

Audience



- Determine community health priorities
- Define the research question
- Design & plan the research
- Conduct research
- Return Results & Value

When



- Electronic health records
- Real world data
- Novel intervention
- AI/ML
- Patient-generated data

Emerging Tech



- Flow chart
- Guidelines
- Manuscript
- Sample
- Template
- Training
- Repository
- Case Study
- Glossary

Resource Type

Community Conversations

How are we getting public input?

Request for Information & Listening Session

1

Strategies for researchers to best partner and work with people & communities

2

Ways for institutions to support partnerships between researchers & communities

3

Approaches for funders to incorporate partnerships between people & researchers

4

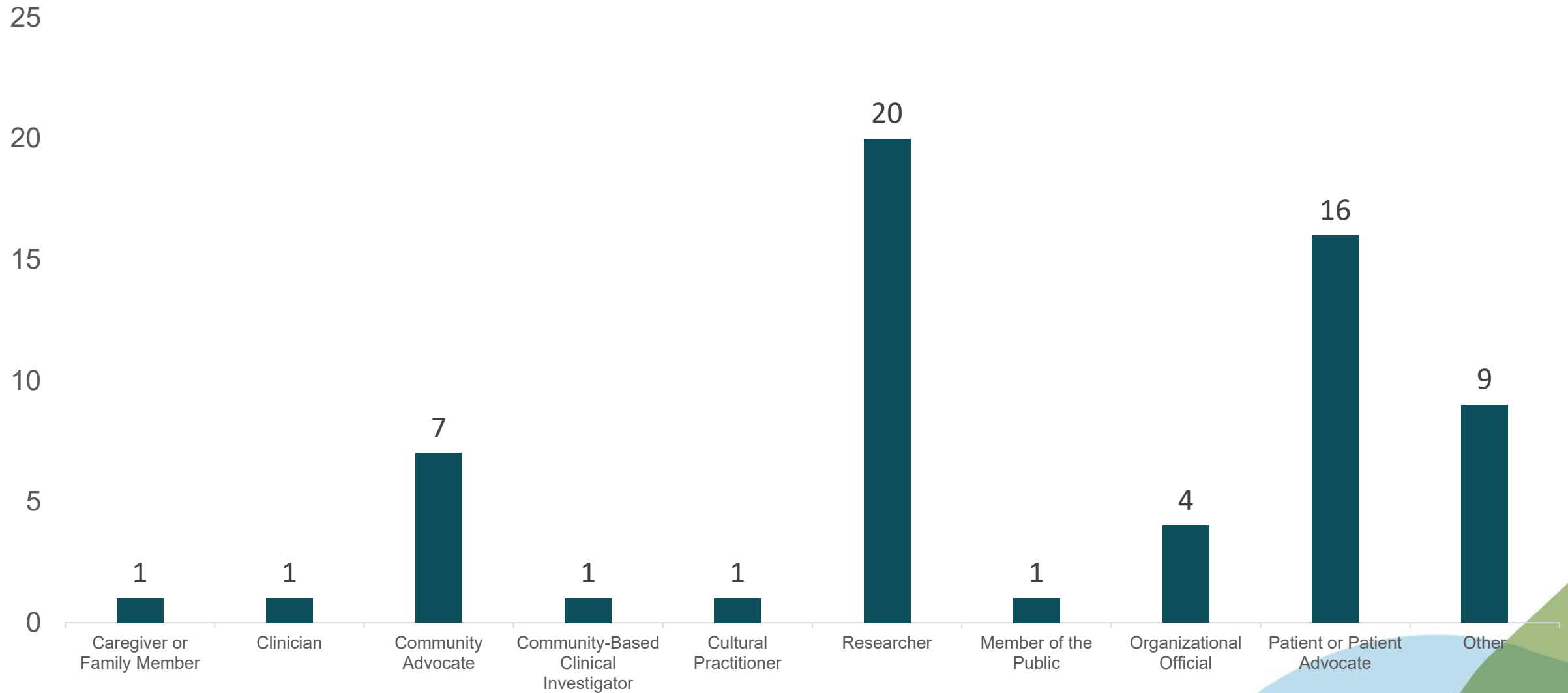
Things that make people more likely to engage with researchers

5

Things that make people less likely to engage with researchers



Role Respondent Identifies With



Key Themes Across All Respondents



**Incorporating patient
and community input
into research**



**Requiring incentives
and compensation
for engagement**



**Lack of resources
and infrastructure
are key barriers**

Key Themes by Respondent Type

Community Members



**Plain language
communication**



**Understand real-
world impacts**



**Building inclusive
environments**

Researchers



**Relationship
building with
communities**



**Fostering trust
between
researchers and
communities**

Community Conversations

GOAL: Gather individual perspectives on different engagement methods, the optimal timing for engagement, and how to ensure engagement is equitable and inclusive.

PLAN: Facilitate 12 conversations with different communities:

- 10 in-person conversations
- 2 virtual conversations



Considerations for Selecting In-Person Locations



**Communities
underrepresented in
clinical research**



**Existing clinical
research infrastructure**



WG connections



Geography



Washington, DC



Chicago, IL



Idaho Falls, ID



Bangor, ME



AI/AN Advocacy
Organizations

COMMUNITY CONVERSATION PLAN

Flint, MI



Baton Rouge, LA



Wichita, KS



Los Angeles, CA



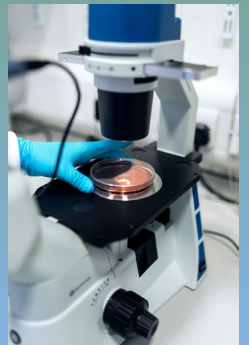
Honolulu, HI



Houston, TX



Research
Community



Approach to Each Conversation

Pre-Conversation



Partner with
community org



Facilitation guide



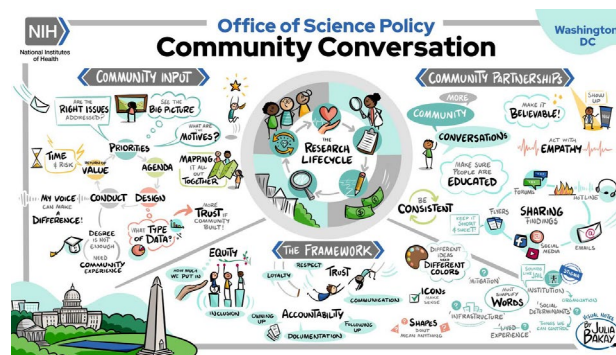
Questionnaire

During Conversation

~25 attendees



Live Illustrator



Post-Conversation



Thank you email



Reports



Updating website

High-Level, Initial Takeaways

- 1 Every detail of the framework graphic should be implemented with purpose. Terms used in the graphic should speak to the community and to researchers.
- 2 Communities should be central in the research framework, prioritizing their needs and providing oversight throughout the research process, and should particularly be involved in design and planning.
- 3 Rely on trusted community voices to work to overcome skepticism and distrust in science and/or the federal government.

Some Unique Ideas

1

Washington, DC: Use of pictures that represent the community in the framework visual to improve understandability.

2

Chicago: Oversight and monitoring of all partners (researchers, organizations, community members, funders) is critical at all phases.

3

Idaho Falls: Community voices cannot overshadow scientific rigor and credibility.

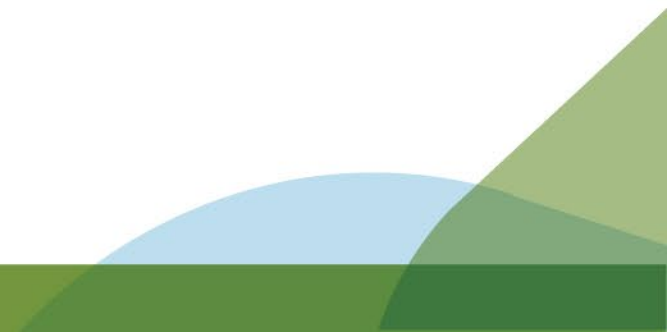
4

Bangor: Need for accessibility considerations at all phases to ensure equitable engagement opportunities.

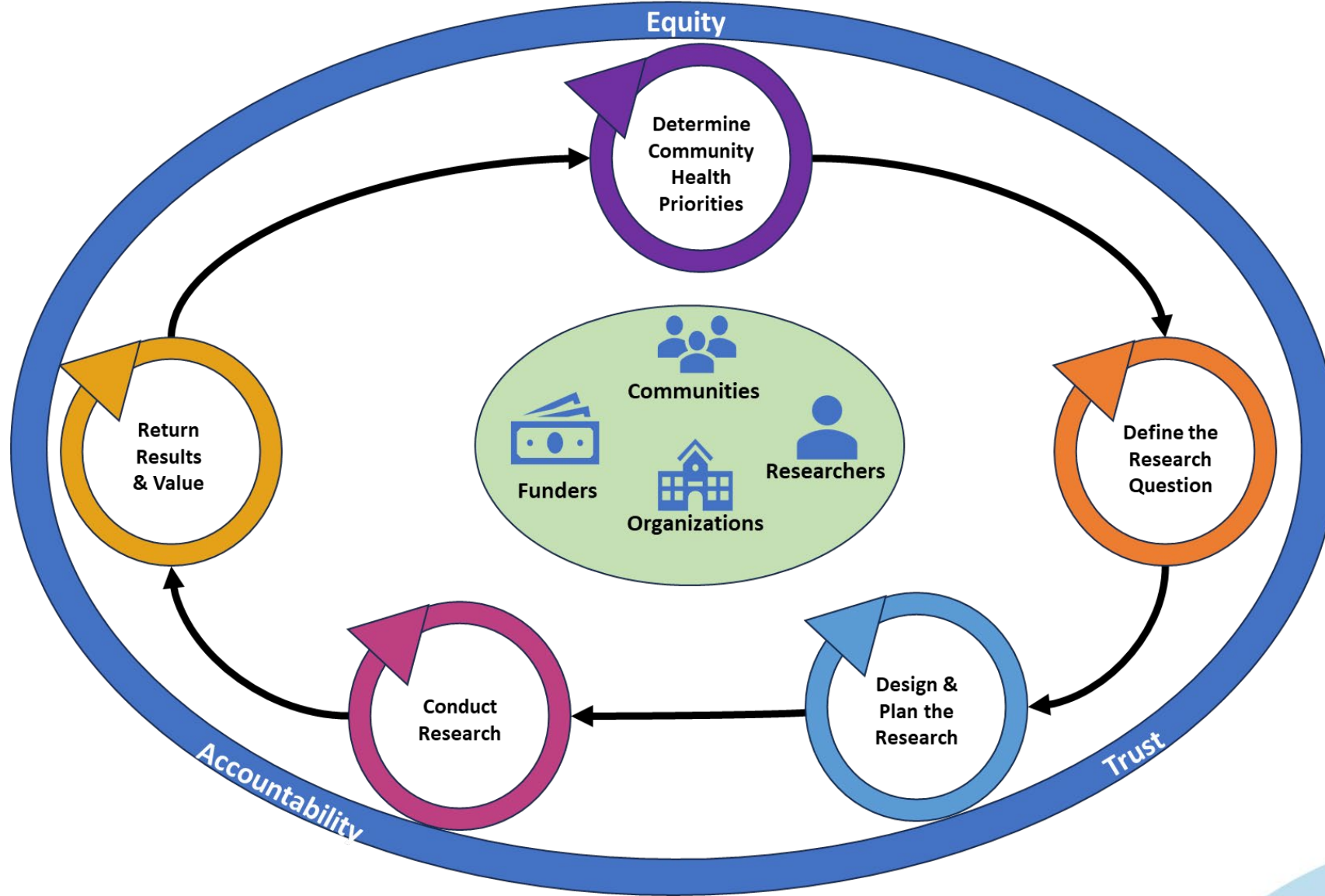
Next Steps and Plan of Action

How are we meeting our goal of a summer 2025 report?

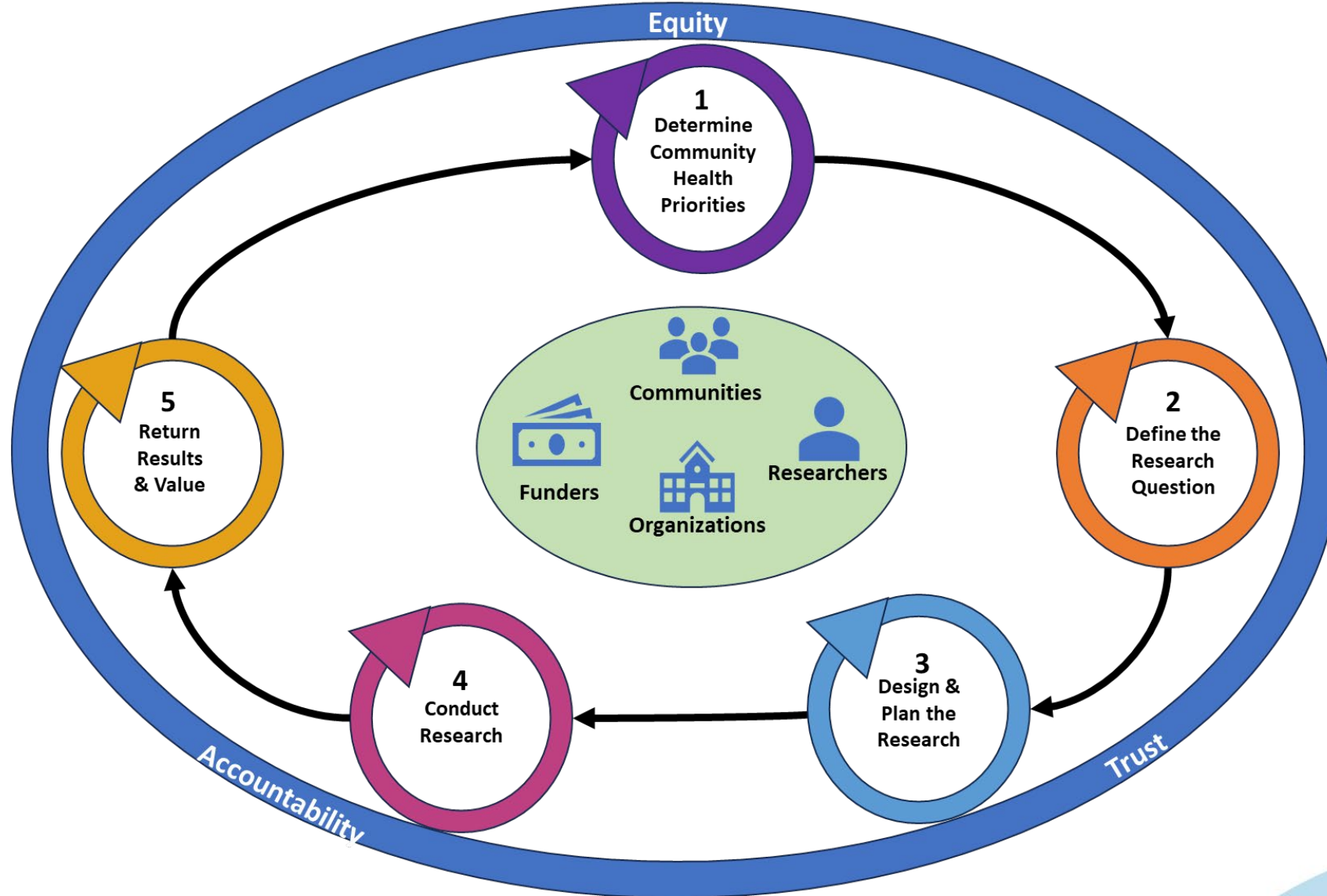
Planned Framework Iteration

- Simplify framework visual
 - Make small adjustments to improve clarity
 - Revise language
- 

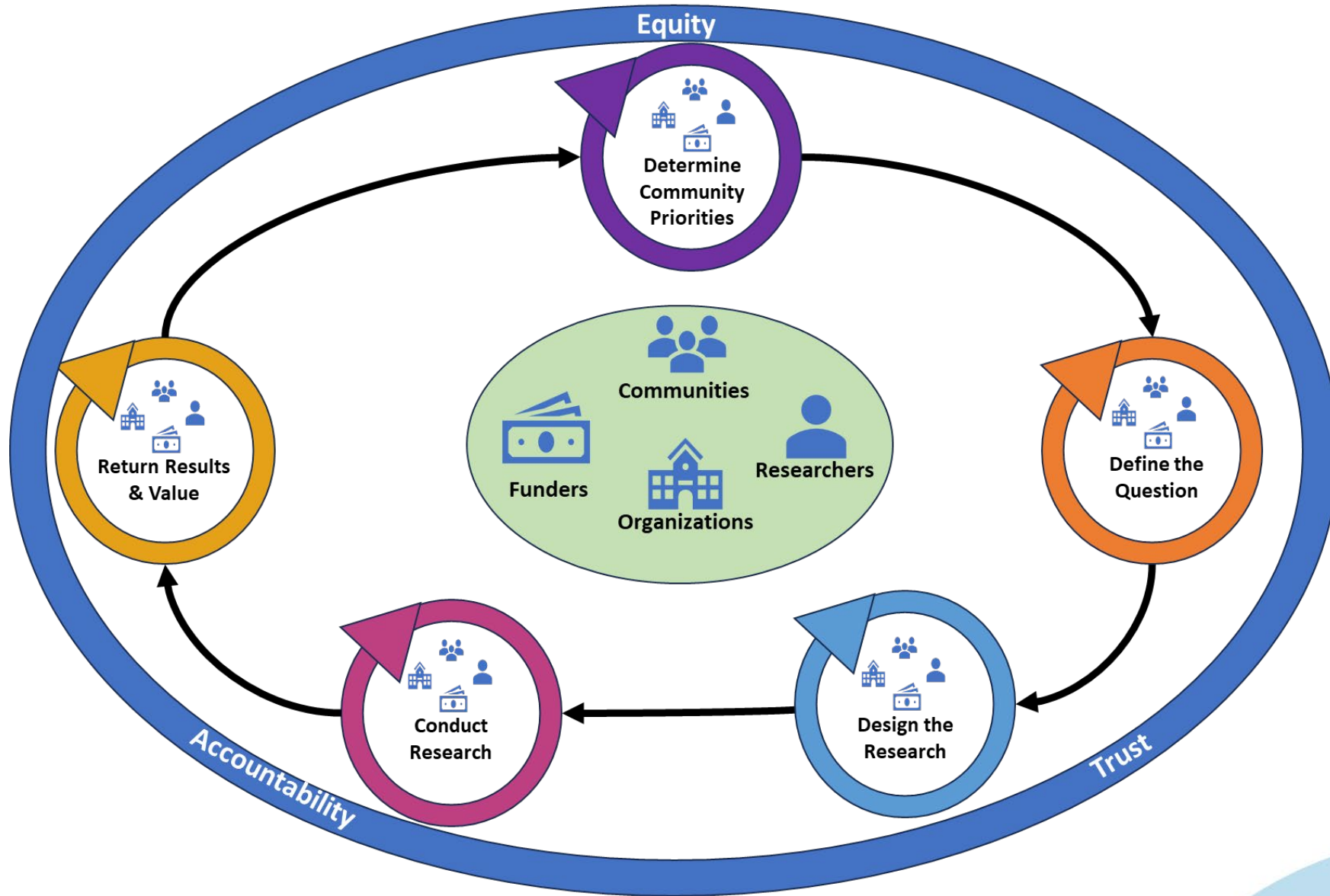
Option 1



Option 2

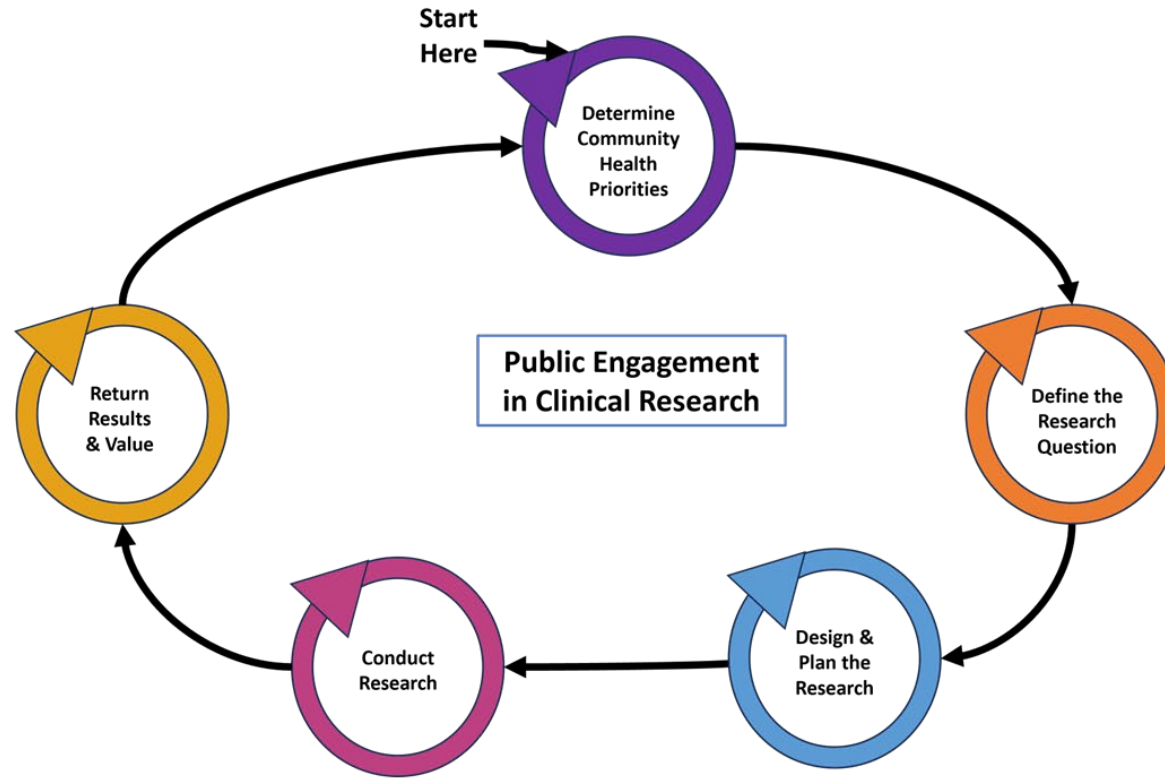


Option 3



Option 4

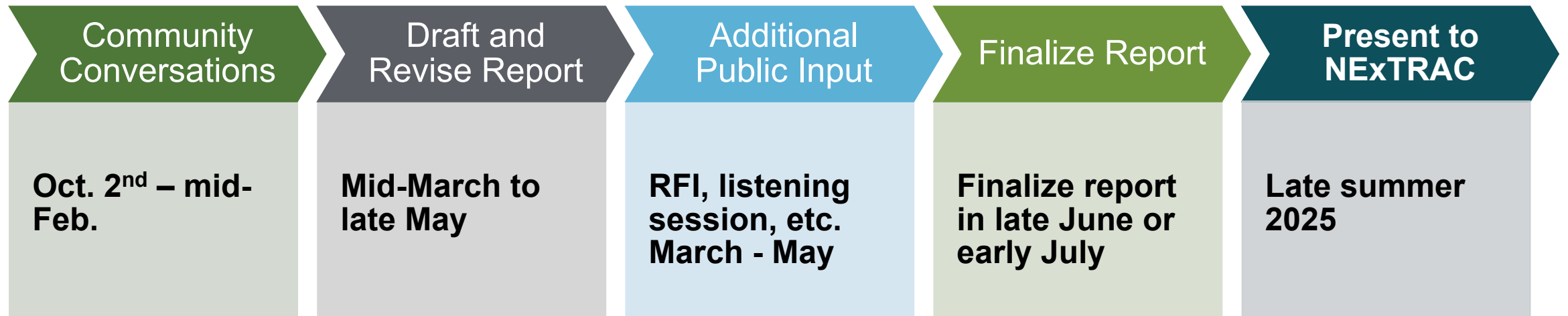
Partners in Public Engagement in Clinical Research



Key Pillars of Public Engagement in Clinical Research



Plan of Action



Thank you!

Questions?

Follow ENGAGE's progress at:

PartnersInResearch.nih.gov