

Advancing Clinical Trial Readiness (ACTR)

- Introduction and Description of Network Activation Call: Mike Stebbins PhD
- Overview of how activation call fits into ARPANET-H: Amy Lin
- Advancing Clinical Trial Readiness (ACTR) Overview: Brian Anderson MD
- Q&A





Introduction and Description of Network Activation Call

Mike Stebbins, Ph.D.

Program Executive of Customer Experience Hub

Consortium Management Firm, Advanced Technology International

Advancing Clinical Trial Readiness (ACTR) Initiative

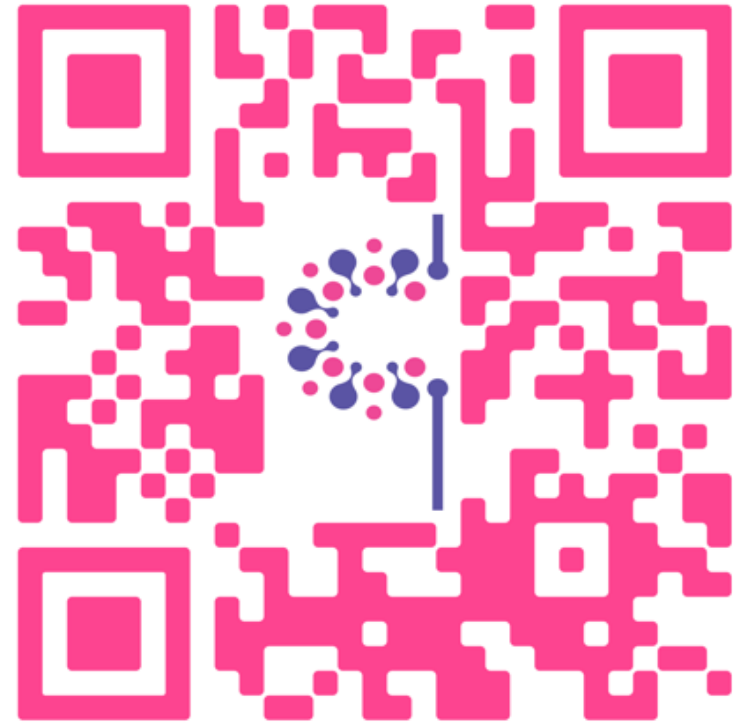
Flow of Opportunities



Collaboration is Key!

Advancing Clinical Trial Readiness (ACTR) Network Activation Call

- Draws on the ARPANET-H Network to source feedback at scale.
- Deadline to provide feedback is *12/1/23*.
- Membership not a requirement to respond.



ARPANET-H Network Activation

**Feedback at scale: tapping into the wisdom of crowds
to inform programs**

Amy Lin, Health Innovation Network Lead



What is a Network Activation?

The Activation draws on the ARPANET-H network to source **feedback at scale** on program concepts, inform technical and funding approaches, and map the landscape of potential partners.

The ARPANET-H hubs draw on the expertise of their spokes and beyond to meaningfully engage diverse stakeholders, end-users, and non-traditional partners.

What can a Network Activation help us better understand?

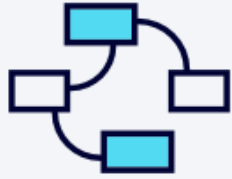
1) Key components of the problem we wish to solve:
What are we missing? What assumptions might be wrong?

2) Capabilities that exist to solve the problem:
Who has valuable expertise or reach, especially those not already working with the government?

3) Constraints that could prevent stakeholders from helping solve the problem:
*Why wouldn't a potential partner want to engage?
(e.g., financial, logistical, regulatory, and collaboration issues)*

Workflow for ARPANET-H Network Activation

Feedback and data gathering mechanism to better understand the unknown and level up ideas



Plan Network Engagement

- Describe respondent archetypes & identify current relevant spokes
- Draft Network Activation Call & feedback questions
- Develop stakeholder Outreach Plan, especially to recruit organizations to fill critical gaps
- Organize Immersive Experience, analogous case studies (*optional*)



Issue Network Activation Call

- Post project description and Call on ARPA-H and Hub websites; host webinars where appropriate (open to all)
- Collect and organize responses, screening those that are clearly nonresponsive
- Engage with current and recruited spokes on Call topics, including expert interviews



Surface Insights

- Review feedback
- Discuss key insights and trends, with implications that will shape the program/opportunity
- Follow-up meetings with select respondents
- Publicize summary report of takeaways



Prepare Funding Opportunity

(if applicable)

- Incorporate Network Activation feedback into the structure of the program/opportunity
- Refine stakeholder Outreach & Advertising plan to target desired respondents for follow-up
- Prepare to post and manage the funding opportunity or other next steps

Workflow reflects *intentionality* in drawing on the best-suited capabilities, *openness* in listening to diverse stakeholders, and *nimbleness* in adjusting to changes.

Advancing Clinical Trial Readiness (ACTR)

Brian Anderson, MD

Senior Advisor for Clinical Trials Innovation

Resilient System Office

Advanced Research Projects Agency for Health (ARPA-H)

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First Customer Experience Hub & Spoke Initiative: Advancing Clinical Trial Readiness (ACTR)

Vision:

- (1) Enable faster, more efficient, decentralized & more representative clinical trials for ARPA-H programs
- (2) Inform nation-wide, pragmatic clinical trial infrastructure

ACTR has been developed in partnership with OSTP, ONC, NCI, and the FDA to address:

- Faster & more representative enrollment
- Bringing trials closer to the point of care across variety of sites & geographies
- Bidirectional, more efficient and interoperable communication of trial protocols & trial data

How organizations can participate:

- Join the CX Hub & Spoke Network
- Provide feedback on the draft initiative description:

Important dates:

- **December 1, 2023:** Feedback on the draft initiative description due

<https://www.customerexperiencehub.org/actr-initiative/>



What if we could standup clinical trials in days and reach 90%+ of all Americans within 30 min of their homes?

ACTR task areas



Task 1: Accelerate patient enrollment

- Develop computational methods that reduce the manual effort required to ID & enroll clinical trial participants
- Develop patient-centered consent processes



Task 2: Shift trials closer to points of care

- Develop new decentralized clinical trial designs
- Integrate computational technologies
- Devise novel statistical methods & demonstrate ways to use real-world data



Task 3: Distributed protocols & data collection

- Create data platform & accompanying software tools to distribute, run, and collect data from a common clinical trial protocol



Task 4: Test & evaluation

- Project will be guided by use cases and a series of challenges, e.g., detection of adverse events during cancer treatment, and a series of challenges, and recruiting hundreds of patients in a short period of time



Task 5: Transition

- Best-in-class capabilities will be integrated into the Customer Experience (CX) Hub to accelerate performance of real clinical trials for ARPA-H created capabilities

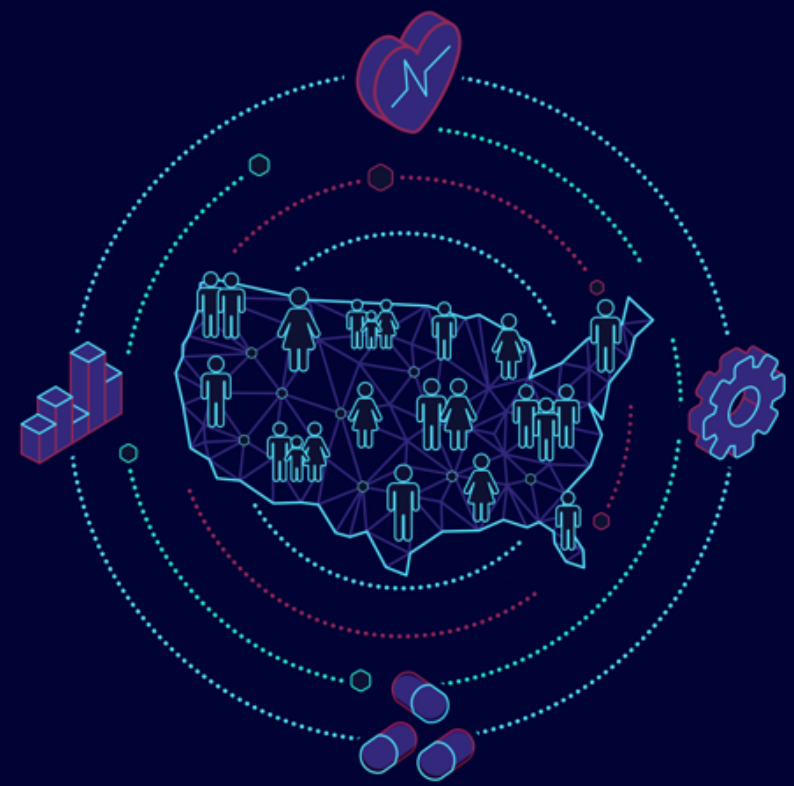
Help us achieve this vision!

**ACTR feedback on draft initiative description
due December 1, 2023**

Please visit:

<https://www.customerexperiencehub.org/actr-initiative/>

to find out how to join the hub & spoke network and submit your input!



What if we could standup clinical trials in days and reach 90%+ of all Americans within 30 min of their homes?

Q&A

ARPA 