ACTR Network Activation Call Frequently Asked Questions (FAQs)

Q: What is a "Network Activation Call"?

R: A "Network Activation Call" is how ARPA-H sources feedback on ARPA-H programs and initiatives at scale. Advancing Clinical Trials Readiness (ACTR) is an ARPA-H initiative seeking to improve the current state of clinical trials for all Americans through the development of tools, technologies, and other enabling capabilities. ARPA-H is using the "Network Activation Call" approach to help solicit stakeholder feedback regarding how the agency could design a potential ACTR funding solicitation.

Q: What disease areas are covered by ACTR?

R: The ACTR initiative is disease-agnostic. ARPA-H is looking at clinical trials broadly, as described in the ACTR Initiative Description.

Q: Are non-profit organizations eligible to respond?

R: Yes. Non-profit organizations are eligible to respond to the ACTR initiative Network Activation Call for feedback.

Q: If an academic center has different disease teams interested in ACTR and with different areas of expertise, should each team submit a response separately?

R: Yes, for the purposes of providing input from different perspectives and types of expertise.

Q: To respond, must the organization be based in the US?

R: No, organizations don't have to be based in the U.S., but ARPA-H is seeking input on clinical trials that would be conducted in the U.S. Thus, ARPA-H invites respondents from anywhere to provide input that could be applied to U.S. settings, including examples or insights drawn from activities conducted outside the U.S.

Q: In what ways can you foresee regional, life science trade organizations meaningfully contributing to specific initiatives?

R: The health ecosystem is composed of many important equities and stakeholders from the private sector, and life science companies are the traditional sponsor of many clinical trials. For the ACTR Initiative, ARPA-H is interested in receiving feedback from this sector on approaches. ARPA-H also recognizes the importance of effective communication with the life science community regarding the outcomes of the ACTR initiative to support future research and development design of products intended to be submitted to clinical trials.

Q: If an organization has an established network, they may have a well-defined use-case and network infrastructure to test initiatives. Would this organization be relevant to see how the

results from a decentralized study compare with the results they obtained though more manual data abstraction and reporting?

R: Yes, this perspective would be important in responding to Task 2: Test and evaluation area of the ACTR initiative. ARPA-H welcomes relevant responses to the ACTR initiative Network Activation Call for feedback, paying particular attention to the tooling and technical approaches that would advance this space aligned with the broader vision for ACTR.

Q: Will there be a funding opportunity coming out of this Network Activation Call?

R: No funding commitments can be made at this time. ARPA-H is at an initial feedback step to learn more about this challenge area (as defined in the ACTR Initiative Description), potential capabilities to address the challenge, and potential constraints. ARPA-H is excited to be getting feedback on these aspects through the Network Activation Call. ARPA-H will then use that feedback to consider possible next steps, including a potential funding opportunity.

Q: If we have initial funding from other government entities, such as the NCI/NIH, does this restrict us from applying for additional funding to test new approaches to clinical trials through ARPANET-H?

R: It does not. Funding from other Government entities, including NCI or NIH, does not restrict an organization from applying to additional funding for different activities that might be offered in the future by ARPA-H through ARPANET-H or other modalities.

Q: Aside from stakeholder participation, are there written references or other resources that can provide a better understanding of current existing operational processes for clinical trial operations, e.g. study & site feasibility and site selection, and then site capabilities and workflow, that precede recruitment/enrollment? There seems to be an emphasis on technology vs process.

R: While technology is part of the challenge for advancing clinical trial readiness, it is not the only challenge. NIH provides a number of resources that focus on clinical trials:

- "NIH Clinical Research Trials and You" is a resource for patients, providers and researchers: https://www.nih.gov/health-information/nih-clinical-research-trials-you
- The Clinical Trials Transformation Initiative (CTTI) website has published information in this space: https://ctti-clinicaltrials.org/.
- The Food and Drug Administration (FDA) also provides significant resources: https://www.fda.gov/

Q: Who is the "customer" in Customer Experience Hub, for the purposes of the ACTR initiative?

R: The customer in this case is the patient, their caregivers, and their providers. All of these stakeholders are critical in ensuring a smooth experience for participants in clinical trials.

Q: Is the formation of ARPA-H or ACTR informed by or related to the Office of Science Technology and Policy's (OSTP) Request for Information (RFI) from last year?

R: Yes, ARPA-H carefully considered the feedback from the two RFIs from OSTP and the Office of the National Coordinator (ONC) on 1) optimizing data capture for clinical trials, and 2) how to better coordinate a clinical research system in the event of an emerging disease outbreak. That feedback helped to align both the overall vision for ACTR and specific technical areas of focus for the initial ACTR initiative description.

Q: What are your thoughts on data sharing with researchers and life sciences as part of a model?

R: ARPA-H recognizes the importance of partnering with stakeholders from research communities to successfully implement technologies in Technical Task Areas (TA) 1-3 (Enrollment and consent; Decentralized trials; and Trial protocols and data collection) and test them appropriately in TA 4 (Test and evaluate), with feedback from the sponsor community in the life sciences (e.g. pharmaceutical companies). Additionally, feedback from life science companies on how to successfully set up technologies in TA1-3 to meet the regulatory requirements for submission to the FDA will also be important.

Q: How can I reach out for more information?

R: For more information related to this Network Activation Call, please send an email with your questions to CXhub@ati.org. For more information regarding ACTR, please send an email to ACTR@arpa-h.gov