NICHD’s Vision for Multisite Clinical Trials Infrastructure

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Four Guiding Principles Shaping the 21st Century Landscape of NIH-Supported Research

From NOT-HD-19-034 (October 10, 2019)

1. Enhancing the **rigor and reproducibility** of clinical trial protocols
2. Promoting greater **availability of infrastructure** to support trials from a wider range of investigators
3. Facilitating **data sharing** and access to **biospecimens**
   - Promote FAIR data principles
4. Facilitating greater involvement of **diverse populations** in multisite clinical trials
   - Address health disparities
Adhering to these principles ensures proper stewardship of public funds, increases accountability and helps NICHD maintain the public’s trust.
Goal 6: Improve Clinical Trial Oversight and Management

• Ensure appropriate funding mechanisms and infrastructure, inclusion criteria, risk management, sharing of clinical trials data, and safeguarding research participants and their data.
NICHD’s Vision for Multisite Clinical Trials Infrastructure

• NICHD is committed to providing critical infrastructure support for multisite clinical trials that involve populations of key relevance to our research mission.

• NICHD is committed to completing all currently active protocols as they were designed.

• There is no “one size fits all” approach to supporting multisite clinical trial infrastructure.
Examples of Multisite Clinical Trial Infrastructure Models

- No “one size fits all” approach
- Centralized approach
  - NICHD supports infrastructure as a central resource
  - Any qualified investigator can use the infrastructure
  - All applications/protocols undergo NIH peer review
  - “Consultation” feature
Examples of Multisite Clinical Trial Infrastructure Models

- No “one size fits all” approach
- Consortia approach
  - Investigators self-select to form a clinical trial consortium, including clinical sites and data center capabilities
  - Consortium application undergoes NIH peer review for infrastructure and protocol
  - Allows flexibility across investigator teams, sites, protocols
Looking Ahead: Harnessing the Power of the Cloud for Biomedical Research

• Cloud computing offers multiple opportunities NIH can leverage to advance biomedical research, including:
  • Computation on biomedical data at an unprecedented scale
  • Broad access to cutting-edge cloud technology with, for example, industry-leading security tools
  • Storage of large, diverse data in a way that enables easier sharing, access, and reuse of data with other researchers
  • A community-driven approach to data science that breaks down disciplinary silos
  • Adopt and develop cloud-based tools from industry or academia for biomedical research
• NIH STRIDES Initiative offers discounts on computing, storage, and cloud-related services
Envisioning a Future of Interconnected Datasets in the Cloud

...and many others!
Release Date: November 8, 2019  
Response Date: December 20, 2019  

Purpose: Soliciting input from the public on its vision for supporting multisite clinical trials infrastructure  

Webinar on November 1, 2019 described NICHD’s vision and four guiding principles:  
1) Enhancing rigor and reproducibility  
2) Promoting greater availability of infrastructure  
3) Facilitating data sharing and access to biospecimens  
4) Facilitating greater involvement of diverse populations in multisite clinical trials  

NICHD is actively exploring mechanisms that incorporate these guiding principles to support multisite clinical trials infrastructure as a means of accomplishing its scientific goals, both intramurally and extramurally. Two potential approaches to supporting multisite clinical trials are a central resource model and a consortia model, but there is no “one size fits all” approach.
Overview of RFI Responses

• 79 responses received
  • Thanks to everyone for their thoughtful responses!
  • 43/79 (54.4%) were in response to Pelvic Floor Disease Research

• Types of organizations that responded:
  • Almost half of responses were from institutions of higher education
    • Hospitals, non-profit, and for-profit organizations, data coordinating centers
  • ~19 different professional societies and associations
  • 16/79 (20.2%) coordinated messages from a single entity

• Individuals that responded:
  • Current & past network principal investigators & their affiliated staff
  • Academicians not affiliated with networks
  • Professional society leaders
  • Patients and patient advocates (PFDN)
Themes of RFI responses

• Broad support for continuing to provide clinical trial infrastructure

• Respondents expressed preferences for:
  • Supporting multiple models of clinical trial infrastructure
  • Sponsoring many clinical sites to account for diverse and rare disease populations
  • Having core sites with well trained staff
  • Increasing diversity of research organizations that can have access to the infrastructure
    • Some communities may feel marginalized by current structure
    • Trade off between network/center and investigator-initiated funding
  • Providing a rich environment for research training
  • Opportunities for mentoring young investigators
  • Enabling follow-up support beyond 5-year typical grant period
Central Resource vs. Consortium Model

• Comments reflected a preference for the Central Resource Model, or a combined model that has features of both
  • Benefits of NICHD-wide resource, policies, governance
  • Easier to standardize across trials
  • Cost benefit from economy of scale and operating efficiency
• Could be difficult for the DCC to manage numerous sites
• Special concerns regarding global health
(Some) Ideas and Recommendations Generated by RFI

• Need a common data model for EHR data and standardized vocabularies

• Need to optimize a centralized platform for data science
  • Would allow building of a federated network, could share outcomes data (potentially linking between mother and baby)

• Perform landscape analysis of best clinical trial practices across NIH
  • NeuroNet, StrokeNet, National Clinical Trials Network (NCI)

• Create a dedicated NICHD study section that enhances external peer review but would allow increased oversight and decrease COI
Questions?