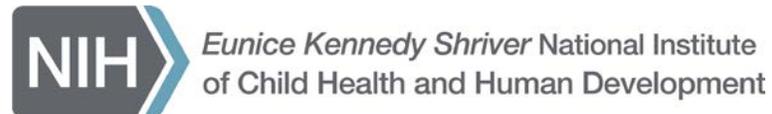


NICHD's Vision for Multisite Clinical Trials Infrastructure

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

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

<https://grants.nih.gov/grants/guide/notice-files/NOT-HD-19-034.html>

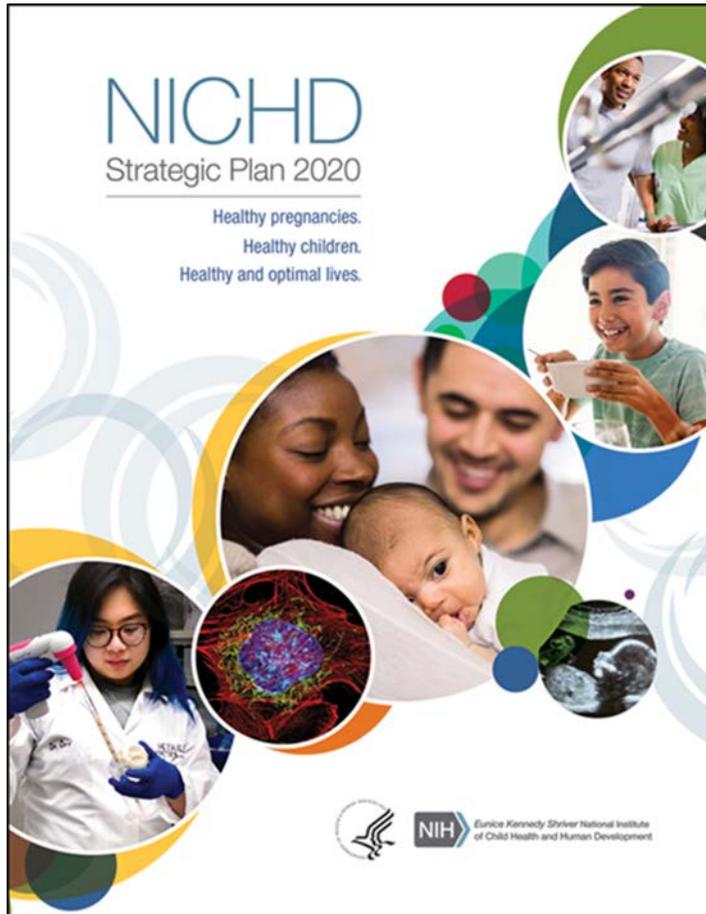
1. Enhancing the **rigor and reproducibility** of clinical trial protocols
2. Promoting greater **availability of infrastructure** to support trials from a wider range of investigators
3. Facilitating **data sharing** and access to **biospecimens**
 - Promote FAIR data principles
4. Facilitating greater 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.



NICHD Strategic Plan 2020: Scientific Stewardship



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



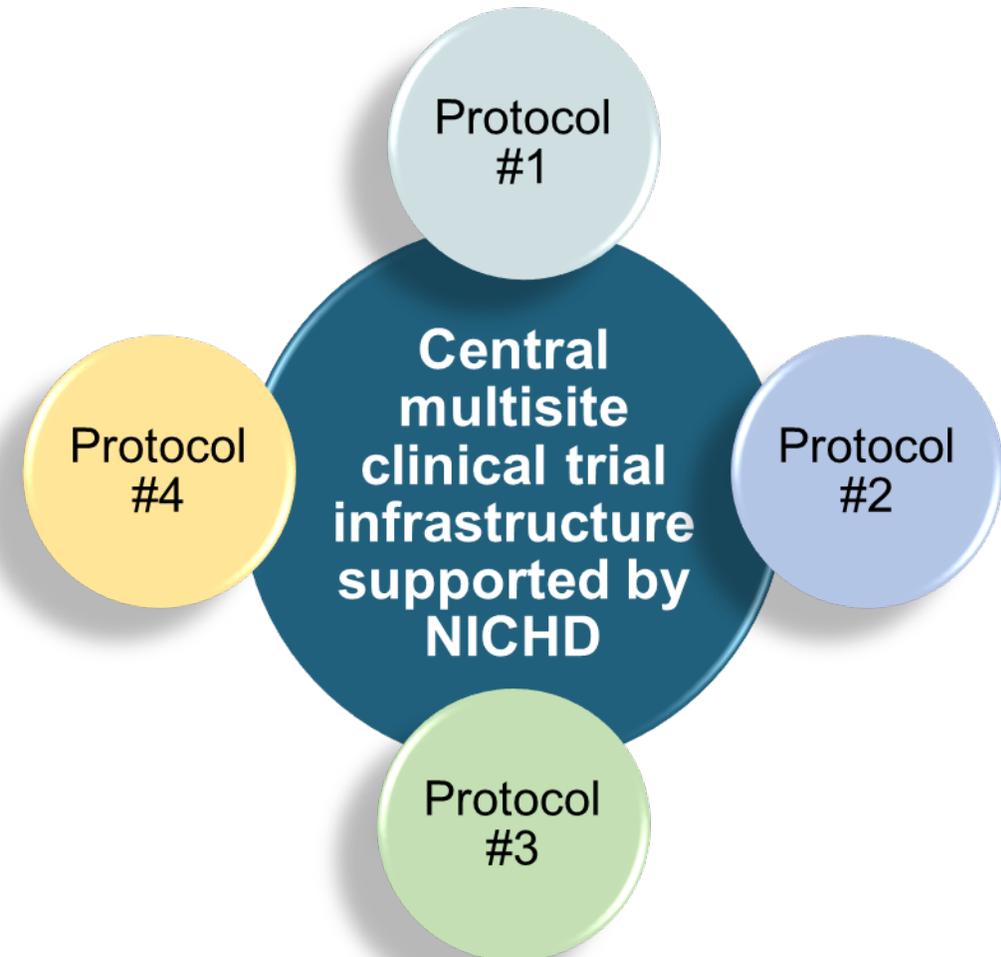
NICHD's Vision for Multisite Clinical Trials Infrastructure

- 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.



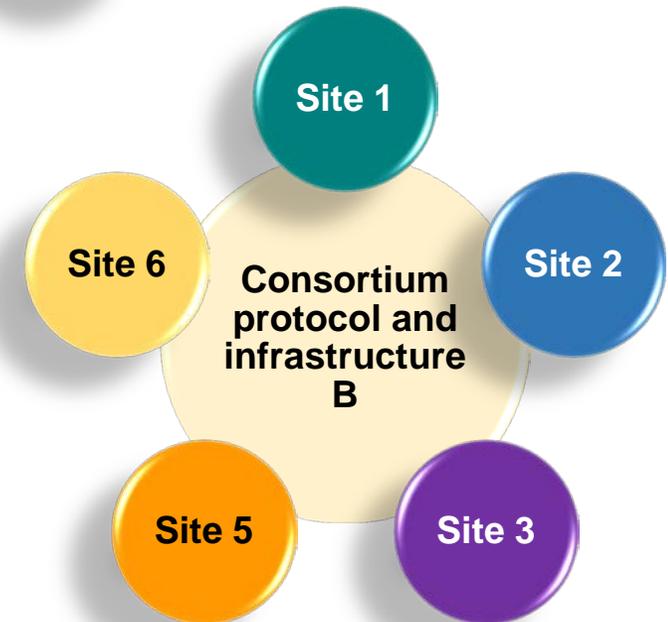
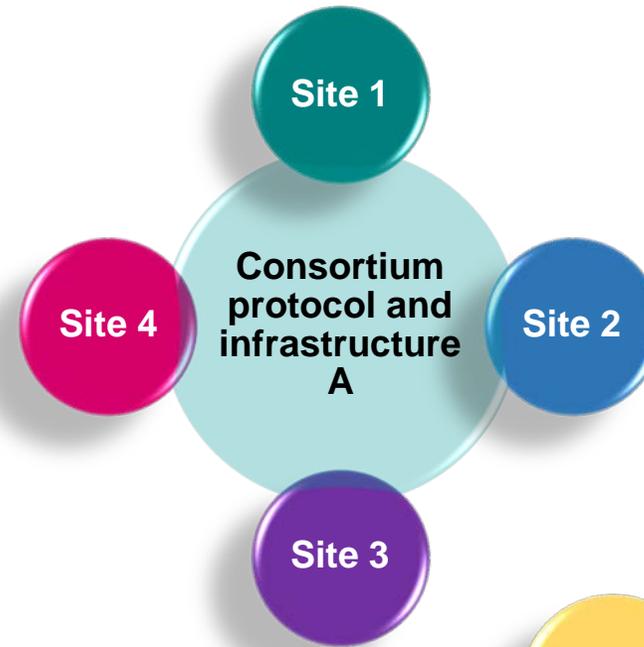
Examples of Multisite Clinical Trial Infrastructure Models

- 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



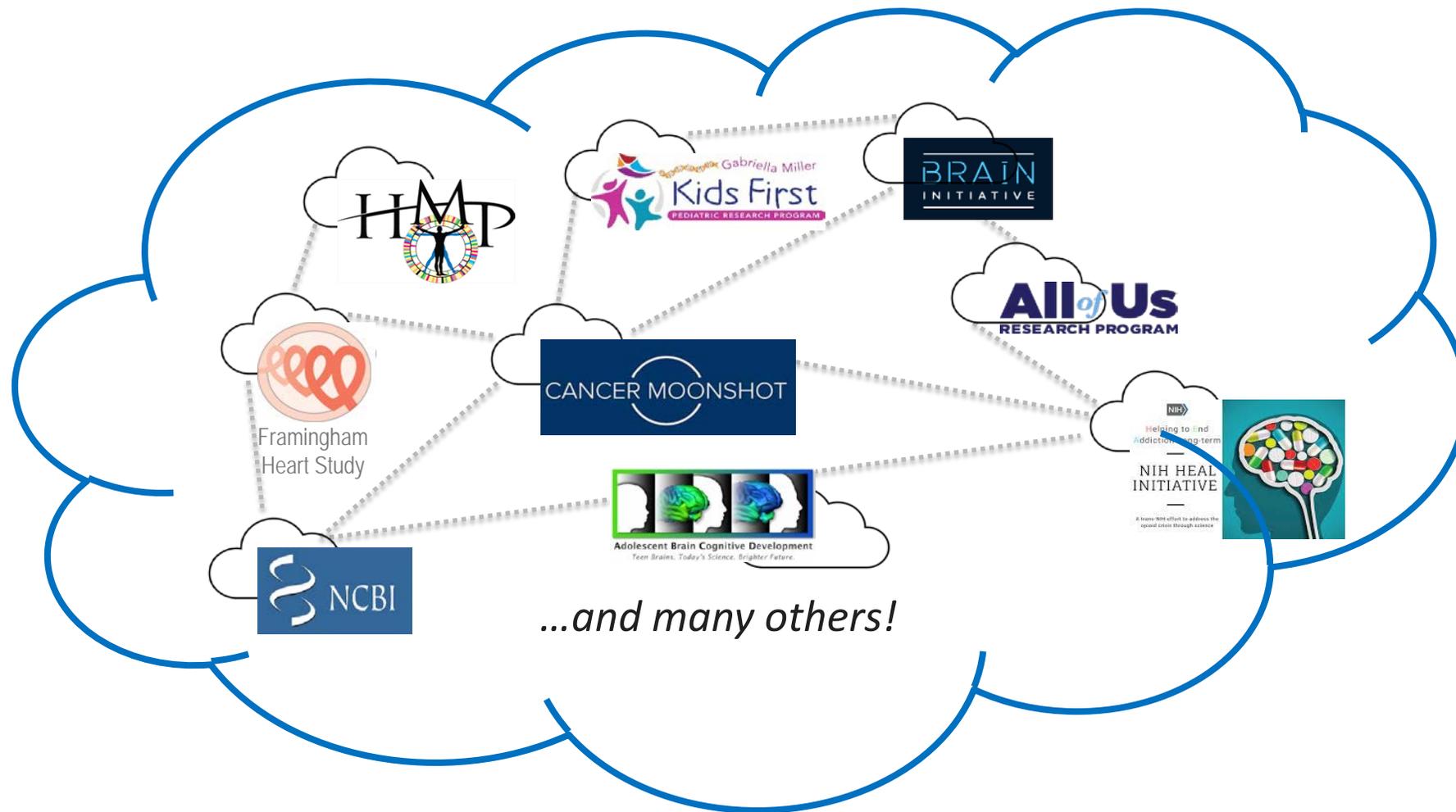
Looking Ahead: Harnessing the Power of the Cloud for Biomedical Research



- **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





RFI Responses

Request for Information on the NICHD Vision for Multisite Clinical Trials Infrastructure

Notice Number: NOT-HD-19-041

Key Dates

Release Date: November 8, 2019
Response Date: December 20, 2019

Issued by

Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)

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

Background

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?