

Environmental influences on Child Health Outcomes (ECHO) IDeA States Pediatric Clinical Trials Network (ISPCTN)

Network Renewal

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**Council of Councils
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Concept Clearance

Reissues of RFA-OD-19-025 and RFA-OD-19-026

Titles

- Data Coordinating and Operations Center for the ECHO IDeA States Pediatric Clinical Trials Network - 2 (U24 Clinical Trial Required - Institutional) (RFA-OD-19-025)
- Clinical Sites for the ECHO IDeA States Pediatric Clinical Trials Network - 2 (UG1 Clinical Trial Required) (RFA-OD-19-026)

Purpose

- To develop, implement, and disseminate results from high-impact multicenter clinical trials to enhance the health of children living in rural or underserved communities in Infrastructure Development Awards (IDeA) states
- To enhance pediatric research capacity among institutions in IDeA states

Funds Available and the number of Awards

- Contingent upon NIH appropriations, \$15 million to fund approximately 18 meritorious Clinical Sites and 1 meritorious Data Coordinating and Operations Center (DCOC)

Award Project Period: 5 years

Council Action: Vote for approval of reissuance of the concept



Environmental influences on Child Health Outcomes (ECHO)

Enhance the health of children for generations to come

PRE-, PERI-
AND POSTNATAL



UPPER AND
LOWER AIRWAY



OBESITY



NEURO-
DEVELOPMENT



POSITIVE HEALTH



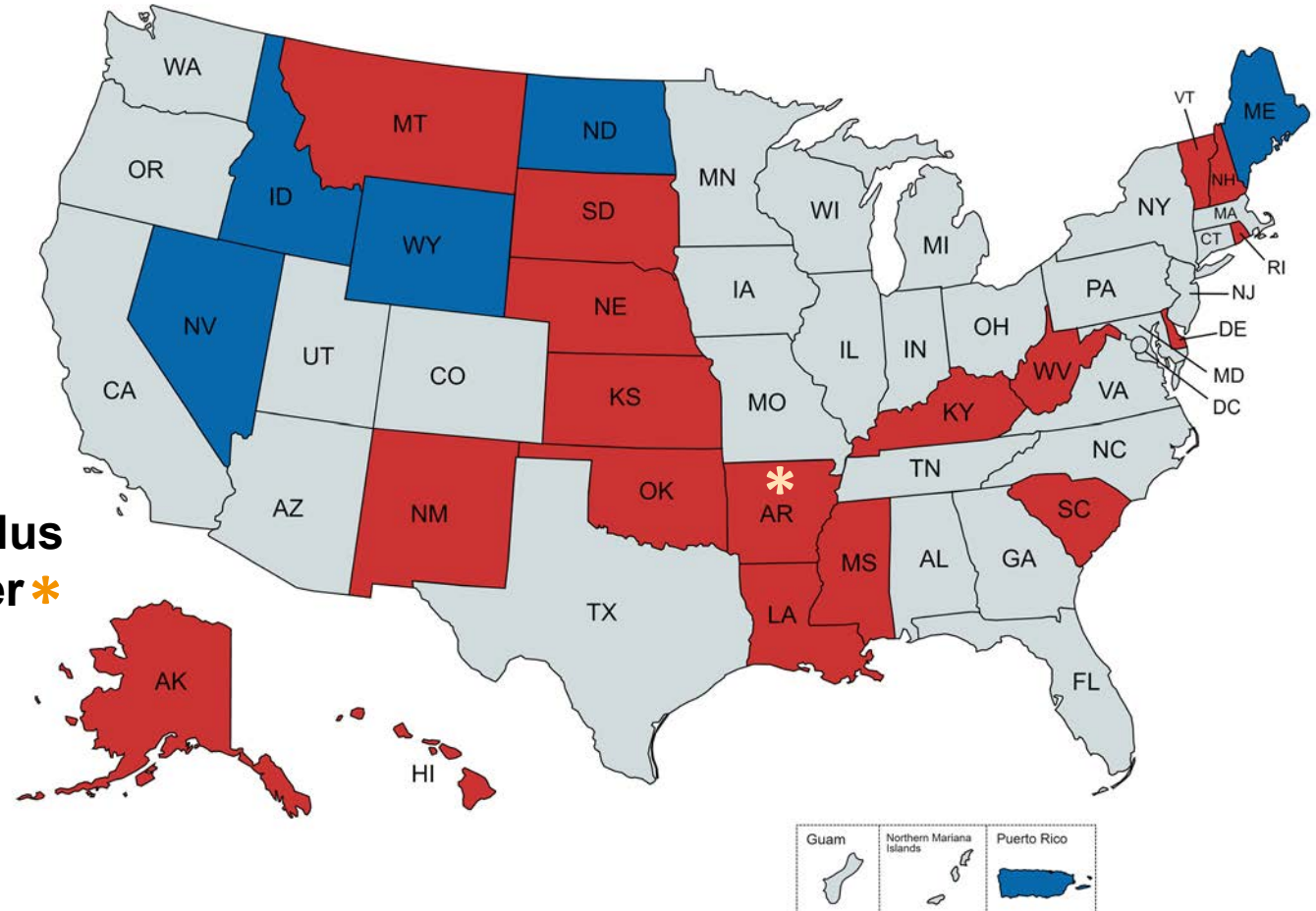
ECHO IDeA States Pediatric Clinical Trials Network

- IDeA States

- 23 States and Puerto Rico with historically low levels of NIH funding

 **ISPCTN: Clinical Sites in 18 IDeA states, plus 1 Data Coordinating and Operations Center ***

 **5 IDeA states and Puerto Rico, not funded by ISPCTN**



ECHO ISPCTN Overall Goals

- Provide children from rural or underserved populations access to state-of-the-art clinical trials
- Build pediatric research capacity within the IDeA States
 - To conduct these trials
- Additional goals
 - Engage stakeholders in ISPCTN research processes
 - Enhance diversity, equity, inclusion, and accessibility in workforce and participants



Rationale for ISPCTN

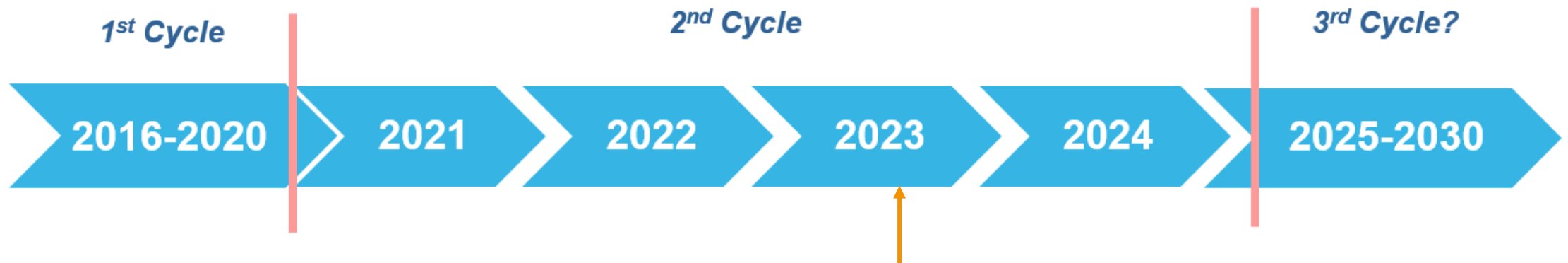
- Children in rural or underserved communities in IDeA states
 - Experience worse health outcomes than children in non-IDeA States
 - Are underrepresented in clinical trials
- IDeA states institutions need capacity building to develop and implement clinical trials
- IDeA states institutions struggle to compete for NIH funding
 - IDeA States: \$2.9 billion (2,583 awards)
 - Non-IDeA States: \$33.8 billion (19,040 awards)



Accomplishments in Cycles 1 and 2

Clinical Trials

- Developed and implemented 9 protocols
 - 6 funded by ISPCTN
 - 4 intervention trials
 - 2 observational studies as precursors for intervention trials
 - 3 funded by NIH-HEAL initiative
 - 2 intervention trials
 - 1 observational study as precursor for the 2 intervention trials



ISPCTN—23 Publications to Date

- 7 of 23 in journals with impact factor >6
- 1 each in
 - *N Engl J Med*
 - *JAMA Netw Open*
 - *Am J Public Health*

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Eat, Sleep, Console Approach or Usual Care for Neonatal Opioid Withdrawal

L.W. Young, S.T. Ounpraseuth, S.L. Merhar, Z. Hu, A.E. Simon, A.A. Bremer, J.Y. Lee, A. Das, M.M. Crawford, R.G. Greenberg, P.B. Smith, B.B. Poindexter, R.D. Higgins, M.C. Walsh, W. Rice, D.A. Paul, J.R. Maxwell, S. Telang, C.M. Fung, T. Wright, A.M. Reynolds, D.W. Hahn, J. Ross, J.M. McAllister, M. Crowley, S.K. Shaikh, K.M. Puopolo, L. Christ, J. Brown, J. Riccio, K. Wong Ramsey, Akshatha, E.F. Braswell, L. Tucker, K.R. McAlmon, K. Dummula, J. Weiner, J.R. White, M.P. Howell, S. Newman, J.N. Snowden, and L.A. Devlin, for the ACT NOW Collaborative*



Accomplishments in Cycles 1 and 2

Capacity Building

- Capacity building
 - Professional Development
 - Trained 37 Early-Stage Investigators (ESI)
 - Funded 5 ESI Proposals, 7 Diversity Supplements, 1 Opportunities and Infrastructure Fund (OIF) award
 - Organizational functioning
 - Continuous quality improvement
 - Monitor and achieve Network goals
 - Develop/implement/disseminate clinical trials
 - Capacity building
 - Community engagement
 - Quality and quantity of Network trials
 - Didactic and experiential approaches
 - Maximize rigor, relevance, feasibility, potential impact



Rationale for ISPCTN Renewal

- Remains only pediatric clinical trials network focused on enhancing health of children living in rural or underserved communities
- Maturing from 1st through 2nd cycle
- Already producing high-impact results
- Poised for increased return on investment



Plans for a 3rd Cycle (2025-2030)

- Complete ongoing trials
- Implement trials in the pipeline
 - Including first FDA-regulated (IND) trial
- Develop and implement 5 new high-impact multicenter trials
- Continue and refine capacity building
- Facilitate stakeholder engagement
 - Multiple points in research process



Council Actions

We are requesting Council vote to approve reissuance:

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