

# NIH Council of Councils

January 26, 2018

## ***Environmental influences on Child Health Outcomes (ECHO) Program after 1 Year***

### ECHO Program

Matthew W. Gillman, MD, SM  
Director

### ECHO External Scientific Board

Nsedu Witherspoon, MPH, Member  
Executive Director, Children's Environmental Health  
Network

Juliana M. Blome, PhD, MPH, Exec Sec  
Chief of Staff, ECHO Program



**ECHO** Environmental influences  
on Child Health Outcomes



National Institutes of Health  
Environmental influences on Child Health Outcomes (ECHO)

# Today

- Introduction to ECHO (Gillman)
  - Mission, guiding principles, scientific goals
  - Observational and intervention research
    - Complexity
- Challenges (Gillman)
  - Program as a whole
  - ECHO cohorts (observational)
  - IDeA States Pediatric Clinical Trials Network (intervention)
  - ECHO Program Office
- External Scientific Board (Weatherspoon, Blome)
  - Issues and recommendations to Council of Councils
- Council discussion and voting



ECHO



National Institutes of Health  
Environmental influences on Child Health Outcomes (ECHO)

# ECHO Mission

Enhance the health of children for  
generations to come



# Guiding Principles

- **Teamwork**

Working well together

- **Impact**

Research that has an impact on health

- **Responsibility**

Scientifically & ethically sound research

- **Value**

Good stewardship, return on investment

# ECHO Overall Scientific Goal

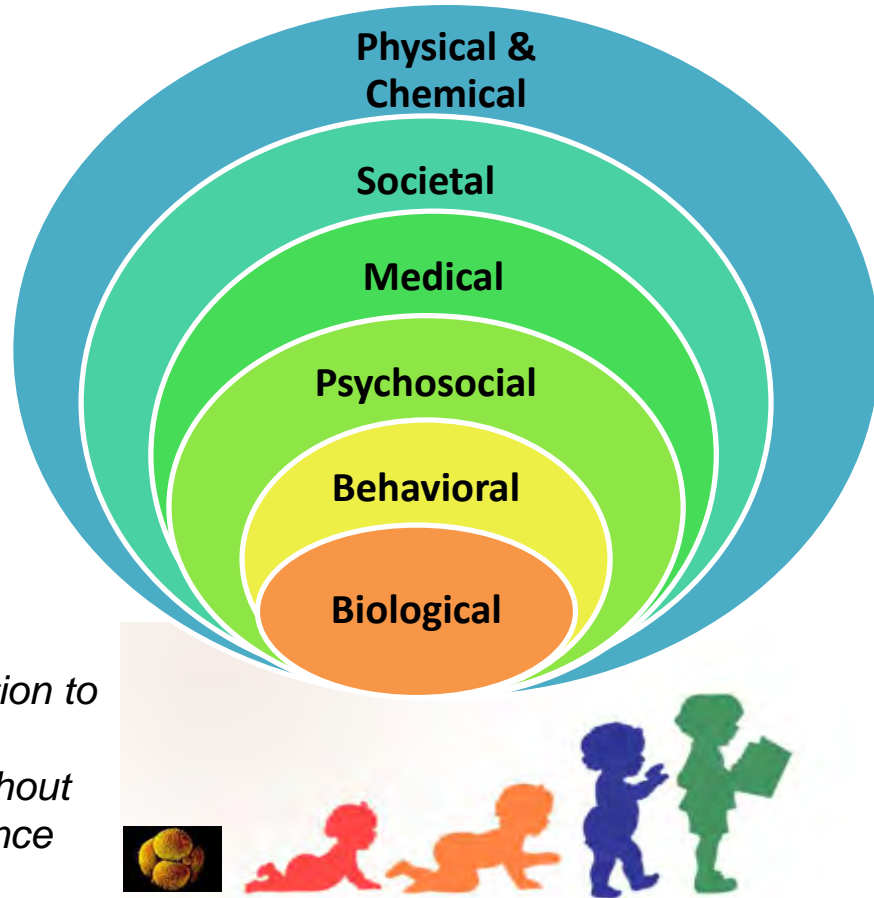
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Address solution-oriented questions about effects  
of  
broad range of early environmental exposures  
on  
child health and development

# Broad Range of Early Environmental Exposures

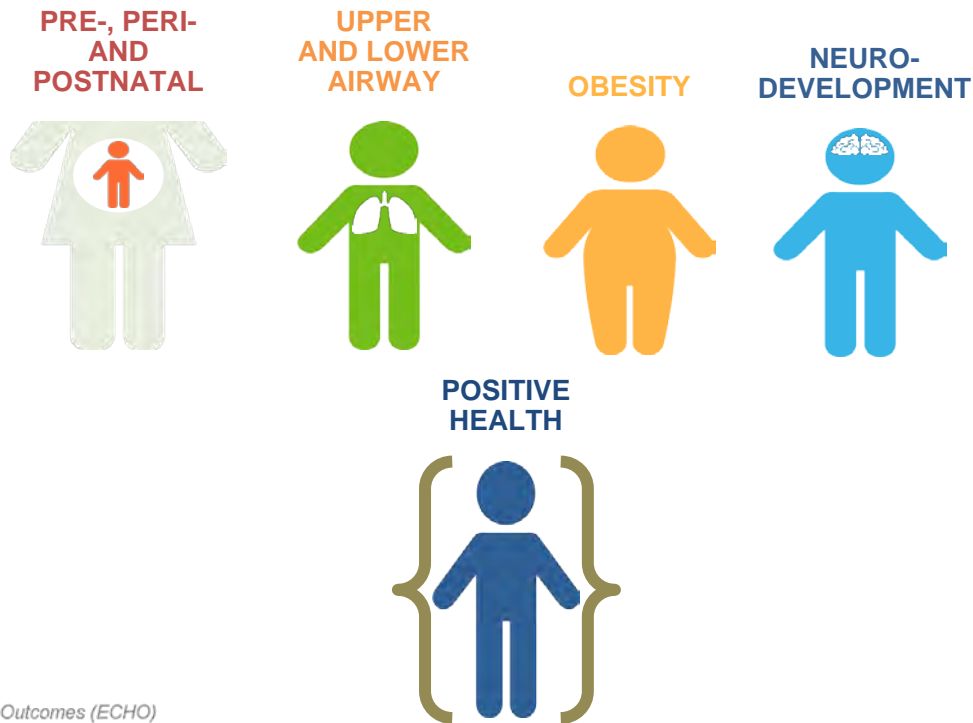
*From society to biology*

- *Exposures from conception to age 5 years*
- *Health outcomes throughout childhood and adolescence*

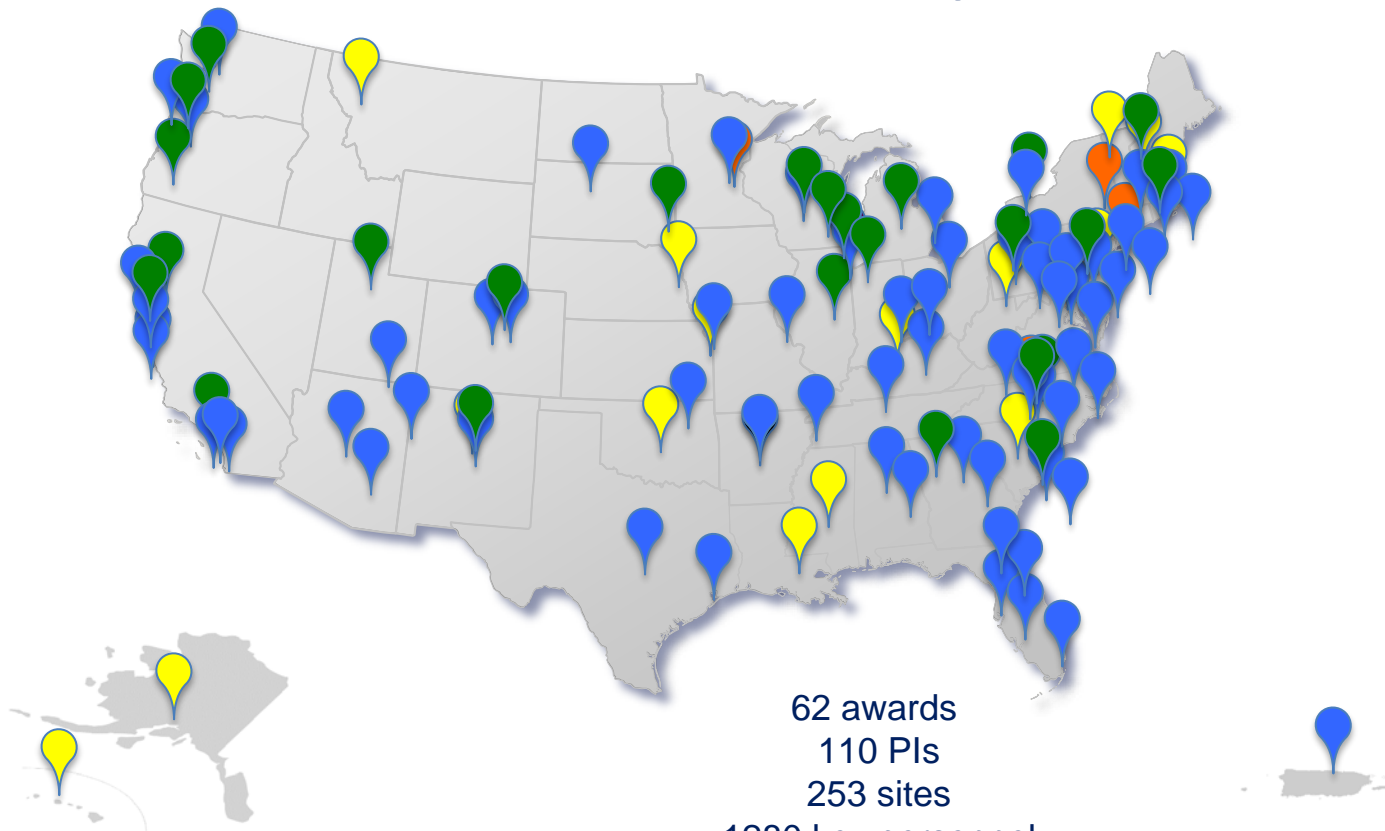


# Health Outcomes

## Focus on High-Impact Pediatric Conditions

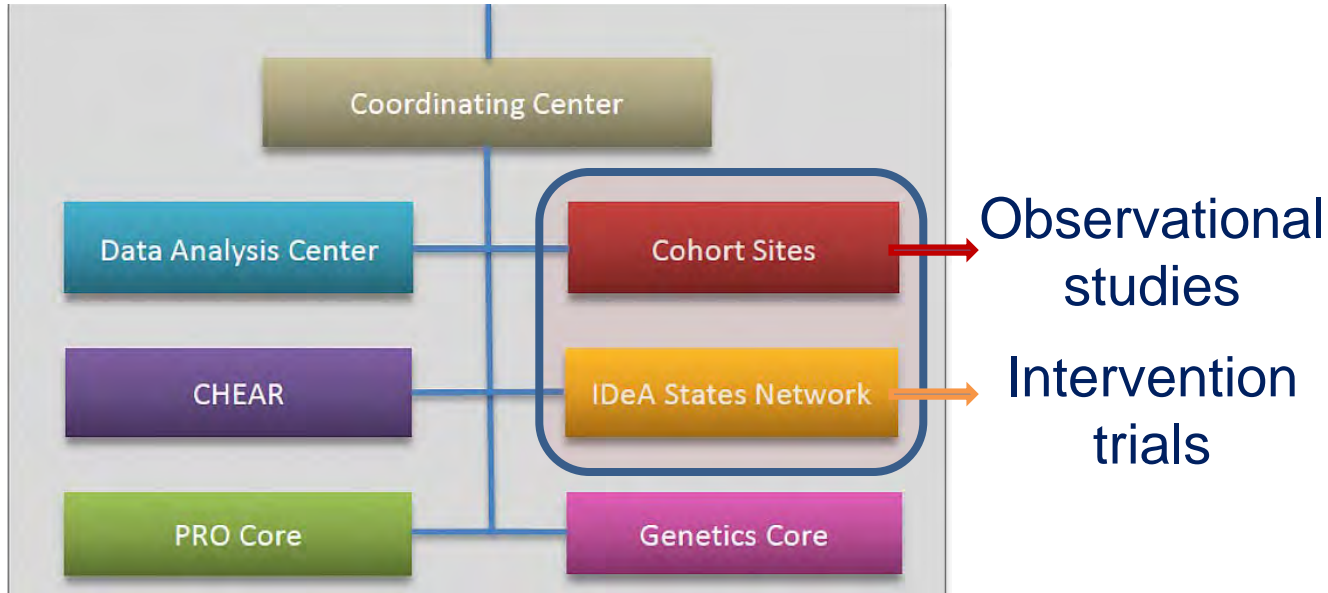


# ECHO—A Nationwide Program





# ECHO Components



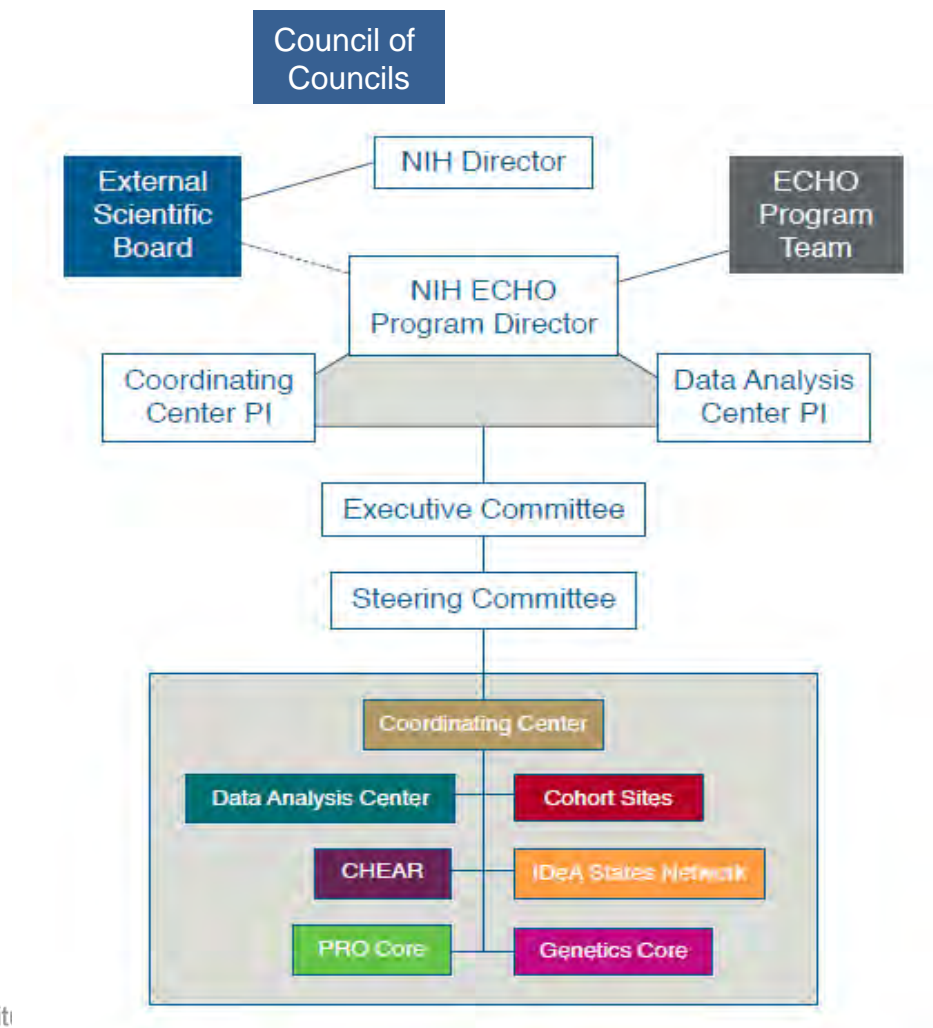


## U Mechanism—Cooperative Agreement ECHO Program Office sets boundaries, offers vision



Investigators drive  
the science  
& policies





# External Scientific Board (ESB)

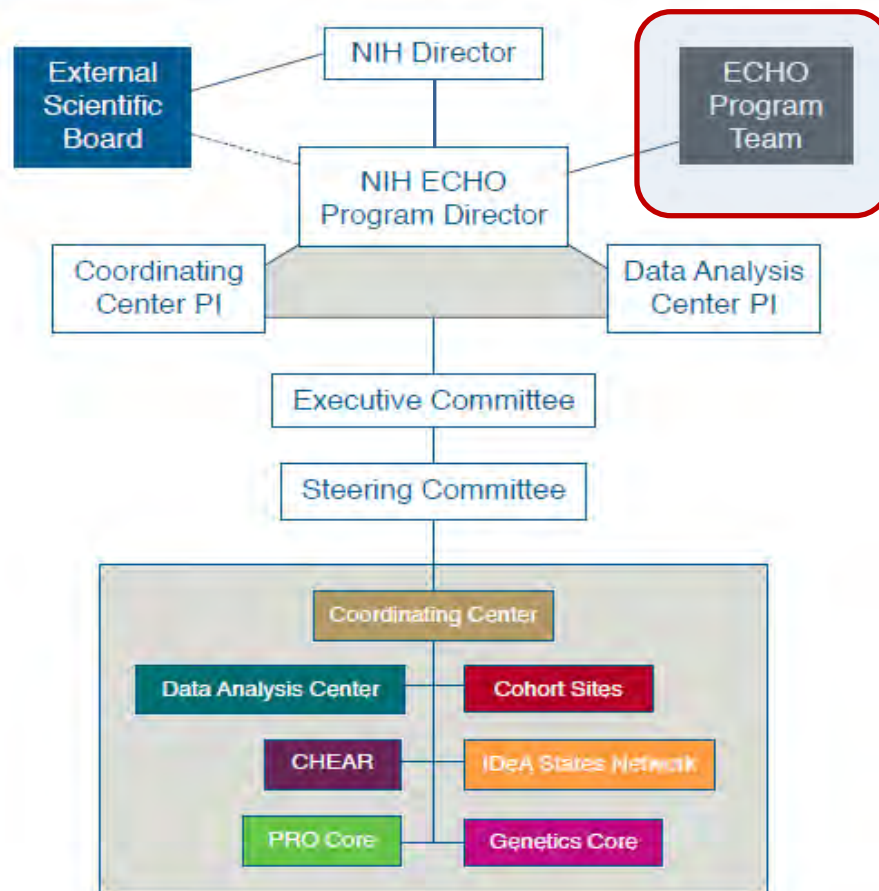
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## **CHARGE:**

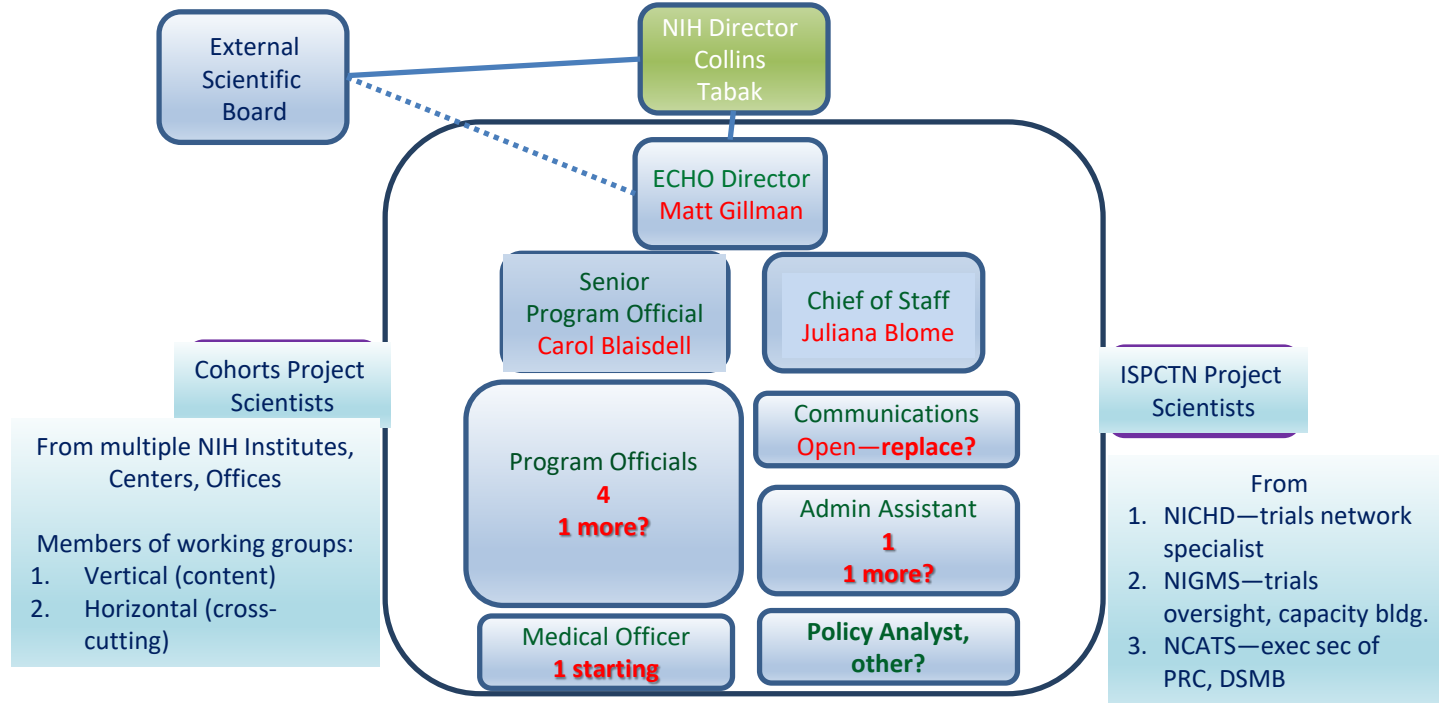
....to provide advice on strategies to ensure the long-term success of the ECHO program and ...to provide advice to the Council of Councils for further consideration.

## **MEMBERS:**

Expertise in pediatrics, early childhood development, public health, environmental toxins, epidemiology, community-based participatory research, and research with American Indian and Alaskan Native peoples.



# ECHO in NIH Office of Director



## ECHO PROGRAM OFFICE

# ECHO Cohorts



35 awards  
74 PIs, 83 cohorts

-Majority started prenatally-

# ECHO Cohorts

- 7 years, annual funding
- Primary Goal: Develop ECHO-wide Cohort
  - Start with existing cohorts of mothers and children
    - All continue follow-up of children
    - Some also still recruiting
  - Create single data platform to conduct etiologic and prediction research
  - Harmonize existing measures & standardize new measures
  - Goal >50,000 children



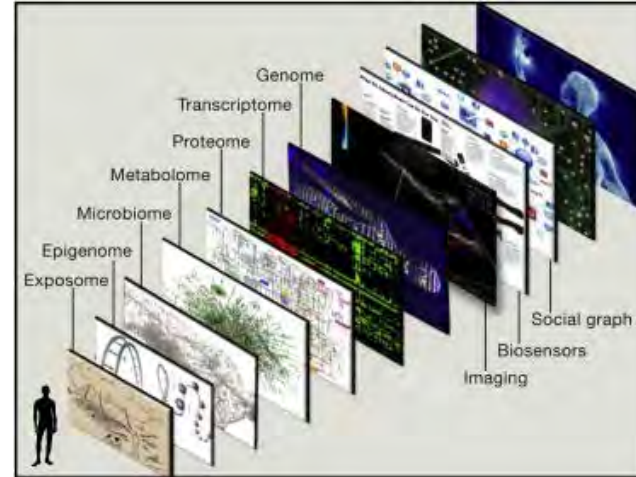
# ECHO-wide Cohort

Weaving together 83 individual cohorts



# ECHO-wide Cohort

Many people, many layers of data,  
many stages of life course

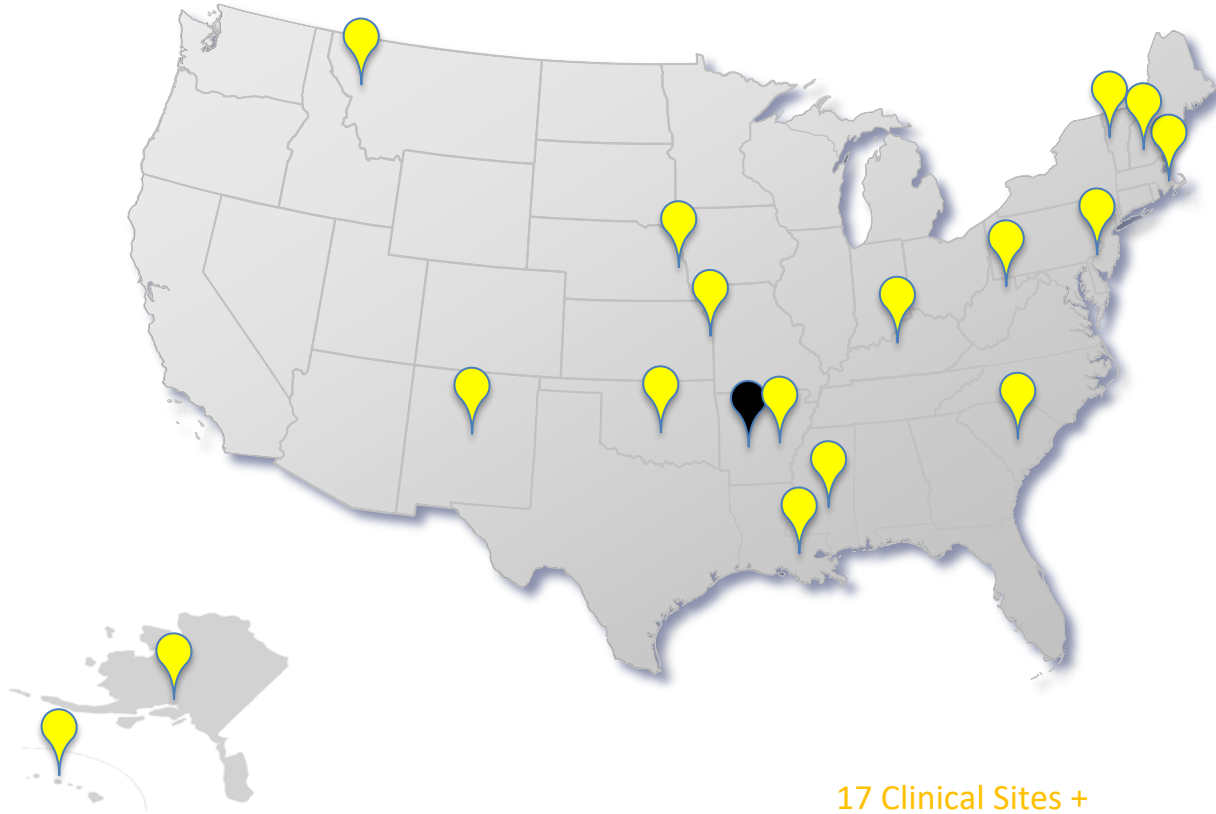


# Promise of ECHO-wide Cohort

- 50,000+ children and their families
  - Address solution-oriented research questions that no single cohort, or even a few cohorts, can answer alone.
- Nationwide research collaboration
  - Resource for many researchers



# IDeA States Pediatric Clinical Trials Network



17 Clinical Sites +

Data Coordinating and Operations Center (DCOC)

# IDeA States Pediatric Clinical Trials Network

- 4 years, forward funded
- Network of clinical sites and own DCOC in IDeA States
- Provide access to state-of-the art clinical trials for medically underserved and rural children
- Build national pediatric research capacity to conduct clinical trials
  - Professional development for faculty and staff
  - Infrastructure and team support

# ECHO Challenges

Tensions	On the one hand...	On the other hand...
<i>Program as a whole</i>		
Short- and long-term success	Engagement, for building a sustainable future	Efficiency, for early wins
All components under one umbrella	ISPCTN, a Network with potential.	Cohorts, already existing.
	Has its own DCOC	DAC/PRO core for Cohorts. CC for both?
Different funding timelines	ISPCTN funded for 4 years	Cohorts, DAC, CC, PRO Core funded for 7 years
Large size	3 Coordinating Centers, 2 Data Centers, 83 cohorts, 17 ISPCTN sites, 6 CHEAR labs– ~1300 key personnel	Nimble decision-making
Cooperative agreement	NIH directs	Investigators lead
Health outcomes	Four disease-oriented initially specified	Bridging across silos
Many layers of stakeholders	Congress, professional and advocacy groups, NIH ICOs	Investigators, participants
Communications	Quantity: too much/too often	Quality: not enough
	Component-specific	Consistency across components

# ECHO Challenges

Tensions	On the one hand...	On the other hand...
<i>Cohorts</i>		
Research Aims	Individual award aims	ECHO-wide Cohort-- whole greater than sum of parts
Data sharing	Awardee control	National resource
Data collection protocol	Feasibility	Comprehensiveness
Useful data	Harmonizing existing data	Standardizing new data
<i>IDeA States Pediatric Clinical Trials Network</i>		
Readiness	Some sites ahead	Include all 17 in trials
Balance of activities	Capacity building	Start a trial
<i>NIH ECHO Program Office</i>		
Leadership	NIH Office of Director: ECHO program staff	Institutes, Centers, Offices: Project scientists
Program resources	Pressing demands	Lack of staff & time; hiring freeze





# ESB Recommendations

## Program as a Whole

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**To ensure the success of the ECHO program, the External Scientific Board endorsed the following recommendations for Council consideration:**

**Leadership:** While the leadership of the National Children's Study was too centralized, the ECHO program may err in the other direction. The Board suggests the model of a mentoring leader who presents information to guide decision-making.

# ESB Recommendations

## Program as a Whole

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**Leadership:** While the leadership of the National Children's Study was too centralized, the ECHO program may err in the other direction. The Board suggests the model of a mentoring leader who presents information to guide decision-making.

### **ECHO approach:**

1. U Mechanism
2. Combine
  - a. Strong Scientific Leadership from NIH
  - b. Engagement, Transdisciplinary Team Science

# ESB Recommendations

## ECHO Cohorts

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**Creating ECHO-wide Cohort:** The main problem for the cohort study is having enough power in the combination of cohorts to get results beyond what the original cohorts brought in. In addition, ECHO is in danger of repeating the approach taken by the National Children's Study, which was too expansive.

The Board strongly recommends

- early progress in harmonization
- focus on producing one or two early wins so benefits of the ECHO program become known
- try to contain the protocol to keep things manageable

# ESB Recommendations

## ECHO Cohorts

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The Board recommends

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### **ECHO Approach:**

- Data Analysis Center/PRO core/Data Harmonization working group for harmonization of existing and new data
- Early wins
  - Review papers (1 approved; more coming)
  - Collective analyses (2 in process)
  - Individual cohort papers (>50 published)
- ECHO-wide Cohort
  - Protocol v1.0 and affiliated publication/data/biospecimen policies ratified by Steering Committee

# ESB Recommendations

## IDeA States Pediatric Clinical Trials Network

**Steering Committee-directed purview too broad for new Network with varying experience, capacity building needs, no single condition or population focus.** The Board recommends that the Network move forward with fewer than 4 home-grown clinical trial protocols, but instead focus on 1-2 trials with the lowest participant burden and risk that can be completed in a short time, thus representing an early win for the whole network. NIH leadership should encourage a realistic assessment of resources.

# ESB Recommendations

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### ECHO Approach:

- Stronger governance
  - Nimble Leadership Committee akin to Cohorts' Executive Committee
- Collaborate with experienced networks for first trials
  - Capacity building and results with impact
    - PK of commonly used medication
    - ACT NOW for opioids
- 4 → 2 home-grown trial protocols
  - Now revise and resubmit to Protocol Review Committee

# ESB Recommendations

## IDeA States Pediatric Clinical Trials Network

**The ESB is also concerned about the leadership and capacity of the DCOC.** Board recommends that the DCOC receive guidance and support from the Coordinating Center, at least through the first clinical trial, after which the roles and responsibilities should quickly be transferred to the DCOC. The Board supports ECHO program working with UAMS in leadership change, including appointment of a PI experienced in multi-center trials with strong leadership skills. The ISPCTN is an important, high profile effort with strong congressional support needs highly performing DCOC to ensure the Network's success.

# ESB Recommendations

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### **ECHO Approach:**

- Facilitated pairing of Duke Clinical Research Institute with DCOC for capacity building
  - “Planned obsolescence”
- Worked with UAMS to effect leadership change
- More comprehensive Network governance/leadership



# ESB Recommendations

## ECHO Program Office

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**Staffing:** While the ECHO program is off to a strong start overall, this is a perilous time. NIH invested a great deal of funding in this program, so the first news to emerge from ECHO will be heavily scrutinized. A major hindrance appears to be the lack of sufficient staff. Given the magnitude and early stages of the project, and given that the Department of Health and Human Services has lifted the hiring freezes of other endeavors, the Board strongly recommends that ECHO be granted a hiring exemption, based on public health need, to allow for new hires.

# ESB Recommendations

## ECHO Program Office

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**Communications and Stakeholders:** While the program started out with the science and investigators, the ESB believes it's now time to start communicating with the public at large, the March of Dimes, and other advocacy organizations. The Board recommends the program ramp up communications via the website, social media, and outreach to stakeholders, including parents and children and tribal communities.

# ESB Recommendations

## ECHO Program Office

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**Staffing:** Given the magnitude and early stages of the project, and given that the Department of Health and Human Services has lifted the hiring freezes of other endeavors, the Board strongly recommends that ECHO be granted a hiring exemption, based on public health need, to allow for new hires.

**Communications and Stakeholders:** The Board recommends the program ramp up communications via the website, social media, and outreach to stakeholders, including parents and children and tribal communities.

### ECHO Approach:

- One new hire (ISPCTN project scientist)
- One planned request (PO focused on exposure science)
- Conducted stakeholder meetings
  - But Program Office lacks communications capacity
- Beginning strategic planning process to justify additional personnel/space

# Discussion



ECHO

Extra slide

# ESB Recommendations

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**Data Sharing Principles:** The Board stressed the importance of data sharing to the ECHO program, noting that without data sharing there is no program.

Board members agreed that safeguards to minimize risk while achieving maximum use of the data were the overarching goal