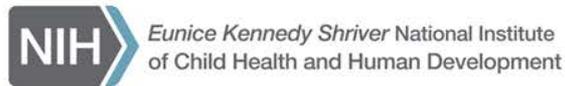


Office of the Director's Report to Council

Catherine Y. Spong, M.D.
Deputy Director, NICHD

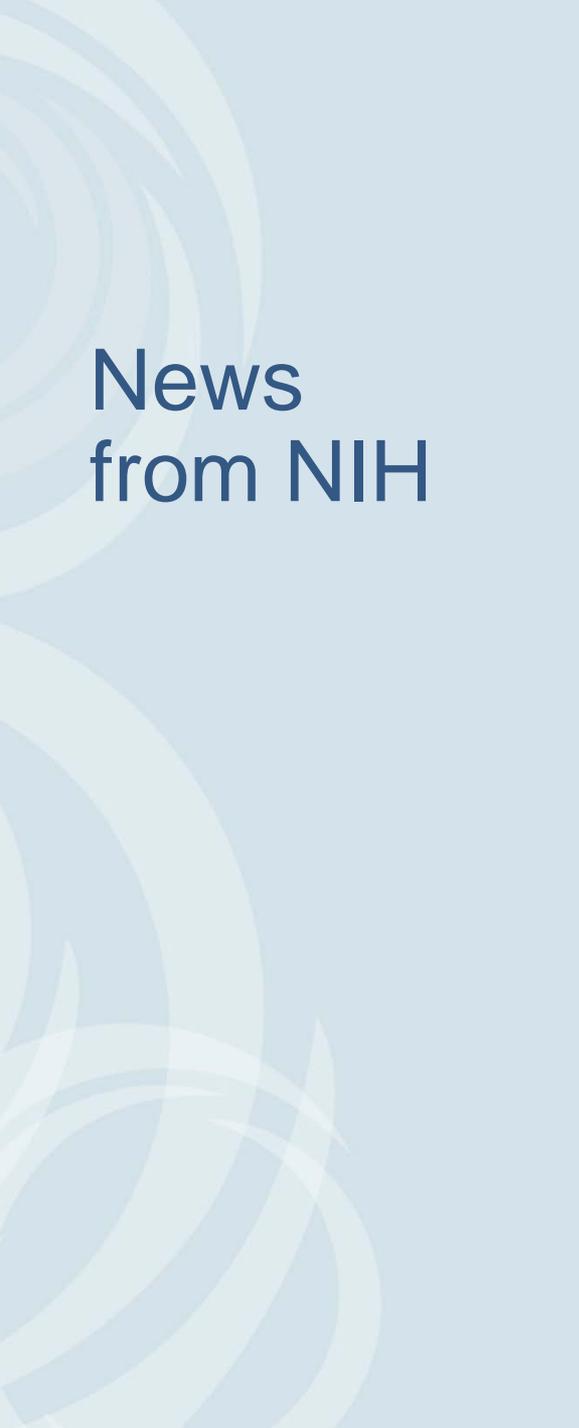


Presentation Overview

- News from NIH
- News from NICHD
- Legislative and Budget Updates
- Questions



News from NIH



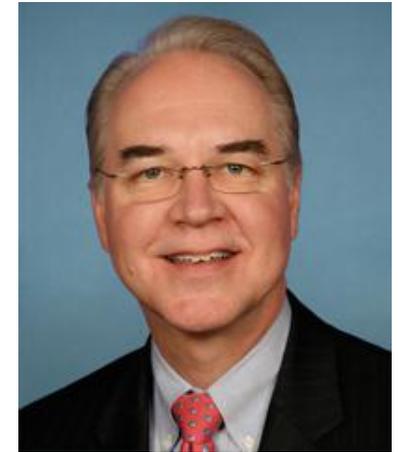
News from NIH

- **Staffing Updates**
- **All of USSM**
formerly Precision Medicine Initiative®
- **ECHO/IDeA**
- **Gabriella Miller Kids First
Pediatric Research Program**
- **Clinical Center**
- **Common Rule**



Nominee for Secretary of HHS

- Representative Tom Price ([R-GA 6th District](#)) nominated as Secretary of Health and Human Services
- January 18, the Senate Health, Education, Labor and Pensions (HELP) Committee held a hearing to consider the nomination
- January 24, met with the Senate Finance Committee and will vote this week to send forward for confirmation, then full Senate expected to vote on nomination before the Presidents' Day recess





NIH Under the New Administration

- Dr. Francis Collins held over as NIH Director by the Trump administration





Hiring of Clinical Center CEO

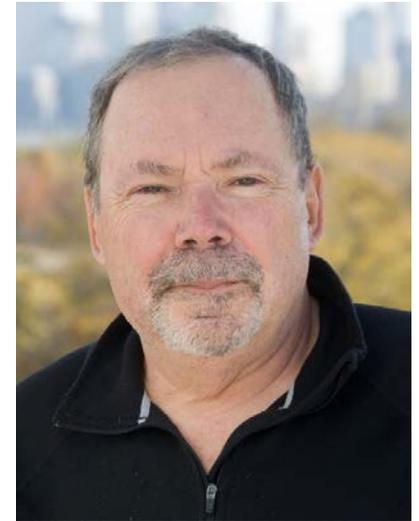
- Major General James Gilman, M.D., U.S. Army (Retired),
- Inaugural chief executive officer of the NIH Clinical Center
- Oversee the day-to-day operations and management of the 200-bed, 870,000-square-foot research center
- Cardiologist and experience commanding the operations of numerous hospital systems





Departure of Dr. Philip E. Bourne

- NIH's first Associate Director for Data Science
 - Last day: April 30, 2017
- Stephenson Chair of Data Science, Director of the Data Science Institute, and Professor in the Department of Biomedical Engineering at the University of Virginia
- National Library of Medicine Director Patricia Brennan, R.N., Ph.D., will serve as Interim Associate Director for Data Science





Presentation this morning on All of UsSM Research Program, formerly known as the Precision Medicine Initiative Cohort Program

ECHO/ IDeA Update

- FY16 awards
 - ECHO
 - IDeA



ECHO/IDeA States Pediatric Clinical Trials Network

- \$157 million in awards in FY2016 to launch a seven-year initiative
- November 9-10, nearly 200 scientists came together to launch the Environmental influences on Child Health Outcomes (ECHO) program
- ECHO program will investigate how exposure to a range of environmental factors in early development — from conception through early childhood — influences the health of children and adolescents



ECHO Cohort Awards

35 awards
74 PIs, 78 cohorts

-Majority started prenatally-



On the way to >50,000...

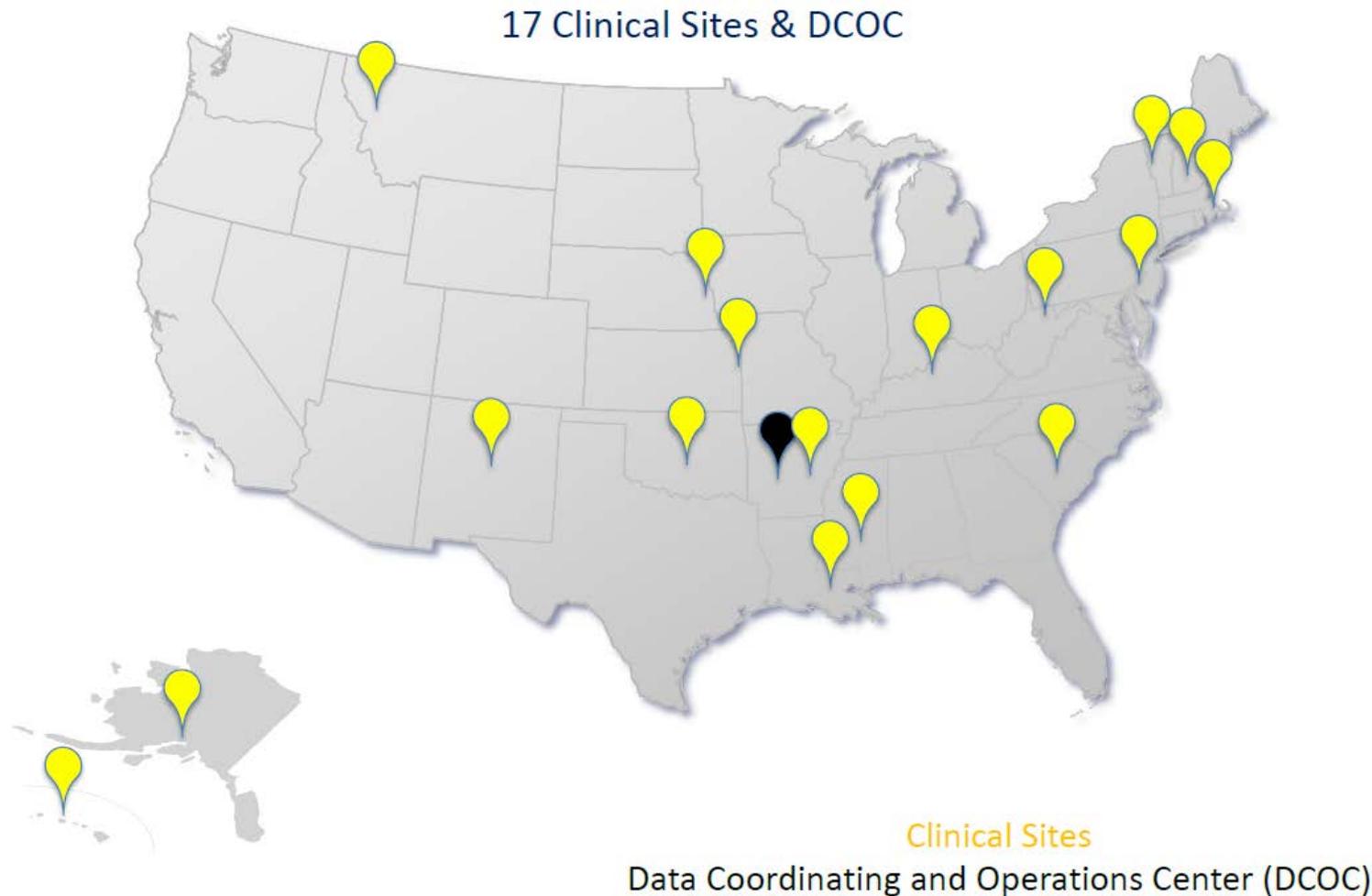
Current:
~33,000 mothers
~46,000 children

Cohort Prime Awardees
Cohort Sub-Awardees





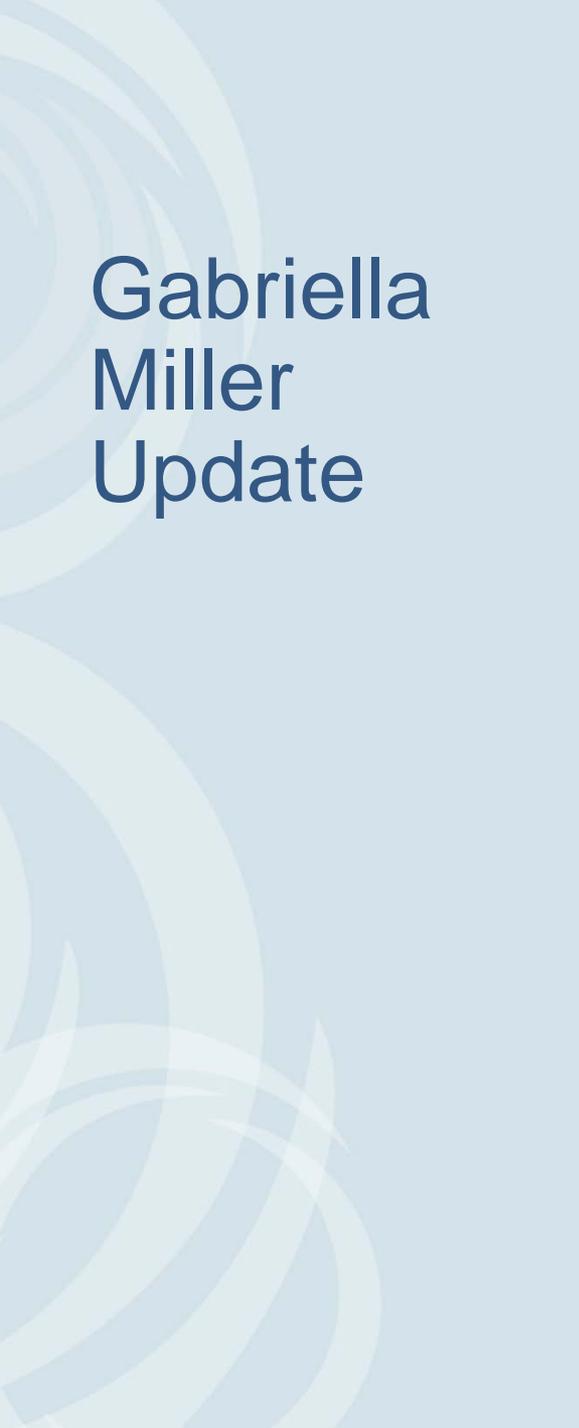
IDeA States Pediatric Clinical Trials Network





All ECHO Components Nationwide Program





Gabriella Miller Update

- Sequencing cohorts
- X01
- Sequencing Centers
- Data Resource



Gabriella Miller Kids First Pediatric Research Program

- Discovery of the Genetic Basis of Childhood Cancers and of Structural Birth Defects: Gabriella Miller Kids First Pediatric Research Program (X01)
- Sequencing of Cohorts
 - FY2015 [PAR-15-259](#)
 - 2 childhood cancer cohorts
 - 5 structural birth defects cohorts
 - FY2016 [PAR-16-150](#)
 - 3 childhood cancer cohorts
 - 5 structural birth defects cohorts
 - FY2017 [PAR-17-063](#)
 - Applications due March, 2017



X01 Mechanism

- Not an “award”
- Recipients are selected for the opportunity to have their cohort sequenced
- No funds, but can apply for R03 to support analysis of X01 project:
[PAR-16-348](#): Small Research Grants for Analyses of Data for the Gabriella Miller Kids First Data Resource (R03)
- Not listed in the NIH RePORTER
 - Abstracts and X01 information listed on Kids First website:
<https://commonfund.nih.gov/kidsfirst/fundedresearch>



Kids First Sequencing Centers

HudsonAlpha Institute for Biotechnology

- Shawn Levy, Ph.D, Director of the Genomic Services Lab

St. Jude Children's Research Hospital

- Jinghui Zhang, Ph.D.
- John Easton, Ph.D.

Broad Institute of MIT & Harvard

- Stacey Gabriel, Ph.D., Senior Director, Genomics Platform
- Michael Talkowski, Ph.D.
- Daniel MacArthur, Ph.D.
- Gad Getz, Ph.D.

Funded in FY16 for three years for sequencing X01 cohorts



Kids First Pediatric Data Resource

- Will harmonize and provide access to well-curated clinical and genetic sequence data for the pediatric research community to facilitate identification of genetic pathways that underlie childhood cancer and structural birth defects
- Applications are pending review; award expected July 2017

Clinical Center Update

Clinical Center Research Hospital Board met 1/13/17

- Clinical Center Focus Groups
- Audits of Delayed Reporting
- Patient and Worker Safety Metrics
- IT infrastructure and security
- Census
- Facilities update

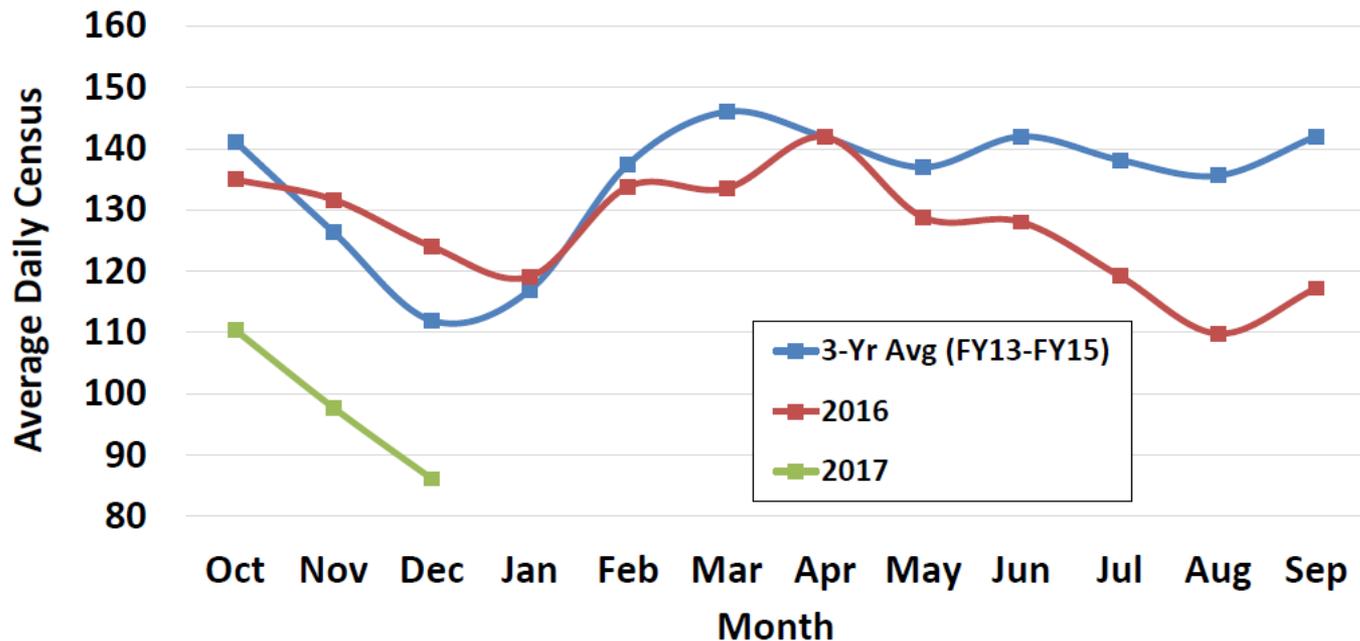


Adverse Event Reporting

- NCI trial of ibrutinib for CNS lymphoma
- NIH Office of Research Support and Compliance: trans-NIH survey found widespread concerns:
 - 711 protocols; 3615 events
 - Protocols with at least one event reported late 274 (39%)
 - ICs with late reporting: 15
- Next steps:
 - Trans-NIH independent audit in 2017
 - Rounds for prompt recognition
 - Standard operating procedures for each IC
 - Cross checking for event reporting
 - Staff Education and Reinforcement of Responsibility



Clinical Center Average Daily Census



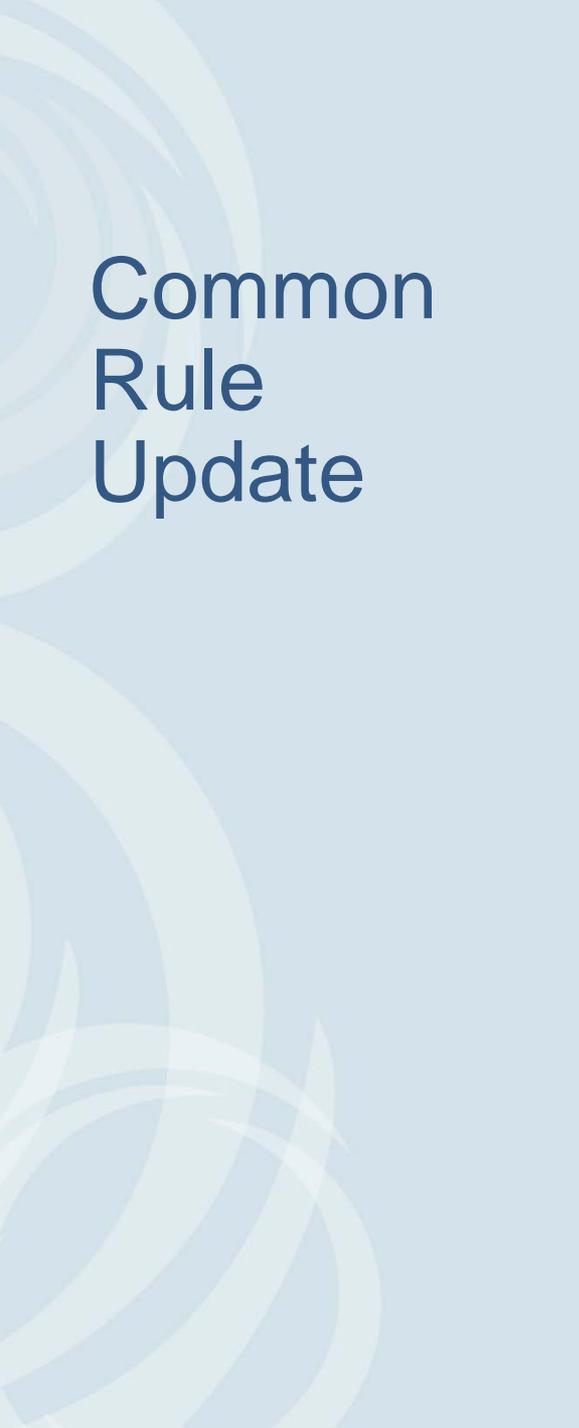
ADC Stats

- 3-Year Average (FY 2013-2015) = 134.7
- Year End FY 2016: 126.8
- Year-to-Date FY 2017 (as of January 2): 97.2



Clinical Center Census

- Working Group established, Dr. Steve Katz (chair)
- Address census and strengthen CC role as local, regional and national research resource
 - Address facilities and capacity
 - Increase OR time
 - Address cost issues for off-label drugs
 - Dedicated clinical support to ACIs
 - Enhance responsibility to IC Directors



Common Rule Update

Federal Policy for Protection of Human Subjects governs the ethics of biomedical and behavioral research involving human subjects in the U.S



Common Rule

- Office of Human Research Protections published 543-pages of revised regulations on January 19
- Of note for NICHD:
 - single IRBs for multi-institutional research studies
 - more detailed consent forms to provide potential participants in research a better understanding of a project's scope
- Unclear whether the new executive order on regulations will complicate implementation



News from NICHD

- 
- OD Staff Updates
 - PECASE Awardees
 - Zika virus Activities
 - PregSource
 - HPP 4



New Office of Health Equity Director

- NICHD's own Charisee Lamar, PhD, MPH, RRT named Office of Health Equity Director
- Previously directed the Reproductive Neuroendocrinology, the Fertility Preservation Programs, and the Reproductive Scientist Development Program within the Fertility and Infertility Branch at NICHD; also served as the Committee Coordinator for the Reproductive Medicine Network
- Brings a wide range of experience in the areas of program management, strategic planning, interagency collaboration, and training





New OSPRA Director

Office of Science Policy, Reporting, and Program Analysis

- G. Stephane Philogene, Ph.D. as the Director for NICHD's Office of Science Policy, Reporting, and Program Analysis (OSPRA).
- Former Deputy Director in the Office of Behavioral and Social Sciences Research (OBSSR)





PECASE

Presidential Early Career Awards for Scientists and Engineers (PECASE)

Highest honor bestowed by the United States Government on science and engineering professionals in the early stages of their independent research careers



PECASE Awardee

- **Adriana Lleras-Muney**,
University of California, Los Angeles
- Grantee NICHD's Population Dynamics Branch
- Research focus: relationships between socio-economic status and health, with a particular focus on education and income





PECASE Awardee

- **Shayne Piasta**, The Ohio State University
- Awarded PECASE through the Department of Education
- Mentored in part under the Florida State Learning Disabilities Research Center (Child Development and Behavior Branch)



Zika Virus Activities

- Sunset of Rapid Funding Announcement
- ZIP Cohort Study
- Executive Summary of Workshop Focused on the Children





Rapid PAR-16-106 to fund Zika virus Research Sunsets

- Rapid opened March 20, 2016 and expired on January 13, 2017; Zika-related R21 applications will no longer be accepted on a rolling basis
- Reissued as [PA-17-085](#) and uses standard application due dates, and timeframes for review, council and award dates now align with standard NIH practices

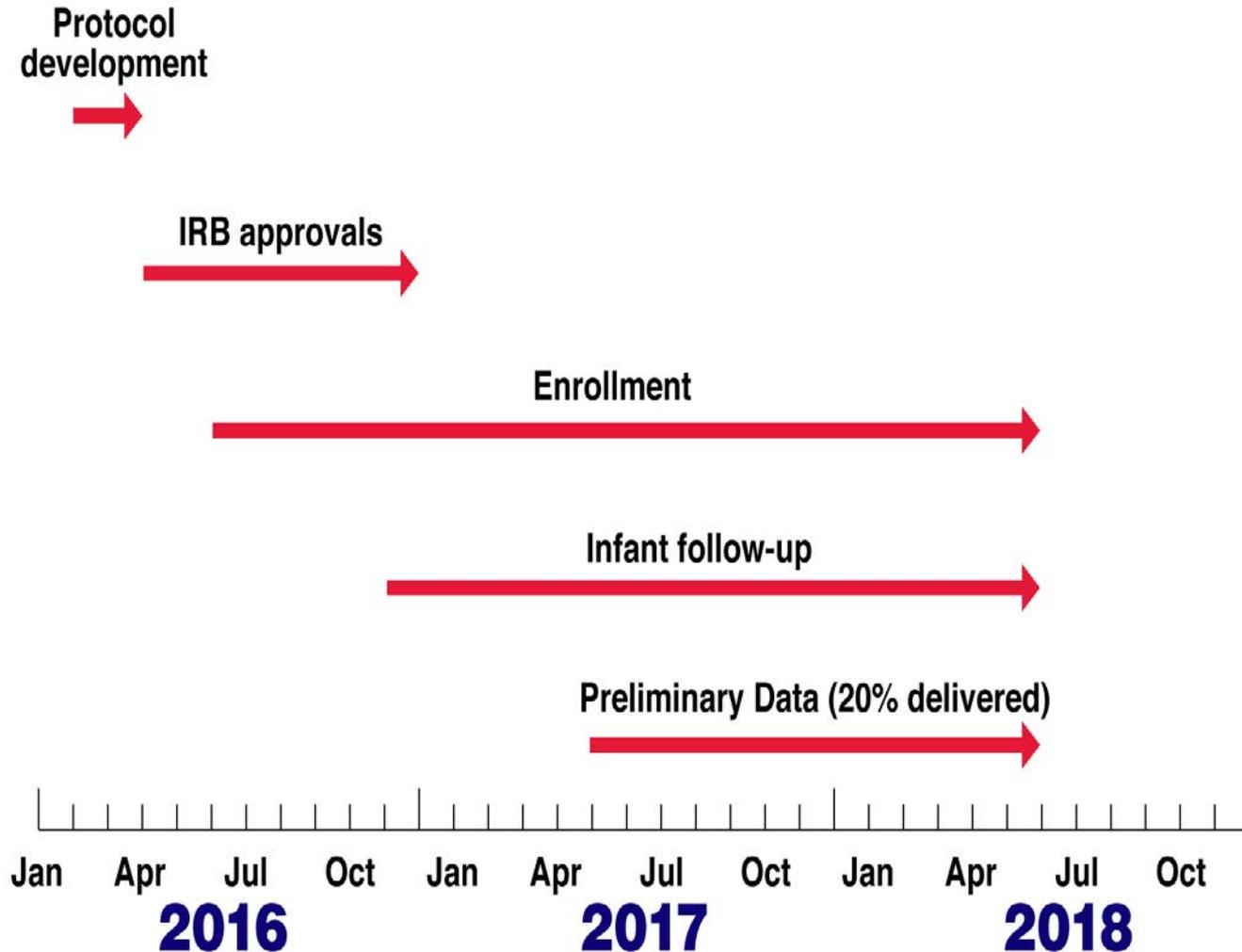


ZIP Cohort Study Sites





ZIP Timeline





Workshop Focused on the Children

- September 22-23, 2016 in Bethesda, Maryland
- Define the evidence to understand how prenatal Zika virus infection affects child development and to identify strategies for evaluation, management, and treatment and outline future research needs
- Webcast available:
 - Day 1: <https://videocast.nih.gov/summary.asp?live=19498&bhcp=1>
 - Day 2: <https://videocast.nih.gov/summary.asp?live=19502&bhcp=1>

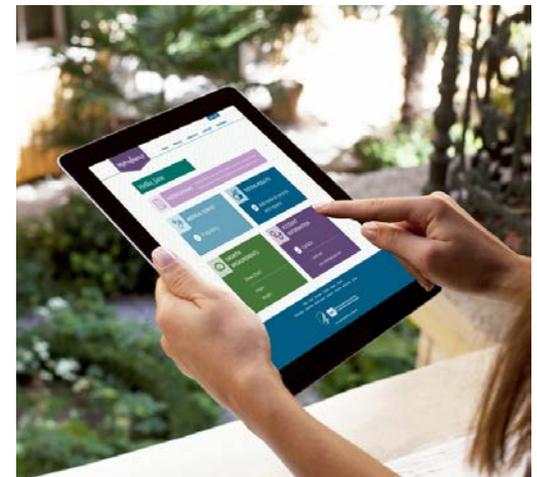


Photo attribution: Agência Brasil



PregSource™

- A crowd-sourced, interactive, mobile app to:
 - Detail the natural history – and variations - of human pregnancy
 - Provide accurate info about pregnancy from trusted sources
 - Let pregnant women know about opportunities to participate in targeted research
- 20 partner organizations
- Beta testing ongoing





4th Human Placenta Project Meeting

- Save the date: July 24-25, 2017 at NIH main campus
- HPP grantee presentations
- Technology and basic science talks
- Technology demonstrations and poster session





Legislative and Budget Updates



Budget Update

- Currently no budget
- Continuing Resolution through April 28
- President Trump indicated he will submit a FY2018 budget request but likely later than the statutory deadline of the first Monday in February



21st
Century
Cures:

Passed in
House
392-26

Provisions Relevant to NICHD

- Reauthorizes NIH for 2018-2020
- \$4.8 billion additional NIH funding over 10 years
 - PMI, Cancer, BRAIN
- \$1 billion additional funding to states to supplement opioid abuse prevention and treatment
- NICHD, as an institute, did not receive additional funds
- \$500 million additional to FDA



21st Century Cures Act: Of Interest to NICHD

Sec. 2040. Improving medical rehabilitation research at NIH

- Requires the NCMRR Director, when developing the current Research Plan, to identify existing resources available to support rehabilitation research and to include objectives, benchmarks, and guiding principles for rehabilitation research.
- Requires the NCMRR Director to develop an annual report for the coordinating committee and advisory board.
- Requires the Coordinating Committee to host a scientific conference or workshop not less than every five years.



21st Century Cures Act: Of Interest to NICHD (cont)

- **Sec. 2041. Task force on research specific to pregnant and lactating women.**
- Establishes a Task Force on Research Specific to Pregnant Women and Lactating Women, to provide advice and guidance to the HHS Secretary with the goal of addressing gaps in knowledge and research regarding safe and effective therapies for pregnant women and lactating women.



21st Century Cures Act: Of Interest to NICHD (cont)

- **Sec. 2071. National Pediatric Research Network.**
- Requires NIH to continue to support the National Pediatric Research Network.
- **Sec. 2072. Global Pediatric Clinical Study Network Sense of Congress.**



Rehabilitation Outreach on the Hill

- Dr. Bianchi met with members of the rehabilitation community at a Capitol Hill briefing
- Dr. Alison Cernich: keynote speech highlighting the need for medical rehabilitation research and promoting the release of NIH's new rehabilitation research plan
- Representatives Gregg Harper (R-MS) and Jim Langevin (D-RI) provided some opening remarks





Friends of NICHD Met Dr. Bianchi

- Representatives of about 20 Friends organizations
- Questions covered a broad range of topics, including the 21st Century Cures Act, updates on the Zika in Pregnancy (ZIP) study, pediatric research activities, and others



Kennedy Forum Event on the Hill

- Former United States Rep. Patrick Kennedy raising awareness to help address mental health and addiction
- Current Surgeon General, Dr. Vivek Murthy, and a former Surgeon General, Dr. David Satcher attended
- Dr. Bianchi was one of four IC directors to attend (NIDA, NIAAA, NIMH)
- An area important to NICHD because of the increased rates of opioid use in pregnancy and neonatal abstinence syndrome, which are both major public health issues





Questions?