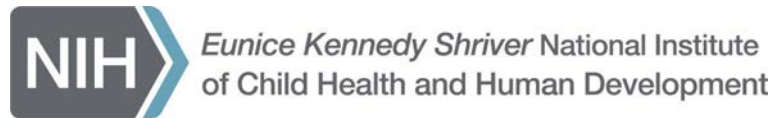# Update on NICHD's support for leveraging data resources

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Background

- Research for pregnant, lactating, and postpartum patients continue to lag behind research for adult and non-pregnant populations.

- Challenges to progress remain:
  - Ethical concerns
  - Lack of patient participation in research
  - Sample collection methodologies
  - Need for novel study designs
  - Shortage in research workforce
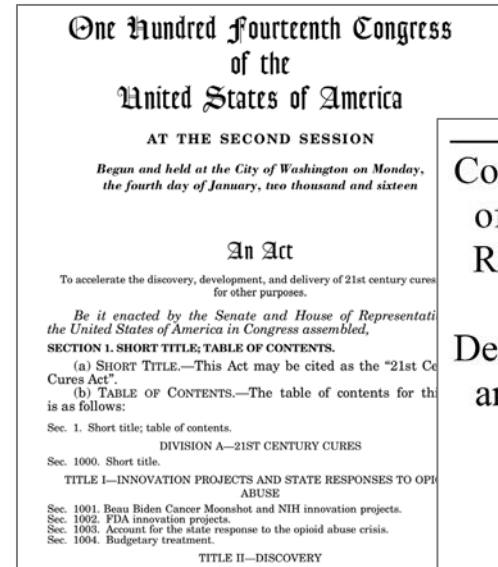 - Lack of appropriate pre-clinical models

Novel methodologies, including utilization of existing, large datasets, must be leveraged to promote innovation in research for pregnant, lactating, and postpartum persons.

Source: July 2023 OPPTB Trans-NIH Survey on Pediatric/Maternal Pharmacology

Momentum in Real-World Data and Real-World Evidence

- Emerging AI/ML/NLP technologies

- Legislation, including 21st Century Cures Act

- FDA RWE Program and guidance documents

- 2023 Data Management and Sharing Policy

- Recent demonstration of utility of RWE

NICHD's Data Science and RWE Portfolio is Growing
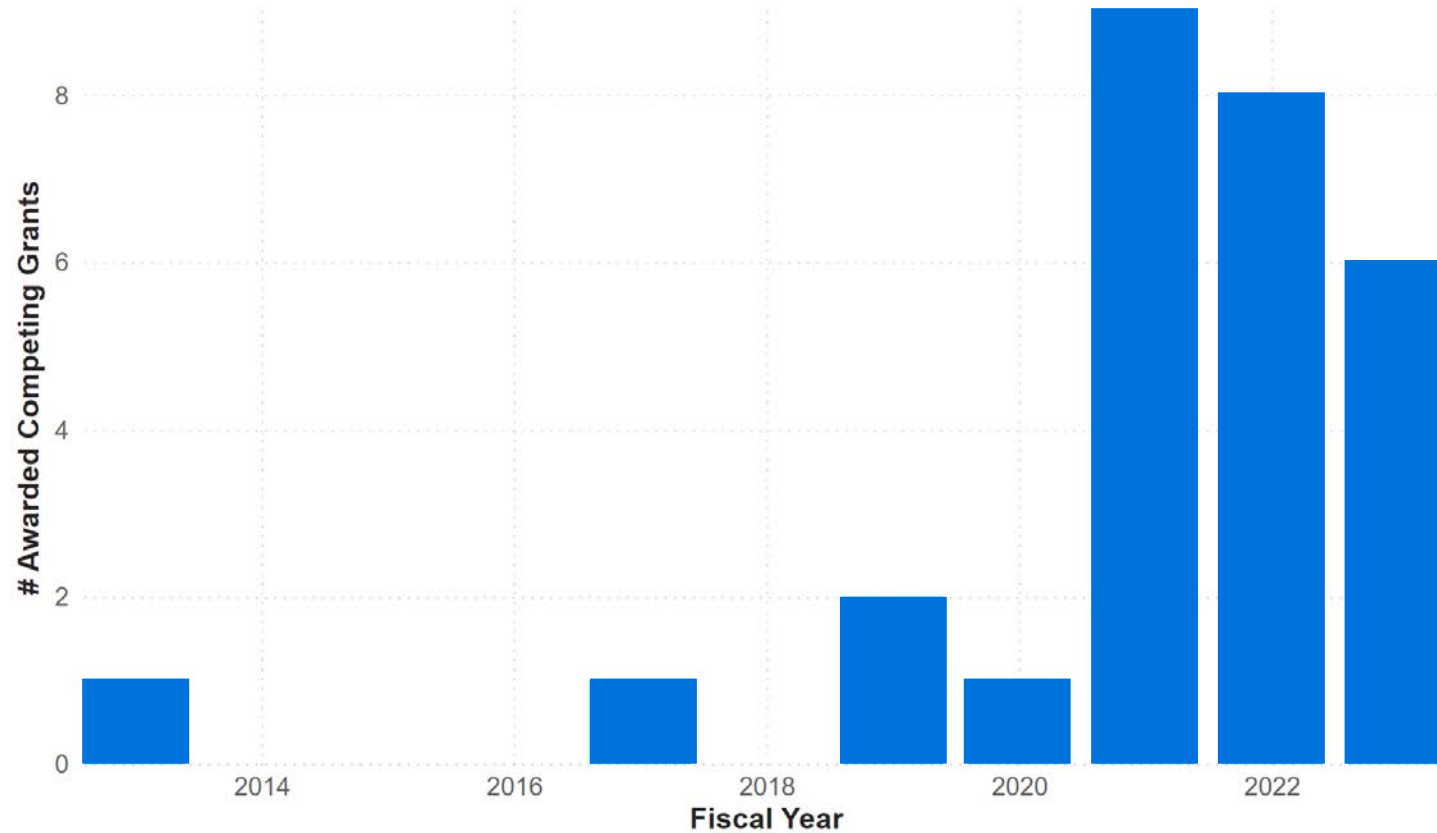
NICHD's grant portfolio in data science and/or real-world evidence studies involving pregnant, lactating, and postpartum persons has increased since 2013

Source: NIH iTools search, October 2023

NICHD's Multi-Faceted Approach to Leveraging Data

NOFOs

New Programs

NICHD Resources

Existing Programs

Trans-NIH Collaborations
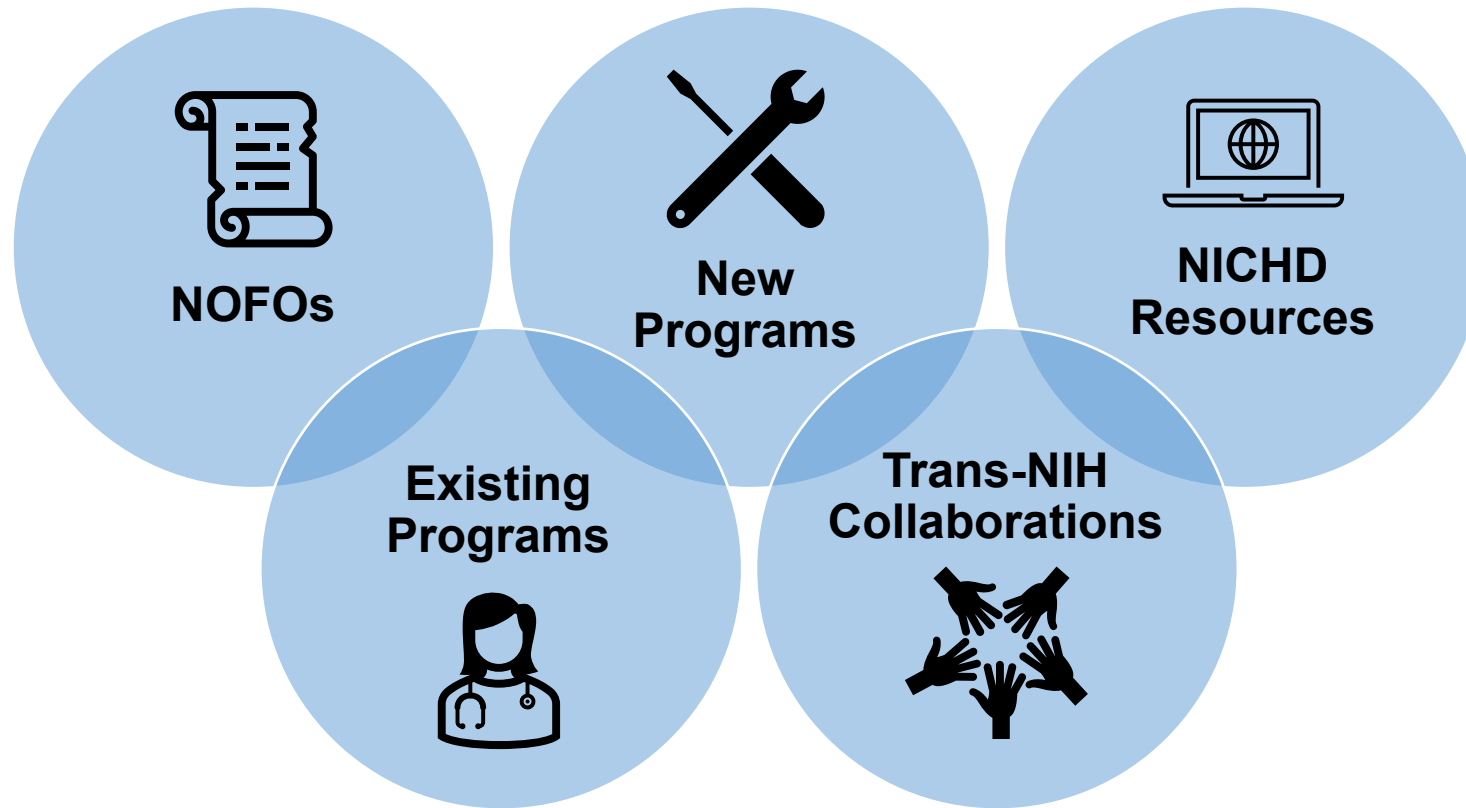
Translational Research in Maternal and Pediatric Pharmacology and Therapeutics Funding Opportunities

- A key goal of these NOFOs is to advance precision medicine in pregnant persons and lactating persons, and children/adolescents through the development of **novel, generalizable tools, models, and other technologies**.

- Encourages applications proposing:

  - Machine-learning model systems incorporating multi-omic and clinical data

  - In silico models utilizing real-world data

  - Tools and other resources using pharmacoepidemiologic data

  - AI/ML/NLP tools to facilitate data extraction, harmonization, and interoperability

PAR supports applications leveraging EHR, claims, and FDA/CDC data

Big data approaches fOr Safe Therapeutics in Healthy Pregnancies (BOOST-HP)
- PI: Judith Maro
- R01HD110107

Leveraging artificial intelligence methods and electronic health records for pediatric pharmacovigilance
- PI: Cosmin Bejan
- R21HD113234

Maternal COVID-19 Vaccination and Lactation Outcomes
- PI: Kristin Palmer
- R01HD107753

Maternal and Pediatric Precision in Therapeutics (MPRINT) Hub

Uses real-world data resources to characterize, study and address research questions on maternal and pediatric physiology, pharmacology, and clinical outcomes with the ultimate goal of enhancing drug safety and efficacy.

RFA-HD-21-025, RFA-HD-21-026

Maternal and Pediatric Precision in Therapeutics (MPRINT) Hub 2
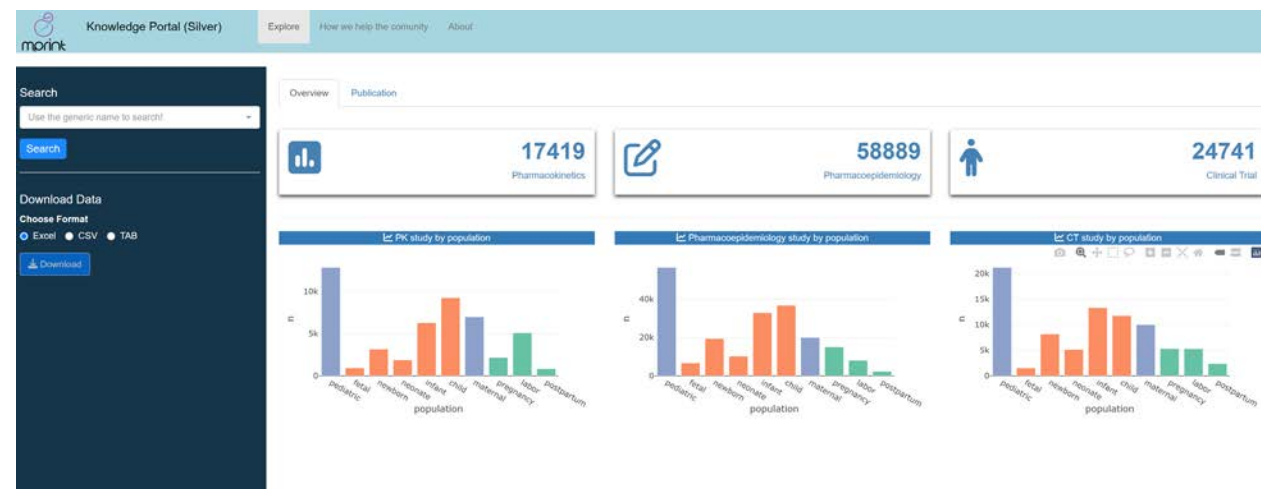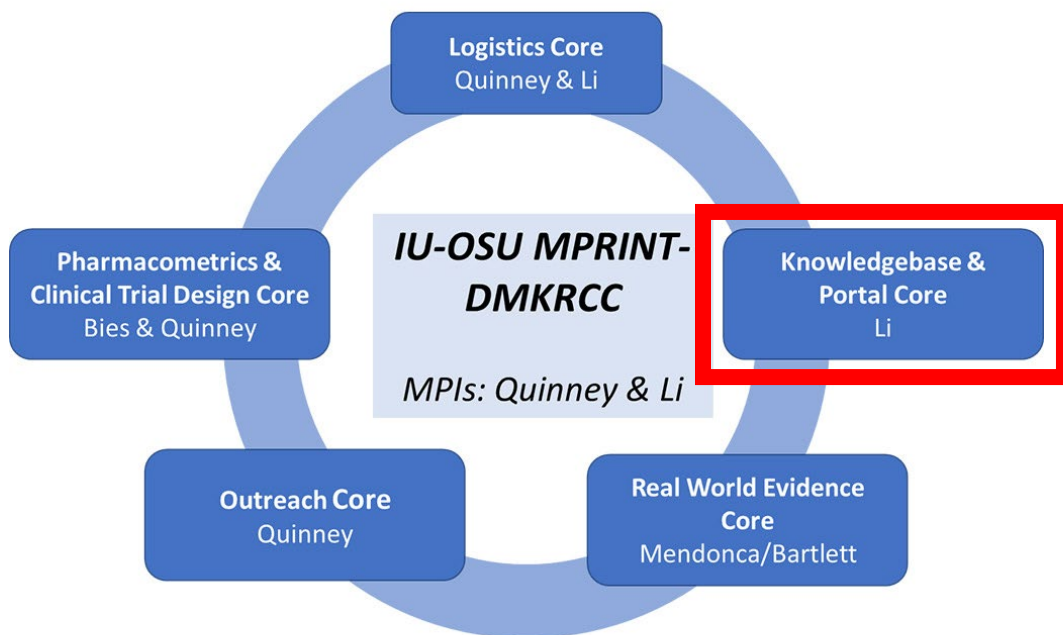
MPRINT Knowledge Portal (Silver)

Developing a knowledgebase of data and resources relating to maternal and pediatric therapeutics, including pharmacokinetics, pharmacodynamics, pharmacogenetics, pediatric ontogeny, and the physiological changes that occur with and around pregnancy and lactation.

RFA-HD-21-025, RFA-HD-21-026

IMPROVE's Maternal Health Research Centers of Excellence

Goal:

- The centers will develop and evaluate innovative approaches to reduce pregnancy-related complications and deaths and promote maternal health equity

Three components:

- Research Centers of Excellence, Implementation Science Hub/Resource Center, Data Innovation and Coordinating Hub

Data Innovation and Coordinating Hub's Goals:

- Provide a coordination infrastructure to foster communication and collaboration for participating Research Centers and the Implementation Science Hub under the Maternal Health Centers of Excellence initiative,

- Support data collection, facilitate data curation, and ensure high-quality data is shared with COE researchers and submitted to public repositories when appropriate (such as NICHD's DASH), and

- Provide cutting edge biomedical research informatics and data science expertise to maximize data comparability and facilitate data harmonization

Trans-NIH Collaborations to Promote the Use of Large Datasets
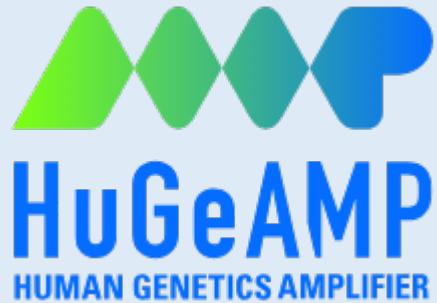
Reproductive System Knowledge Portal

- Software platform and infrastructure that aggregates, integrates, and analyzes human genetic and genomic data.
- Knowledge portals will allow public to identify new targets, biomarkers and development paradigms
- Reproductive system KP recently released to accelerate research on reproductive traits and conditions.
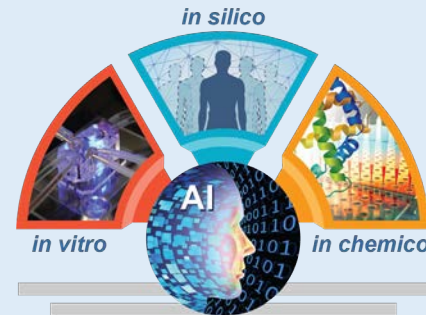
Complement Animal Research in Experimentation (Complement-ARIE)

- NIH is conducting planning activities to inform a potential Common Fund program (Complement-ARIE)
- Goal: catalyze the development, standardization, validation, and use of New Approach Methodologies (NAMs).
- In silico models: Computational models built using RWE and/or complex datasets.

NIH Pediatric Research Consortium (N-PeRC)

- Trans-NIH consortium established in 2018 to improve child health research collaboration.
- Recently voted to establish a subgroup focusing on pediatric and maternal pharmacology.
- Planned areas of focus include leveraging large datasets, repositories, and data science.

Trans-NIH Collaborations to Promote the Use of Large Datasets (2)

Explore Data ⌄   Exp

Site Map

Feedback

Welcome to the Data and Specimen Hub

The NICHD Data and Specimen Hub (DASH) is a centralized resource that allows researchers to share and access de-identified data from studies funded by NICHD. DASH also serves as a portal for requesting biospecimens from selected DASH studies.

| Studies ▼ | Search for studies... | 🔍 | ❓ |

New to DASH?

New users are encouraged to visit our Tutorial

Explore Studies

Find and request studies of interest

Submit Your Data to DASH

Share your data through DASH in alignment with new NIH Policy for Data Management and Sharing

Have Questions?

Browse through the Frequently Asked Questions

13

Goals for promoting the use of large datasets

Expand data access and ecosystem

Identify novel therapeutic targets and biomarkers

Develop tools, algorithms, and software

Inform Learning Health Systems

Improve reproductive health outcomes

Questions?