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N3C Community Forum

April 27, 2026

Today's Forum

- **Leadership Welcome and Overview**
  - Joni Rutter, PhD, Director, National Center for Advancing Translational Sciences (NCATS)
- **Engagement and Governance**
  - Michael Kurilla, MD, PhD, Director, Division of Clinical Innovation, NCATS
  - Rebecca Baker, PhD, Senior Advisor to the Director, NCATS
- **Technical Team Updates**
  - Nathan Hotaling, Ph.D.
  - Luca Calzoni, Ph.D.
  - Technical Leads, N3C, Axle Informatics

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Welcome and Overview

Joni Rutter, Ph.D.
Director, National Center for Advancing Translational Sciences (NCATS)

NCATS and N3C are fully funded for FY2026

- At time of January N3C Community Forum, NIH facing another shutdown
- NCATS received a slight increase in 2026, $942,323,000
    - Most NIH Flat
- $4 million increase to National Clinical Cohort Collaborative (N3C)
- Additional economies of scale expected through collaboration with other parts of HHS and NIH

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STATEMENT Friday, August 15, 2025

Advancing NIH's Mission Through a Unified Strategy

Real-World Data Platform:

NIH is establishing a robust and secure national infrastructure to integrate and link data from various real-world sources consistent with a deep respect for individual privacy rights. This new Real-World Data Platform will provide advanced computational analysis resources for investigators across numerous research areas, including neurodevelopmental disorders and chronic diseases.

N3C and DataCOUNTS are the bones of the RWDP

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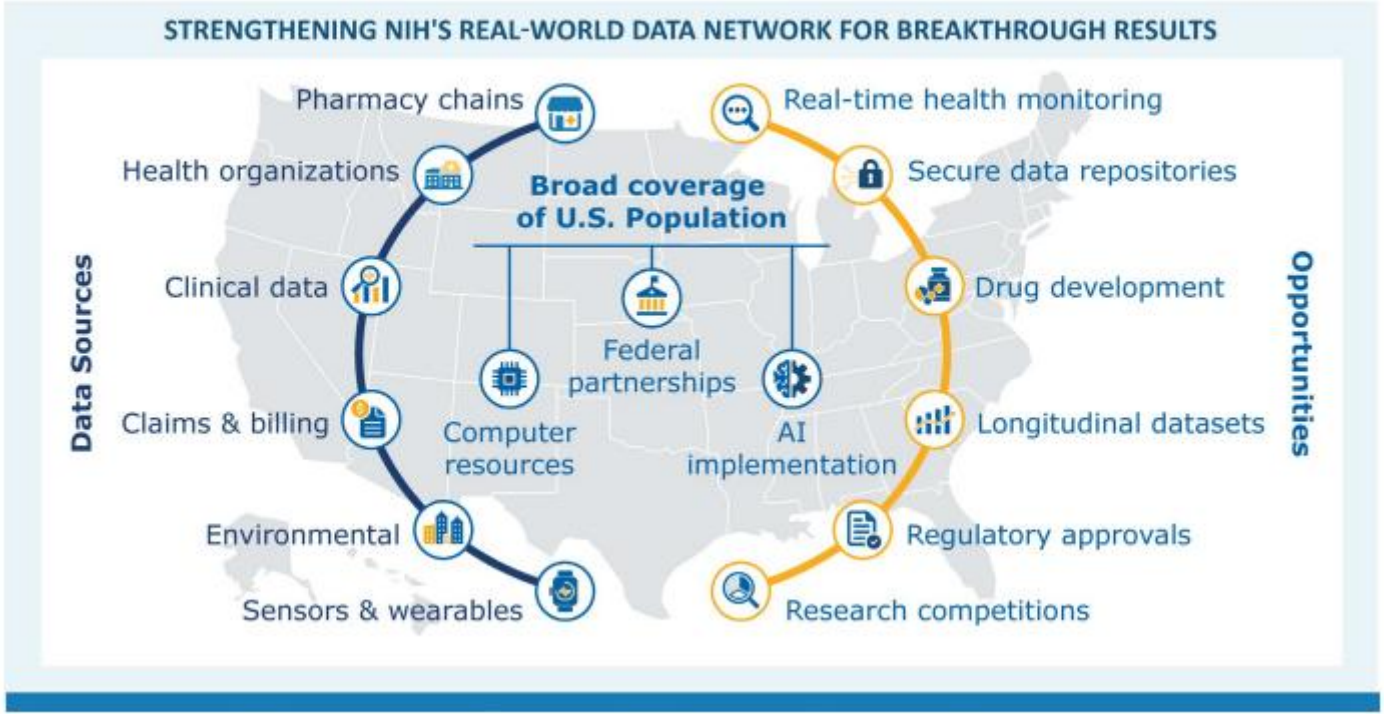
HHS 2027 Budget Priorities $60M

Leveraging Real-World Data to Deliver Actionable Insights



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Where Are We Today?

Reopening

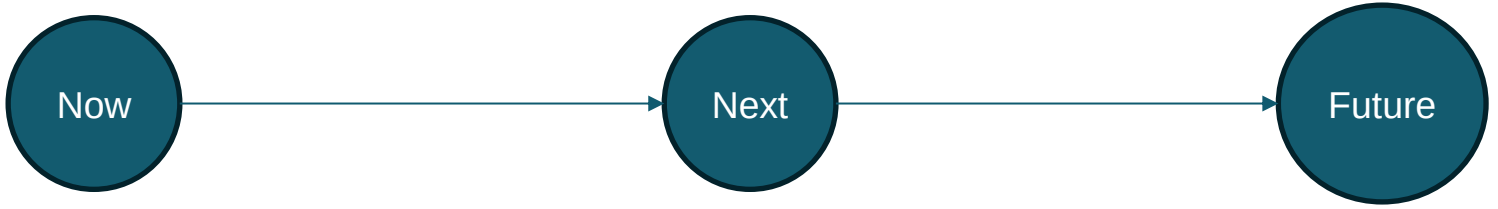
- Access to the COVID Enclave data restored
- Analytic tools available for continued research
- Stood up the Strategic Partners Committee (March)

Transitional Phase

- Bridging to the Next Phase
- All clinical data
- Governance and review processes evolve
- Architectural decoupling
  - future proof of the environment and reliance on one contractors/vendors

Looking Ahead

- Dynamic Workspaces
- Piloting data sharing models
- Scalable infrastructure to support broader research
- NOTE: Planned/ scheduled maintenance May 22-26



Who is who “in” N3C?

- **NCATS**
  - Joni Rutter (Oversight)
  - Mike Kurilla (Program Lead & System Owner)
  - Andy Kelly (Point Person for all things N3C)
  - Rebecca Baker (Engagement Lead)
  - Chris Dillon (DTA/DUA/DAR Agreements)
- **Governance**
  - SPC – Data contributors
  - DAC – Federal staff from NIH (will add others from CMS)
  - Community Forum – Open
  - Publications Committee
  - Download Committee
  - Additional governance being considered
- **Contractors**
  - Palantir – 4 contractors to provide cloud infrastructure (Foundry) and software
  - Axle Leads – Nathan, **Luca**, Kristen, and Amit
    - Aubry (education), Brittany (Orbit), Breezy (PM)
    - 3 total people at Axle oversee raw data storage space (Kristen, Amit, and Madhukar) for security infrastructure (ATO)—no access to raw data files
    - Data Engineering – 5 people (led by Kristen) for automated pipeline development and holding the “N3C office hours” – COME MEET THEM!

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Engagement and Governance

Michael Kurilla, M.D., Ph.D.
Director, Division of Clinical Innovation, NCATS

Rebecca Baker, Ph.D.
Senior Advisor to the Director, NCATS

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The Challenge – and Opportunity

No single institution has enough data

- **Complex diseases**
- **Rare conditions**
- **Health disparities**
- **Evidence for regulatory processes…**

All require longitudinal data across millions of patients, scale no single system can provide

N3C is the answer – if institutions contribute

- **1 of 1**
  No comparable NIH platform combines this clinical depth with open researcher access
- **~1 month**
  vs. 12+ months to conduct the same study through traditional data partnerships
- **$0** **Cost to approved researchers—unlike commercial health data vendors**

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N3C Engagement Goals

- Establish trust for the expanded N3C platform through transparent governance and communication
- Drive adoption across research communities
- Demonstrate value through showcasing platform capabilities, efficiencies, and research outcomes
- Build sustainable community of researchers, institutions, and community partners committed to collaborative science

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N3C Strategic Partners Committee

- 20 thoughtful, experienced voices to help guide N3C
- Representing data contributor and user communities, federal and community partners to come
- Create transparent forum for information exchange
- Shaping the future direction of N3C across a broad range of health and disease domains

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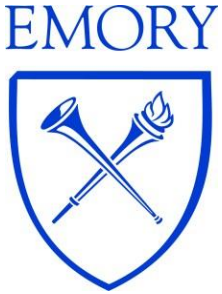
Strategic Partners Committee: Activities

- Facilitating partnerships by connecting N3C leadership with potential data contributors and research collaborators;
- Providing feedback and insights from the N3C community, including researcher needs, platform usability;
- Identifying scientific priorities, emerging opportunities, and barriers to adoption;
- Providing testimonials, educate colleagues around the new N3C model;
- Helping N3C goals align with organizational goals.

Strategic Partner Organizations



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Strategic Partners: Potential Areas of Focus

1. Data Contributor Engagement: strategies for institutional buy-in, addressing legal/privacy concerns, peer-to-peer onboarding
2. Researcher Experience: platform usability, documentation, training resources for new users
3. Trust & Transparency: communications approach, addressing community concerns, feedback loops

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Technical Team

Nathan Hotaling, Ph.D.
Luca Calzoni, Ph.D.
Technical Leads, National Clinical Cohort Collaborative (N3C)

Luca Calzoni

Physician & Research Informaticist

N3C Program Lead

Axle Informatics

April 2026

Joining the N3C community

A bit about me — and how I'd like us to work together.

Where I come from

Physician and research informaticist with 15+ years at the intersection of clinical innovation, real-world data, and federal research infrastructure at NIH.

What I bring

Co-led NIH-NIMHD's ScHARe — a cloud-based, AI-powered platform that grew to 2,500+ researchers, with adoption built through community partnership.

How I'd like to work with you

- Listening before announcing.
- Partnering before delivering.
- Earning trust through what we build together.

Looking forward to the conversations ahead.

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Data Governance

Nathan Hotaling, Ph.D.

Technical Lead, National Clinical Cohort Collaborative (N3C)

Co-Governed Data

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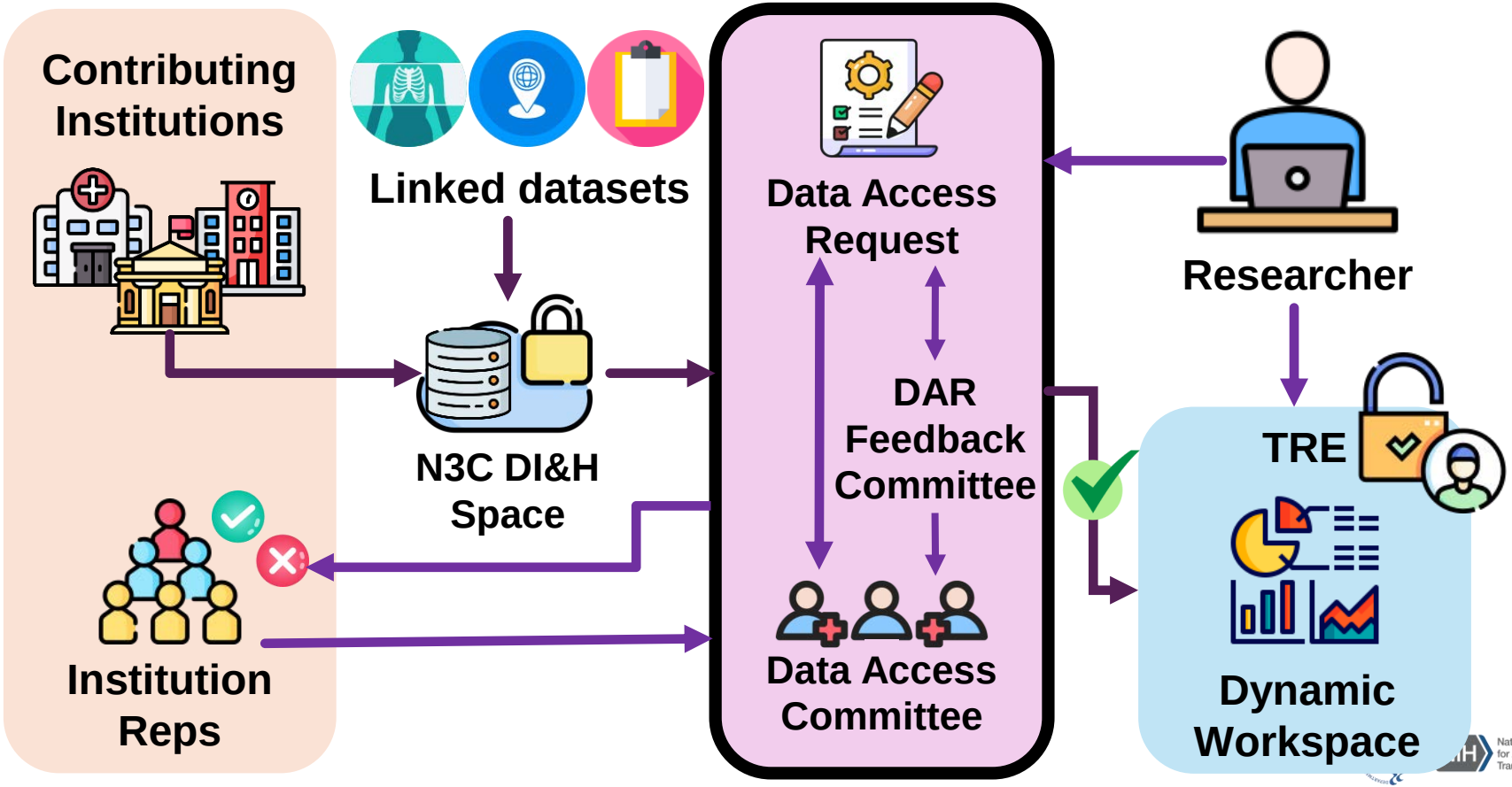

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Trusted Research Environment (TRE)

Old N3C the platform

- Where researchers analyzed data and where raw data was ingested, harmonized, standardized, etc. were the same

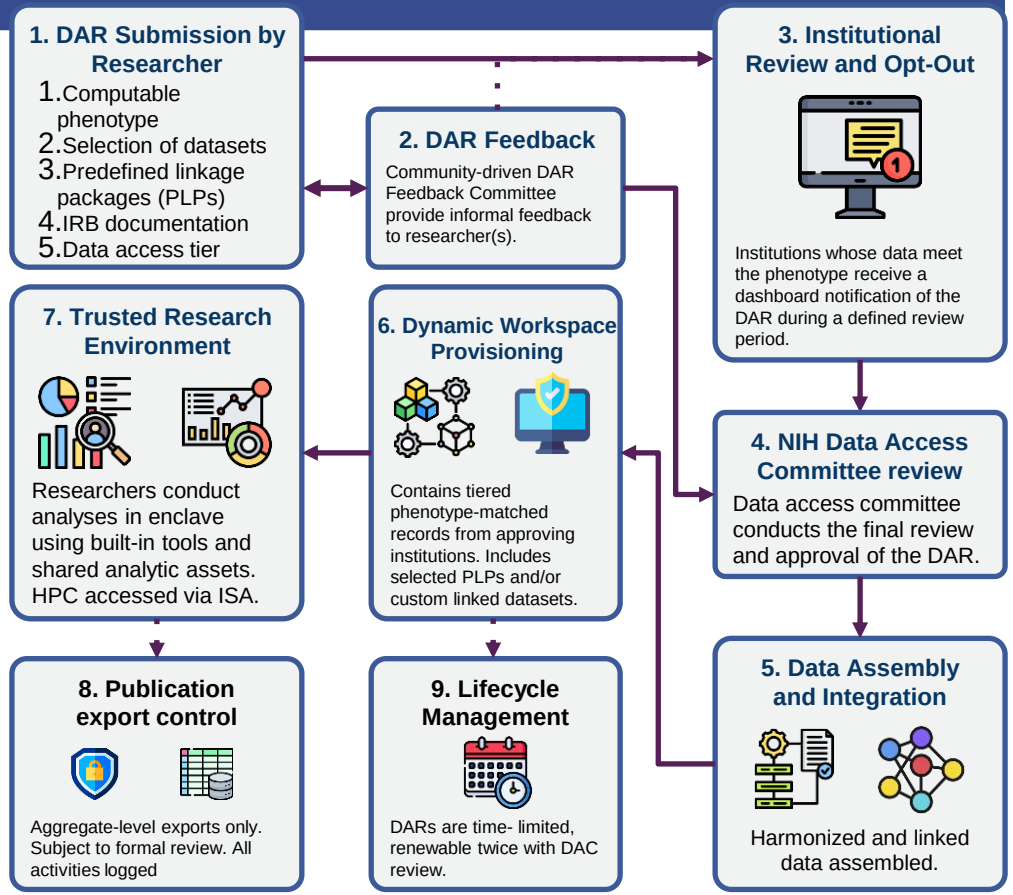
We've heard your concerns

- Isolating the Data Ingestion and Harmonization (DI&H) space from the Trusted Research Environment (TRE) - Palantir Foundry.
- No raw data will be in Foundry only "gold standard" processed Limited and De-identified datasets.

The DI&H Space

- No data ingestion happening today and we are prototyping (with synthetic data) in multiple platforms to see which scale.
- On premise High Performance Compute, Databricks, & Snowflake all being assessed.

Researcher Data Access Lifecycle



1. **DAR Submission**
   Researchers submit a Data Access Request (DAR) with a computable phenotype, IRB documentation, access tier, pre-defined linkage packages (PLPs) and selected datasets.
2. **DAR Feedback**
   Members of the research community forming a DAR Review Committee provider researchers with informal optional feedback on their DAR submission.
3. **Institutional Review**
   Institutions who have selected to review individual DARs review and opt out. Lack of response within 30-days is treated as approval.
4. **NIH DAC Review**
   The Data Access Committee reviews the DAR for IRB, policy alignment, phenotype alignment to study design, data use limitations, linkages, and privacy.
5. **Data Assembly & Integration**
   The platform harmonizes data from institution-pushed payloads.Data payloads are auto-integrated; novel linkages follow DAC approvals
6. **Dynamic Workspace Provisioning**
   A secure workspace is provisioned with approved data, including linked external datasets. Access is restricted to authorized team members.
7. **Trusted Research Environment**
   Data Access and analysis occurs within a FedRAMP-authorized enclave. ISAs enable access to HPC environments for advanced analytics.
8. **Publication Data Export & Oversight**
   Only aggregate results are exportable, following privacy review. All activity is audit-logged for compliance.
9. **Lifecycle Management**
   DARs are time-limited (1 year) and renewable (twice). Phenotypes may be reused across studies. Phenotypes evolve to support common research needs.

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Can N3C Data be accessed without an approved DAR?

Simply put, NO.

- No back door to get access to N3C Data
- All Users, Federal and Non Federal alike, must adhere to the access process:
  - Executed and active Data Use Agreement
  - Meet all policy requirements for access
    - Completed Trainings
    - Necessary IRB approvals/clearance
    - Necessary attestations
    - Level 3 restricted to ONLY US BASED Institutions/Investigators
    - Row level data will NOT leave the N3C Enclave
  - Approved Data Access Request by NIH DAC.

Can N3C Data be accessed without an approved DAR? Continued

- Data is protected by the same Certificates of Confidentiality (CoC) as before.
- Data Transfer agreements, Data Use agreements, Linkage Honest Broker Agreements all protect your data and require the above governance.

Data Access Committee (DAC) Workflow

Data Access Committee Workflow

01

Access Level

Review requested data Access Level to ensure appropriate authorization.

02

IRB Alignment

Conduct Institutional Review Board (IRB) Alignment and Data Linkage Review.

03

Prohibited Activities

Screen for and verify the absence of any Prohibited NIH/HHS Activities.

04

NEW IN 2026

DAR/Phenotype

Screen for Data Access Request (DAR) and Phenotype Alignment.

05

NEW IN 2026

Institutional DUL

Screen for Institutional Data Use Limitation (DUL) Alignment.

06

Final Determination

Complete all assessments and proceed with Finalizing the Determination.

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What Hasn't Changed

Privacy, Security, & Compliance

Minimum Necessary

Data provisioning follows minimum necessary principles. Retains only data needed for analysis, supporting secondary use only with no participant contact.

Enclave Controls

Dynamic workspaces prevent raw data extraction. Individual browsing is restricted, results are reviewed, and staff access is strictly limited.

Representation

The phenotype imposes no demographic exclusions, ensuring the data accurately reflects the source populations at contributing sites.

Procedure Maintenance

Operational decisions, code revisions, and phenotype changes are strictly versioned, logged, and issued as controlled document revisions.

Results Sharing

Approved projects must return results, methods, and code to the community, supporting reproducibility and FAIR-aligned data reuse.

Other Improvements and Updates

DI&H Space Architecture

Isolating the Data Ingestion and Harmonization (DI&H) space from the Trusted Research Environment (TRE).

> This fundamental separation strengthens security by clearly delineating data processing from analysis, ensuring that research activities occur solely within the enclave environment but raw data is kept isolated in the DI&H Space..

Automation-First & Zero-Trust

All standard ingestion, transformation, and harmonization processes run through controlled pipelines. Human access is strictly limited to authorized operational roles.

Operational DARs Only

Access requires an approved Operational Data Access Request (DAR). Users are authorized solely for platform functions, with zero permission for research or exploration.

Community Transparency

All Operational DARs are discoverable. Any authenticated user can now view approved personnel, their roles, and affiliated organizations to ensure full visibility.

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Questions?

Mike Kurilla, M.D., Ph.D.
Director, Division of Clinical Innovation, NCATS