National
Clinical
Cohort
Collaborative

N3C Community Forum

January 26, 2026

Joni Rutter, Ph.D.

Director, National Center for Advancing Translational Sciences (NCATS)

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N3C 2025-2026 Notable Moments

- Late January 2025 - Communications Moratorium
- February 14 2025 – Communications staff (among others) RIF'd
- May 2025 - Communications moratorium lifted and centralized
- June 2nd 2025 - N3C Community Forum
- September 27th 2025 - N3C platform goes offline
- October 1st 2025 - Government shutdown
- October 22nd 2025 – Special Allowance to Update CTSA SC
- November 12th 2025 - Shutdown ends
- December 1st to 12th 2025 - N3C platform re-opens temporarily
- December 10th 2025 - HHS Provides path forward for N3C platform
- January 12th 2026 - N3C platform online for rebuild
- Late February 2026 - N3C platform will open to public

Strategic Context for N3C Disruption: HHS Consolidation

- **HHS Initiative:** The sudden and unexpected shutdown was driven by a broader HHS mandate to consolidate platforms, rather than any performance issues with N3C.
- **Early Impact:** N3C and NCATS were among the first programs impacted by this consolidation directive.
- **Timeline TBD:** The timeline for the availability of the new consolidated platform was not initially clear.
- **Leadership Action:** Worked closely with NIH leadership Jay Bhattacharya, HHS CIO -Clark Minor, and HHS Deputy Chief of Staff –Jake Levene to resolve this transition as quickly as possible.

NCATS team worked non-stop through the federal Government shutdown to protect N3C data and property.

Securely backed-up 80TB of harmonized health data to the N3C Enclave amidst HHS platform consolidation

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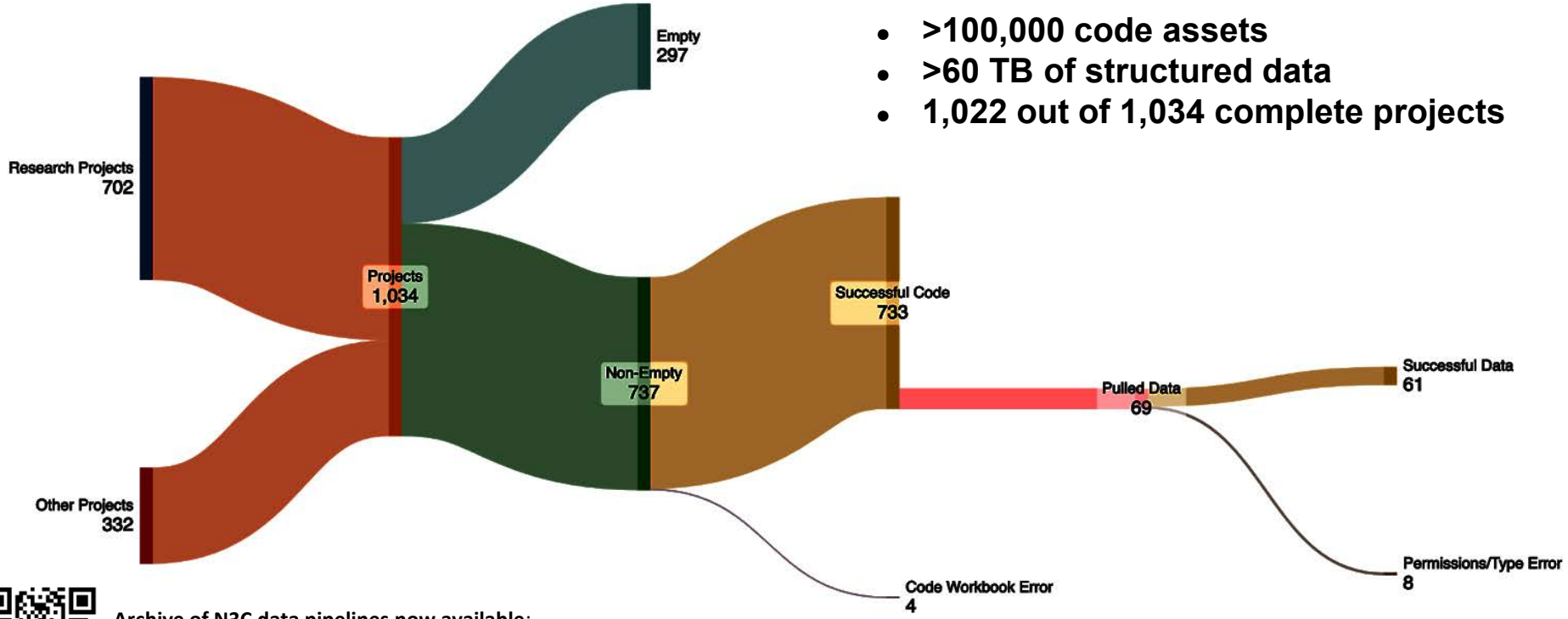
N3C Data and Code Backup

- >100,000 code assets
- >60 TB of structured data
- 1,022 out of 1,034 complete projects



Archive of N3C data pipelines now available: https://github.com/National-Clinical-Cohort-Collaborative/n3c-pipelines-archive

Used the Time to Plan for the Future

Access Dashboard

A searchable, web-based dashboard has been developed to enable stakeholders to review and programmatically access the backed-up assets efficiently.

Communication

We created comprehensive back-up reports and training materials to guide users through the transition timelines and new access procedures.

N3C Technical Mtg
Jan. 21-22

Future Platform

All cleaned & harmonized data are safely housed in the same place as all raw data. All Data is organized and ready to be rebuilt.

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N3C: Five Years of Radical Collaboration

We owe our progress to the hundreds of individuals across the country whose collaborative spirit and hard work made N3C a reality

Abhishek Bhatia, Adam B. Wilcox, Adam M. Lee, Alexandra Dest, Alexis Graves, Alfons von Rosty-Forgách, Alfred (Jerrod) Anzalone, Amin Manna, Amit Saha, Amy Olex, Andrea Volz, Andrea Zhou, Andrew Barros, Andrew E. Williams, Andrew J. Neumann, Andrew Laitman, Andrew M. Southerland, Andrew T. Girvin, Anh Nguyen, Anita Walden, Anitej Biradar, Anjali Sharathkumar, Anna O'Malley, Bengt Ljungquist, Benjamin Amor, Benjamin Bates, Benjamin Zook, Brian Hendricks, Briana Abraham, Brijesh Patel, Bruno Rahle, Bryan Laraway, Carolyn T. Bramante, Cavin Ward-Caviness, Charisse Madlock-Brown, Chris Roeder, Christopher Dillon, Christopher G. Chute, Clair Blacketer, Claire Draeger, Clare Schmitt, Cliff Takemoto, Connor Cook, Dan Housman, Daniel Yeomans, Danny Puller, Dave Eichman, Davera Gabriel, Diego Mazzotti, Donald E. Brown, Eilis Boudreau, Elaine L. Hill, Emily Carlson Marti, Emily Clark, Emily Niehaus, Emily R. Pfaff, Evan French, Farrukh M. Koraishy, Federico Mariona, Fred Prior, G. Caleb Alexander, Gary Clark, George Sokos, Gianna Beck, Greg Martin, Guillaume Soulé, Hadrien Maupard, Harish Ramadas, Harold P. Lehmann, Heidi Spratt, Hemalkumar B. Mehta, Hongfang Liu, Hythem Sidky, Hyun Woo Kim, J.W. Awori Hayanga, James Cavallon, James Evans, Jami Pincavitch, Janos Hajagos, Jasvinder A. Singh, Jaylyn Clark, Jeremy Richard Harper, Jessica Yasmine Islam, Jin Ge, Joel Gagnier, Joel H. Saltz, Johanna Loomba, John B. Buse, Jomol Mathew, Joni L. Rutter, Joseph Kane, Julie A. McMurry, Justin Guinney, Kanchan Chaudhari, Karen Crowley, Kate Sanders, Katie Rebecca Bradwell, Kellie M. Walters, Kelly Jones, Ken Wilkins, Kenrick Cato, Kimberly Murray, Kristen Hansen, Kristin Kostka, Lavance Northington, Lee Pyles, Leonie Misquitta, Lesley Cottrell, Lili M. Portilla, Lisa Eskenazi, Liz Zampino, Margaret Hall, Mariam Deacy, Mark Bissell, Mark M. Bissell, Marshall Clark, Mary Emmett, Mary Morrison Saltz, Matthew Owens, Matthew Pagel, Matthew Steele, Matvey B. Palchuk, Maya Choudhury, Melissa A. Haendel, Meng-Hao Li, Mengshuo Ye, Meredith Adams, Meredith Temple-O'Connor, Michael G. Kurilla, Michele Morris, Mika Jugovich, Muhammad Emir Amaro Syailendra, Nabeel Qureshi, Nasia Safdar, Nathan Turlington, Nick Schaub, Nicole Garbarini, Nirup Menon, Noha Sharafeldin, Ofer Sadan, Patricia A. Francis, Penny Wung Burgoon, Peter Leese, Peter N. Robinson, Philip Sparks, Poorna Bharanikumar, Pradeep Bandaru, Racquel R. Dietz, Rafael Fuentes, Ran Dai, Randeep Jawa, Rebecca Erwin-Cohen, Rena C. Patel, Rhea Bhakhri, Richard A. Moffitt, Richard L. Zhu, Rish Jain, Rishikesan Kamaleswaran, Robert Hurley, Robert T. Miller, Saad Ljazouli, Sai Mada, Saiju Pyarajan, Sam G. Michael, Samuel Bozzette, Sandeep K. Mallipattu, Scott Chapman, Shawn T. O'Neil, Shijia Zhang, Sigfried Gold, Sofia Dard, Soko Setoguchi, Sruthi Magesh, Stephanie S. Hong, Steve Makkar, Steven G. Johnson, Taylor DuPree, Tellen D. Bennett, Thomas Dillon, Thomas Shouler, Tiffany J. Callahan, Tim Schwab, Timothy Bergquist, Umit Topaloglu, Usman Sheikh, Valery Gordon, Victor Garcia, Vignesh Subbian, Wenndy Hernandez, Will Beasley, Will Cooper, William Hillegass, Xiaohan Tanner Zhang, Yi-Ju Chen, Yooree Chae, Yun Jae Yoo, Yurii Mashtalir

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Hythem Sidky, Ph.D.

Technical Lead, National Clinical Cohort Collaborative (N3C)

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N3C: Technical Risk Mitigation

From Monolithic Dependency to a Resilient Ecosystem of Applications

De-Coupled Architecture

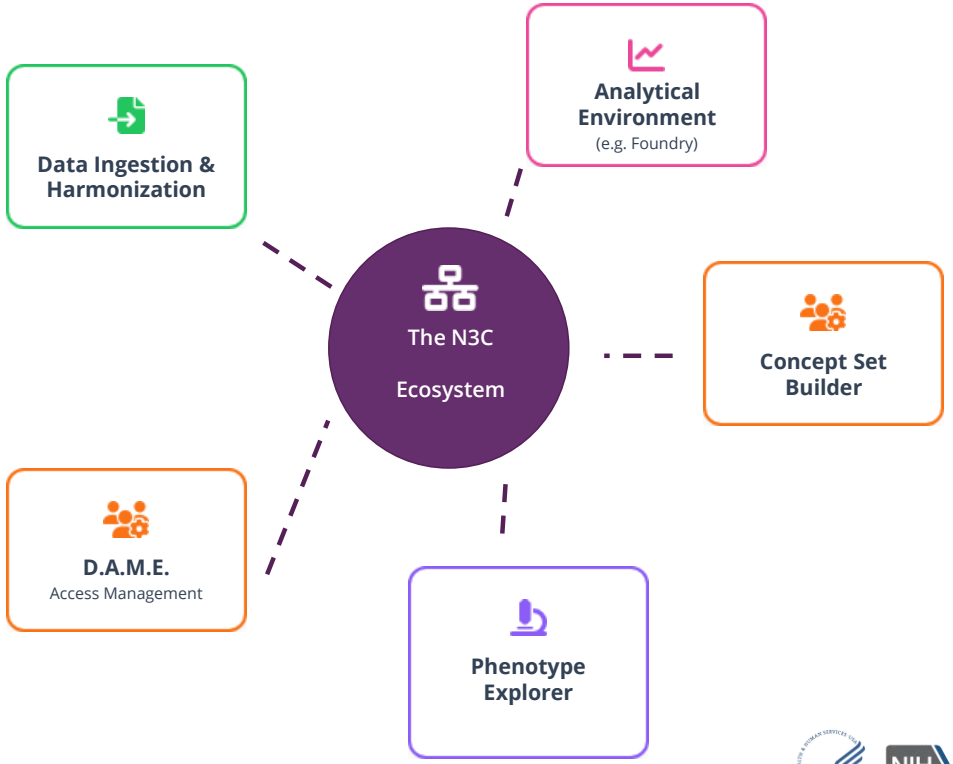
Separating critical functions (Ingestion, Analysis, Phenotyping, etc...) into independent applications eliminates single points of failure.

Platform Agnostic

Each component is portable. We will no longer be locked into a single infrastructure provider. This ensures maximum continuity even in the face of massive disruption.

Foundry as an analytical environment

The analytic environment (Foundry) is now downstream. It is simply where the code runs, not where everything lives.



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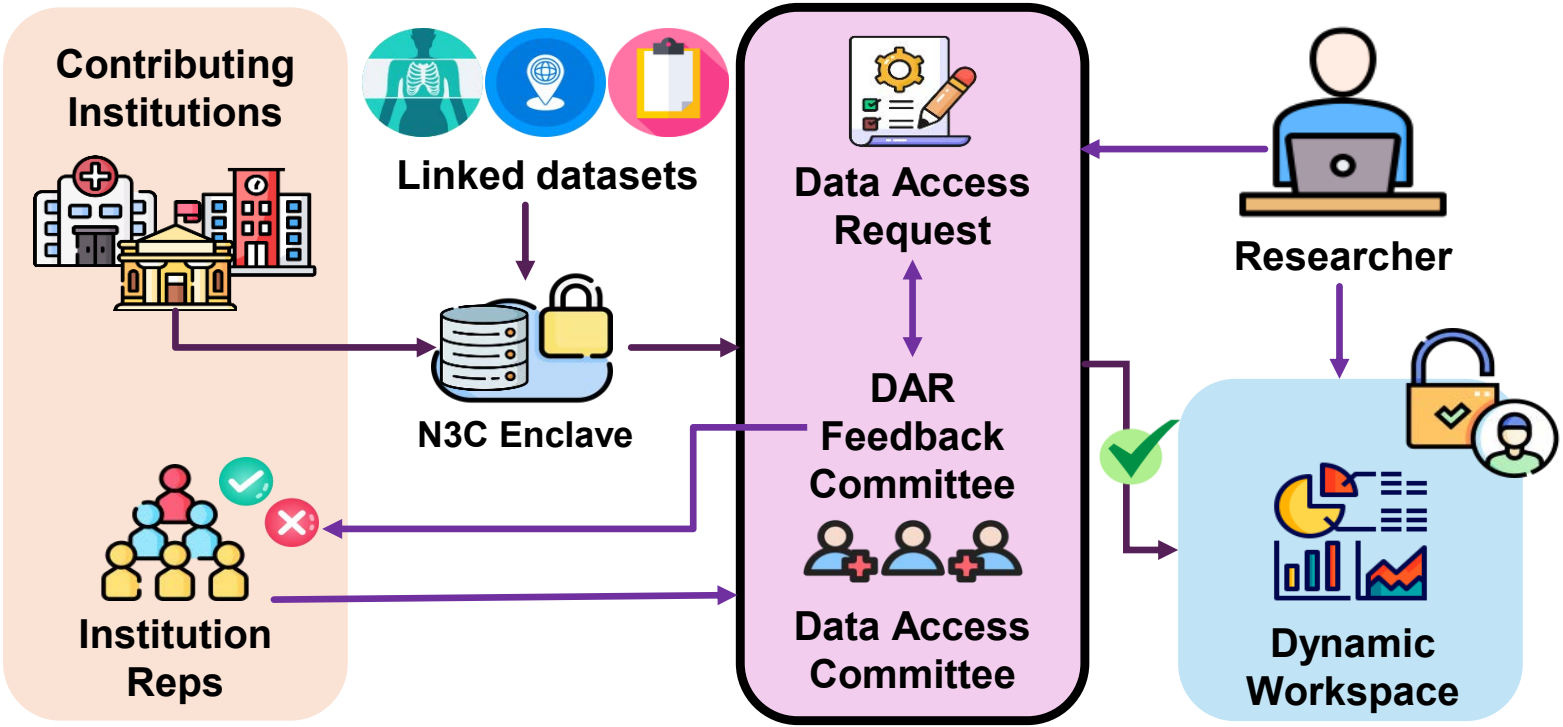
N3C: Dynamic Workspaces



Researcher Data Access Lifecycle

1. DAR Submission by Researcher

1. Computable phenotype
2. Selection of datasets
3. IRB documentation
4. Data access tier

2. DAR Feedback

Community-driven DAR Feedback Committee provide informal feedback to researcher(s).

3. Institutional Review and Opt-Out

Institutions whose data meet the phenotype receive a dashboard notification of the DAR during a defined review period.

4. NIH Data Access Committee review

Data access committee conducts the final review and approval of the DAR.

5. Data Assembly and Integration

Harmonized and linked data assembled.

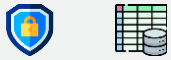
6. Dynamic Workspace Provisioning

Contains tiered phenotype-matched records from approving institutions. Includes selected PLPs and/or custom linked datasets.

7. Research and Analysis

Researchers conduct analyses in enclave using built-in tools and shared analytic assets. HPC accessed via ISA.

8. Publication export control



Aggregate-level exports only. Subject to formal review. All activities logged

9. Lifecycle Management

DARs are time- limited, renewable twice with DAC review.

1. **DAR Submission**
   Researchers submit a Data Access Request (DUR) with a computable phenotype, IRB documentation, access tier, and selected datasets.
2. **DAR Feedback**
   Members of the research community forming a DAR Review Committee provider researchers with informal feedback on their DAR submission.
3. **Institutional Review**
   Institutions whose data match the phenotype can review and opt out. Lack of response within a prespecified number of days is treated as approval.
4. **NIH DAC Review**
   The Data Access Committee reviews the DAR for probability of technical success, policy alignment, and privacy.
5. **Data Assembly & Integration**
   The platform harmonizes data from institution-pushed payloads. Linked datasets are auto-integrated; novel linkages follow expert review.
6. **Dynamic Workspace Provisioning**
   A secure workspace is provisioned with approved data, including linked external datasets. Access is restricted to authorized team members.
7. **Secure Research & HPC Access**
   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**
   DURs are time-limited (1 year) and renewable (twice). Phenotypes may be reused across studies. PLPs evolve to support common research needs.

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Kristen Hansen, Ph.D.

Lead, Data and Geospatial Engineering

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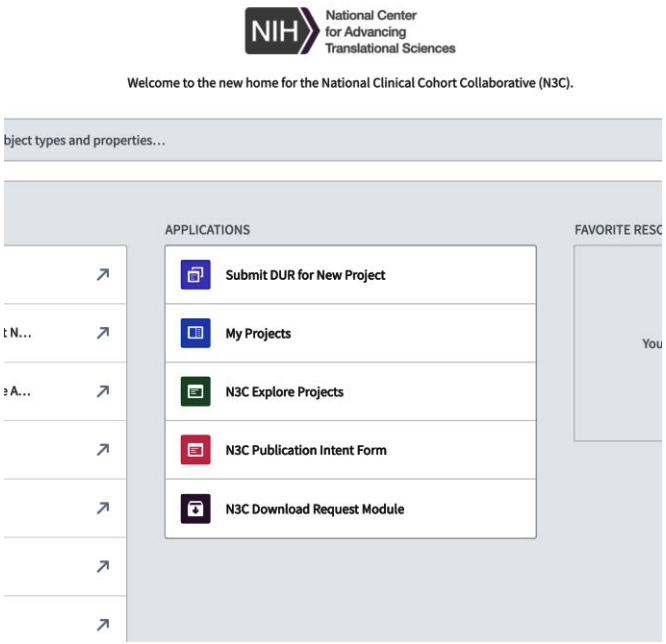
New UI and Changes to Processes



- You will still be registered
- New investigators will not be able to register (for now)
- Login will work the same
- What will look different?
  - Concept set builder will not currently available
  - Code workbooks are no longer available (more later)
  - Projects are available to join as placeholder
- What is in progress?

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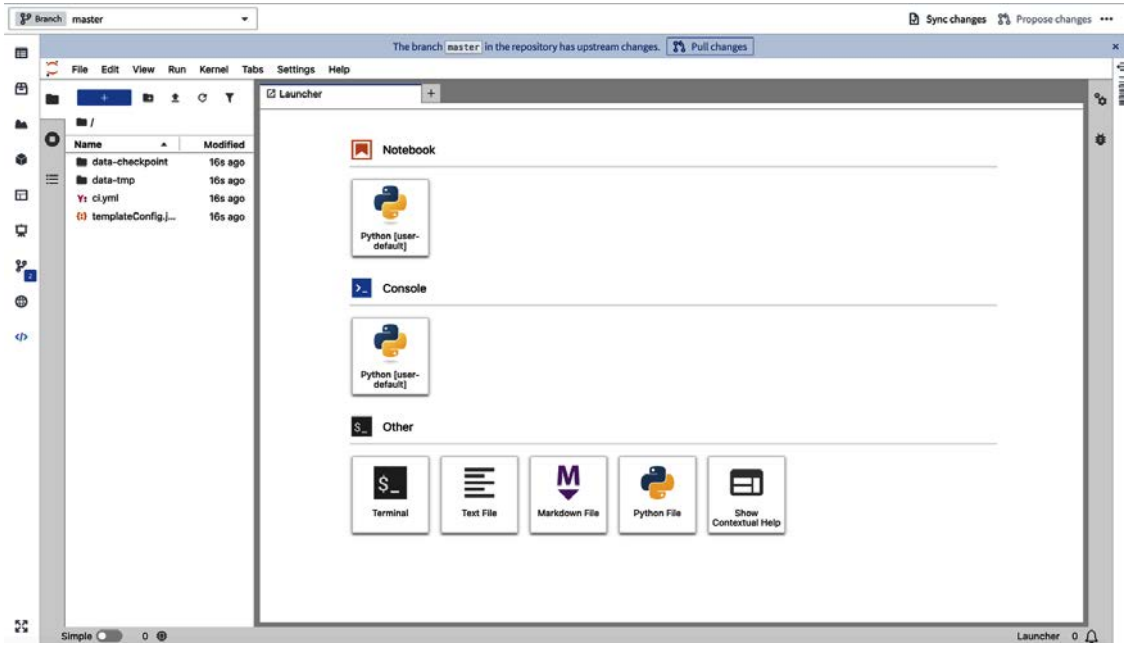
Workbooks are not available - what to do?



We are working on solutions to allow users to bring their workbook code back through jupyter notebooks

- Logic Liaisons templates will not be present. Working on replacement.
- Producing help documents currently

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What did we lose in the new platform?

- Historical Download Request and Publication Intent data
- Research project contents
- The data pipelines
- All but 2 releases of both the de-identified and LDS data releases - lost > 190
- Concept Set Builder
- No Code workbooks
- Logic Liaison Templates - due to loss of code workbooks

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Legacy Data/ Processes

- Publication intent process will be available.
- Download Request submission will be available
- Existing Registered users can submit new Data Use Requests
- Pre-DTA expiration data release will be available to the same investigators. Latest release will also be available.
- No longer receiving COVID submissions.

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Chris Dillon

Team Lead, Office of Strategic Alliances, NCATS

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New Agreements with transparency

- Revised but contain core T/Cs from original agreements
- Auto renew: no extensions needed
- D.A.M.E. (Data Access Management Environment) system to assist in the workflow and transparency
- Flexibility implemented to allow for the graduation out of Pilot phase

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Governance Pilot – How will your data be used?

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Control Level	Institutional Trust	Categorical Restrictions	Project-Specific granularity
Institutional Effort	Minimal (set once)	Low (Periodic Updates)	Active (preset review cycles)
Governance	N3C DAC	N3C DAC + Preset Limitations	N3C DAC + Contributor Review

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NIH CADR Transition

Binding Official – This individual has the legal authority to bind the institution to the terms and conditions of the agreement.

Institutional Signing Official – This role is for approving Data Access Requests (DAR) and is typically someone who oversees grant actions e.g. Sponsored Research Officer

Data Access Requestor – Is a permanent employee equivalent to but not limited to a tenure/tenure track or senior level researcher. This role will have oversight and accountability for the Users and how they use the data

Approved User – Anyone approved by the NIH DAC to access data within a DAR and perform research consistent with the approved DAR

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Rebecca Baker, Ph.D.

Senior Advisor to the NCATS Director

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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

- 8–15 thoughtful, experienced voices to help guide N3C
- Data contributors and users, future federal and community partners
- Transparent forum for information exchange
- Shaping the future direction of N3C across a broad range of disease domains

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N3C Strategic Partners Committee Continued

- Ongoing, frequent communication about platform status, evolution
- Resources for data contributors and users to maximize value
- Collaborations with technical and scientific partners
- Storytelling to build sense of shared mission
- Email us: ncats_n3c@nih.gov

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Questions?

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