

NCATS

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CTSA Program Steering Committee

March 27, 2023

2:30 – 3:30 ET

CTSA Clinical & Translational
Science Awards Program



NIH National Center
for Advancing
Translational Sciences

Agenda March 27, 2023

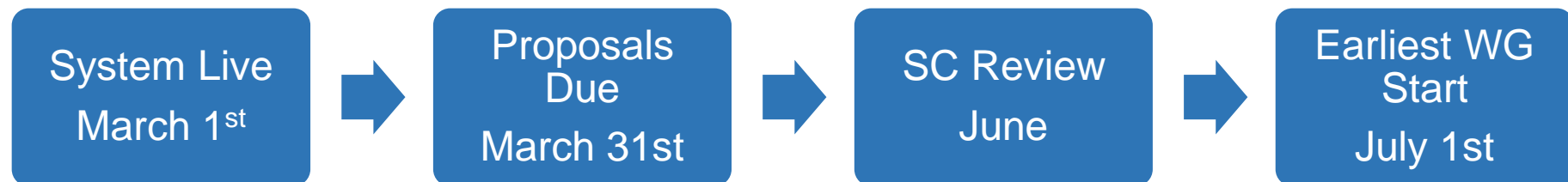
Time	Topic	Speaker(s)
2:30 – 2:35	Welcome *WG Cycle 10 reminder	Michael Kurilla & Duane Mitchell
2:35 – 3:00	NIH Data Management and Sharing Policy: Considerations for CTSAs	Josh Fessel
3:00 – 3:30	Considering NCATS supported data platforms: What do the hubs need?	Karen Johnston Steven Reis Melissa Haendel



Solicitation of CTSA Working Group Proposals

The CTSA Program Steering Committee encourages the consortium to create Working Group proposals that align with the following areas:

- Learning health and research systems
- Best practices for navigating the Science of Translation
- Causes of rising midlife mortality in America (Case & Deaton, PNAS, 2015)
- Climate change and health
- National training curricula in CTS
- Diversity, equity, inclusion, and accessibility
- Enhancing the impact of clinical trials



Submission Page: <https://clic-ctsa.org/groups/working-groups-proposal-information>



National Center
for Advancing
Translational Sciences

NIH Data Management and Sharing Policy: Considerations for CTSAs

Josh Fessel, MD, PhD

Senior Clinical Advisor, Division of Clinical Innovation

Brief Outline

- Overview of new NIH DMSP
- Specific points for consideration
- Unique aspects of CTSA Hub award applications
- Current thinking



Please Keep in Mind...

- We're all learning together
- Practices are likely to evolve over time
- Patience will get all of us very far
- We will all live our way to the goals

We will help one another!



NIH Data Management and Sharing Policy

- Policy: NOT-OD-21-013
 - <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-013.html>
 - 5 Supplemental Info Notices as of March 19, 2023, linked in the parent Notice
- Website: <https://sharing.nih.gov/data-management-and-sharing-policy>
- Applies to applications submitted on or after January 25, 2023 including:
 - Competing grant applications that are submitted to NIH for the January 25, 2023 and subsequent receipt dates;
 - Proposals for contracts that are submitted to NIH on or after January 25, 2023;
 - NIH Intramural Research Projects conducted on or after January 25, 2023; and
 - Other funding agreements (e.g., Other Transactions) that are executed on or after January 25, 2023, unless otherwise stipulated by NIH.
- Does NOT apply to all Activity Codes
 - List can be found at: <https://sharing.nih.gov/sites/default/files/flmngr/List-of-Activity-Codes-Applicable-to-DMS-Policy.pdf>
- Does NOT apply to competing applications submitted before Jan 2023

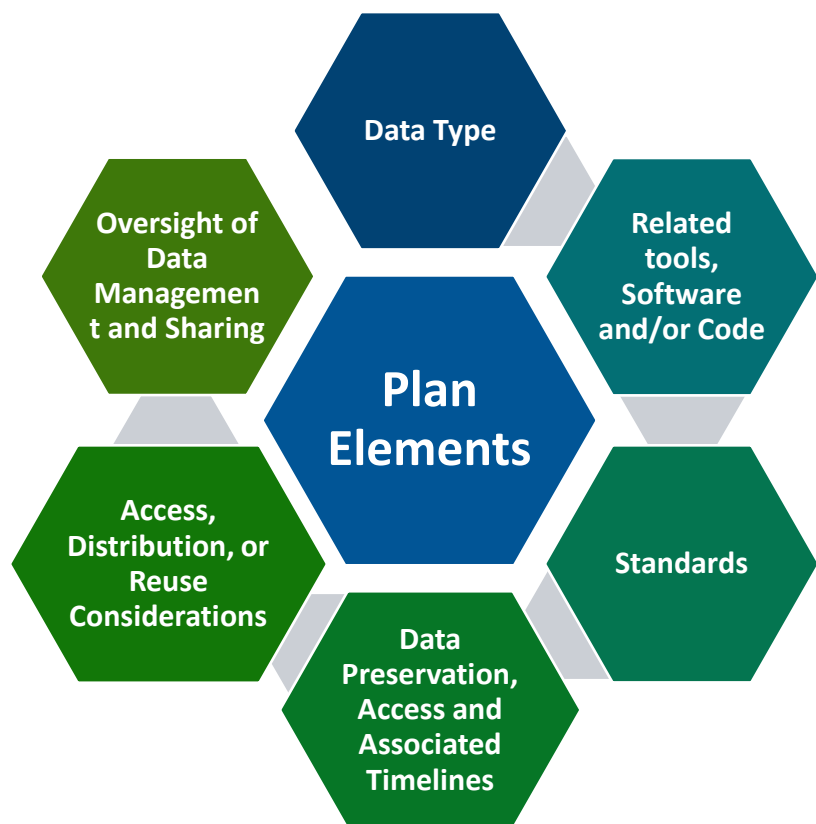


NIH Data Management and Sharing Policy

- The policy requires:
 - A **plan** for the management and sharing of scientific data generated with the support of the award
 - **Adherence** to the version of the plan assessed as acceptable by NIH staff and incorporated into the Terms and Conditions of award
 - Periodic **reporting** on/updating of activities described in the plan (typically linked to RPPR)
- Not all data must be shared, but all data must be managed
- “Scientific data” is a defined term for the purposes of the policy
 - “[D]ata commonly accepted in the scientific community as of sufficient quality to validate and replicate research findings, regardless of whether the data are used to support scholarly publications... **includes** any data needed to validate and replicate research findings... **does not include** laboratory notebooks, preliminary analyses, completed case report forms, drafts of scientific papers, plans for future research, peer reviews, communications with colleagues, or physical objects such as laboratory specimens.”
- Sharing of data is expected at the time of publication or at the end of the award, whichever is sooner
 - Currently in the NIH-wide policy, timing of sharing is not linked to preprints or other interim products of research



Elements of a DMS Plan



- **Data type**
 - Identifying data to be preserved and shared
- **Related tools, software, code**
 - Tools and software needed to access and manipulate data
- **Standards**
 - Standards to be applied to scientific data and metadata
- **Data preservation, access, timelines**
 - Repository to be used, persistent unique identifier, and when/ how long data will be available
- **Access, distribution, reuse considerations**
 - Description of factors for data access, distribution, or reuse
- **Oversight of data management and sharing**
 - Plan compliance will be monitored/ managed and by whom

See [Writing a Data Management & Sharing Plan](#) for details

DMS Plan Submission

- A new “**Other Plan(s)**” field added to the PHS 398 form to collect a single PDF attachment
- Data Sharing Plans and Genomic Data Sharing Plans will no longer be submitted to the “Resource Sharing Plan(s)” field

Research Plan Section			
5. Vertebrate Animals	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/> <input type="button" value="View Attachment"/>
6. Select Agent Research	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/> <input type="button" value="View Attachment"/>
7. Multiple PD/PI Leadership Plan	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/> <input type="button" value="View Attachment"/>
8. Consortium/Contractual Arrangements	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/> <input type="button" value="View Attachment"/>
9. Letters of Support	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/> <input type="button" value="View Attachment"/>
10. Resource Sharing Plan(s)	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/> <input type="button" value="View Attachment"/>
11. Other Plan(s)	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/> <input type="button" value="View Attachment"/>
12. Authentication of Key Biological and/or Chemical Resources	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/> <input type="button" value="View Attachment"/>

Submitting DMS Budgets

Direct costs to support the activities proposed in DMS Plan must be indicated as “**Data Management and Sharing Costs**”

- **R&R Budget Form:** line item in section F. Other Direct Costs

F. Other Direct Costs		Funds Requested (\$)
1.	Materials and Supplies	
2.	Publication Costs	
3.	Consultant Services	
4.	ADP/Computer Services	
5.	Subawards/Consortium/Contractual Costs	
6.	Equipment or Facility Rental/User Fees	
7.	Alterations and Renovations	
8.	Data Management and Sharing Costs	
9.		
10.		

- **PHS 398 Modular Budget Form:** within Additional Narrative Justification

2. Budget Justifications			
Personnel Justification		Add Attachment	Delete Attachment View Attachment
Consortium Justification		Add Attachment	Delete Attachment View Attachment
Additional Narrative Justification		Add Attachment	Delete Attachment View Attachment

Submitting DMS Budgets

Direct costs to support the activities proposed in DMS Plan must be indicated as “**Data Management and Sharing Costs**”

Please please **PLEASE** review the guidance on budgeting for data management and sharing! Guidance can be found at this link:

<https://sharing.nih.gov/data-management-and-sharing-policy/planning-and-budgeting-for-data-management-and-sharing/budgeting-for-data-management-sharing>

Personnel Justification	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/>	<input type="button" value="View Attachment"/>
Consortium Justification	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/>	<input type="button" value="View Attachment"/>
Additional Narrative Justification	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/>	<input type="button" value="View Attachment"/>

Justifying DMS Budgets

Brief summary of DMS Plan and description of DMS costs must be **included within the budget justification attachment**

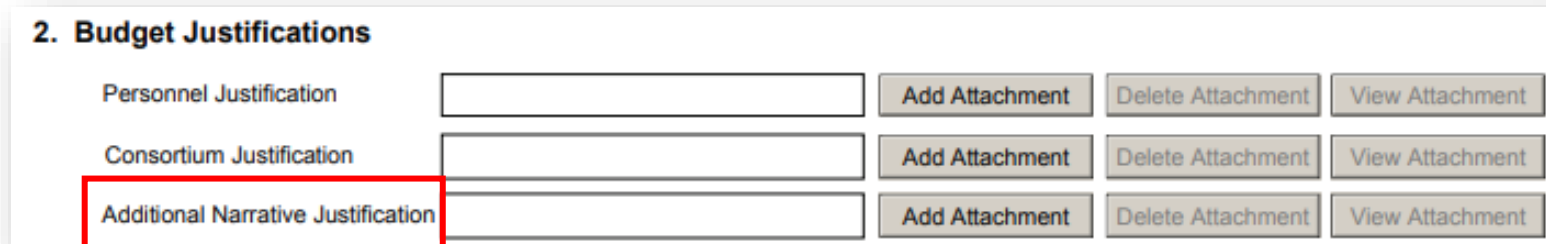
- **R&R Budget Form:** section L. Budget Justification



L. Budget Justification

(Only attach one file.)

- **PHS 398 Modular Budget Form:** Additional Narrative Justification



2. Budget Justifications

Personnel Justification	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/>	<input type="button" value="View Attachment"/>
Consortium Justification	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/>	<input type="button" value="View Attachment"/>
Additional Narrative Justification	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/>	<input type="button" value="View Attachment"/>

DMSPs and CTSA Hub Awards

- The first receipt date for UM1 and RC2 applications that will need to include a DMSP is May 12, 2023
 - Many NCATS FOAs/NOFOs have receipt dates other than the standard dates. Always double-check!
- The DMS Policy does **NOT** apply to T32s, K12s, or R25s
 - Be sure to double-check regarding other CTSA-related applications – e.g., RC2s
 - If you're not sure, PLEASE ASK
- Unique features of CTSA Hub awards
- **KEY POINT**: The DMSP for the UM1 applies to all pilots supported by the UM1. Each pilot will **NOT** submit its own DMSP!



<u>FOA/NOFO</u>	<u>Activity Code</u>	<u>DMSP Required?</u>	<u>First Applicable Receipt Date</u>
PAR-21-340	RC2	YES	May 12, 2023
PAR-21-293	UM1	YES	May 12, 2023
PAR-21-121	R03	YES	Feb 17, 2023
PAR-21-339	R25	NO	N/A
PAR-21-337 and PAR-21-338	T32	NO	N/A
PAR-21-336	K12	NO	N/A
PAR-22-167	UG3/UH3	YES	Feb 15, 2023
Admin supplements	Various	Not for the supplement. HOWEVER, if the awarded supplement changes parent award's approach to data mgmt & sharing, parent award's DMSP must be updated.	

DMSPs and CTSA Hub Awards

- Unique features of CTSA Hub awards
 - Supported projects and associated types of data are not completely defined at the time of application submission – e.g., pilot studies
 - Specific pilot project leads are not completely defined at the time of application submission
 - Assuring adherence to the DMSP may thus present unique challenges for the PI and institution
 - DMSPs will need to cover the bases in terms of data types
 - Adherence is ultimately the responsibility of the grant/Hub PI(s) and the institution
 - Responsibility does NOT ultimately fall to pilot project leads
- **KEY POINT**: The DMSP for any parent award that supports pilot studies (or similar activities) applies to **ALL** pilots supported by the parent award. Each pilot will **NOT** submit its own DMSP!



DMSPs and CTSA Hubs – DCI Perspective

- DMSPs for UM1s will be assessed by a *group* of program staff in DCI for acceptability prior to issuance of NoA and for adherence at the time of RPPR submission
- DMSP acceptability/adherence issues will be handled by the Program Officer/Program Director for the Hub, just as for all other program aspects of the award
- DMSPs are NOT limited to 2 pages
 - 2 pages is a guideline that is sufficient for many Research Project Grants but may well be insufficient to capture the data management and sharing needs of a CTSA Hub
- **STRONGLY** encourage including in the DMSP a strategy for ensuring that leads of supported projects are aware of the DMSP and requirements for adherence
- Encourage Hubs to share their DMSPs with one another and to share best practices and effective approaches



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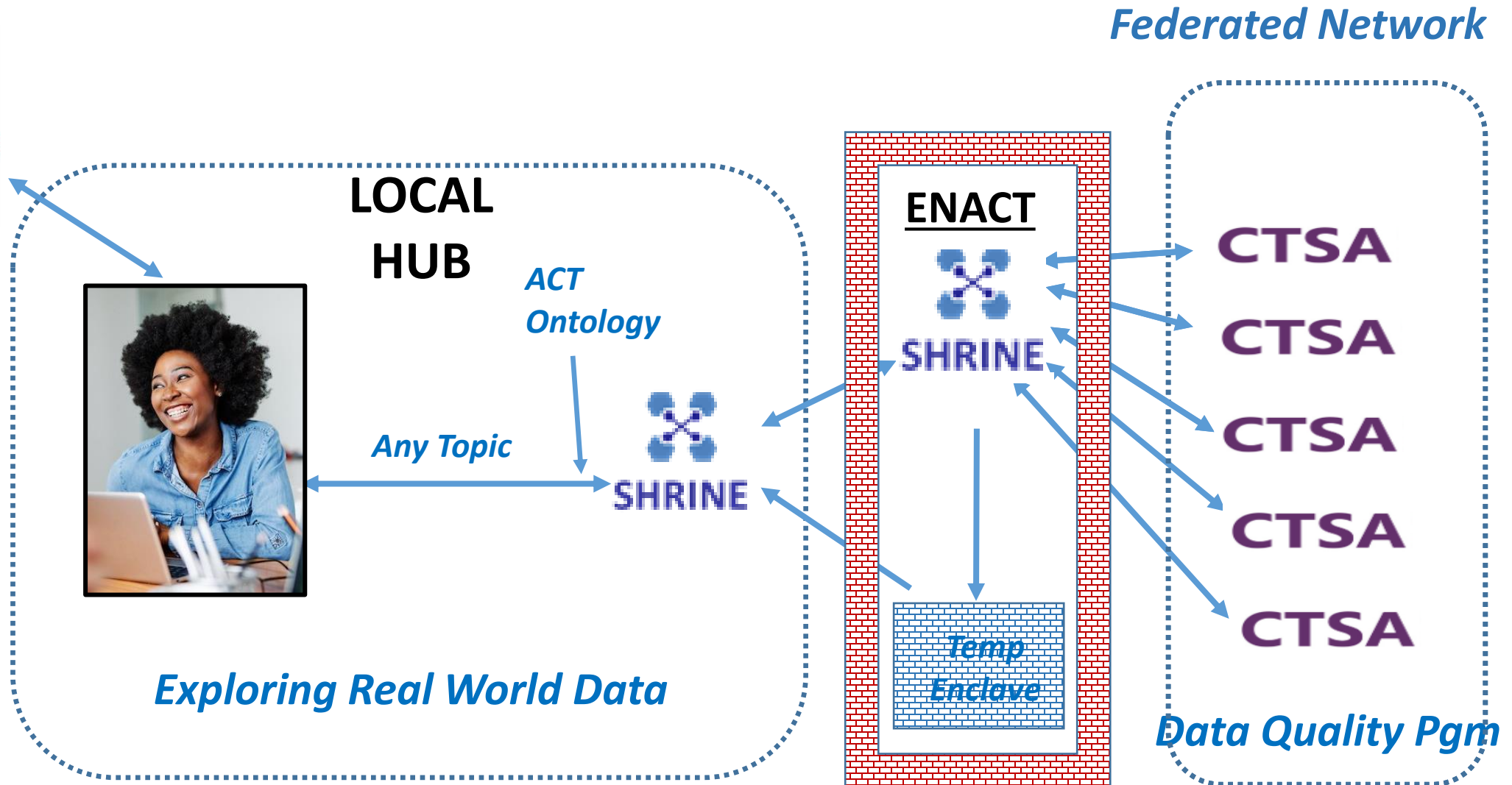
Crowd Sourced Topic

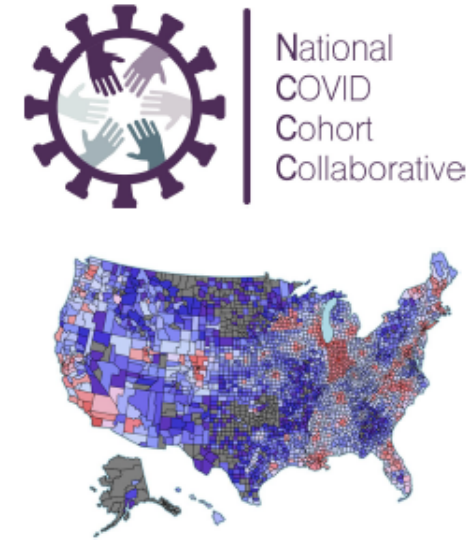
Steering Committee Meeting Discussion

3/27/23

Considering NCATS supported data
platforms: What do the hubs need?

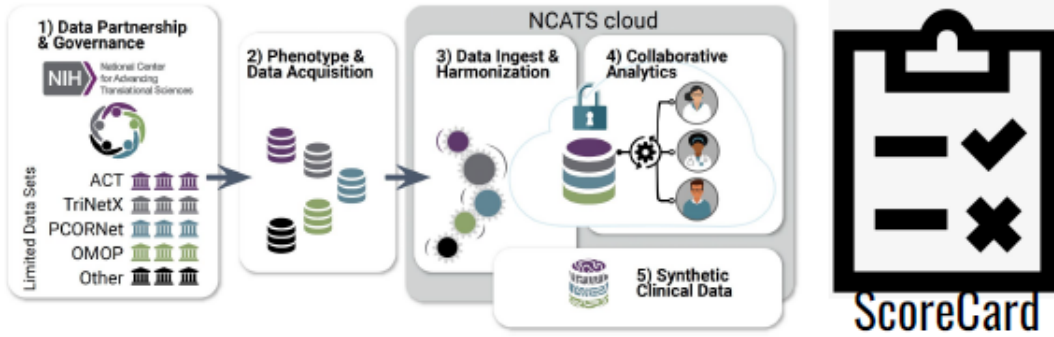
- **E**ffectiveness
- **N**ovel prelim data
- **A**ny Disease
- **C**linical decisions
- **T**est hypotheses





National
COVID
Cohort
Collaborative

Largest publicly available, free, centralized & linked EHR dataset in US history available NOW



- ✓ **Representative US Census:** All 50 States: race, ethnicity, gender, geography, socio-economic status, health background
- ✓ **Harmonized:** 18M+ patient-level records from 4 data models (OMOP, ACT, PCORnet, TriNetX); overcomes source data heterogeneity; ScoreCard reports greatly aid sites' DQ; master universal contract (DUA/DTAs)
- ✓ **Linked:** Integration of multiple data types (clinical, claims, mortality, imaging, viral variants, vaccine data) into a single de-duplicated data warehouse
- ✓ **Public Health & Analytics:** Robust Machine Learning/AI (i.e. not only counts); comparative effectiveness; temporal & risk predictions; synthetic data available

Team science: 84 CTSA hubs/affiliates have active users, ~5K users

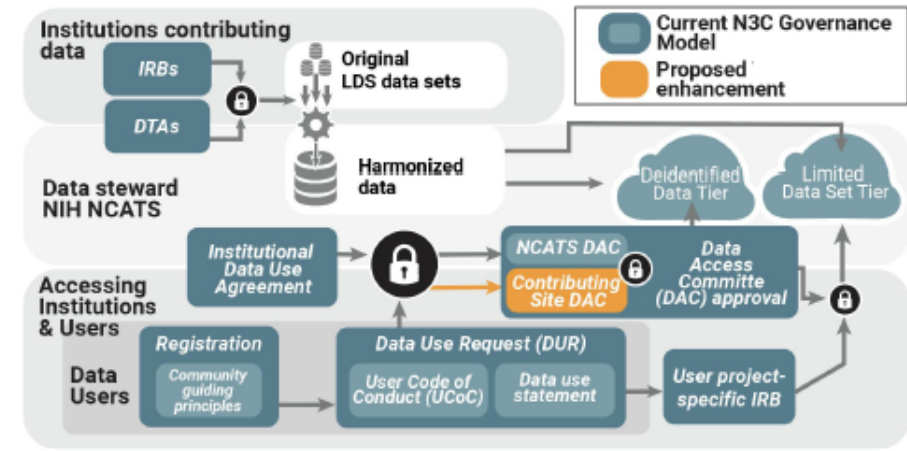
IMPACT

Scholarship: ~200 hub investigator manuscripts/preprints (2043 authors from 96 CTSA/affiliate orgs, h-index 24 & ~2K citations in 2 yrs)

Public outcomes: Changed care guidelines (in multiple countries); White House & State requests; NPR and NIH Director Blog; Dataworks! Grand Prize

National **CLINICAL** Cohort Collaborative

Community-driven, institutional governance



N3C-CLINICAL Functionality

Governance: Institutions have authority about which projects/people can use their data

Disease Agnostic: includes a longitudinal phenotype that covers all life stages

Data harmonization & DQ: centralization provisions each site with their own enhanced & transformed data back

Collaborative Analytics: centralized data enclave is secure and enables cross-CTSA analytics, reduces computing costs for hubs

Partnerships: ONC, FDA, NCI, ASPE, ASPR, AHRQ, NIBIB, HL7, OHDSI, All of Us, NHLBI

Discussion:

N3C and ENACT are 2 different platforms that represent a centralized network and a distributed network and are platforms that do different things.

1. How do we leverage the potential of both and identify synergies across the systems?

2. What additional resources do the hubs need to maximize utilization?



Next SC Meeting:
April 20th, 1:30-6:00 PM ET