Update on Status of the NCATS National COVID Cohort Collaborative (N3C)

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CTSA Program Consortium Call
May 8, 2020
Goals for today’s brief call

1. Provide a status update on efforts to create a centralized clinical COVID database
2. Acknowledge the collaboration and spirit of community that has gotten us to this point
3. Ask the hubs to take the first step to participating by signing the Data Transfer Agreement (DTA)
4. Provide insight into next steps
COVID-19 research: current status

Background

• Ongoing pandemic
• No approved treatments for COVID-19, Emergency Use only
• A number of potential treatments are being tested or used clinically without adequate data
• Many new treatment development efforts are underway

Problem

• No standardized way to collect needed clinical data to understand how best to direct our efforts or care of COVID-19 patients
• Huge amount of clinical activity underway, and a need for systematic coordination or harmonization
• Institutions are under stress to meet and address different study requirements
The NCATS National COVID Cohort Collaborative (N3C)

• A shared vision for rapid collection of clinical, laboratory, and diagnostic data from hospitals and healthcare plans, at the peak of the pandemic, and as the pandemic evolves, to understand COVID-19, and identify effective interventions

• Critical design elements
  • **Speed is critical.** Need to collect data now, before the pandemic abates
  • **Make access to the data fast and easy,** and do not prescribe the analysis
    • As data models are developed, test/validate with on-going data collection
  • **Evolve** to **support clinical trials**
How is NCATS doing this?

Turning Data into Knowledge

CTSA hubs

& other organizations

ACT
TriNetX
PCORI
OMOP

Common Data Model

NCATS Cloud and Stewardship

Clinical Data

Data Harmonization

NCATS Cloud

Investigators

Researchers from CTSA hubs and other institutions

NIH National Center for Advancing Translational Sciences
What exists:
Federated models/formats of data that allow us to ask specific questions

What we are creating:
Centralized Model that allows investigation of broad iterative questions

Is **drug X** beneficial to covid-19 patients?
Does **disease Y** impair course?

What **drugs** help covid-19 patients, and which hinder?
What **diagnoses** impact outcome?
Who is in the N3C?

• CTSA Program National Center for Data to Health (CD2H)
  • Including community effort in organizing N3C work areas
• NCATS-supported informatics teams, esp. in CTSA program
• NCATS teams: multi-disciplinary leadership and program teams, informatics expertise
• Collaborators, data partners
• ...and now the critical ingredient: data from the hubs
Why we are ready now

• **NCATS** has a secure cloud-based enclave ready to ramp to scale
• **NCATS** has worked out data management issues with NIH OGC, OSP
• **CD2H** has honed its ability to harmonize data derived from EHR for maximum interoperability and research use
• **CTSA hubs** have data on a combined ~250 million patients that can be brought to bear to understand the immediate health impacts as well as the longer-term sequelae of COVID-19

Developed by the CTSAs, for the entire research and care community
What are the first steps for your hub to take part?

• NCATS has established a Data Transfer Agreement (DTA) to provide terms and conditions for data transfer and to outline the general terms of data use

• Institutions sign the DTA, then work with NCATS to transfer a “Limited Data Set” relevant to COVID-19, in your institution’s preferred common data model (derived from EHRs) to a centralized, secure, cloud-based enclave on a recurring basis
  • Several hubs have signed DTA in the last few days
  • Data Use Agreement is being drafted now
  • JHU is the central IRB for this effort
What can you do now?, cont’d

- Let us know if you would like us to provide you with the DTA for your consideration
  - Contact NCATS Office of Strategic Alliances, NCATSPartnerships@mail.nih.gov
  - Suggest looping in your legal point of contact or sponsored research office

- Intent is to start immediately and show proof of principle for answering important COVID-19 research/care questions by June 1
Limited funding support for data transfer is available to hubs who need it

- Hubs are able to contribute data immediately and we hope most will be willing to do without additional funds
- If needed, limited funds are available to support personnel and resources for data transfer

- **NOT-TR-20-028** Emergency NOSI
  - N3C Effort: Provision of clinical data in specified formats to support illness/infection status/surveillance determinations and/or clinical study data
  - UL1 Administrative Supplement and Competitive Revision
  - Awards anticipated to be $50,000 to $100,000 Total Costs
  - Rolling submissions; however, as we near the end of the fiscal year we must defer some applications for FY21 funding considerations
This is the beginning of the end of COVID-19... and the beginning of the beginning for the N3C Model!

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FAQs, “User’s Manual” coming shortly; will be regular communications with the community via update calls
Questions and discussion

• Data Transfer Agreement: NCATSPartnerships@mail.nih.gov

• Technical questions
  • Ken Gersing, NCATS Director of Clinical Informatics, kensheng.gersing@nih.gov
  • Sam Michael, NCATS Chief Information Officer, michaelsg@mail.nih.gov

• Applying to NOSI: your hub’s Program Officer

• More to come: Webpage communications, FAQs, etc.