

Tribal Consultation Informational Webinar: National COVID Cohort Collaborative (N3C)

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Purpose of Webinar

- Describe the NCATS N3C electronic health records (EHR) data resource, why it was created, and how it can be used
- Describe how N3C handles AI/AN data while awaiting a Tribal Consultation.
- Start a dialogue for considering a path forward for use of tribal data for public health research on COVID-19, and to work together on policies and governance on the use of this data, including methods for ongoing Tribal Consultation and governance
- Understand Tribes' perspectives on benefits/risks of N3C
 - Consider how N3C can directly benefit Tribal communities
 - Consider both individual and community privacy concerns



National
COVID
Cohort
Collaborative

MORE TREATMENTS, MORE QUICKLY.

That's the goal
of translational
science.

95% of diseases have no treatments.

THOUSANDS
OF DISEASES



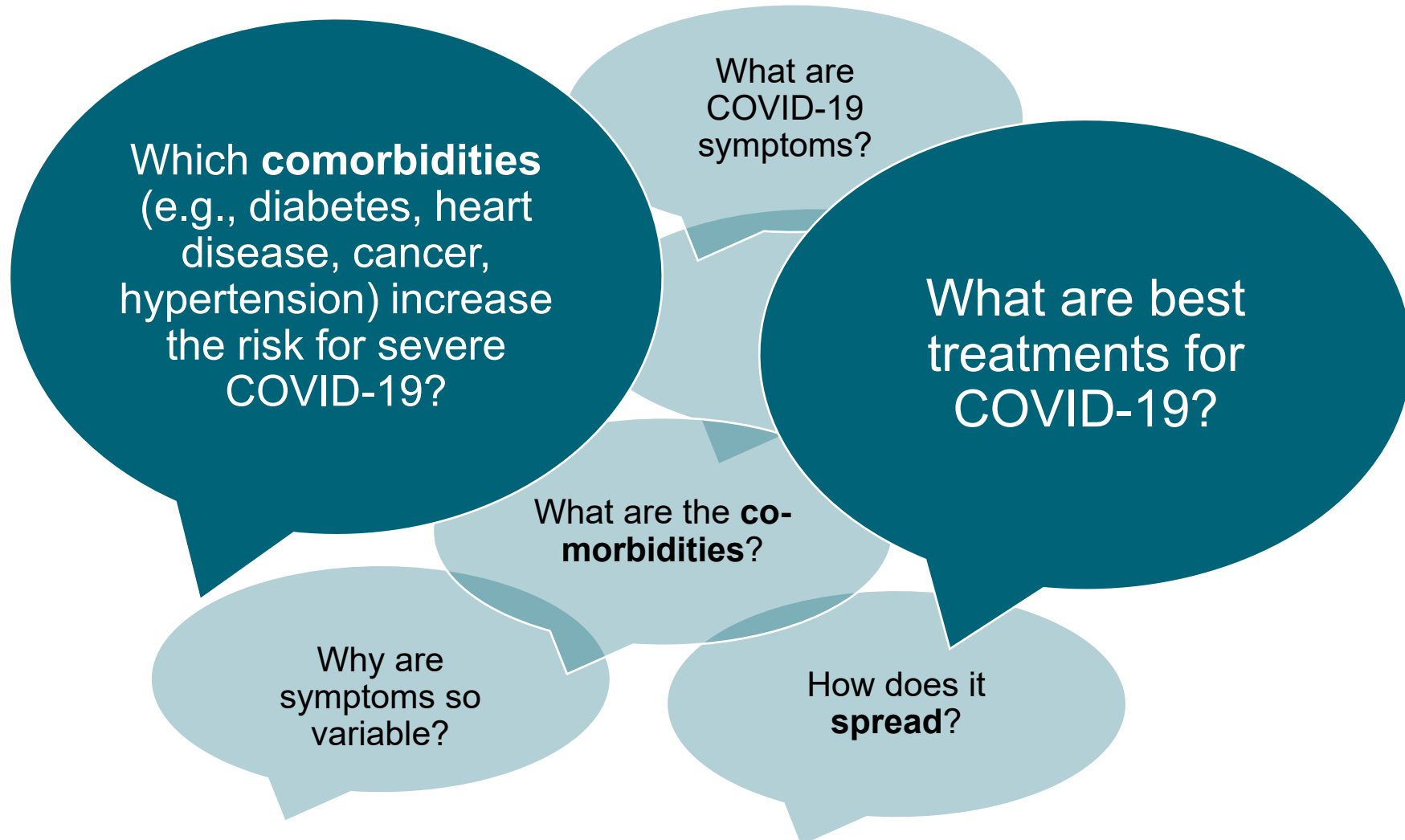
ONLY

HUNDREDS
OF TREATMENTS



To catalyze the generation of innovative methods and technologies that will enhance the development, testing and implementation of diagnostics and therapeutics across a wide range of human diseases and conditions.

When the pandemic began, there were so many questions and few answers...



What types of information can be found in an Electronic Health Record (EHR)?



Created by ArtWorkLeaf from the Noun Project

Medical History



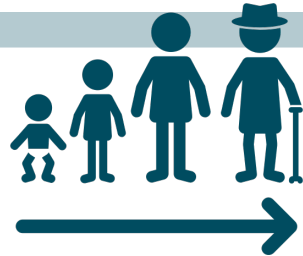
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Diagnoses



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Billing Data



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Patient Demographics



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Vital Signs



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Medications



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Immunization Dates



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Allergies



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Radiology Data



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Lab Results



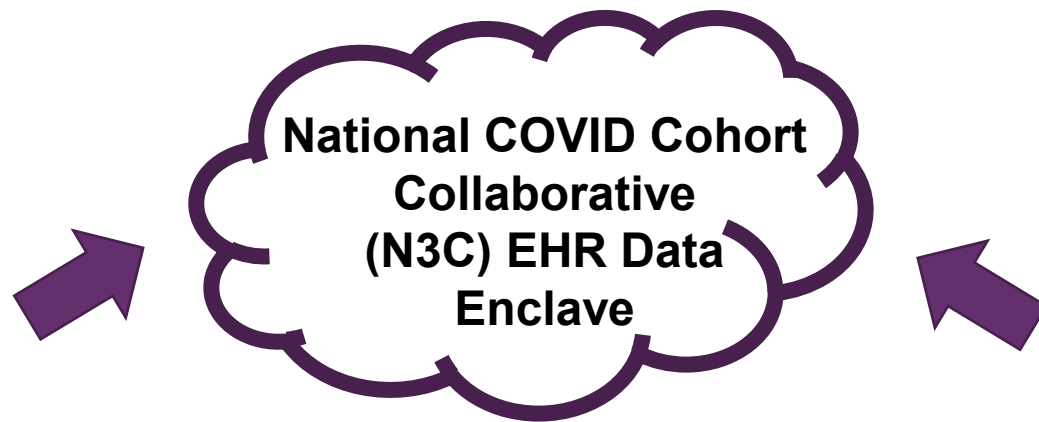
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Translational Research Need: Making EHRs Interoperable and Accessible for Research

- In the U.S., we do not have a standard process to collect and manage electronic health record (EHR) data
- No standard way to use patient EHRs for research or help make or inform public health decisions using near real-time data

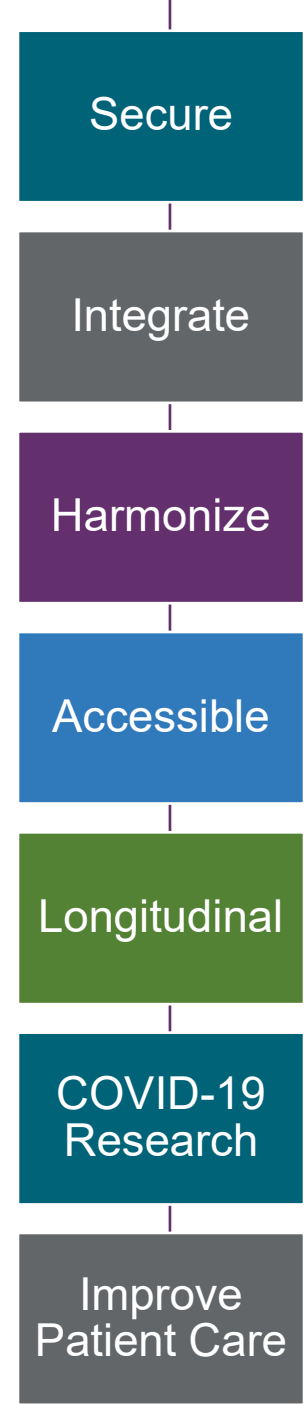


Silos, Doc Searls, Text added to original photo



What is the NCATS National COVID Cohort Collaborative (N3C)?

- The N3C is collecting data from EHRs, harmonizing them into a single format and making them available to researchers in the N3C research platform, the N3C Data Enclave. The data are not consented.
- Researchers cannot take data out of the Data Enclave. It is a secure platform for the data, and it provides tools that let researchers collaborate within it.
 - Data are refreshed on a regular basis to capture COVID-19 as it evolves, including the introduction of viral variants.



National COVID Cohort Collaborative



National Center for Advancing Translational Sciences

N3C Partners and Goals

Harnessing resources of the Clinical and Translational Sciences Awards (CTSA) Program institutions, CTRs in IDeA States, and the Center for Data to Health (CD2H), **the goals are to:**

- Generate a **secure, national resource** of electronic medical record data from COVID-19 tested patients
 - Make available real-world clinical data for **speeding COVID-19 research and improving patient care**
- Translational Tools & Tech**



CTSA Clinical & Translational Science Awards Program



NATIONAL CENTER FOR DATA TO HEALTH




NIGMS IDeA Program

OCHIN




NIH Clinical Research Networks and their partners: Leveraging Real World EHR Data to Research COVID-19


 Sites: 67

 Persons: 9.5 million

+ COVID+ Cases: 3,312,134

 Total Number of Rows: 10.6 billion

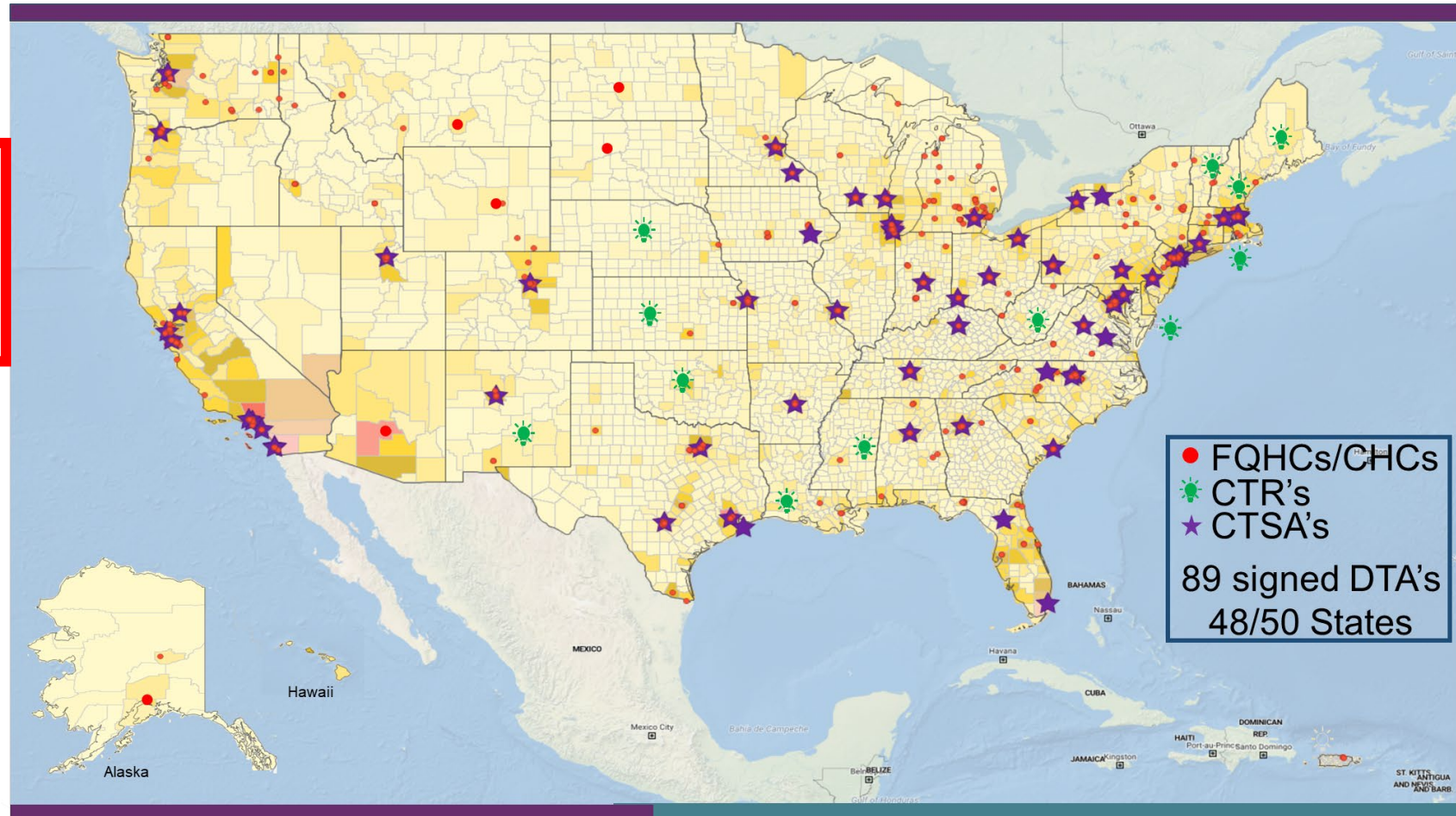
 Clinical Observations: 957.2 million

 Lab Results: 5.1 billion

 Medication Records: 1.6 billion

 Procedures: 511.9 million

 Visits: 506.5 million



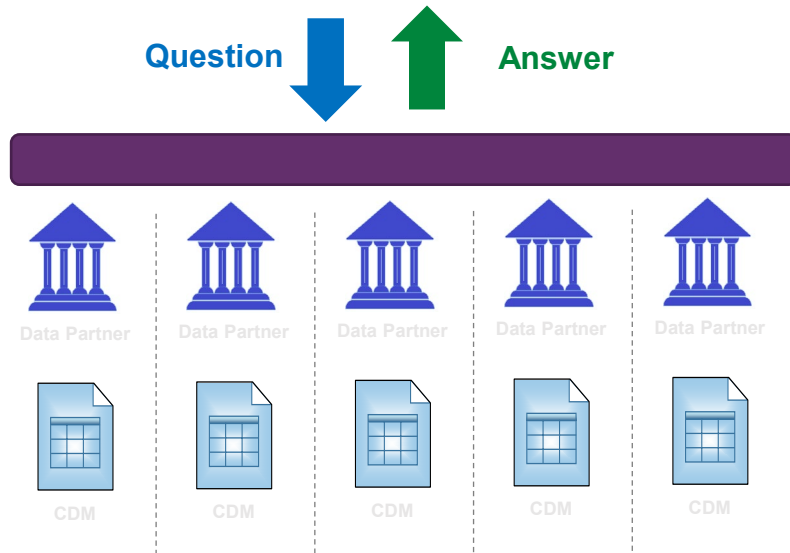
<https://covid.cd2h.org/dashboard/>

N3C Data Enclave Statistics as of December 2, 2021



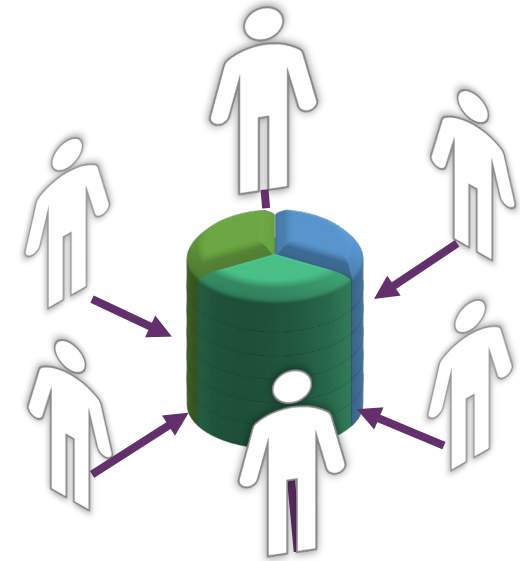
Why centralize COVID-related data?

Local information



Is **drug X** beneficial to covid-19 patients?
Does **Disease Y** impair course?
Does an **income > \$50,000** per year improve outcomes?

Nationwide information, e.g., N3C



Is **drug X** beneficial to covid-19 patients?
Does **Disease Y** impair course?
Does an **income > \$50,000** per year improve outcomes?



What **drugs** help covid-19 patients, and which hinder?
What **Diagnoses** impact outcome?
What **Social Determinants** impact course and outcome?





Four Pillars of Data Protections



Regulatory & Policy

- Data-Contributing Sites abide by the HIPAA Privacy Rule
- N3C research is subject to the Federal Policy for the Protection of Human Subjects in research ('Common Rule')
- Data are provided as HIPAA-defined Limited Data Set
- NIH IRB oversight & waiver of consent
- For COVID-19 related research only
- No genomic data
- No emergency public health authorities were used to obtain the data under these conditions.

Privacy Measures

- Certificate of Confidentiality
- Data stays within the Enclave: No download or capture of raw data
- Privacy Impact Assessment
- Review of project requests by Data Access Committee
- Additional Tribal data privacy measures (while seeking a consultation with Tribal Nations)

Security Testing and Monitoring

- Federal Government Compliant Enclave managed by NCATS
- Meets government security controls for cloud security and privacy
- Data encryption in transit and at rest, without exception
- Scheduled penetration testing
- Active monitoring and logging by NIH and HHS
- Auditing of activities in the N3C Enclave

Researcher Responsibilities

- A User's organization signs a Data Use Agreement with NCATS for terms and conditions of use
- Users Adhere to a Code of Conduct
- Required NIH IT Security Training
- Required Human Subjects' Protections Training
- Follow Community Guiding Principles



Additional privacy measures for AI/AN data, while we seek Consultation

Data Characteristics

- Self-identified or provider identified information
 - OMB Race Categories
 - No tribal affiliation
- Existing data only; no connection to patients directly

Current Strategy Until Consultation

- AI/AN is concealed in “other” category
- 2,659 zip codes overlapping Tribal lands are not available, to block any inference of tribal affiliation
- Tribal affiliation is NOT provided to N3C by the contributing sites



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Prioritizing Tribal Perspectives

- Working with THRO
 - Monthly Meetings since September 2020
- Conversations with external experts
 - Johns Hopkins Center for American Indian Health (August 2020)
 - Southcentral Foundation (September 2020)
 - Tribal Epidemiology Center Directors (September & November 2020)
- Learning from NIH COVID-19 Tribal Consultations
 - May 2020 – NIH Tribal Consultation on COVID-19 Research
 - July 2021 – NIH Tribal Consultation on Rapid Acceleration of Diagnostics (RADx) Tribal Data Repository
 - April 2019 – NIH Tribal Consultation on Draft Policy for Data Management and Sharing

Respect for
Sovereignty

Solidarity

Mitigate Harms

Maximize
Benefits

Inclusion

Education and
Opportunities

Communication



What research does N3C enable?

N3C's Utility

- Largest EHR research resource
- Longitudinal data
 - **Variant Waves**
 - **Long COVID**

- Characterizing the short- and long-term effects of COVID-19
- Understanding the social determinants of health (SDoH) and outcomes for SARS-CoV-2 infected patients
- Identifying effective drugs, repurposed as a treatment for COVID-19
- Predicting who might have severe outcomes if they have COVID-19
- Observing and tracking the progress of COVID-19 over time and geographically



N3C is contributing to our understanding of COVID-19

In the news...

Publications

- Description of N3C
- Health equity
- Diabetes
- Cancer
- Machine Learning
- COVID meds

Pre-prints:

- HIV COVID risk
- Rural population mortality rates
- Long COVID
- others

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Current Covid Health and Safety Guidelines

RESEARCH & INNOVATION

How does COVID-19 affect patients with cancer? Largest study shares first results

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N3C Registration Instructions

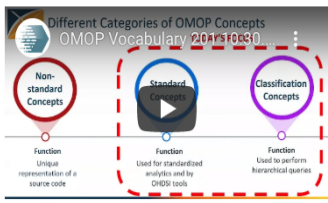
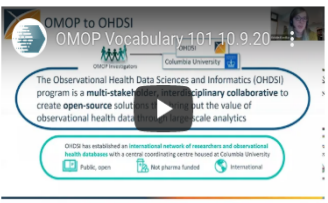
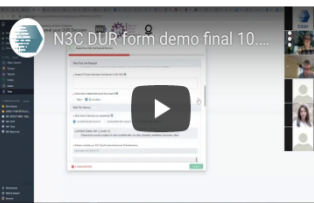
 Thank you for your interest in the National COVID Cohort Collaborative (N3C). 

Please follow the steps below to register to N3C:

- 1 **Register for membership** [Register Here](#)
 - The form will collect your profile information (name, email, etc), and provide additional instructions.
- 2 **Follow the instructions provided in the form (and detailed below) to gain access to the N3C Team Drive, google groups, Slack, and Calendar/meeting invitations.**
 - Applications for membership will be reviewed/approved rapidly during the week, but may extend to 48 hours over weekends. Your patience and understanding is appreciated.

 <p>Details for Workstreams Provides helpful links for all N3C Workstreams, Subgroups, and Task Teams and includes information about Google Drive, Notes, GitHub repos, etc.</p> <p>View Document</p>	 <p>N3C Team Drive Contains all N3C documents, spreadsheets, and slides for the entire initiative.</p> <p>Request Access Here</p>	 <p>N3C Researcher Essentials Contains important information on how to get started, such as N3C Data Enclave registration instructions, links to governance documents, and current DUA signatories.</p> <p>Learn More</p>	 <p>N3C Governance Documents Contains the Data Transfer Agreement (DTA) and other important information such as the OMOP common data specifications.</p> <p>View Documents</p>
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Tutorials

<p>OMOP Vocabulary 201</p>  <p>2020-10-30</p> <p>This training takes a deeper dive from the OMOP Vocabulary 101 Part 1 training on October 9th and will explore the uses of the OMOP common training model in the N3C Data Enclave. OMOP 301 is coming soon!</p>	<p>OMOP Vocabulary 101</p>  <p>2020-10-09</p> <p>Learn about OMOP and get acquainted with the common data model used in the N3C Data Enclave and its functionality. The training provides an overview using the Athena search function with concept and vocabulary IDs and other standards to facilitate search of the vocabularies and see relationships between other ontologies.</p>	<p>N3C DUR Appeal</p>  <p>2020-10-06</p> <p>Learn how to navigate the Data Use Request (DUR) interface in the N3C Data Enclave. View steps to create an appeal to the Data Access Committee's (DAC's) decision by amending initial information submitted to validate required criteria and/or strengthen the rationale for level of data requested.</p>
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Registration for Documents, Meetings & the N3C Data Enclave

Requires Authentication

[Enclave Checklist](#)

Training Office Hours:

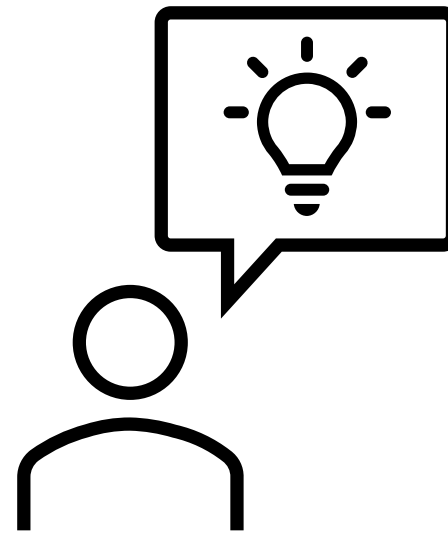
Tuesdays & Thursdays at 10-11 am PT/1-2 pm ET

[Registration Required at this link](#)

Additional Training Tutorials available in the Enclave

Seeking input from Tribal Nations

- N3C receives AI/AN data from contributing health sites
 - AI/AN demographic data
 - Zip codes that overlap with tribal land
- AI/AN data are obscured
 - AI/AN → “other”
 - Zip codes → Not available (00000)



*We want your opinions +
ideas!*



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Translational Sciences

Examples of Potential ideas for managing AI/AN data within N3C

Ideas to consider	Impact of this idea...
Should the data continue to be obscured?	Demographics and zip codes remain unavailable for research purposes
Should we create a separate enclave for the AI/AN data?	Researchers with AI/AN data approvals would be able to access unobscured data; Tribal representatives determine process and level of involvement
Should AI/AN data be made available in the same way as other demographic categories?	Visibility by all researchers in the Enclave; greatest impact of data



Seeking Input (pre-consultation questions)

- Should AI/AN data be unobscured and made available for COVID-19 research?
 - How would Tribal communities want to be involved in governance, access, use, etc.?
- What steps would the N3C need to take to consider making the data available?
 - Which aspects of governance would be particularly critical for this resource?
 - How can ongoing partnerships with Tribal communities and researchers be instituted and maintained?
- If Tribal nations identify benefits to using the N3C resource, what outreach is needed to better engage AI/AN researchers?



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To learn more about N3C, visit us at <https://ncats.nih.gov/n3c>

