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Tribal Consultation: National COVID Cohort Collaborative (N3C)

Meeting will begin shortly

- *Please stay muted with your camera off unless you are speaking.*
- *This meeting will be recorded and broadcast on NIH Videocast. (Zoom chat will not display in videocast)*
- *Closed Captioning is available.*
- *In the event of technical difficulties, please email N3CConsultation@nih.gov.*

February 11, 2022

NIH National Center for Advancing Translational Sciences

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Tribal Consultation: National COVID Cohort Collaborative (N3C)

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National Center for Advancing Translational Sciences

February 11, 2022

https://ncats.nih.gov/n3c/about/tribal-consultation

NIH National Center for Advancing Translational Sciences

Purpose of Consultation: Engaging Tribes for Use of N3C to study COVID-19 Health Outcomes

- Describe the NCATS National Covid Cohort Collaborative (N3C) electronic health records (EHR) data resource
- Describe current and future status of American Indians and Alaska Natives (AI/AN) data in N3C
- Understand Tribal Leaders' perspectives on benefits/risks of N3C
  - Consider how N3C can directly benefit Tribal communities
  - Engage Tribes to use N3C for COVID-19 health research, for example research to understand long COVID or Post-acute sequelae of COVID-19 (PASC).

Event Details

Date and Time
February 11, 2022
1:30 p.m.–2:30 p.m. EST

Location
NIH Videocast*
Tribal leaders will be emailed a Zoom link to participate.

Materials
- Dear Tribal Leader Letter
- Framing Letter
- Tribal Consultation Informational Webinar
- Webinar slides

*An **audio described** version of the webinar is available.*

https://ncats.nih.gov/n3c/about/tribal-consultation

National COVID Cohort Collaborative

Working to Understand 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

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What the N3C Database Resource Is and Is Not

Overarching Purpose and Duration:

- N3C was built because of the urgency to understand clinical course of COVID-19
- N3C is a 5-year program that can be renewed (ability to extend with renewed agreements)

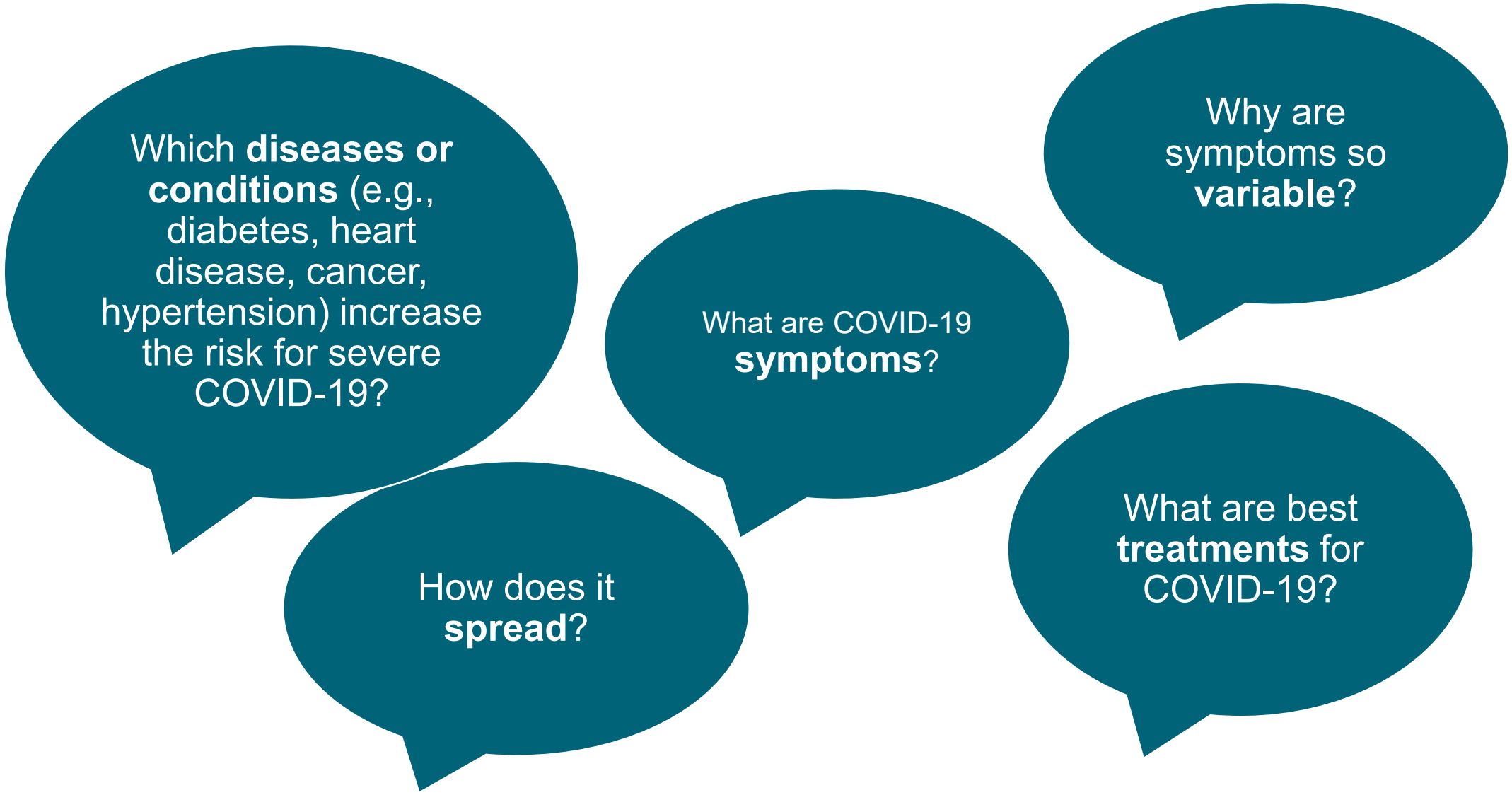
N3C:

- ***Is*** de-identified health data from existing EHRs
- ***Does*** utilize existing data
- ***Is*** provided by health care organizations, specifically for researching COVID-19 with the goal of improving health outcomes
- ***Is*** a secure resource; data cannot be downloaded or removed
- ***Does*** contain obscured AI/AN information (self- or provider-reported) and zip codes

N3C:

- ***Is not*** a resource that contains Tribal affiliation information; nor IHS data
- ***Is not*** the same as the RADx Tribal Data Repository
- ***Is not*** inclusive of biospecimens
- ***Is not*** engaging with participants
- ***Is not*** consented (waiver of consent obtained)
- ***Is not*** a repository for human genomic data; human genomic data are not allowed

When the pandemic began, there were so many questions and few answers: Need for holistic approach



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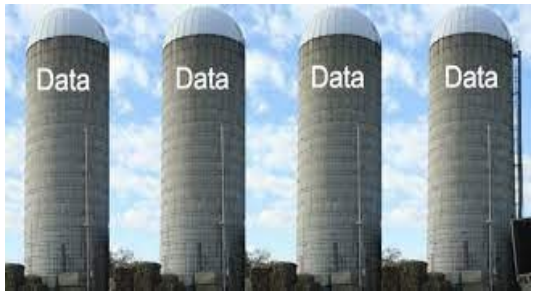
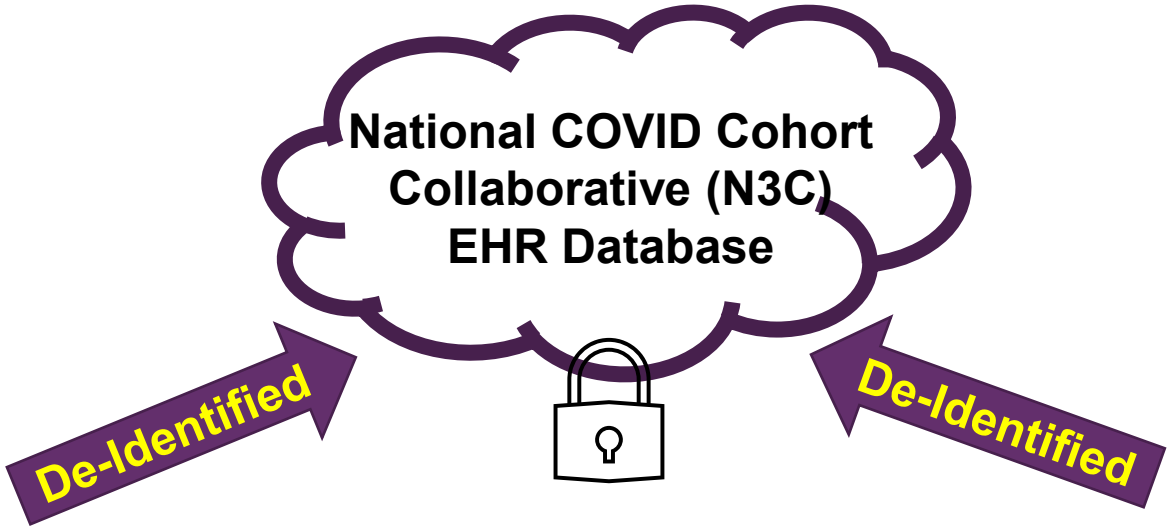
Need: Standardized electronic health records to aid information sharing

- Electronic health records (EHRs) are not standardized
  - No standard process to collect and manage 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



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CTSA Clinical & Translational Science Awards Program

NATIONAL CENTER FOR DATA TO HEALTH

NIGMS IDeA Program

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N3C Project: What, How, Why, and Impact

Individuals Tested for COVID-19

Refreshed
De-Identified

N3C EHR Database

Diverse Set of Clinical Health Information From Electronic Health Records

Medical history, diagnoses, billing data, patient demographics, vital signs, medications, immunization records, allergies, radiology data, and lab results

DAC Controls

Important Public Health Questions

- What are COVID-19 **symptoms**?
- What are risk factors for severe COVID?
- What are risk factors for Long COVID?
- What are best **treatments** for COVID-19?

Potential Impacts

- Better prevention & treatment
- Long COVID
- Optimized care for specific communities
- Improved health equity
- *Save lives*

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National COVID Cohort Collaborative

N3C Database Controlled Access

1

Data Provided to N3C

Institutions Sign **Data Transfer Agreement**

2

Data Access & Use

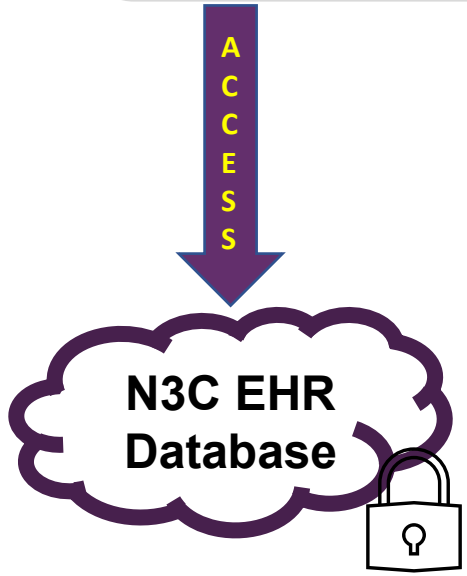
1. Institutions Sign **Data Use Agreement** for their researchers
2. Researchers Register & Submit **Data Use Request**
   a. Human Research Participant Protections (HRPP) Training
   b. NIH IT Security Training
   c. User Code of Conduct

3

NIH Data Access Committee (DAC)

Reviews data use requests

- Ensure COVID-19 related research
- Assess that requested level of access is justified
- Confirm compliance with training requirements
- Ensure that certification of institutional review board (IRB) approval is provided if needed



Additional N3C Security

- Data cannot be removed
- Platform has several layers of security
- Adheres to Federal and NIH policies & regulations
- Privacy protections
- Security testing & monitoring

Additional privacy measures for AI/AN data as we seek consultation

We are seeking consultation to inform Tribes of this COVID-19 resource and to seek input on whether or how these data could be made most useful for Tribal interests

Approach Pending Tribal Consultation

- AI/AN is currently obscured in an aggregated category with other data
- 2,659 zip codes overlapping Tribal lands are not available, to block any inference of Tribal affiliation

Tribal Consultation

- NCATS has posted relevant materials on its website: https://ncats.nih.gov/n3c/about/tribal-consultation
- After the Consultation, Tribal Nations will have time to submit written testimony to NIH and NCATS
- NCATS will prepare a report and action plan based on the Tribal Consultation

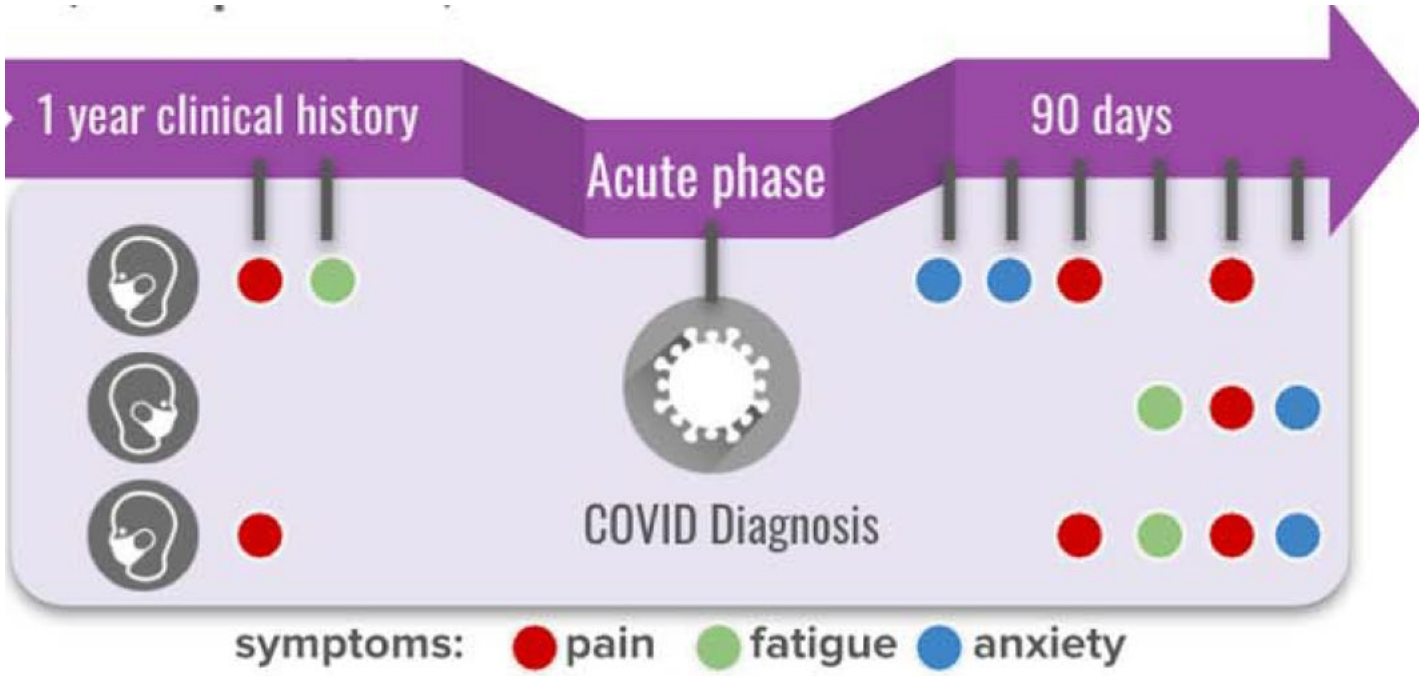
How can the N3C contribute to our understanding of COVID-19?

N3C's Utility

- Largest EHR research resource

Evolution of COVID

- Viral variants
- Long COVID



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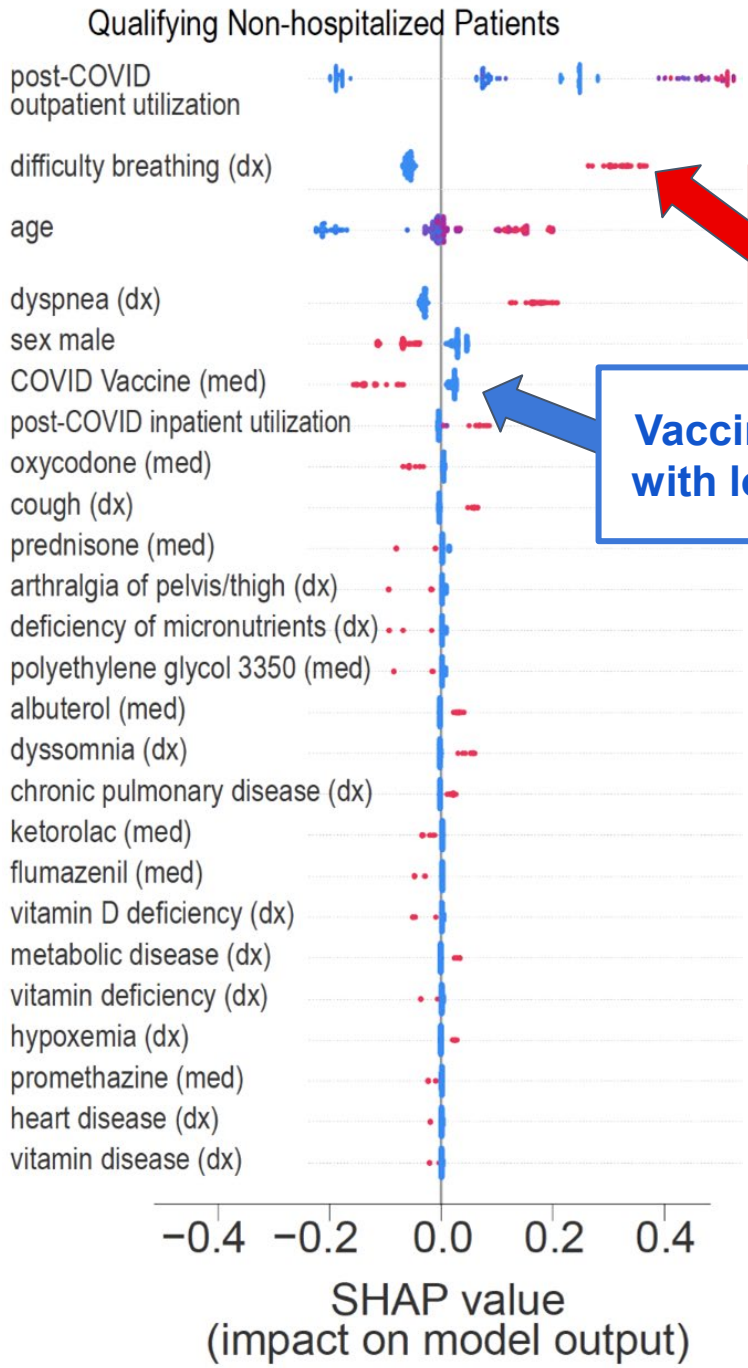
Long-COVID: Feature importance



Difficulty breathing associated with higher risk of PASC

Vaccination associated with lower risk of PASC

The tremendous amount of data within the N3C enables researchers to characterize long-COVID and predict who may be vulnerable.

N3C Data Enclave Statistics

Release Set: January 27, 2022

Production version: Release-v61-2022-01-27

- **Sites:** 69
- **Persons:** 11.0 million
- **COVID+ Cases:** 3,923,853
- **Total Number of Rows:** 12.3 billion
- **Clinical Observations:** 1.1 billion
- **Lab Results:** 5.9 billion
- **Medication Records:** 1.8 billion
- **Procedures:** 579.2 million
- **Visits:** 597.5 million

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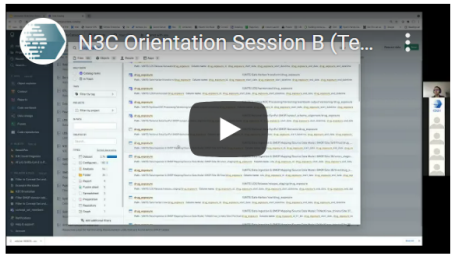
Learning and Training Resources in the N3C

- Help Desk
- Weekly office hours
- 20+ Training Videos
- 31 Domain teams (support from subject matter experts)
- Personal Trainer

Tutorials

The following tutorials provide information for researchers to learn about the tools, vocabulary, and resources available within the N3C Data Enclave. For those users with a current N3C Data Enclave account, more detailed tutorials can be found within the internal Training Portal (Log in required). For additional support options, please visit the N3C Support Desk.

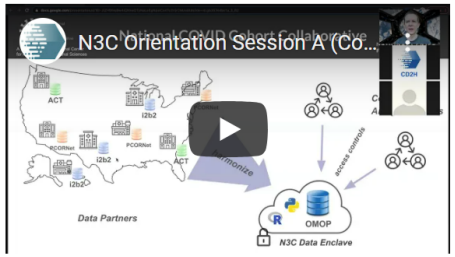
Enclave Orientation Session B



2021-04-13

This session is for analysts, statisticians, data scientists, or anyone who wants to gain a broader understanding of the tools needed to work with the

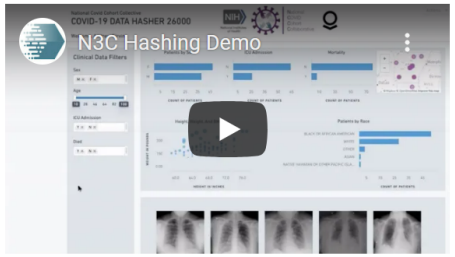
Enclave Orientation Session A



2021-04-13

This session is for those who want to learn about N3C, as well as how to engage with project teams and access the data. Learning objectives: (1) Provide

Privacy Preserving Record Linkage



2021-02-05

Learn about hashing and how it allows for privacy-preserving record linkage (PPRL) within the N3C Data Enclave. A demonstration of these linkages is

N3C

Support Desk

If you need assistance with the N3C Data Enclave, the following options are available:

- Attend Support Desk office hours on **Tuesdays & Thursdays at 10-11 am PT/1-2 pm ET** Register here.
- Submit a Support Request.
- Consult the Frequently Asked Questions (FAQs).
- A quick start tour is available inside the Enclave.
- Video tutorials will be uploaded as they are created.

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How can we make this resource more useful to the Tribal communities?

- How should AI/AN data be shared responsibly for COVID-19 research?
  - How would Tribal communities want to be involved in governance, access, use, etc.?
- What steps should NCATS consider in making AI/AN data available?
  - Which aspects of governance would be particularly important for incorporating Tribal?
- How can ongoing partnerships with Tribal communities and researchers be enhanced?

How should AI/AN data be shared responsibly: Examples* of options

Model	Access to AI/AN data	Impact of this model
Current Model	AI/AN data are obscured.	Demographics and zip codes remain obscured for research purposes, limiting community-specific benefits.
Tribal Data Access Committee (TDAC)	Tribal Data Access Committee (TDAC) as part of the current DAC process	Allows strict control for AI/AN data with relatively low administrative burden. Only researchers with specific approvals could access unobscured data, broadening community-specific benefits
Tribal Data Use Request (TDUR) for data	One TDUR for all Tribal research	One overarching TDUR with locus of control at lead researcher level. Higher burden for few people.
Tribal Data Space	Create a protected Tribal-specific space within the N3C?	Allows strict control for AI/AN data with moderate administrative burden. Only researchers with specific approvals could access unobscured data, broadening community-specific benefits
All open	Unobscure all AI/AN and zip code data	Allows the broadest level of access for all researchers.

*Not mutually exclusive or exhaustive

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Q&A

Please submit questions through the Zoom chat box.

Tribal Leaders may also send written testimony
to NIHTribalConsultation@nih.gov before Friday, March 18, 2022

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

National COVID Cohort Collaborative

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 Projection 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

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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**

CTSA Clinical & Translational Science Awards Program

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