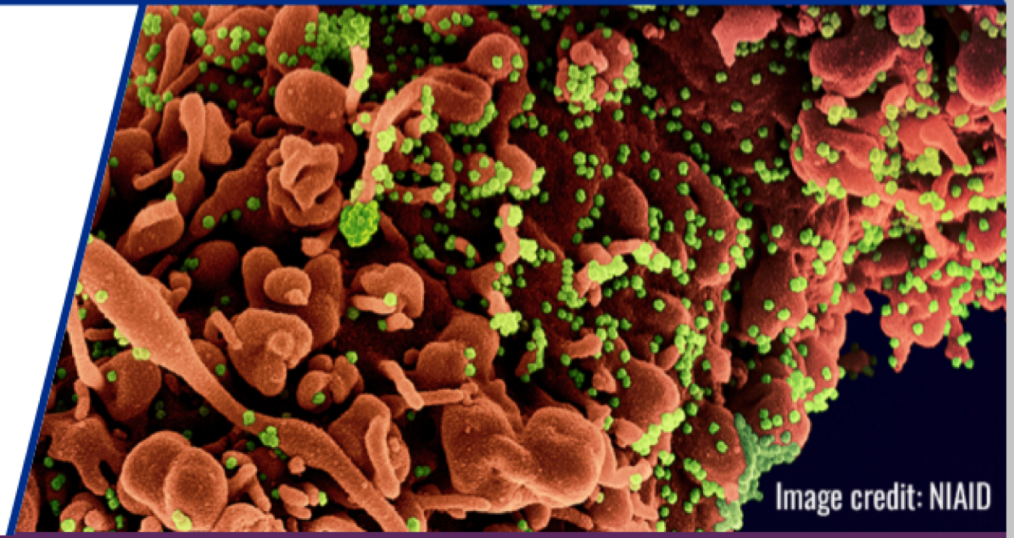
COVID-19 Clinical Data Analysis on a National Scale: T*he National COVID Cohort Collaborative (N3C)*

July 29, 2020

Science through Synergy

National COVID Cohort Collaborative (N3C)

The N3C is a partnership among the NCATS-supported Clinical and Translational Science Awards (CTSA) Program hubs and the National Center for Data to Health (CD2H), with overall stewardship by NCATS. Collaborators will contribute and use COVID-19 clinical data to answer critical research questions to address the pandemic.

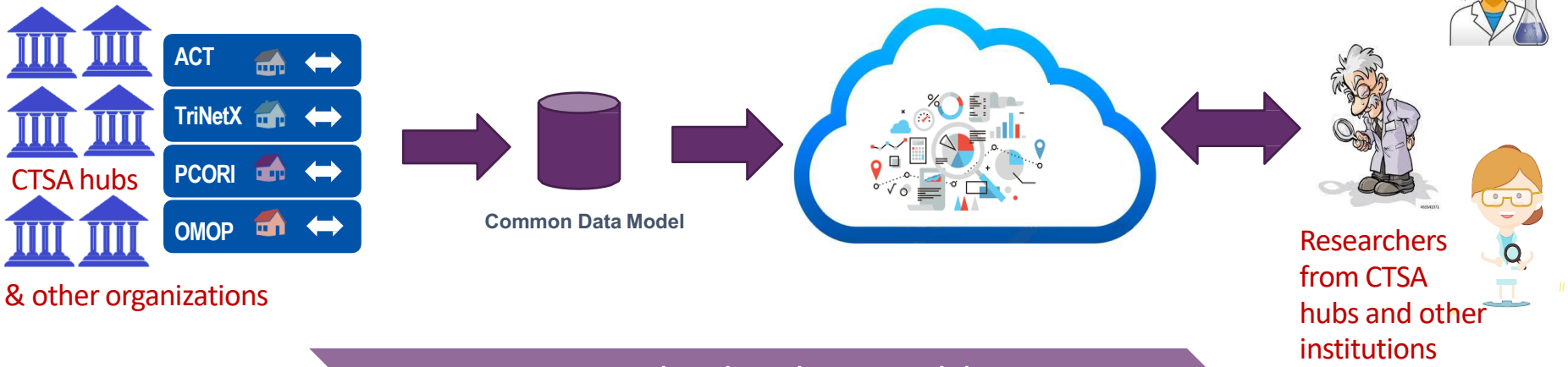


Building an Innovative Analytics Platform to Study COVID-19

The N3C is a new effort that aims to build a centralized national data resource that the research community can use to study COVID-19 and identify potential treatments as the pandemic continues to evolve.

How is NCATS doing this?

Turning Data into Knowledge



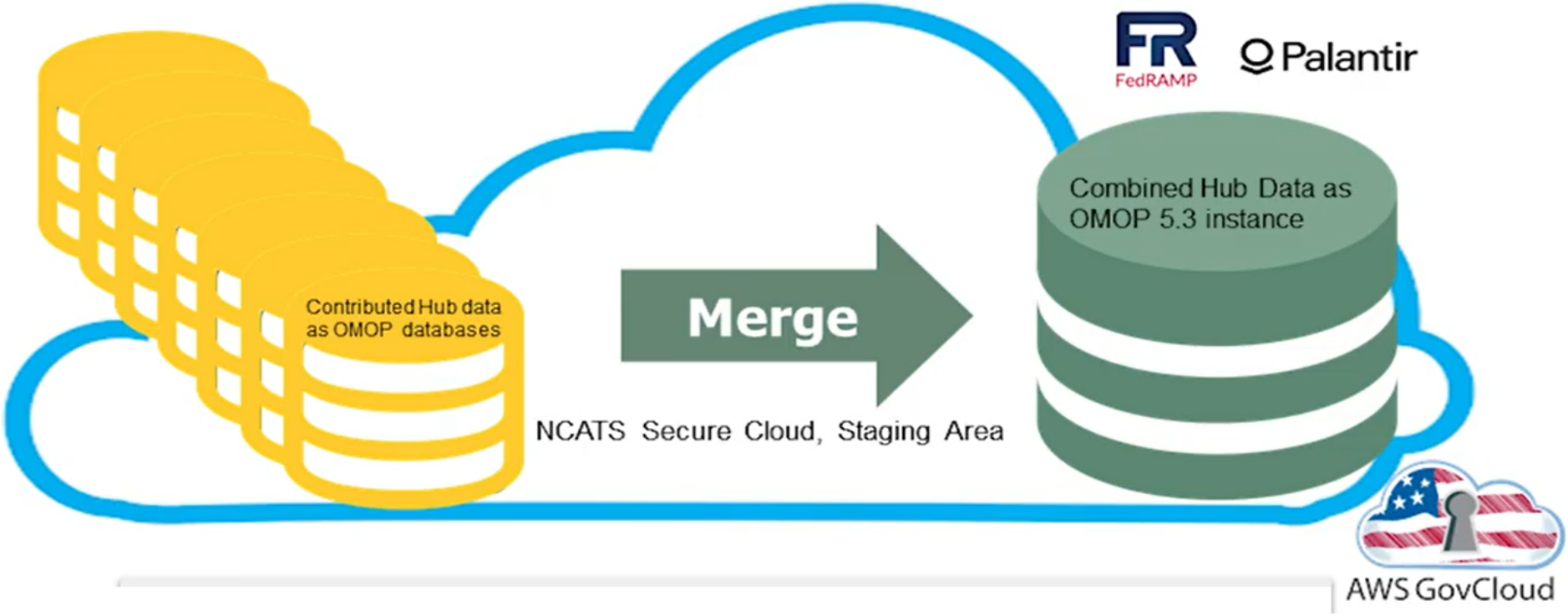
NCATS Cloud and Stewardship

Clinical Data | Data Harmonization | NCATS Cloud | Investigators

Electronic Health Record Data

- Person (demographics, location)
- Observation Period
- Specimen
- Death (including cause)
- Visit Occurrence (admissions, visits, services)
- Procedure Occurrence (CPT, ICD10, HCPCS)
- Drug Exposure (orders and administration)
- Device Exposure (instruments, supplies, implantables)
- Condition Occurrence (problems, billing codes)
- Measurement (labs, vital signs, other quantities)
- Observation (other facts such as medical and family history)

Harmonized to OMOP and Palantir



N3C Participation

- EHR data contribution
  - Institutional **data transfer** agreement
  - Data transmission: OMOP, i2b2/ACT, PCORNet, TriNetX
  - Ingestions and harmonization
- Analysis of synthetic data set
- Analyze limited data sets
  - Institutional **data use** agreement with NCATS
  - Individual researchers obtain institutional approval (similar to dbGAP)
  - Multi-institution collaborations possible

Analytics

- Get an N3C Enclave account (join the Analytics Workstream)
- Get project approval
- Analyze limited data sets in the Enclave
- No direct visualization or download of patient-level dataa

Recent Statistics

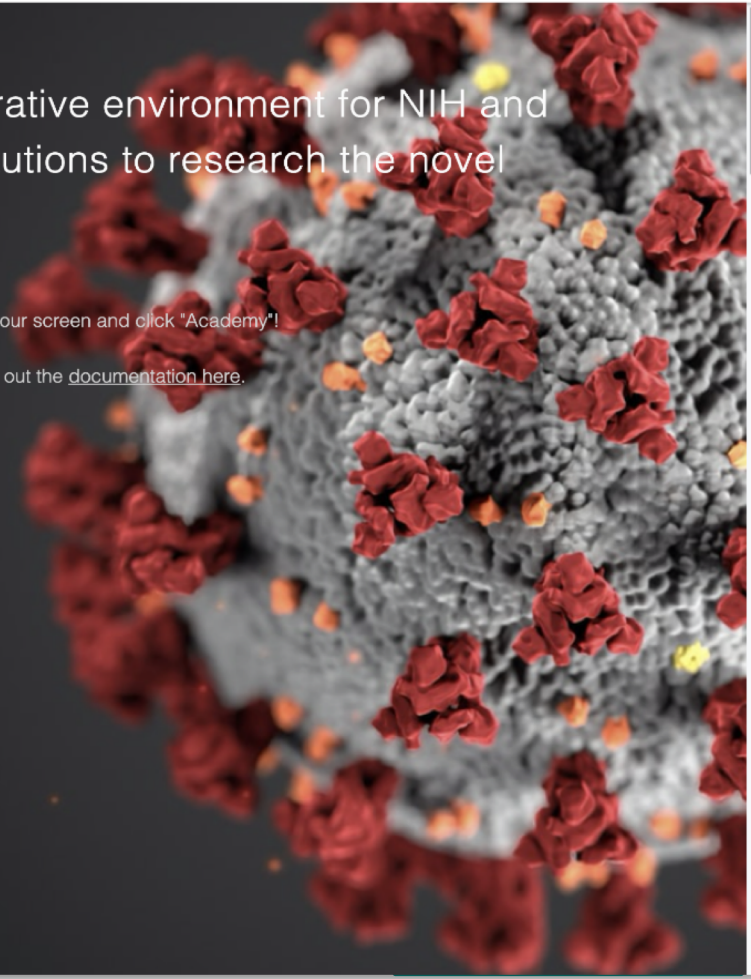
COVID-19 Positive Patients	Total Patients	Sites Signed DTA	Sites Data Ingested	Rows of Data
16158	309237	43	7	473.5m

Procedures	Lab Results	Visits	Observations	Drug Exposures
41.1m	253.6m	13.3m	25.1m	94.9m

Amin, welcome to the N3C platform!

The N3C Analytical Platform is a collaborative environment for NIH and researchers from the USA's leading institutions to research the novel coronavirus (SARS-CoV-2).

Welcome! To get started:
1) For self guided tutorials, click here, or click the question mark on the bottom-left of your screen and click "Academy"!
2) Sign up for a training here and access your training materials here.
3) To go through documentation or detailed tutorials for any part of the platform, check out the documentation here.



National Covid Cohort Collective

N3C Sites Dashboard

Palentir Demonstration

Christopher G. Chute, MD, DrPH, Johns Hopkins University

Actions

Selected tab

Show Filters

Key Statistics

N3C Project Statistics / Metrics so far

COVID-19 Positive Patients	Total Patients	Sites Signed DTA	Sites Data Ingested	Rows of Data
2394	17904	26	3	19.3m

Procedures	Lab Results	Visits	Observations	Drug Exposures
441k	8.2m	246k	5.3m	1.4m

Cohort characteristics

Summary statistics for all patients

	COVID (N=2394)	Non-COVID (N=15510)	Overall (N=17904)
Gender			

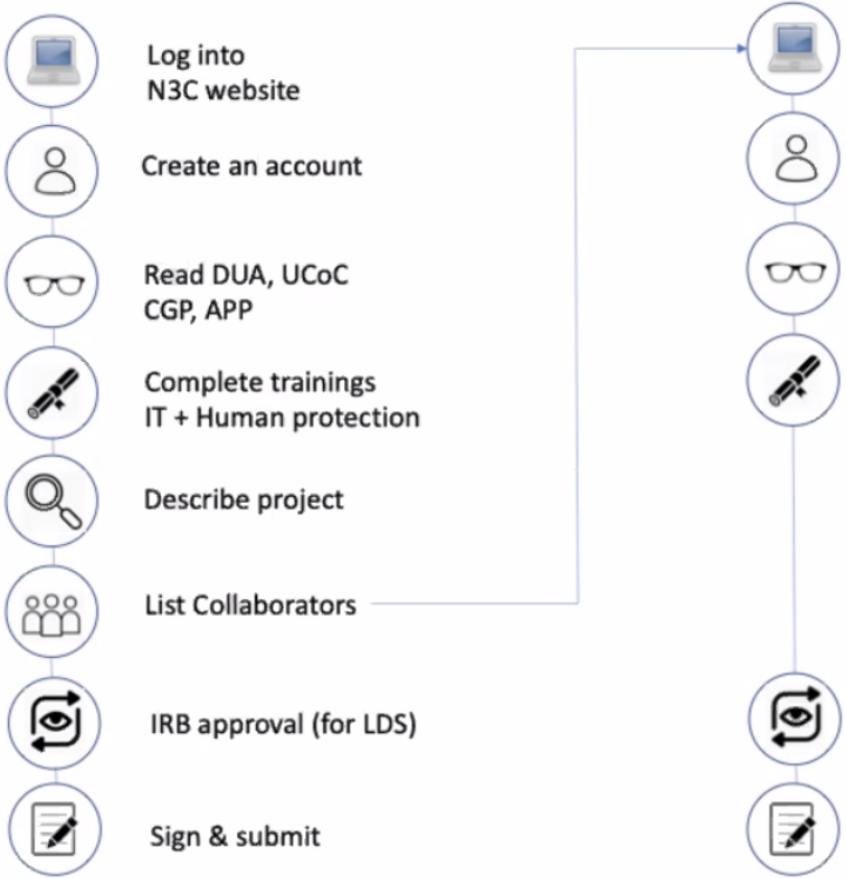
To plot: Age Group

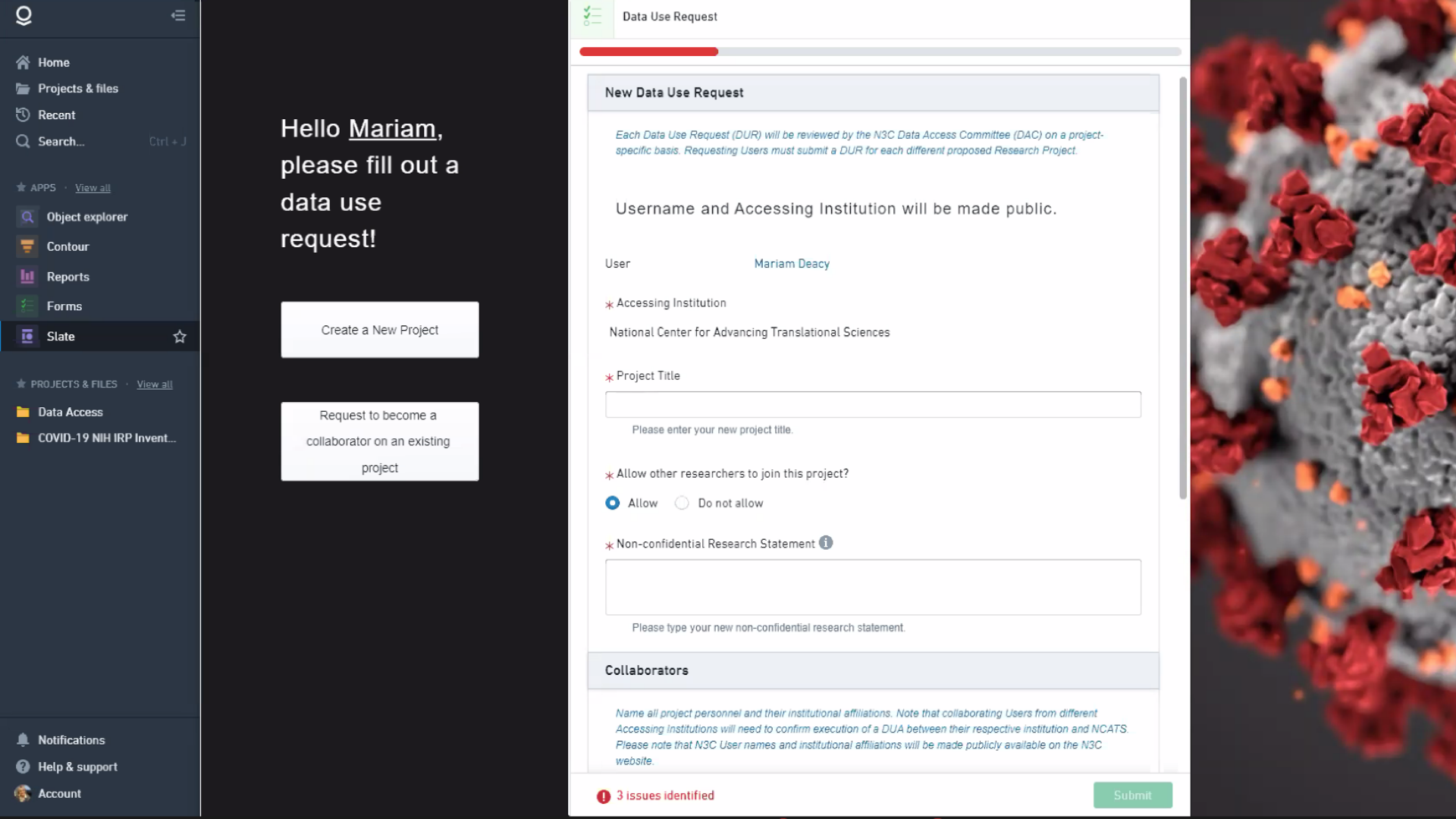
Getting Started with N3C

- Have your institution establish a data use agreement
- Institutional data transfer agreement (and data transfer) optional
- Identify collaborators
- Formulate clinical questions
- “On-board” with N3C (https://cd2h.org/onboard)
- Obtain IRB exemption for limited data set use
- Obtain institutional approval of your project
- Obtain N3C approval for your project
- Do science

Data Partnership & Governance Workstream

Data Access

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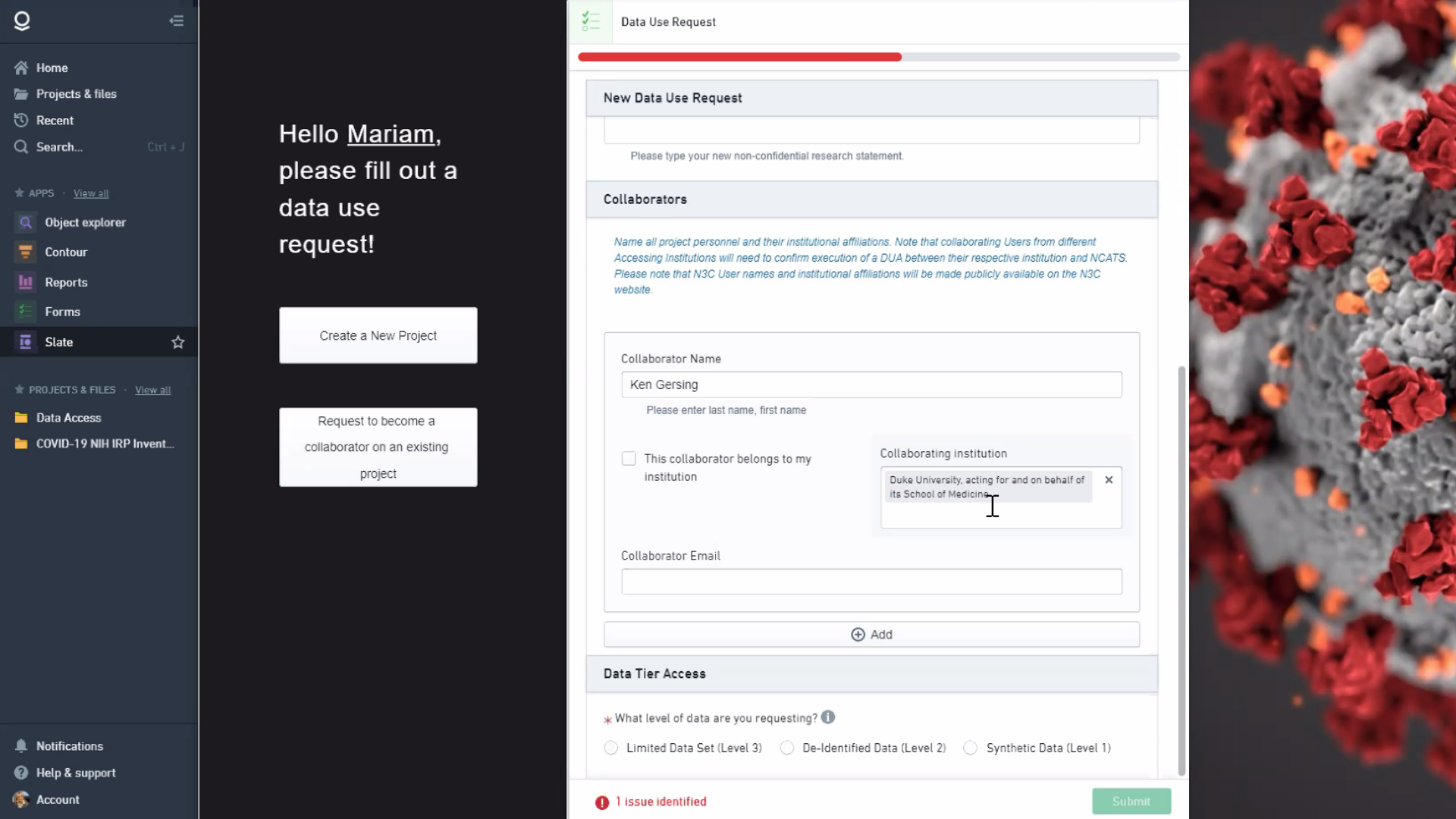
Data Access
COVID-19 NIH IRP Invent...
Notifications
Help & support
Account
Hello Mariam, please fill out a data use request!
Create a New Project
Request to become a collaborator on an existing project
Data Use Request
New Data Use Request
Each Data Use Request (DUR) will be reviewed by the N3C Data Access Committee (DAC) on a project-specific basis. Requesting Users must submit a DUR for each different proposed Research Project.
Username and Accessing Institution will be made public.
User
Mariam Deacy
* Accessing Institution
National Center for Advancing Translational Sciences
* Project Title
Please enter your new project title.
* Allow other researchers to join this project?
Allow
Do not allow
* Non-confidential Research Statement
Please type your new non-confidential research statement.
Collaborators
Name all project personnel and their institutional affiliations. Note that collaborating Users from different Accessing Institutions will need to confirm execution of a DUA between their respective institution and NCATS. Please note that N3C User names and institutional affiliations will be made publicly available on the N3C website.
3 issues identified
Submit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Data Use Request
New Data Use Request
Please type your new non-confidential research statement.
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Name all project personnel and their institutional affiliations. Note that collaborating Users from different Accessing Institutions will need to confirm execution of a DUA between their respective institution and NCATS. Please note that N3C User names and institutional affiliations will be made publicly available on the N3C website.
Collaborator Name
Ken Gersing
Please enter last name, first name
This collaborator belongs to my institution
Collaborating institution
Duke University, acting for and on behalf of its School of Medicine
Collaborator Email
Add
Data Tier Access
What level of data are you requesting?
Limited Data Set (Level 3)
De-Identified Data (Level 2)
Synthetic Data (Level 1)
1 issue identified
Submit

What variables will be in the enclave?

- That is a great question.
- Will have a better idea as the soft launch of the enclave begins.
- We can make an educated guess based upon what NCATS/N3C requested to be uploaded.
- We are gaining insight by listening N3C weekly workgroup calls.

What was uploaded?

- https://ncats.nih.gov/files/OMOP_CDM_v5_COVID_042720.pdf

- Person demographics (date of birth, gender, race, ethnicity)
- Location (county, state, zip)
- Observations (subject history including smoking status, alcohol)
- Death (date of death)
- Complete Visit History (begin and end dates, Inpatient/Outpatient)

What was uploaded?

- https://ncats.nih.gov/files/OMOP_CDM_v5_COVID_042720.pdf

- History of Prescriptions (begin and end dates, doses, drug)
- History of Device Exposure (X-rays, CT Scans, etc)
- Condition Occurrences (All ICD9, ICD10 codes)
- Measurement Histories (A1C, Glucose, Blood Pressure, Weight, BMI, Creatinine, etc)

Listening to the calls, what do we hear?

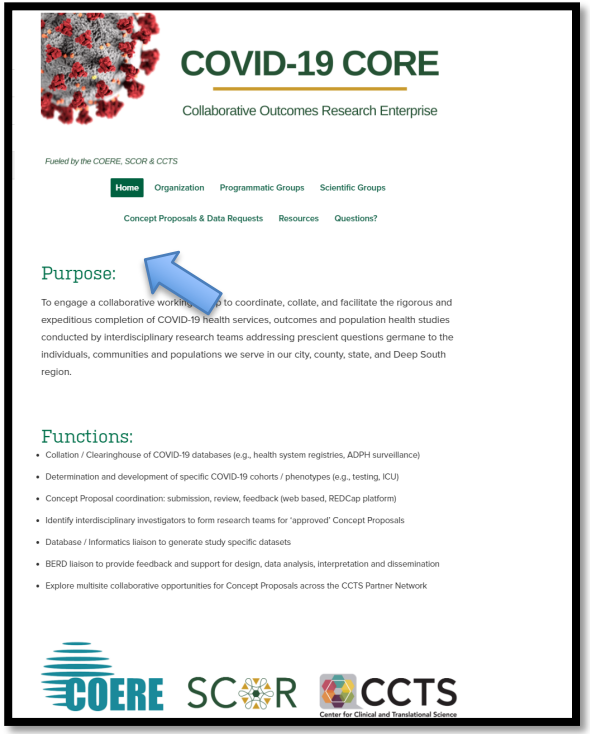
- Data cleaning and quality control procedures.
- Transforming and mapping to constructs (History of Acute Kidney Injury, Type II Diabetes, etc.)
- Calculating comorbidity scores (Charlson, Elixhauser)
- Adding Social Determinants of Health (zip code level)
- Natural Language Processing of the data.
- Data Use Requests – you must propose an analysis and be approved to access the data (synthetic, de-identified, or limited data sets)

Will you be ready for D3C?

- Test your hypotheses with local data!

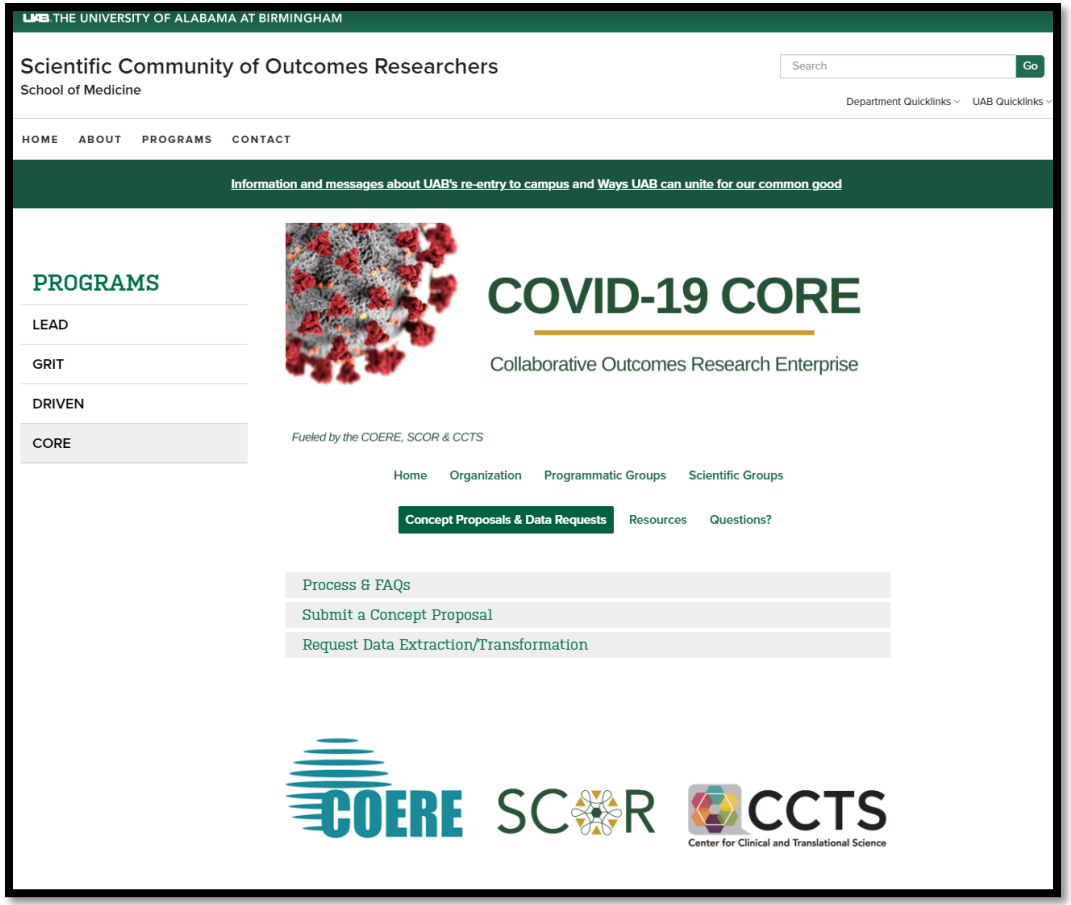
https://www.uab.edu/medicine/scor

Collaborative outcomes research enterprise



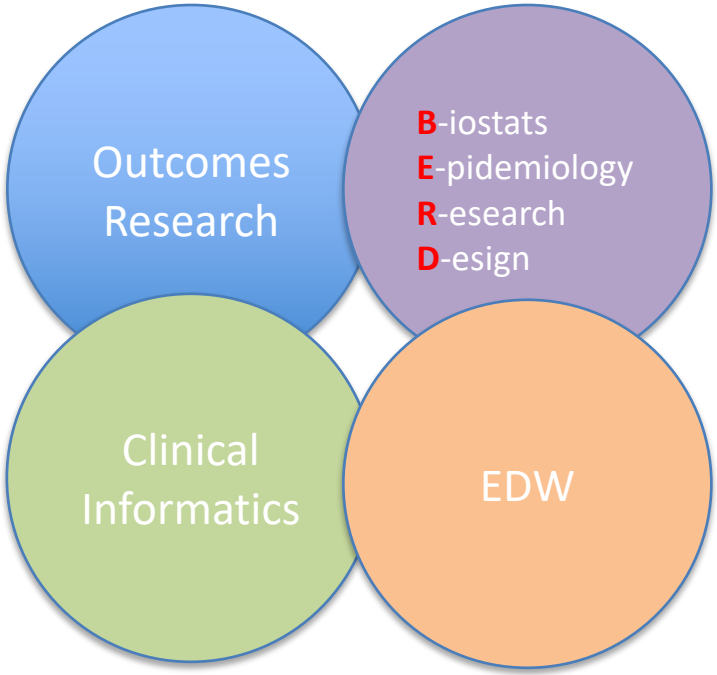
Concept proposals & data requests

https://www.uab.edu/medicine/scor



UAB INFORMATICS INSTITUTE
The University of Alabama at Birmingham

Step 1: Scientific Gateway

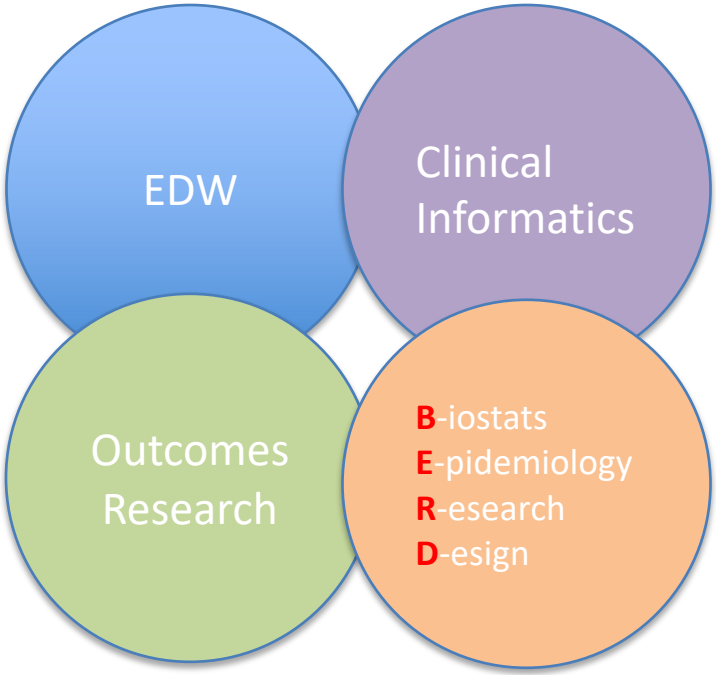


- Interdisciplinary feedback
- Emphasis on study design
- Emphasis on analytic plan
- Get to skeleton tables!

Scientific Gateway: Concept Proposal

- Investigators; contact info
- Research question
- Background
- Study sample/population
- Outcome, control variables
- Statistical analysis
- Limitations
- Target journal
- References

Step 2: Data Extraction/Transformation Gateway



- Variables precisely defined
- Data surrogates explored
- Extraction plan
- Transformation plan
- Groupings needed/Plan

Scientific Gateway: Concept Proposal

- Investigators; contact info
- Research question/objectives
- Purpose (grant, feasibility, etc.)
- Define population
- Outcome, control variables
- Study period (time tether)
- Format for data delivery
  - .CSV, .xlsx
- Mechanism for secure data delivery
- Copy of your IRB

Extraction/Transformation

- Extraction
  - All patients with a Covid19 RT-PCR Positive test starting 3/1/20-Present
  - All encounters in the EDW for those patients 3/1/20-Present

- Transformation
  - Study population equals: Date of first hospital admission closest in days to first Covid19 RT-PCR
    - Use mappings for inpatient – bedded ER, observation, inpatient
    - Use mappings for all Covid19 RT-PCR tests
  - PT ID/MRN/Date of Positive RT-PCR/Date of first inpatient admission
  - Groupings for Cancer, CHF, DM, etc.

Next Steps

- Encourage your institution to sign DUA
- Formulate a question
- Identify collaborators
- IRB approval
- Resources:
  - N3C Web site: https://ncats.nih.gov/n3c
  - On-boarding: https://cd2h.org/onboard