Services and tools that Support Translational Research at the Department of Biomedical Informatics

Friday, November 4th, 2022

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Learning Objectives:

1) Become familiar with the various tools, services and capabilities that support Translational Research

2) Describe different data types, de-identification, and the Privacy Rule

3) Identify the differences between research and QA and QI

Target Audience:

Clinical Research Professionals (CRPs) at UC/H and Cincinnati Children's Hospital Medical Center (CCHMC): including Principal Investigators (PIs), Research Nurses (RNs), Critical Care Unit Nurses (RNs), Pharmacy Technicians and Regulatory Specialists.

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The University of Cincinnati is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

The University of Cincinnati designates this live activity for a maximum of 1 *AMA PRA Category 1 Credit*™. Participants should claim only the credit commensurate with the extent of their participation in the activity.

CRPs, NPs, PAs, and RNs can count activities certified for *AMA PRA Category 1 credit*™ for professional credit reporting purposes. Other healthcare professionals should inquire with their certifying or licensing boards.

Disclaimer Statement

The opinions expressed during the live activity are those of the faculty and do not necessarily represent the views of the University of Cincinnati. The information is presented for the purpose of advancing the attendees' professional development.

Off-Label Disclosure Statement:

Faculty members are required to inform the audience when they are discussing off-label, unapproved uses of devices and drugs. Physicians should consult full prescribing information before using any product mentioned during this educational activity.

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Speaker and Planner Disclosure Policy:

In accordance with the ACCME Standards for Integrity and Independence Integrity and Independence in Accredited Continuing Education and the University of Cincinnati policy, all faculty, planning committee members, and other individuals, who are in a position to control content, are required to disclose all relationships with ineligible companies* (commercial interests) within the last 24-months. All educational materials are reviewed for fair balance, scientific objectivity, and levels of evidence. The ACCME requires us to disqualify individuals who refuse to provide this information from involvement in the planning and implementation of accredited continuing education, or whose conflicts of interests cannot be mitigated.

**Companies that are ineligible to be accredited in the ACCME System (ineligible companies) are those whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients.*

All relevant relationships have been mitigated. The following disclosures were made:

Planning Committee Members:

- Maria Stivers, MS, CIP; Course Director – No Relevant Relationships
- Nathaniel L. Harris, BS, Course Coordinator – No Relevant Relationships
- Heather Muskopf, CME Program Manager – No Relevant Relationships

Speaker:

Brett M. Harnett, MS-IS
Asst. Professor, Field Service
Director, Center for Health Informatics
Department of Biomedical Informatics (BMI)
Consultant for Johnson & Johnson

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UC Health Compliance Training REQUIRED for all CLINICAL RESEARCH PROFESSIONALS and CLINCAL RESEARCH STAFF

Annual Compliance Training is open in ONE TOUCH for all Clinical Research Professionals & Clinical Research Staff.

Assigned training must be completed by 5pm Friday, Nov. 11th, 2022 or disciplinary action will be taken.

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Please contact MYHR@uchealth.com or 585-MYPC.

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UC Health Annual Flu Vaccination Requirement

The UCH annual flu campaign began the week of October 3rd, 2022.

If you are a Contractor (MOST CLINICAL RESEARCH STAFF or those who are ONLY University of Cincinnati, FALL UNDER THIS CATEGORY), You will need to fulfill this requirement with one of the following 4 options:

- **Email proof of vaccine documentation completed elsewhere to UCH-Employee-Health@UCHealth.com**
- **Drop off proof of vaccine documentation at UC Health Employee Health**
- **Receive your flu vaccine at UC Health Employee Health**
- **Or attend one of the UC Health vaccine blitz events and fill out a paper form.**

If you are a UCH Employee, or a UCP employee hired prior to April1, 2022, the survey (consent form) will be in Readyset. ***This survey must be filled out prior to receiving your vaccine, and also if you receive the vaccine elsewhere.***

CLINICAL RESEARCH Staff and related services are required to receive an annual flu vaccination by Friday, Nov. 11, 2022 at 5 p.m.

Please contact UCH Employee Health for any questions

UC / UC Health
Clinical Research Orientation and Training (CRO&T)

Thursday, December 8th, 2022
9:00 am - 3:00 pm
Virtual presentation

The last day of registration is Friday, December 2nd, 2022

Register Here

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Please reach out to Nate Harris, nate.harris@uchealth.com for any questions

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Today's Presentation:

Services and tools that Support Translational Research at the Department of Biomedical Informatics

Join us in this session to become familiar with the various tools, services and capabilities provided by the Department of Biomedical Informatics at the UC College of Medicine, where you'll gain a high-level understanding of data types, de-identification, the Privacy Rule, and an understand of the differences between research and QA/QI, as well as where the lines are often blurred.

Brett M. Harnett, MS-IS

Asst. Professor, Field Service

Director, Center for Health Informatics

Department of Biomedical Informatics (BMI)

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UC College of Medicine | Biomedical Informatics

From Blood and Guts
To Bits and Bytes

Services and tools to Support Translational Research
UC Biomedical Informatics
First Fridays

Brett Harnett, MS-IS
Director, Center for Health Informatics
Asst. Professor, Field Service
brett.harnett@uc.edu

November 4, 2022

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Learning Objectives:

1. Become familiar with the various tools, services and capabilities provided by the Department of Biomedical Informatics at the UC College of Medicine.
2. Have a clear understanding of data types, de-identification and the Privacy Rule.
3. Understand the differences between research and QA/QI, as well as where the lines are sometimes blurred.

Learning Objectives

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"I have nothing to disclose nor and financial interests regarding the content of this presentation."

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In a message to Congress, the President of the United States said:

"Millions of our citizens do not now have a full measure of opportunity to achieve and to enjoy good health. Millions do not now have protection or security against the economic effects of sickness. And the time has now arrived for action to help them attain that opportunity and to help them get that protection."

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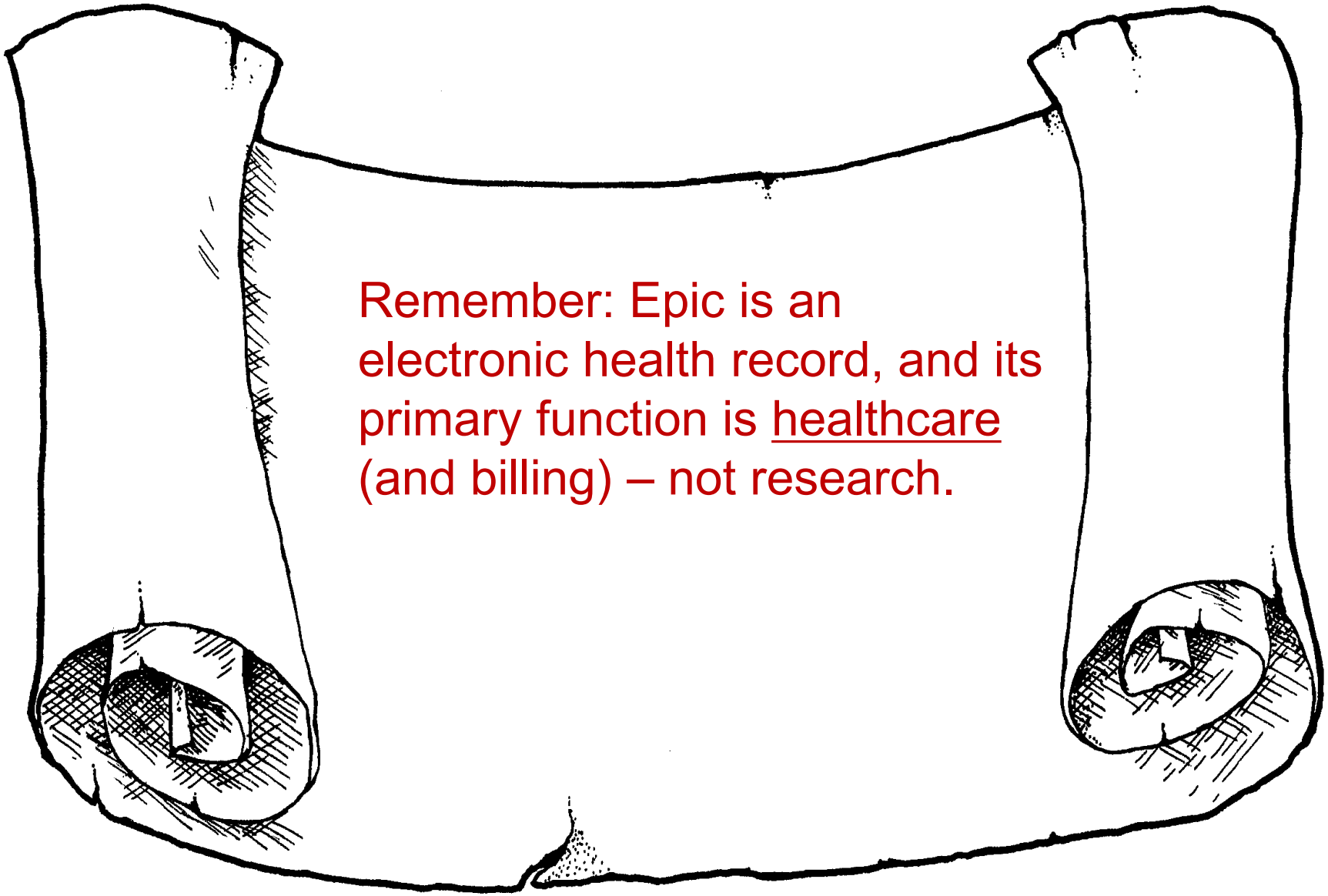
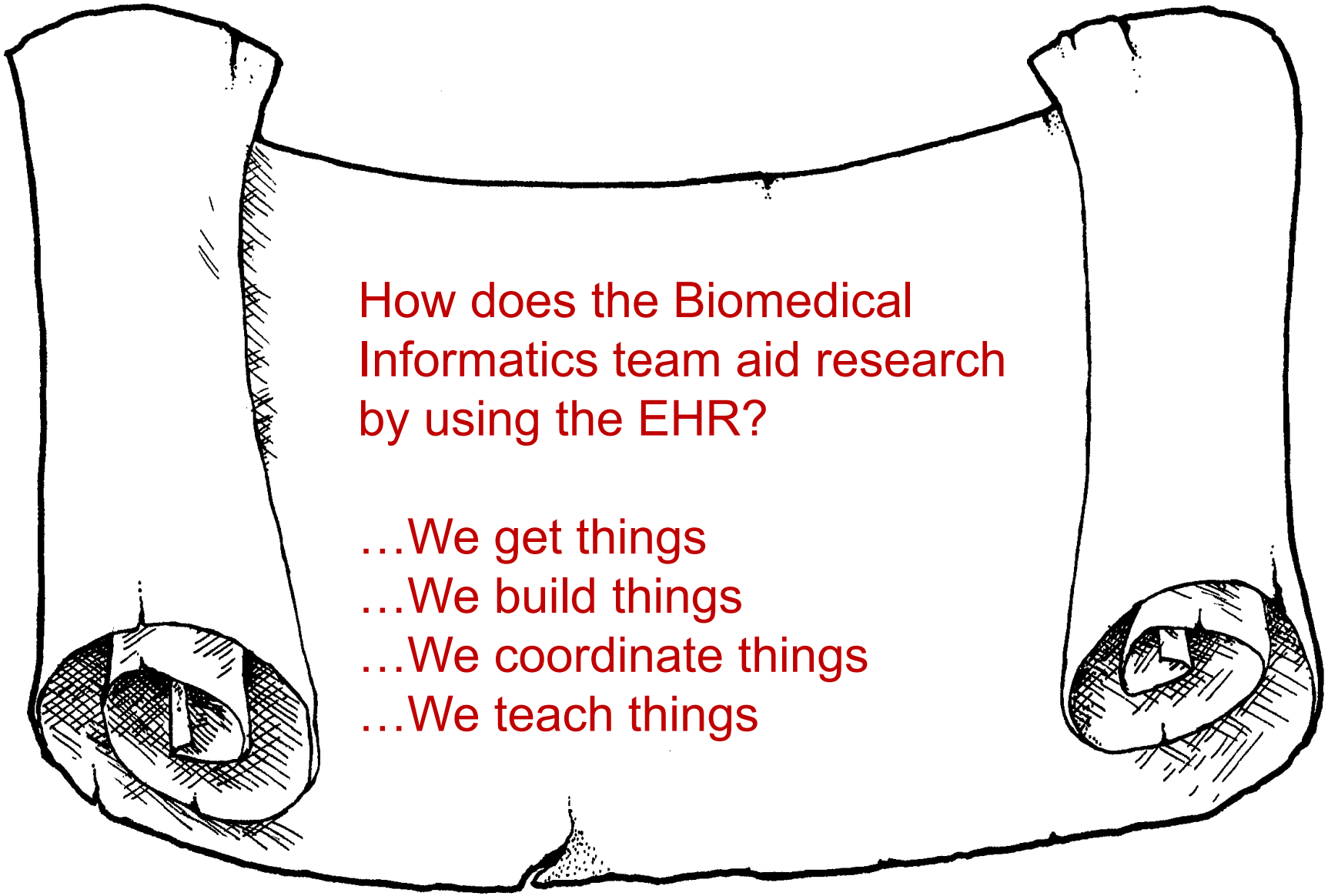
This was President Truman in 1945


Remember: Epic is an electronic health record, and its primary function is healthcare (and billing) – not research.



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I need data, where do I go?
If it’s clinical QA/QI = UC Health
If it’s research = BMI/CHI
If unsure, we will figure it out

Albert Sabin Way, Cincinnati, OH 45219, hereinafter "CHI". Each of ACE and
o herein as a "Party" and collectively, as the "Parties".

HEREAS, the ACE is a covered entity, as defined in HIPAA, which uses and maintains a
ctronic Medical Record ("EMR") and related information systems (e.g. scheduling systems,
llectively referred to as Health Information Systems ("HIS"), as described in Exhibit A;

WHEREAS, in order to effectively carry out certain of the healthcare operations and
search missions of the ACE's participants and of the University of Cincinnati, the ACE desires to
enter into an agreement with CHI to help the ACE manage the uses and disclosures of data that
includes protected health information ("PHI") from the HIS, exclusively for furthering certain of the
ACE's clinical, operations, research and public health purposes as more fully described in this
Agreement (and any amendments thereto); and

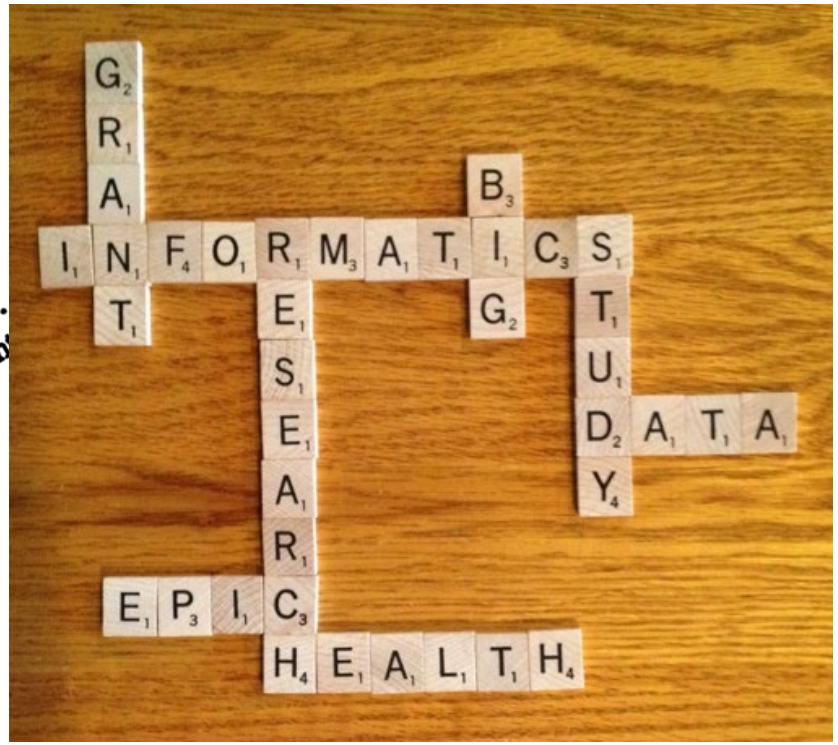
WHEREAS, the ACE and CHI agree that any uses or disclosures of ACE PHI or de-
identified information accessed from UC Health will comply with all applicable privacy and
security requirements of federal and state law including HIPAA.

NOW, THEREFORE, the Parties agree as follows:

SECTION I. GENERAL PROVISIONS AND DUTIES OF THE PARTIES.

A. Throughout this Agreement, the term "Participants" is used to refer to the members of the
ACE with whom the CHI is joining in this Agreement. "DR" refers to Data Repository.
CHI will extract data and create DRs from the HIS data as necessary under this Agreement
Agreement, the Participants authorize the use and disclosure of their data

The CHI is the designated Honest Broker for the University of Cincinnati and affiliates



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QA/QI vs Research

QA/QI

- Systematic data-guided activities designed to bring about immediate positive changes in healthcare delivery and practices
- Integral part of continuous improvement
- A form of clinical and managerial innovation and adaptation
- Combines discipline-specific knowledge and experiential learning and discovery

Research

- Systematic investigation designed to develop or contribute to generalizable new knowledge
- Implementation of research is a separate process – and commonly referred to as a “Learning Health System”
- Usually performed by researchers independent of clinical care – often retrospective but also prospective

Categories of Data

BMI/CHI:

Aggregate numbers [?]
Counts on patient cohorts

De-identified data [?]
All PHI stripped out using Safe Harbor or Expert Determination method

Limited Data Set [?]
A specific set of data where 16 of the 18 patient identifiers are removed, usually dates of service and geographic locations more granular than state or zip codes <20k people.

Fully identified patient data [?]
For research purposes, a valid IRB HIPAA waiver is required.

Identified data for preparatory research [?]
These are special conditions and can only be accessed with mediation at the CHI with no recording of data.

UC Health:

Quality Improvement or Operations data [?]
Fully identifiable data is available but under special rules, no IRB is required.

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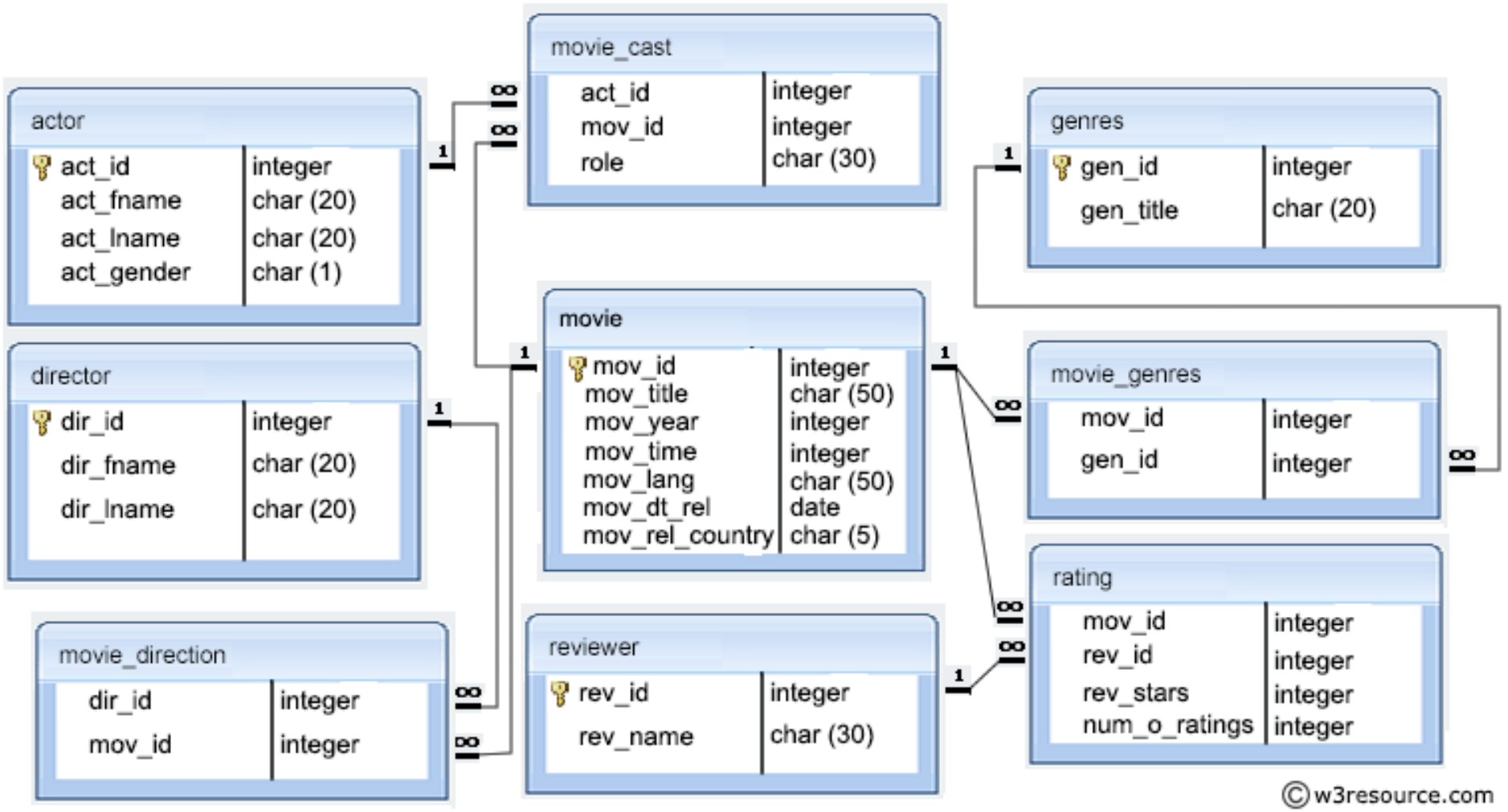
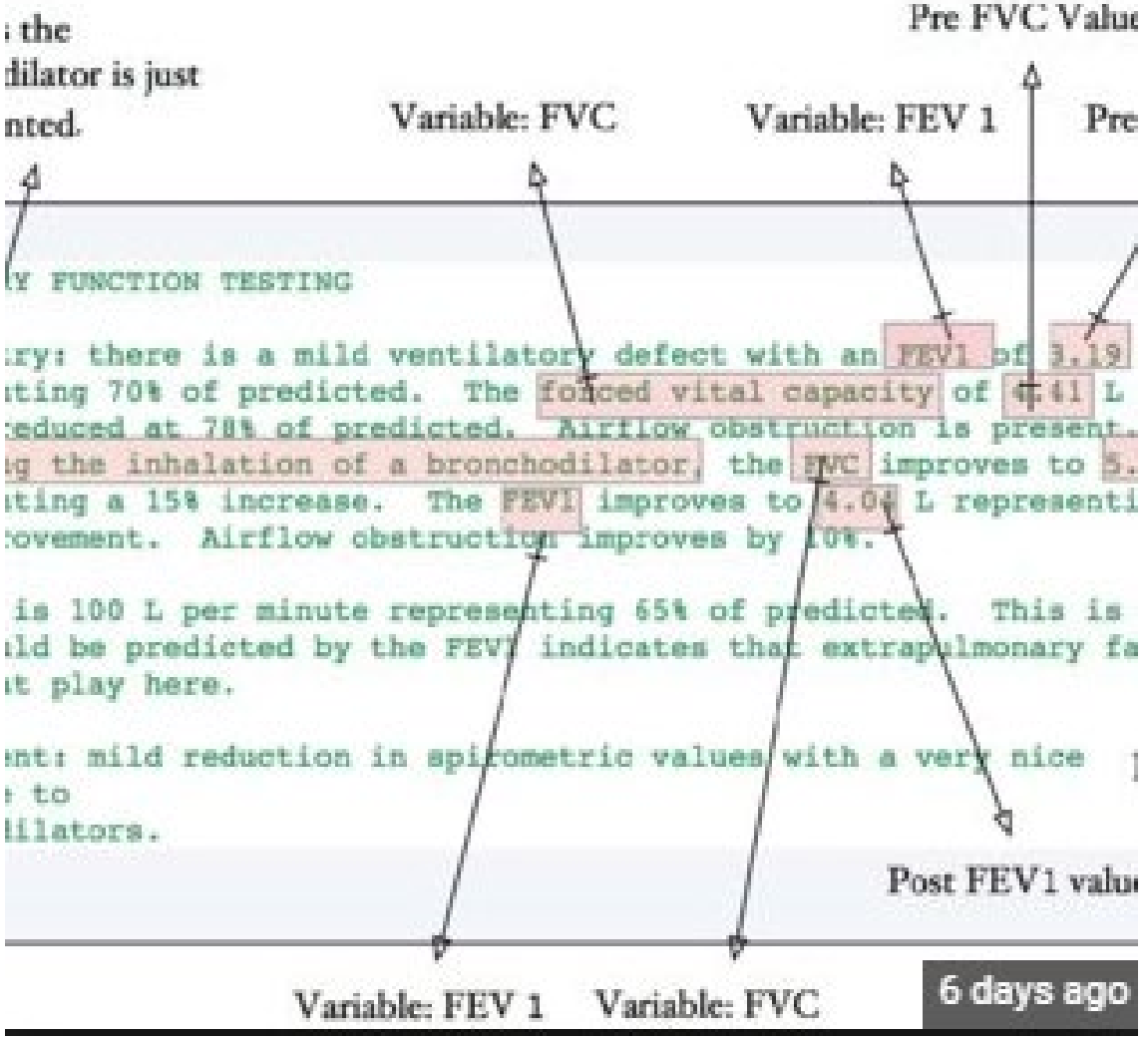
Types of Data

- Structured
- Unstructured
- Semi-structured

Structured Data



Unstructured Data

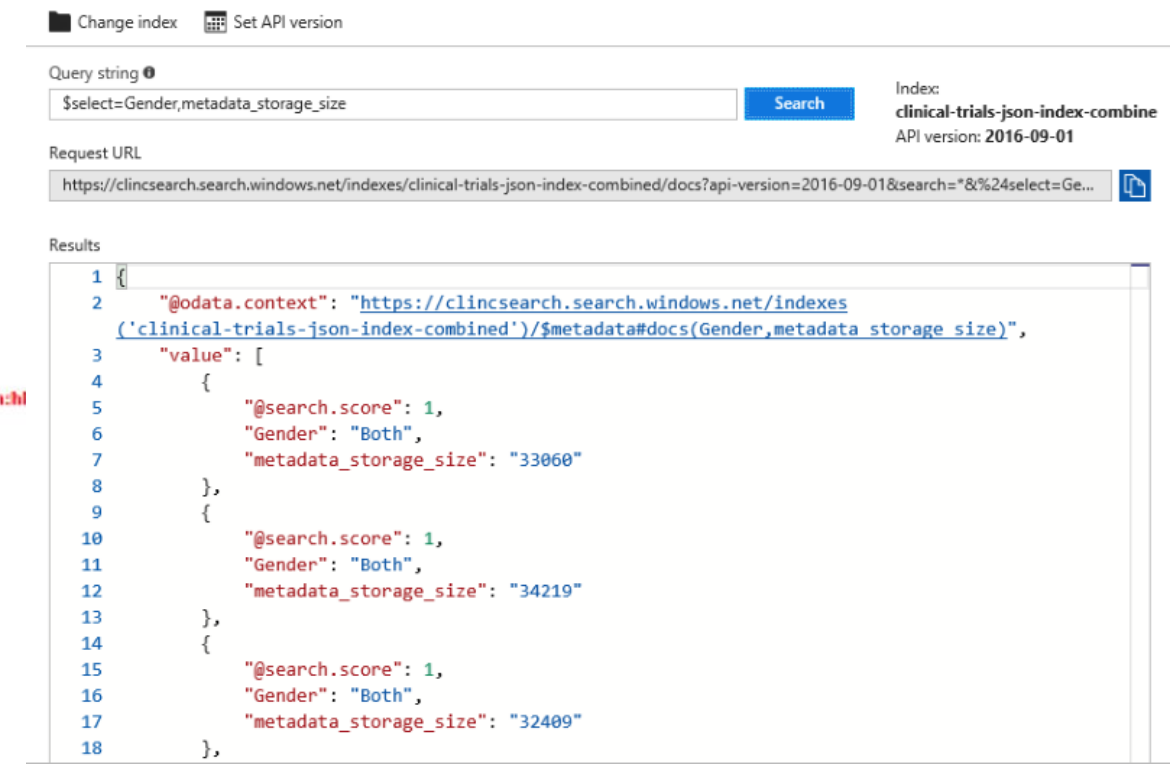


Semi-structured Data

```
<?xml version="1.0" encoding="UTF-8" standalone="no" ?>
- <ClinicalDocument NS2:schemaLocation="urn:hl7-org:v3 CDA.ReleaseTwo.Committee.2004.xsd" templateId="2.16.840.1.113883.3.27.1776" xmlns="urn:hl
   xmlns:NS2="http://www.w3.org/2001/XMLSchema-instance">
   <id extension="c266" root="2.16.840.1.113883.3.933" />
  + <recordTarget>
  - <component>
    - <StructuredBody>
      - <section>
          <code code="10160-0" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC" />
          <title>Medications</title>
        + <Observation>
        + <Observation>
        - <SubstanceAdministration>
          - <text>
              <content ID="m1">Theophylline</content>
              20 mg every other day, alternating with 18 mg every other day, for 2 weeks. Stop if temperature is above 103F.
            </text>
          + <consumable>
          </SubstanceAdministration>
        </section>
      - <component>
        - <section>
            <code code="10164-2" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC" />
            <title>History of Present Illness</title>
          - <text>
              3 month old baby who has been transferred to MCH CICU for VSD repair. He was born FT, but had resp. distress requiring mehcanical ventilation for 3 days for
              pulmonary edema. He was diagnosed then to have a large VSD. He was prescribed
              <medication IDREF="m1">Theophylline.</medication>
              He was admitted in the hospital for about a month for his resp. issues. He was sent home but after 3 weeks developed bronchiolitis and had been in the hospital
              since then. During this admission he was also diagnosed to have GE Reflux and Aspiration. He was also found to have Chronic lung disease -- possibly due to
              aspiration. He also had complex partial seizures due to resp. distress which were being treated with Phenobarb. For the last 4 days his feeds were switched to
              NJ and is now transferred to Miami for surgery on 11/15/06 to have the VSD closed.
            </text>
          </section>
        </component>
      </StructuredBody>
    </component>
```

XML

Extensible Markup Language



JSON

JavaScript Object Notation

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Research = IRB

How and Why

1. * **If you will use hospital or other healthcare provider records, data from a research data repository or any other information maintained by a hospital, academic medical center or another healthcare entity, how will you gain access to this information?**

- [x] **Through a HIPAA Authorization signed by the participant (or their legally authorized representative).**
- [ ] As a limited data set under a data use agreement.
- [x] **Requesting that the IRB approve a waiver of authorization in this application.**
- [ ] The research will not use hospital or other healthcare provider records, data from a research data repository or any other information maintained by a hospital, academic medical center or another healthcare entity.

Request for Waivers:

• An explanation as to why obtaining consent/authorization would prevent the research from being completed.
• An explanation as to whether it is possible or feasible to obtain informed consent, given the scope of the research, including whether the research could still occur if consent was obtained.
• An explanation as to how the removal of the consent process from the conduct of this research will not adversely affect the rights or welfare of participants. (Note: "participants" in this case is human data/specimens. The use of human data/specimens for research purposes constitutes human subjects research.) An example of adverse effects might include a person's right to decide whether or not they want to be a participant in a research study.

Please note the following requirements:

Consent Requirements
Per 45 CFR 46.116 the IRB has waived the requirement to obtain informed consent for all adult participants.

Parental Permission Requirements
There are no items to display

Assent Requirements
There are no items to display

HIPAA Requirements
Per 45 CFR 164.512 the IRB has granted a waiver from the requirement to obtain an authorization for the use and/or disclosure of protected health information (PHI).

AMENDMENTS: The principal investigator is responsible for notifying the IRB of any changes in the protocol, participating investigators, procedures, recruitment, consent forms, FDA status, or conflicts of interest. Approval is based on the information as submitted. New procedures cannot be initiated until IRB approval has been given. If you wish to change any aspect of this study, please submit an Amendment via ePAS to the IRB, providing a justification for each requested change.

CONTINUING REVIEW: The investigator is responsible for submitting a Continuing Review via ePAS to the IRB at least 30 days prior to the expiration date listed above. Please note that study procedures may only continue into the next cycle if the IRB has reviewed and granted re-approval prior to the expiration date.

UNANTICIPATED PROBLEMS: The investigator is responsible for reporting **unanticipated problems** promptly to the IRB via ePAS according to current reporting policies.

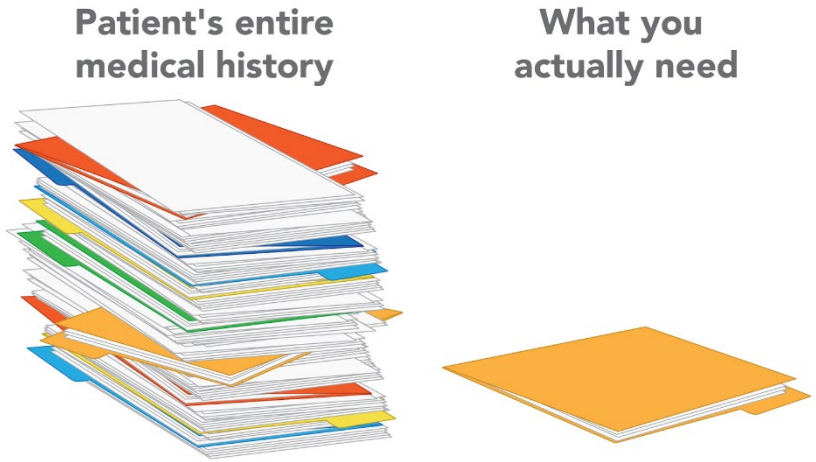
STUDY COMPLETION: The investigator is responsible for notifying the IRB by submitting a Request to Close via ePAS when the research, including data analysis, has completed.

Please note: This approval is through the IRB only. You may be responsible for reporting to other regulatory officials (e.g. VA Research and Development Office, UC Health – University Hospital). Please check with your institution and department to ensure you have met all reporting requirements.

Statement regarding International conference on Harmonization and Good clinical Practices. The Institutional Review Board is duly constituted (fulfilling FDA requirements for diversity), has written procedures for initial and continuing review of clinical trials: prepares written minutes of convened meetings and retains records pertaining to the review and approval process; all in compliance with requirements defined in 21 CFR Parts 50, 56 and 312 Code of Federal Regulations. This institution is in compliance with the ICH GCP as adopted by FDA/DHHS.

Minimum Necessary Restriction

- Law imposes a minimum necessary requirement on all permitted uses and disclosures of PHI by a covered entity.
  - This means that a covered entity must apply policies and procedures, or criteria it has developed, to limit certain uses or disclosures of PHI, including those for research purposes, to "the information reasonably necessary to accomplish the purpose [of the sought or requested use or disclosure]."

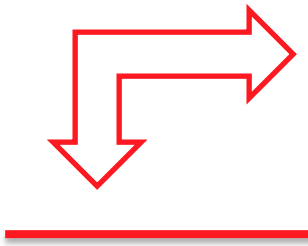


IT@UC Office of Information Security

Data Classification and Data Types

Export Control

- Information or technology that is labeled with any versions of the following: Export Controlled, ITAR USML category, EAR CCL ECCN, 22 CFR 120-125,15 CFR 730-774, 10 CFR part 810
- Any information or technology that is classified as export controlled
- Any information or technology that you believe may be export controlled, must be controlled as such until a review from the UC Export Controls Office is complete



Restricted

Breaches must be reported to the unit head, who will forward information to information security,

- Social Security Number, Driver's License Number, State ID Card Number
- Financial Account Number, Credit/Debit Card Number
- Electronic Stored Biometric Information
- Protected Health Information (HIPAA)
- Data from Human Subject Research
- Transcripts, ISO Number
- Data deemed highly sensitive by the University

Controlled

Breaches must be reported to the unit head, who may forward information to information security.

- Graded work, grade books, etc.
- Data from research germane from intellectual property
- Data whose integrity must be maintained
- Other data designated by the university

Public

This data requires no confidentiality protection

- Data that is readily available to the public

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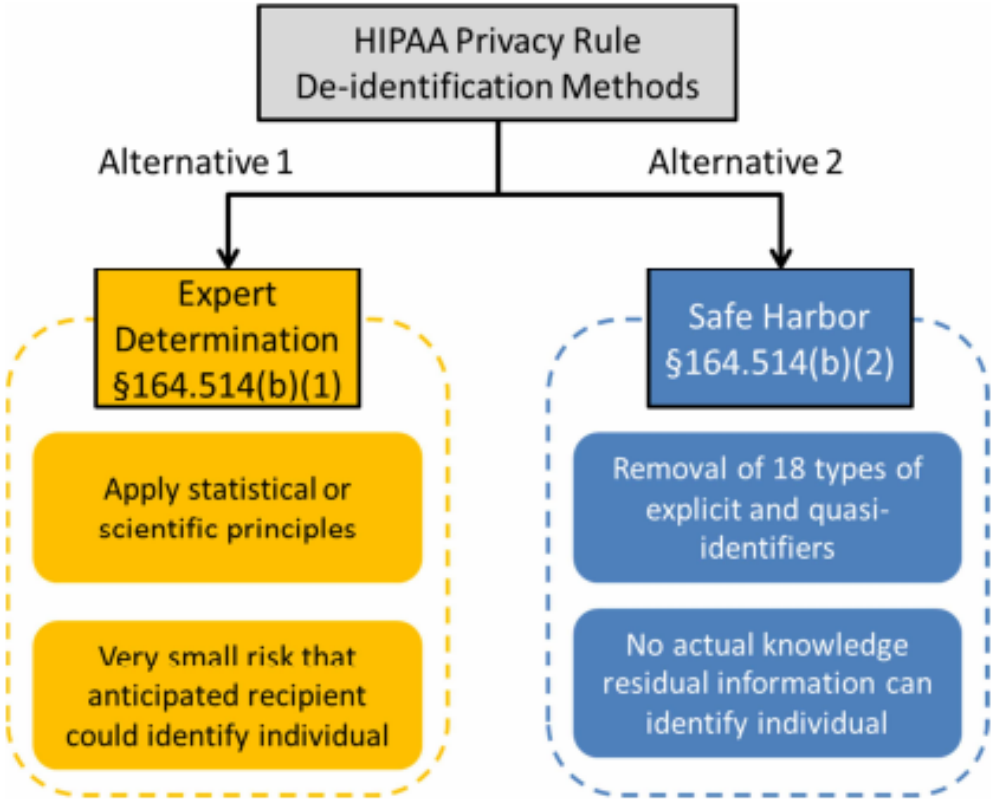
Two methods for the de-identification of health information

"Safe Harbor" - remove 18 specified identifiers - intended to provide a simple, definitive method for de-identifying health information with protection from litigation (also called heuristic method).

"Expert Determination" - retain some of the 18 safe harbor's specified identifiers and demonstrate the standard is met if person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods, e.g., a Biostatistician, makes and documents that the risk of re-identification is very small.



18 HIPAA identifiers

Obvious identifiers

- name
- address
- SSN
- phone
- fax
- e-mail
- full face photo

Less obvious identifiers

- any dates
- MRN
- health plan #
- account #'s
- license #
- VIN
- device #
- URL's
- IP address
- finger/voice print
- any other unique identifying numbers, characteristics or codes

CHI Services

ABOUT OUR SERVICES

- Consultations/Grant Development
- Data from Epic
- Research Recruitment
- Custom Software Development
- Data Science/Visualization
- Automated Data Collection (FHIR)

CHI Terms of Service

CHI Data Use Agreement

The CHI is a Government Cost Control Service Center and charges for services.

Need *UC Health patient data* or *custom IT solutions* for your research data?

Whether you're looking to collect it, clean it, query it, visualize it, explore it, analyze it or mine it - CHI's team of IT professionals and data scientists can help.

Use the menu to the left to browse our services, or request a general consultation if you're not sure what you need.

NOTE: Demand for data services fluctuates during the year. While some data requests are filled within a week or two, it may take 4 weeks plus. Please plan ahead to avoid delays that may affect deadlines in your research pathways.

POPULAR SERVICES

General Consult

Discuss with CHI about your data, technology development, or data analysis needs. We have Epic-certified analysts, application developers and data scientists on staff, along with closely aligned data science faculty. From study design, to designing ways for more effective utilization of biohealth data, to enhancing your grant submissions, our integrated group in Biomedical Informatics can help enhancing your biohealth data science. If you are a student, we can provide certain subsidized services, see Terms of Service.

More info

Study Feasibility & Publishing using TriNetX

TriNetX is an intuitive, elegant, and ultra-fast tool for querying UC Health's Epic data and the global research network. TriNetX can find patient cohort counts defined by clinical criteria such as diagnoses, demographics, clinical procedures, lab results and medications. These queries can be used for feasibility, subject recruitment, hypothesis generation, or defining a clinical data extract for analysis. TriNetX is a self-service tool but complex queries can be mediated by CHI for a fee. If TriNetX does not have the detailed elements required, we will escalate the request to a search within Epic. (See 'Study Feasibility directly from Epic')

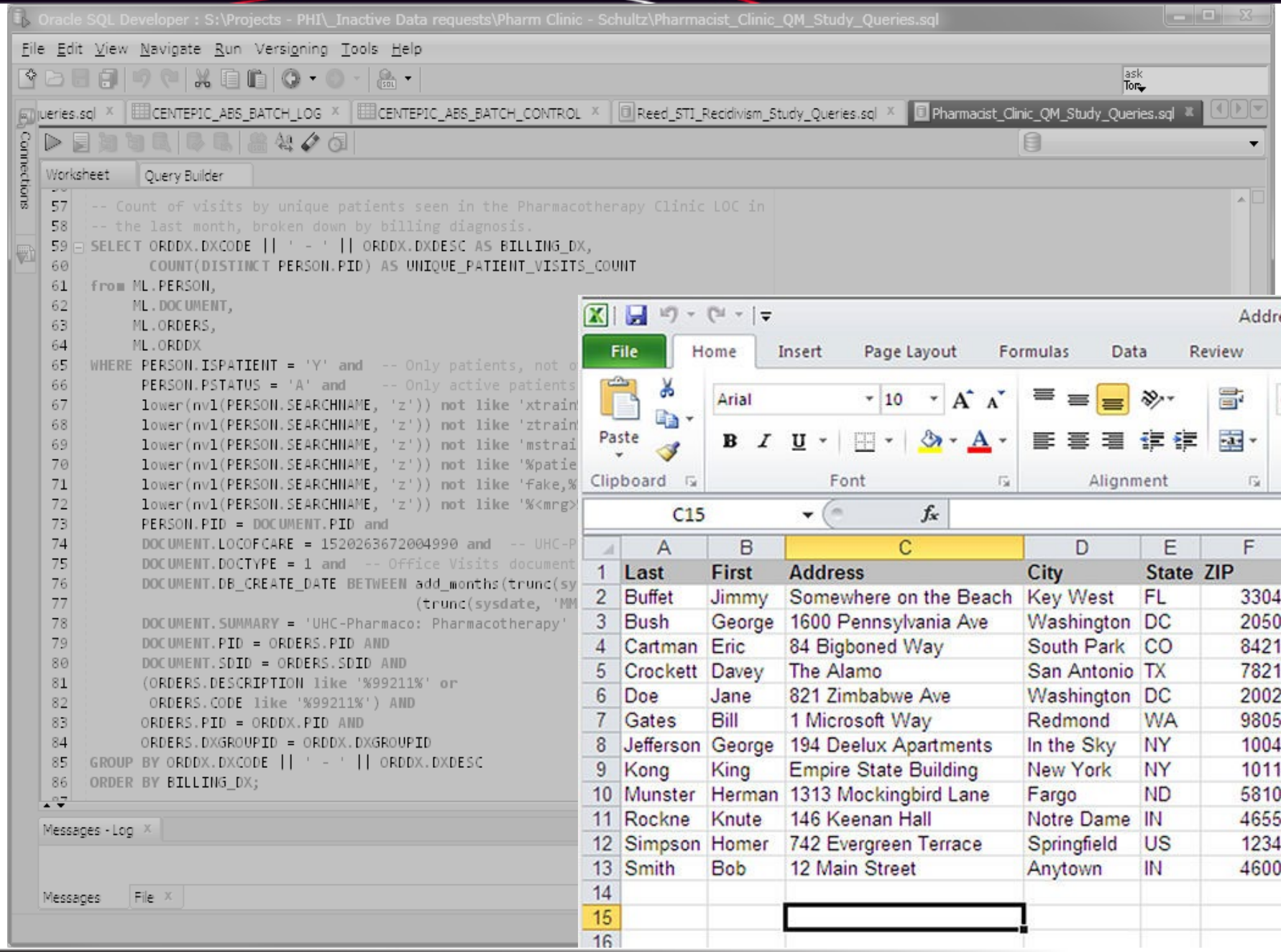
More info

Clinical Data Extractions: FULLY Identified Data Sets

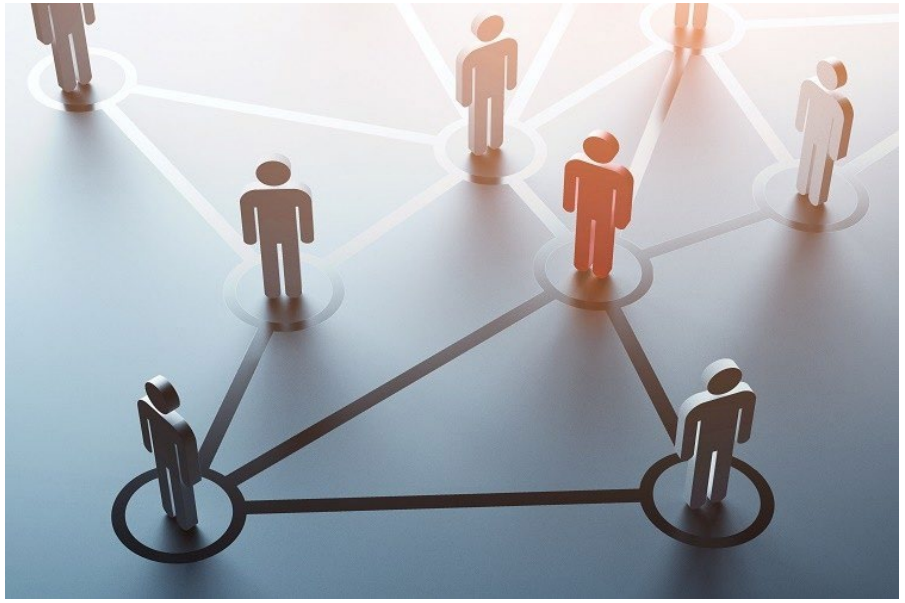
CHI can provide fully identified data sets from UC Health's Epic Electronic Health System and other clinical systems for research use. Fully identified data sets can include HIPAA identifiers that requires an approved IRB protocol.

More info

What do our data analysts do?



TriNetX



A network where HCOs supply de-identified patient data so pharmas and CROs can identify sites with certain patient populations.
And fund studies here.

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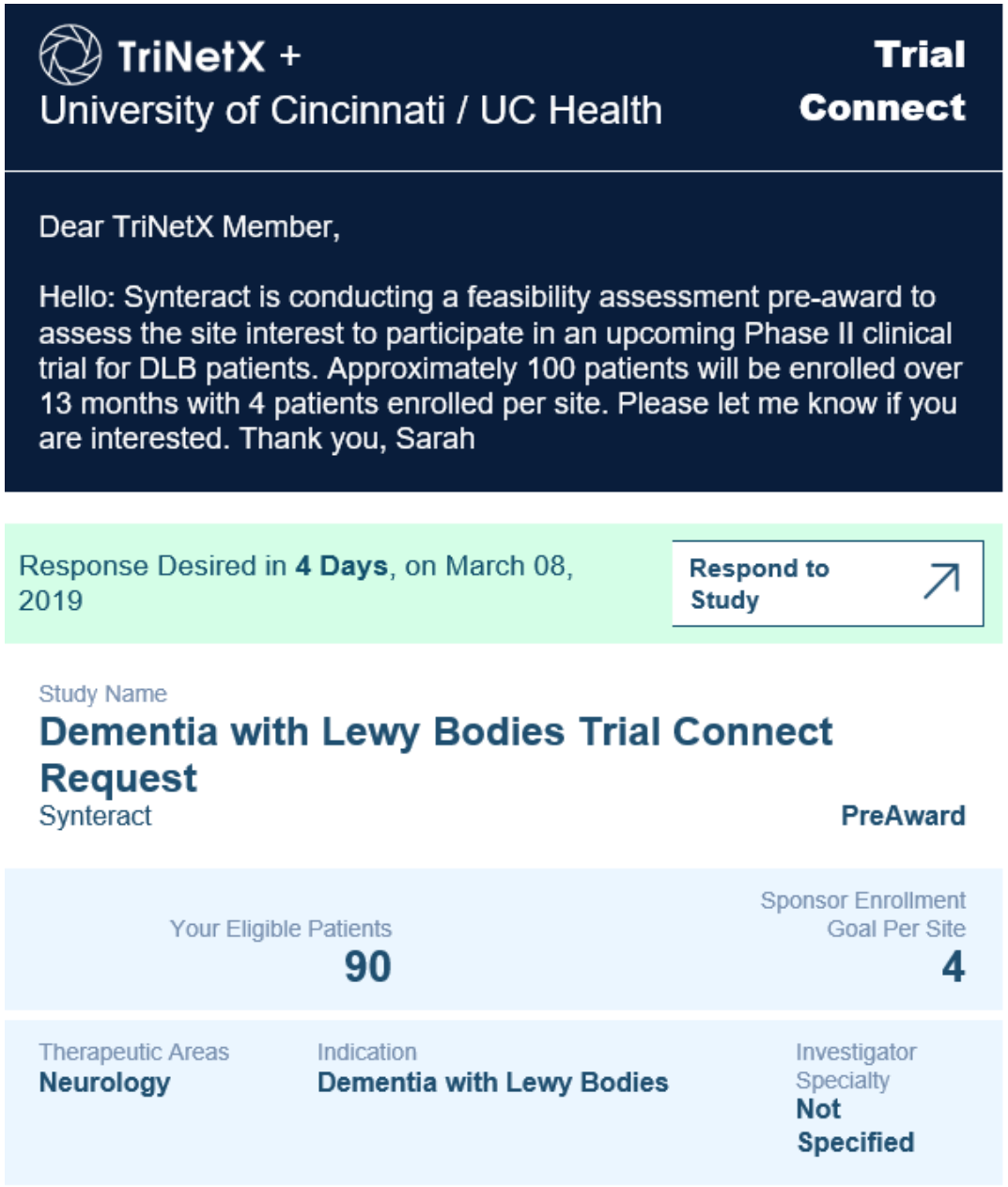

TriNetX has three primary use cases:

1. Clinical Trials. UC has been offered almost 200 trials since 2015, taken about a third.

2. Local cohort analysis. Over 28,000 queries since 2015.

3. Generalizable research using Real World Evidence. That is, the TriNetX Research Network.

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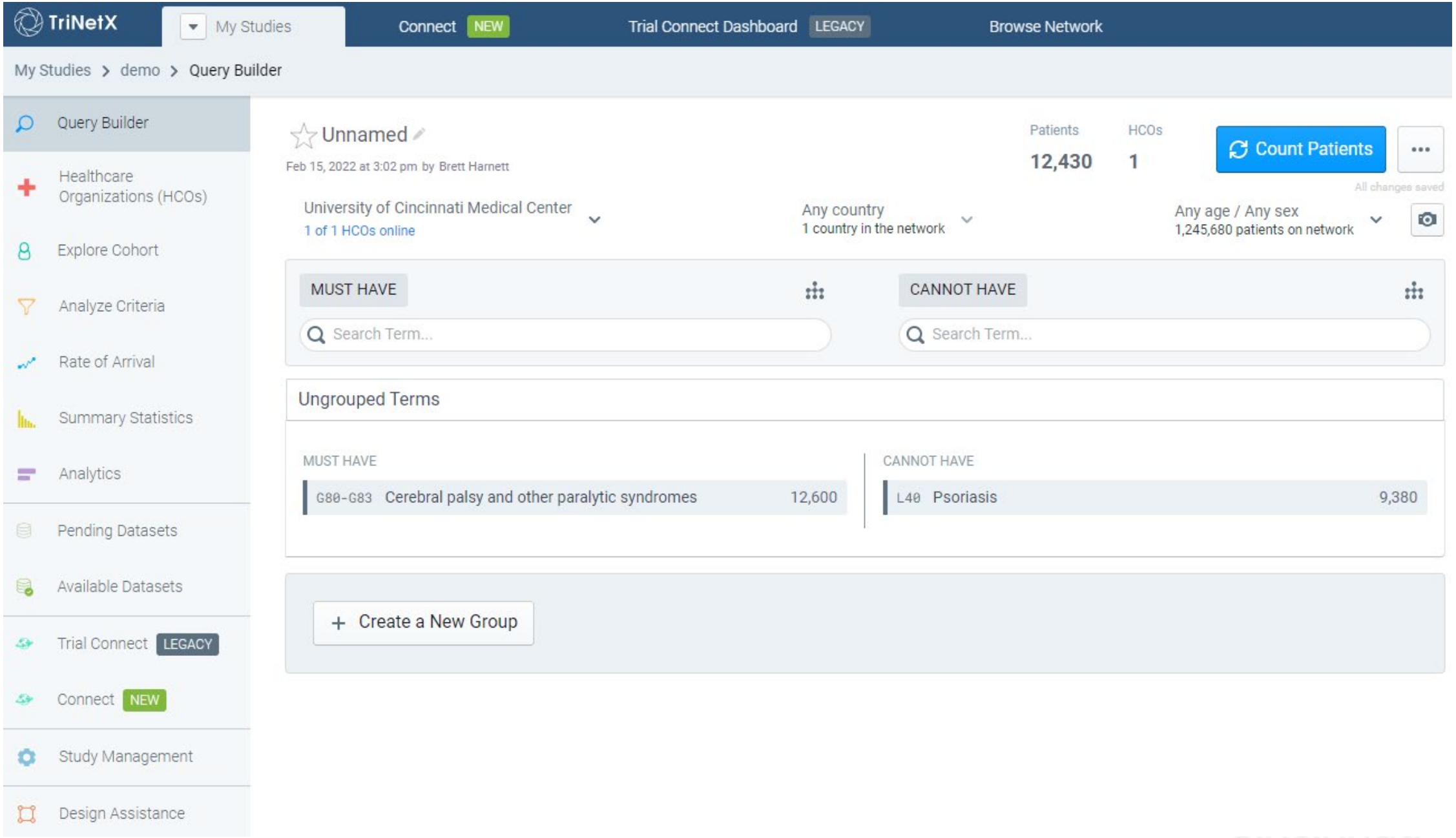
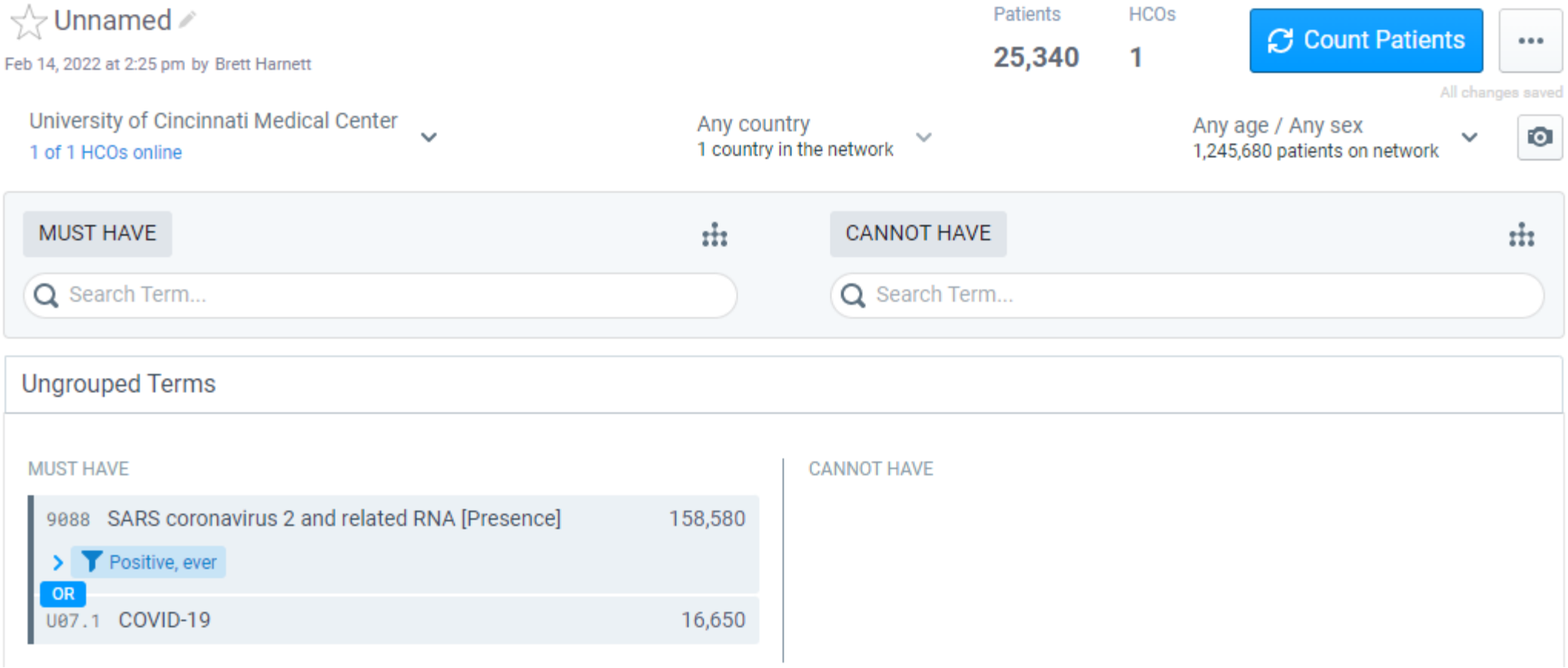
Most Basic Level



How many people developed Chronic Kidney Disease within three months after a COVID infection?
- temporal analysis -



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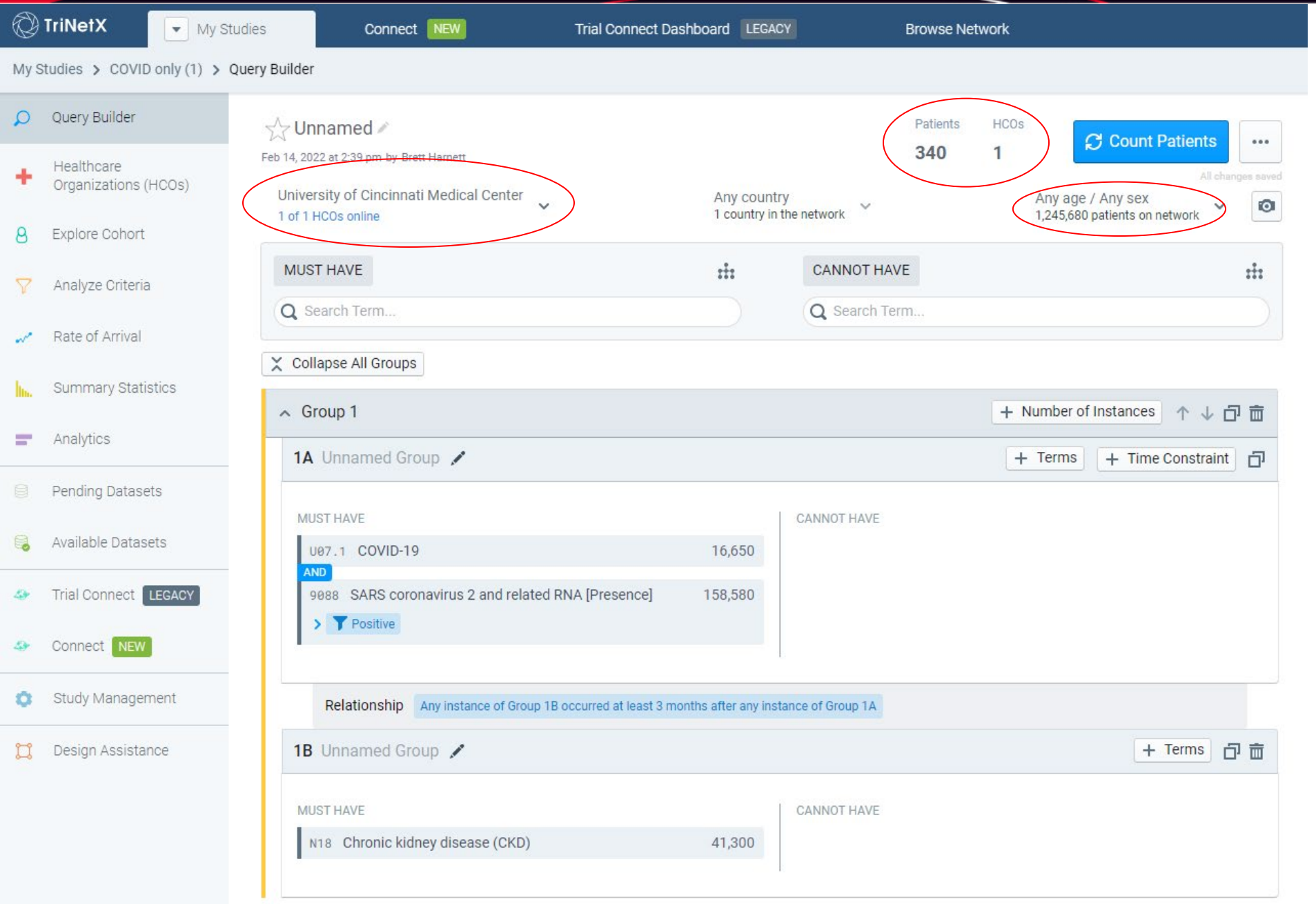

Create two groups, related by a temporal constraint – Event 1B occurred at least three months after Event 1A

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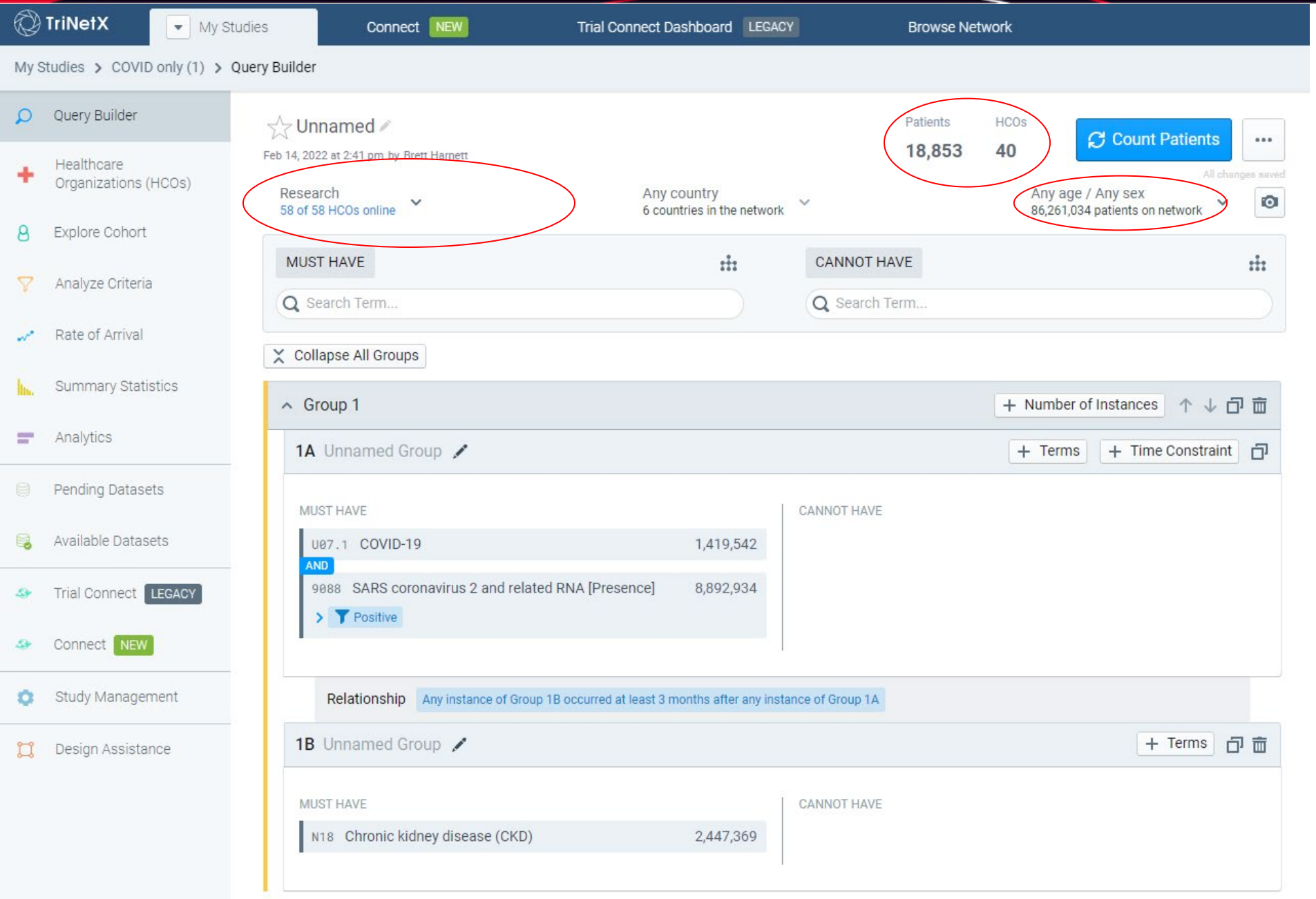

Using the exact same logic, select the Research network to run the query against 39 other sites equating to >86M instead of 1.2M.

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Unnamed

Feb 14, 2022 at 2:45 pm by Brett Harnett

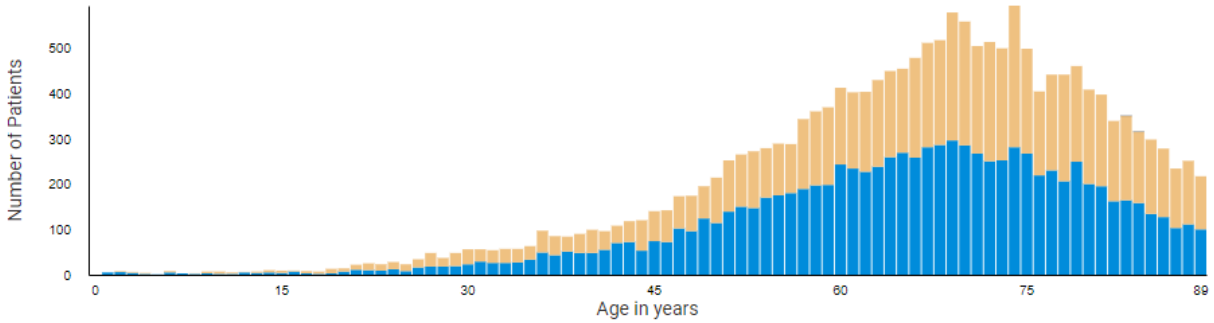
Patients	HCOs
18,853	40

Run

View History

Demographics

Grouped | Stacked | F | M | U



Patients 90 and Older: 797

Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
18,853	1	90	66	15

Sex

Male	52%
Female	48%
Unknown	0%

Ethnicity

Not Hispanic or La...	73%
Unknown Ethnicity	17%
Hispanic or Latino	10%

Race

White	53%
Black or African A...	30%
Unknown Race	15%
Asian	2%
American Indian or...	0%
Native Hawaiian or...	0%

Tools for exploring the cohort are part of the interface with drill-down capabilities.

Medications

Medications within | 3M | 6M | 12M | 24M | Anytime

Search...

Medication		Patients	% of Cohort
CV000	Cardiovascular medications	420	100%
CN000	Central nervous system medi...	410	98%
GA000	Gastrointestinal medications	410	98%
GA100	Antacids	360	86%
GA200	Laxatives	350	83%
GA900	Gastric medications,other	300	71%
GA605	Antiemetics	220	52%
GA300	Antiulcer agents	130	31%
GA200	Antidiarrheal agents	110	26%

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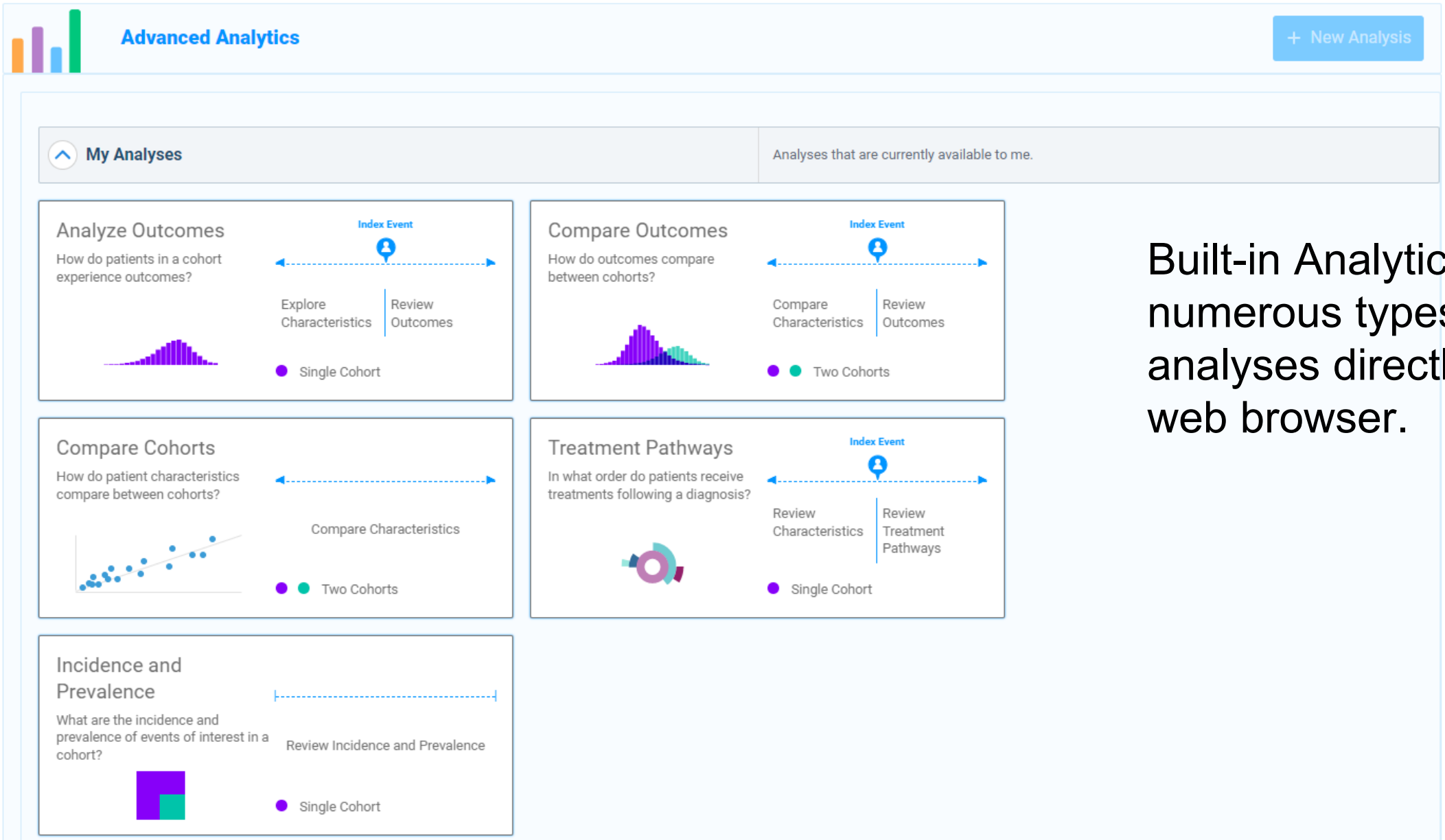

Built-in Analytics allow for numerous types of analyses directly in the web browser.

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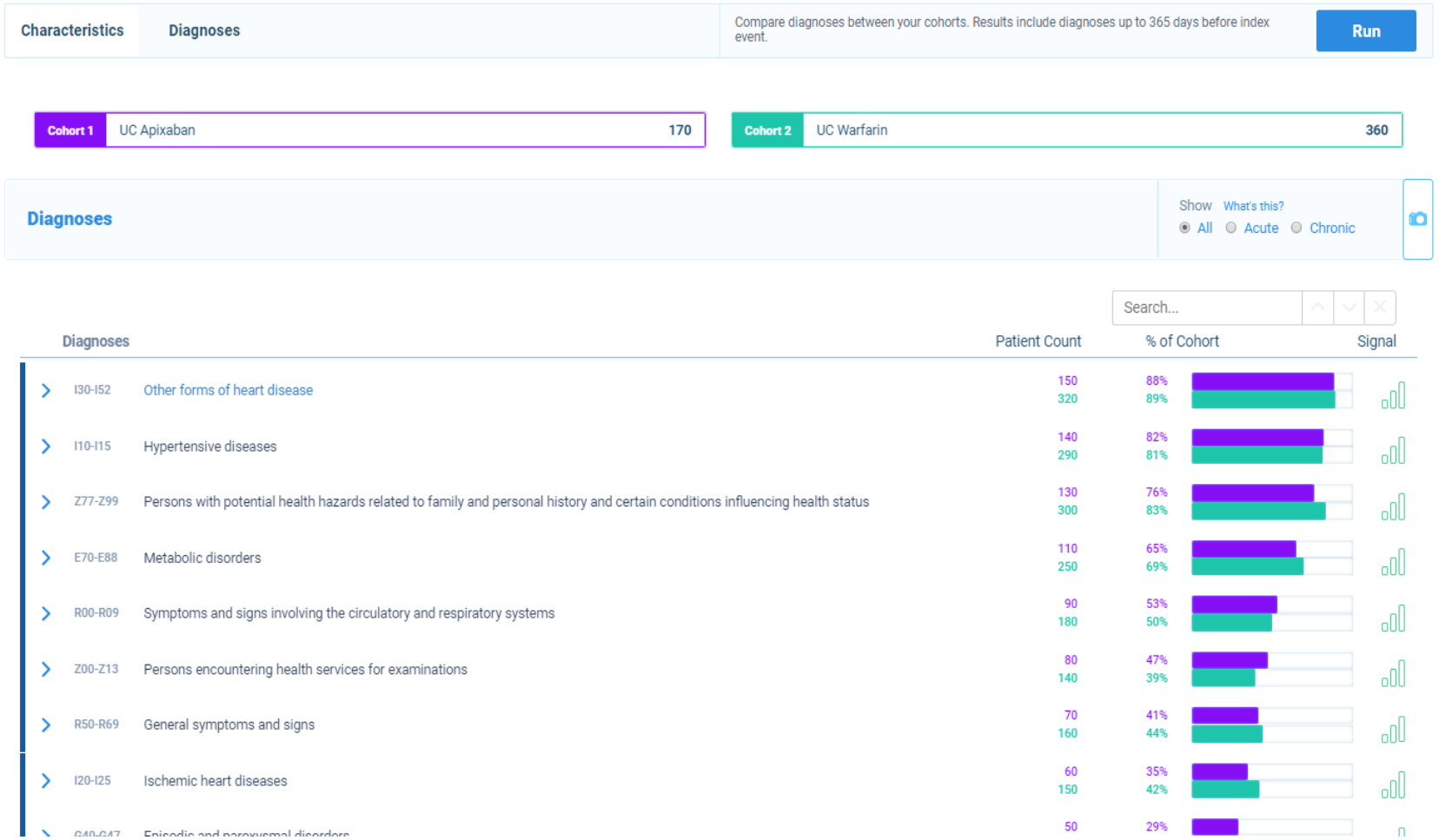
Built-in Outcomes Analysis



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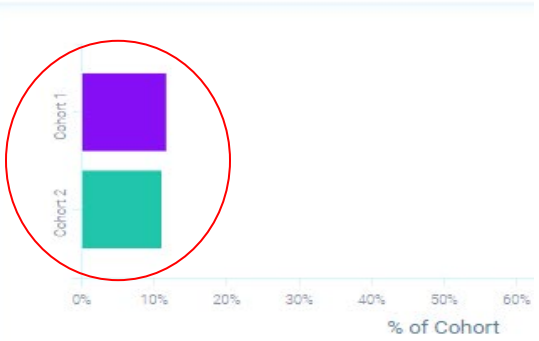
Unnamed Outcome

Must Have Nontraumatic subarachnoid hemorrhage OR Other and unspecified nontraumatic intracranial ... OR Cerebrovascular diseases OR Nontraumatic intracerebral hemorrhage

1a : Measures of Association

		Cohort Statistics		
Cohort		Patients in Cohort	Patients with Outcome	Risk
1	UC Apixaban	170	20	11.765%
2	UC Warfarin	360	40	11.111%

Risk Difference				Risk Ratio		Odds Ratio	
Risk Difference	95 % CI	z	p	Risk Ratio	95 % CI	Odds Ratio	95 % CI
0.654%	(-5.177%,6.484%)	0.222	0.8246	1.059	(0.639,1.754)	1.067	(0.603,1.888)



Must Have INR in Plasma or Blood

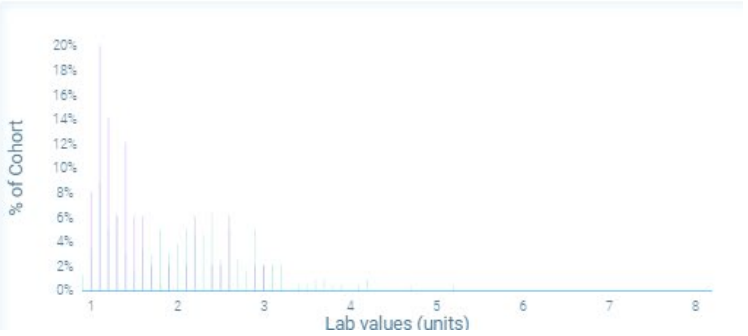
2a : Lab Distribution

		Cohort Statistics				Test Statistics		
Cohort		Patients in Cohort	Patients with Outcome	Mean	Standard Deviation	t	df	p
1	UC Apixaban	170	50	1.549	0.559			
2	UC Warfarin	360	240	2.078	0.794	-4.436	278	< 0.0001

* For Cohort 1, 10 data points for 10 patients were excluded because they fell outside the sanitization limit; of the 10 patients, 0 patients had no other lab in the time window.

* For Cohort 2, 50 data points for 20 patients were excluded because they fell outside the sanitization limit; of the 20 patients, 0 patients had no other lab in the time window.

Learn more



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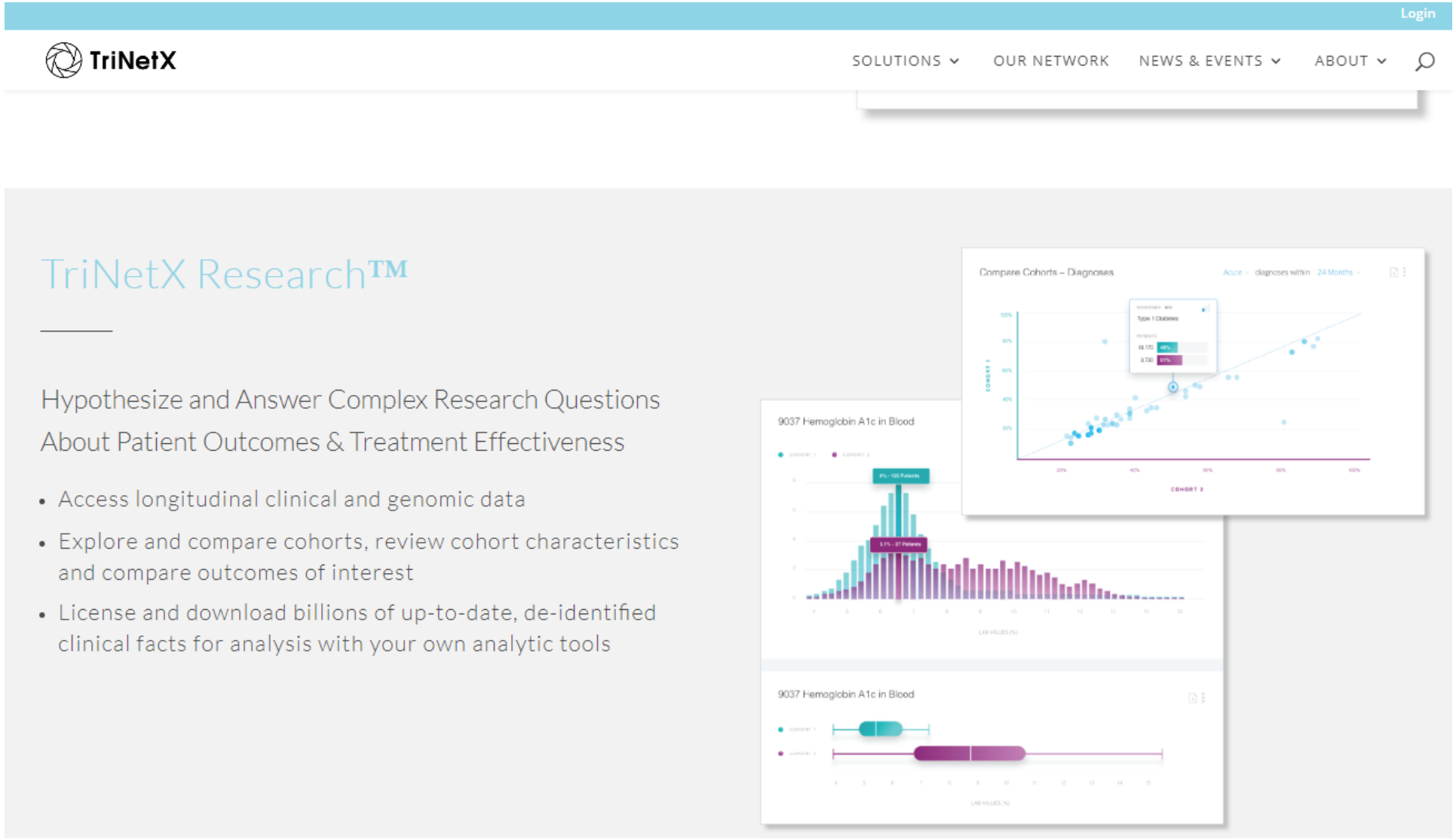
Research Network: Increase the *n* from 1.2M to over 85M



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TriNetX Data Access Guidelines and Publishing Policy and Procedures

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UNIVERSITY OF MICHIGAN | MICHIGAN MEDICINE | U-M MEDICAL SCHOOL | eRESEARCH

MEDICAL SCHOOL
UNIVERSITY OF MICHIGAN

OFFICE OF RESEARCH

OUR UNITS | FUNDING & PROPOSAL DEVELOPMENT | REGULATORY REVIEW & COMPLIANCE | RESEARCH PROJECT MANAGEMENT | CORES & RESEARCH RESOURCES | EDUCATION & TRAINING | ABOUT US | CONTACT US

Home › Our Units › Data Office for Clinical & Translational Research › Self-Serve Data Tools › EMERSE

EMERSE

EMERSE (Electronic Medical Record Search Engine) enables users to search clinical notes (dictated or typed) from our electronic medical record (CareWeb and MiChart) for terms. The clinical notes include text from radiology, pathology, and other reports dating back to 1998. EMERSE is easy to use and provides valuable features to help you find the information you need. The search function includes thousands of synonyms to help you find alternative wording for clinical concepts, including generic and brand names of medications. EMERSE aids in cohort identification, eligibility determination and data abstraction in a variety of research, clinical, and operational settings. It currently requires that you input a list of medical record numbers (MRNs) in order to use the tool. MRNs may be obtained from the Data Office through a data request.

Log in to EMERSE here

Collaborators
U. Michigan
Case Western
UNC
UK
Columbia

Almost 200 publications

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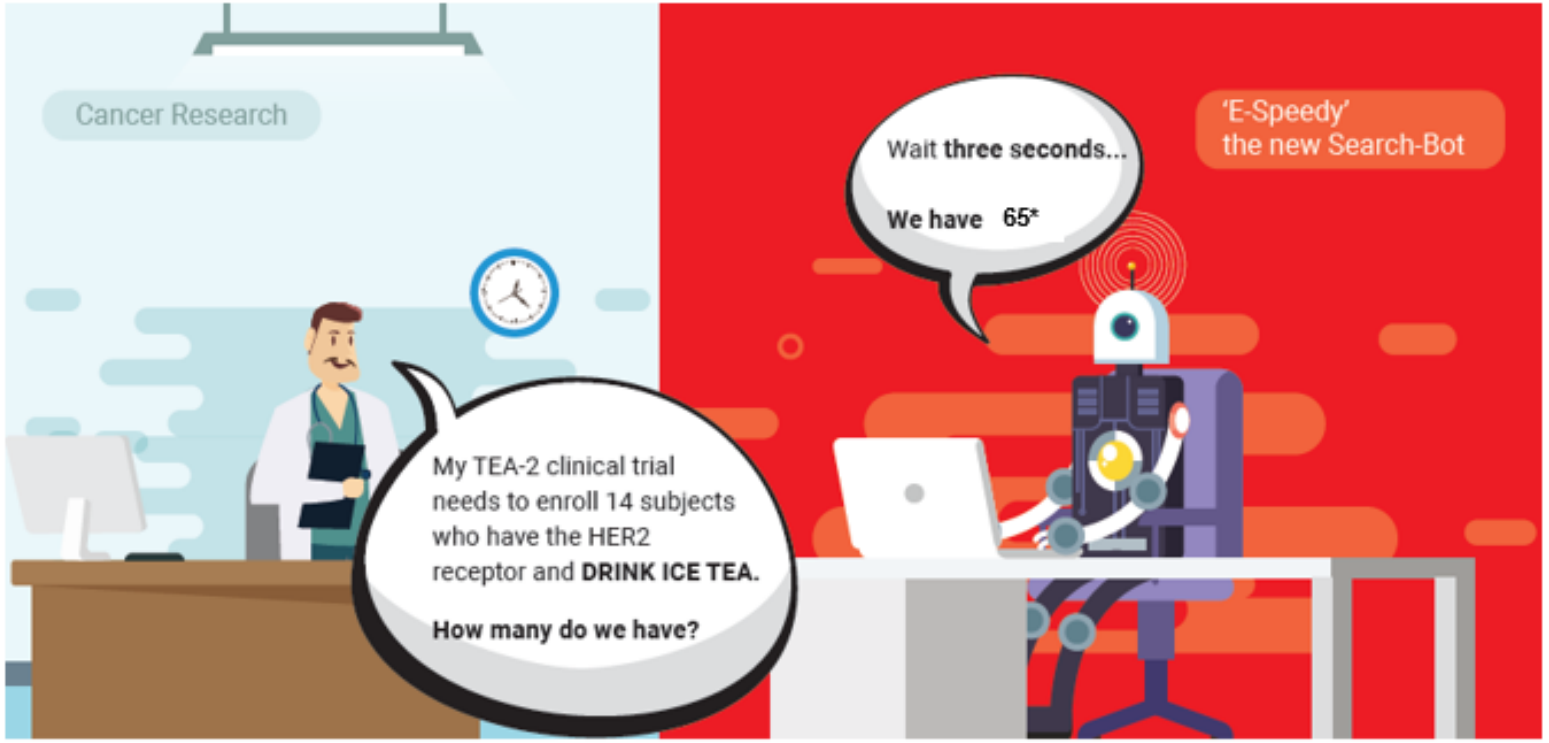

*** Based on a true story: Actual query executed 10/08/2019**

Just like Google!

Clinical Note Search Technology

BIOMEDICAL INFORMATICS

CHI Services / Data Exploration/Visualization / Term Searching of Clinical Notes (e

Term Searching of Clinical Notes (e-Speedy)

CHI has co-developed and implemented a tool known as EMERSE that can search for s across all clinical notes in Epic at UC Health. Currently, this includes 27 million notes as patients seen at UC Health since Epic's implementation in 2012. EMERSE will **identify al that contain a specific word or phrase.** CHI can also provide the entire note and/or pat search via a clinical data extraction. An example is **you want to find patients where the anywhere in any note, e-Speedy will find those patients in seconds.** Truly unique.

Pricing

Non Cancer-related Research[1]	$288.00
Cancer-related Research	No Cost

1) First two requests are provided at no cost to demonstrate the power.

See the CHI Terms of Service for more details. You will receive a Work Order with the f started.

We provide discounts on many services to CCTST members. Create your free CCTST ac

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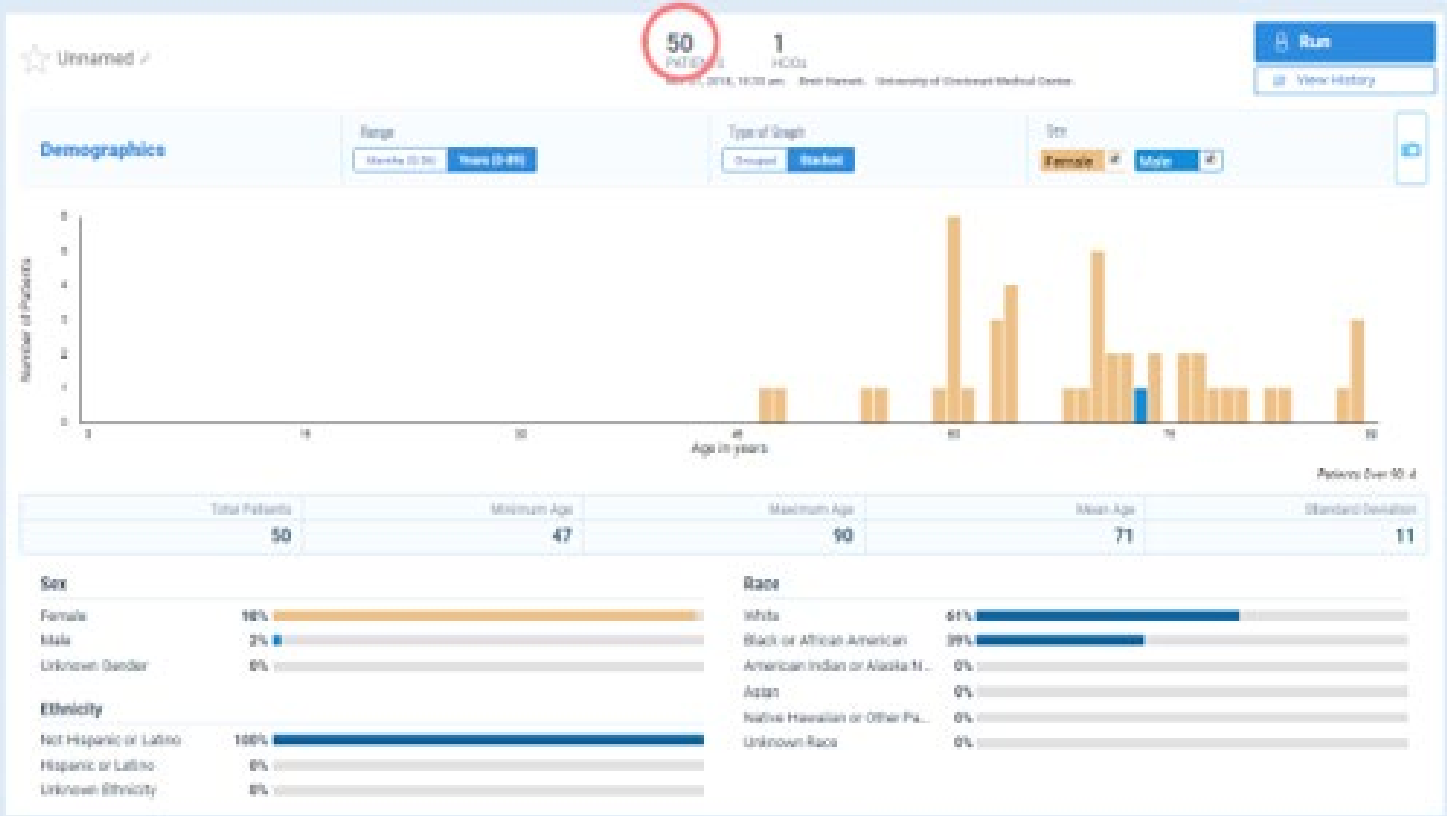
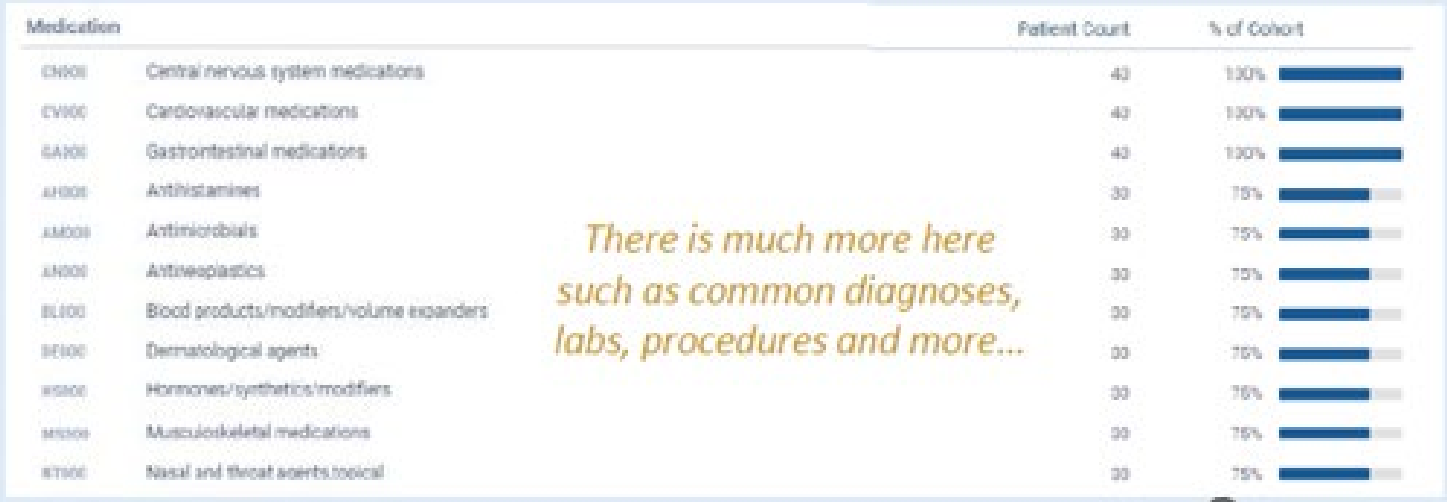
BMI Project 480

I'm interested in how many patients we have with a diagnosis of malignant breast cancer and a CEA test result greater than 6 – have to exclude any diagnosis of MRSA. Ideally, it would be helpful to scrub the notes to find where where the term HER2 receptor is mentioned... That would definitely narrow the cohort.

High-Level Superset (link to report provided to researcher) (STEP 1)





There is much more here such as common diagnoses, labs, procedures and more...

Text mining sub-filter applied (STEP 2)

...Left **breast** mucinous carcinoma, ER/PR+, **HER2**- Malignant...
...of the left **breast** ER/PR positive, **HER2** negative s/p...

...Carcinoma of R **breast**. ER/PR +, **HER2** -ve. Stage IA....

... ER/PR + ve/**HER2** negative Right **breast** cancer T1c N1....

...Carcinoma of R **breast**. ER/PR +, **HER2** -ve. Stage IA....

...inflammatory **breast** cancer, cT4d, N2, M0, ER/PR+, **Her2**+, ypTis...

...of the left **breast** ER/PR positive, **HER2** negative s/p...

... ER/PR + ve/**HER2** negative Right **breast** cancer T1c N1....

...ER+/PR+/**Her2** neg. Patient had benign R **breast** biopsy...
...significant for ER+/PR+/**Her2** neg. **Breast** History: Race:...

...positive and **HER2**-neu negative of the left **breast** with micrometastases...

...the right **breast**, grade 3, ER/PR-, **Her2**+, s/p BCT with...

... ER/PR + ve/**HER2** negative Right **breast** cancer T1c N1....

BMI 480 filtering results

Filtered Subset = 22 patients

National
COVID
Cohort
Collaborative

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National COVID Cohort Collaborative

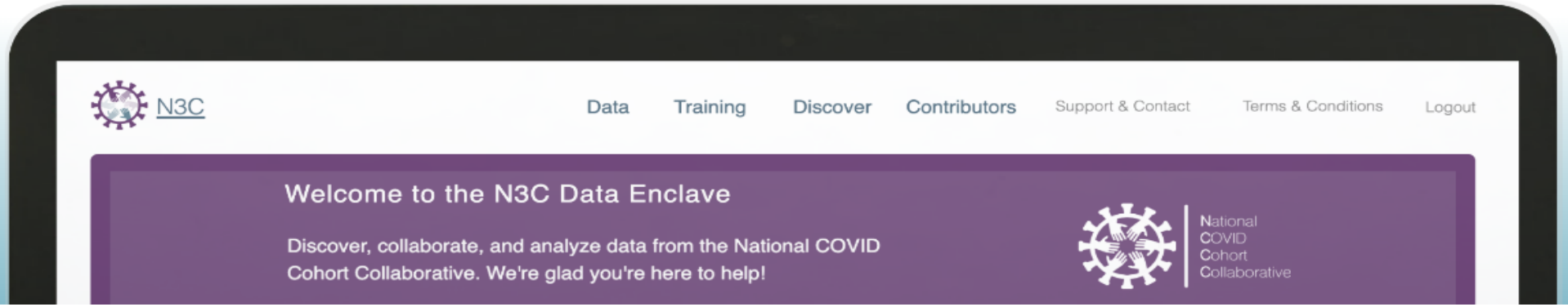
The N3C Data Enclave is a secure platform through which the harmonized clinical data provided by our contributing members is stored. The data itself can only be accessed through a secure cloud portal hosted by NCATS and cannot be downloaded or removed. N3C invites you to begin your journey with the Enclave and join the collaborative efforts of our partners to better understand and address the most pressing COVID-19 clinical questions.

Help make science go faster and save lives.

Access the Enclave

19.4B	1,760.0M	16.0M	6,251,459
Total Rows	*Clinical Observations*	*Persons*	*COVID+ Cases*

Explore the Full Cohort Dashboard



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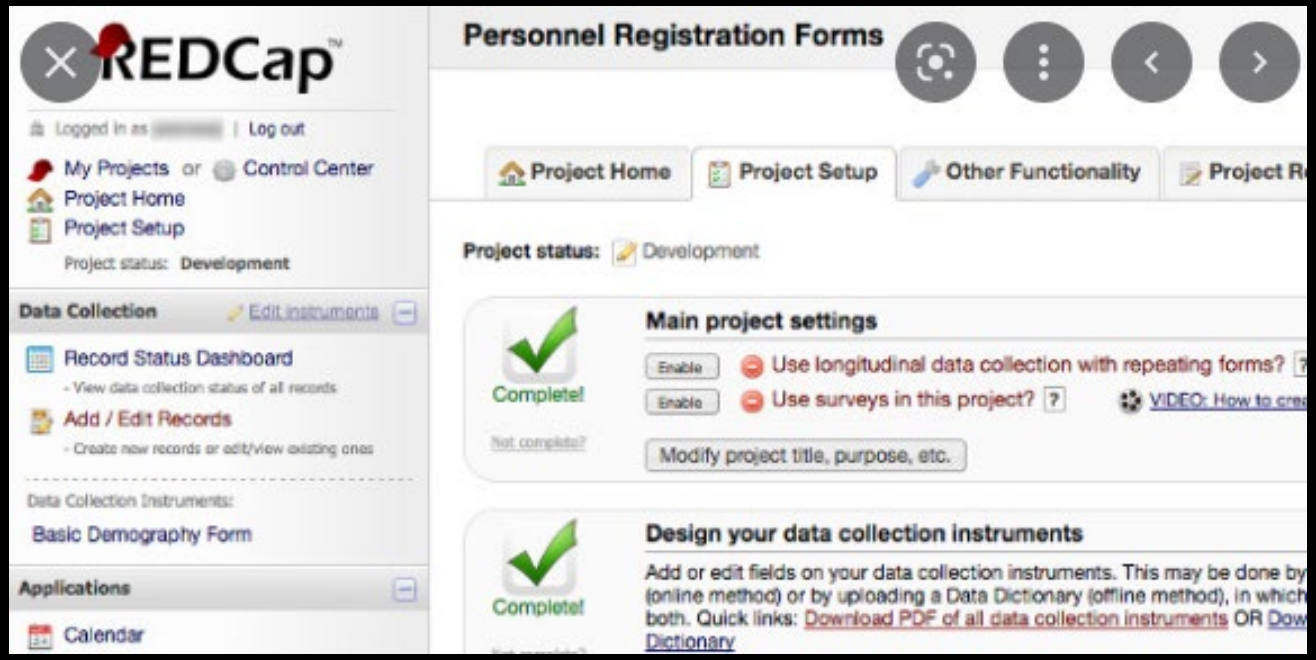
REDCap (Electronic Data Capture)

REDCap
Research Electronic Data Capture

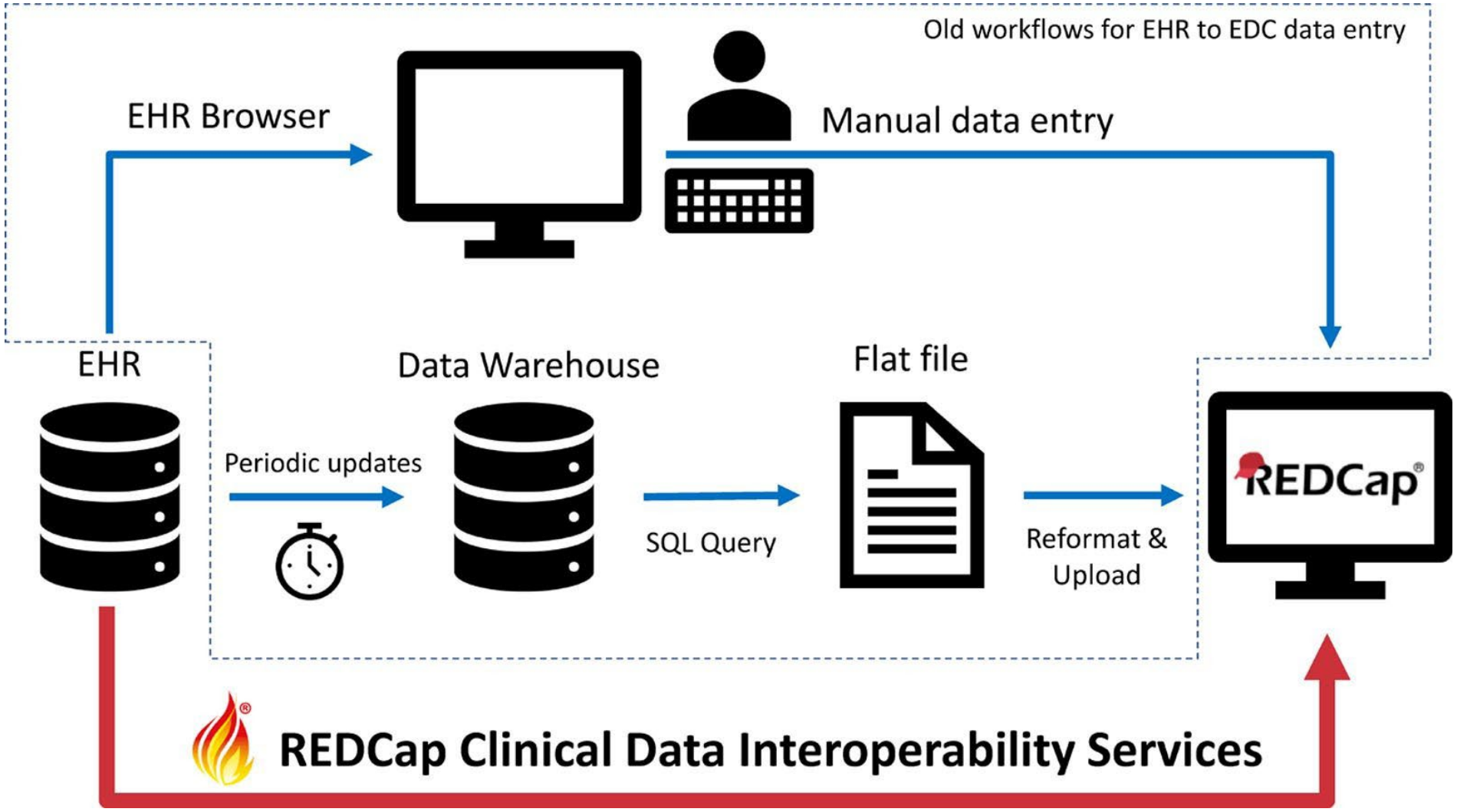
Institutions	Countries	Projects	Users	Articles
6210	149	1.6M	2.3M	21.7k

ABOUT PARTNERS RESOURCES SOFTWARE



REDCap is a secure web application for building and managing online surveys and databases. While REDCap can be used to collect virtually any type of data in any environment (including compliance with 21 CFR Part 11, FISMA, HIPAA, and GDPR), it is specifically geared to support online and offline data capture for research studies and operations. The REDCap Consortium, a vast support network of collaborators, is composed of thousands of active institutional partners in over one hundred countries who utilize and support their own individual REDCap systems. Please visit the Join page to learn how your non-profit organization can join the consortium, or explore the first section on our FAQ for other options to use REDCap.

REDCap on FHIR (use of APIs)



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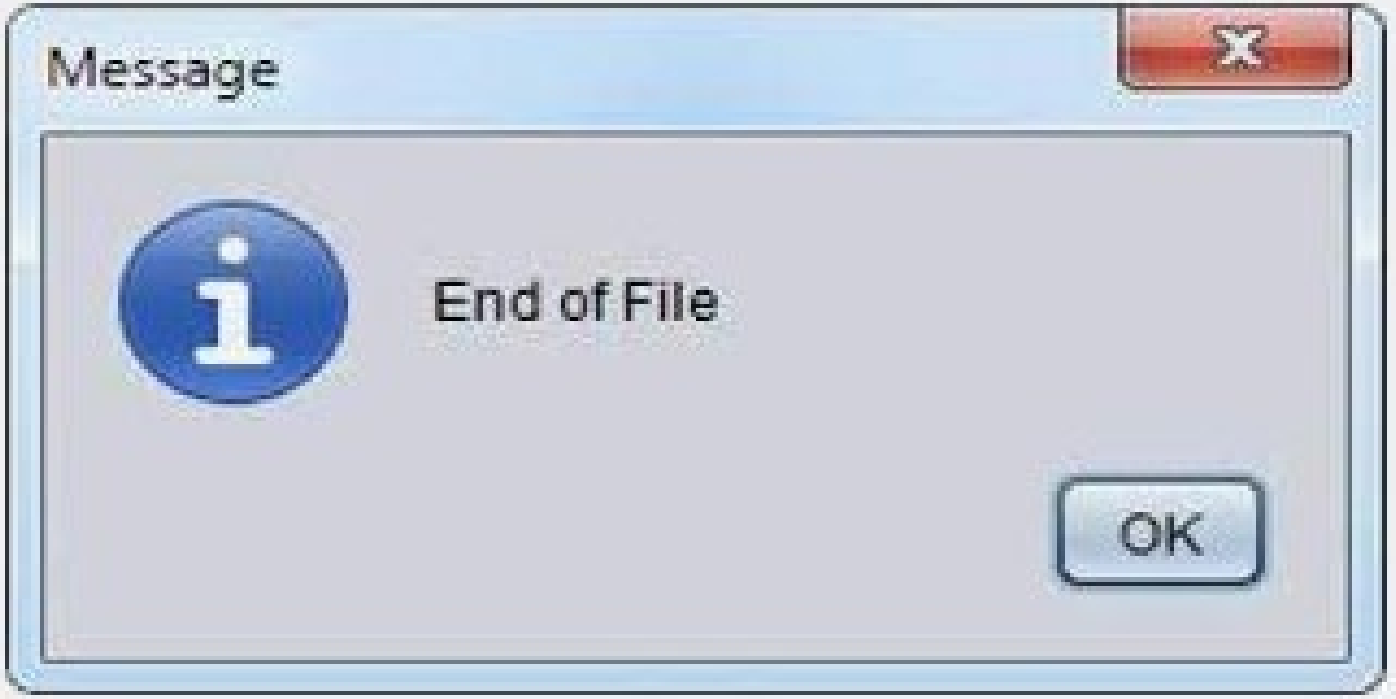
HHS: 9 New Announcements
-> COVID

The HHS Office for Civil Rights has made nine HIPAA announcements related to COVID-19 since March 2020:

1. OCR Announces Notification of Enforcement Discretion for Telehealth Remote Communications During the COVID-19 Nationwide Public Health Emergency - March 17, 2020.
2. OCR Issues Guidance on Telehealth Remote Communications Following Its Notification of Enforcement Discretion - March 20, 2020.
3. OCR Issues Guidance to Help Ensure First Responders and Others Receive Protected Health Information about Individuals Exposed to COVID-19 - March 24, 2020.
4. OCR Issues Bulletin on Civil Rights Laws and HIPAA Flexibilities That Apply During the COVID-19 Emergency - March 28,2020.
5. OCR Announces Notification of Enforcement Discretion to Allow Uses and Disclosures of Protected Health Information by Business Associates for Public Health and Health Oversight Activities During The COVID-19 Nationwide Public Health Emergency - April 2, 2020.
6. OCR Announces Notification of Enforcement Discretion for Community-Based Testing Sites During the COVID-19 Nationwide Public Health Emergency - April 9, 2020.
7. OCR Issues Guidance on Covered Health Care Providers and Restrictions on Media Access to Protected Health Information about Individuals in Their Facilities - May 5, 2020.
8. OCR Issues Guidance on How Health Care Providers Can Contact Former COVID-19 Patients About Blood and Plasma Donation Opportunities - June 12, 2020.
9. Trump Administration Adds Health Plans to June 2020 Plasma Donation Guidance - August 24, 2020.[5]

21st Century Cures Act

- Signed into law on December 13, 2016, is designed to help accelerate medical product development and bring new innovations and advances to patients who need them faster and more efficiently.
- The law builds on FDA's ongoing work to incorporate the perspectives of patients into the development of drugs, biological products, and devices in FDA's decision-making process. Cures enhances our ability to modernize clinical trial design including the use of real-world evidence…
- No Information Blocking


Message
End of File
OK

Thank you - Questions

This is our Chief Information Officer. He's encrypted for security purposes.