TriNetX Research Network
Data Access Guidelines
Publishing Policy and Procedures

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A: Introduction

TriNetX is a global health research network enabling healthcare organizations (HCOs), biopharma, and contract research organizations (CROs) to collaborate, enhance trial design, accelerate recruitment, and bring new therapies to market faster. UC/UC Health has a strategic partnership with TriNetX.

The TriNetX analytics website provides access to the local/UC Health patient populations and the TriNetX Research Network (TRN), this document is specific to the TRN.

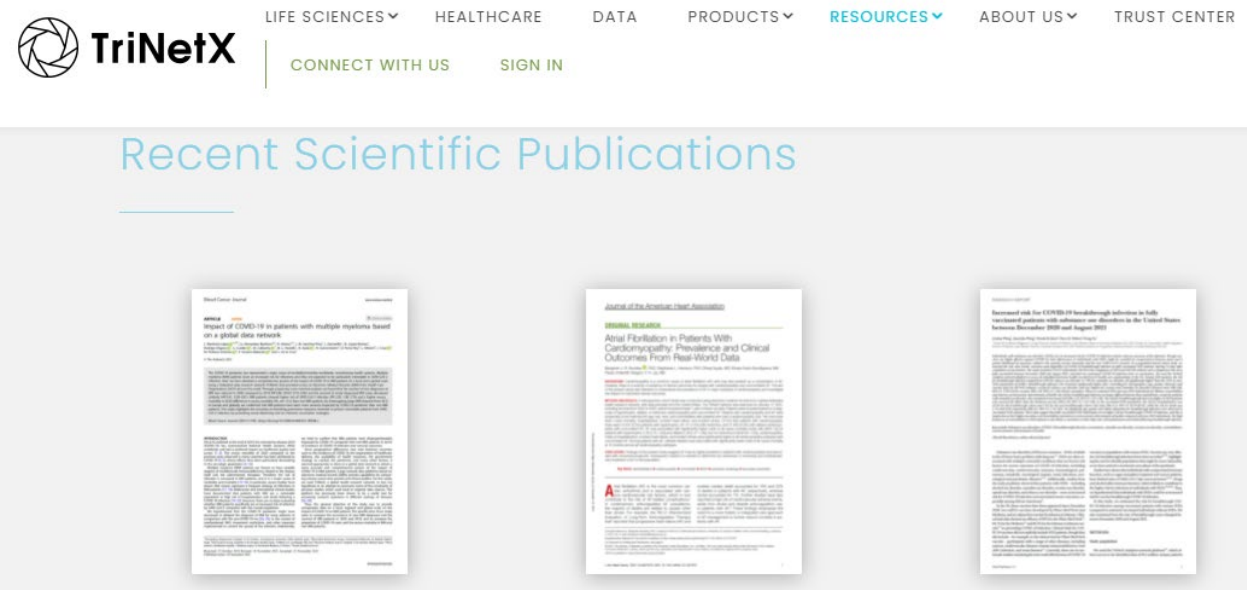
B: Scope

This guide is targeted to researchers who want to use TriNetX for analyzing data from the TRN which allows researchers to run queries and perform analysis across populations 90x larger than our local population. This guide is about *how to acquire data and publish*, not about how to use TriNetX.

This capability is for those interested in 'Real World Evidence' analysis, that is, data from electronic health records from scores of healthcare organizations who participate in the TriNetX Research Network.

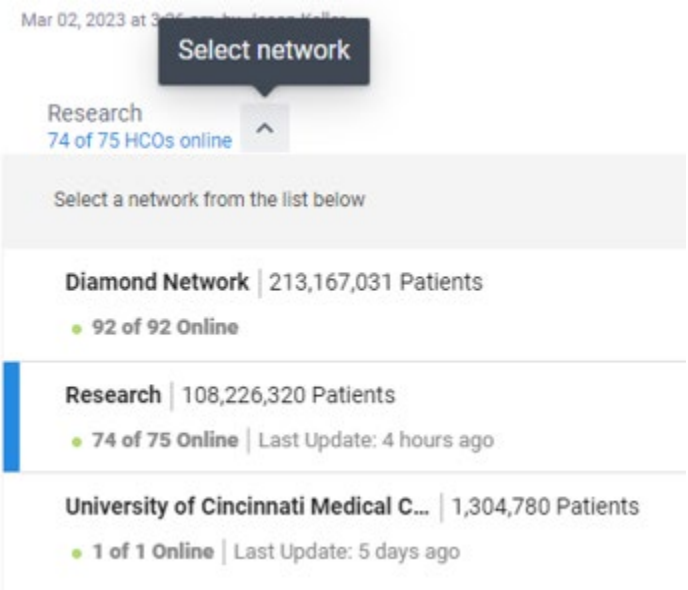
The TriNetX Research Network (TRN) is de-identified and does not need IRB approval but still requires a Data Use Agreement (DUA) with TriNetX (summarized in Section D).

Over a thousand papers have been published using only TriNetX Research Network data.



https://trinetx.com/real-world-resources/publications/

To use RWD from TriNetX, you must run queries against the "Research" network (see the blue bar).



Ignore the "Diamond Network" in this context (not relevant)

C: Analysis

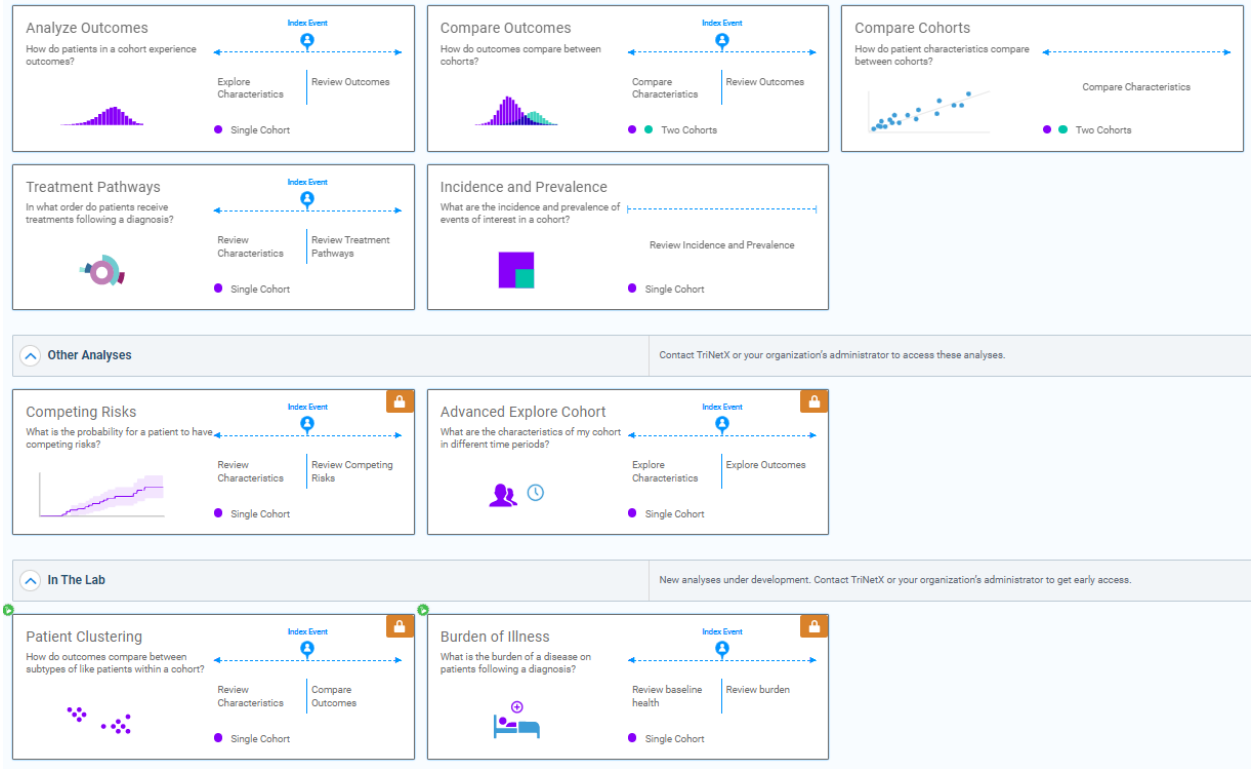
There are *two methods to test* hypotheses and analyze data:

1. Using the analytic tools built into the TriNetX website (Online Analysis)
2. Request actual data and analyze locally on your own (Exported/Offline Analysis)

C1: Online Analysis

Options for online analytics are integrated into the TriNetX application and can be done entirely within the interface, usually within minutes. Data is de-identified; thus, no IRB approval is needed.

Various types of analyses can be done such as Compare Cohorts, Analyze Outcomes, Incidence and Prevalence, and Treatment Pathways.



Because electronic health records have been widely deployed over the past decade, there are 10 years or more (depending on the site) of retrospective data that then can be used to look "prospectively" at outcomes using relative dates/temporal methodologies.

For example, "How do different medications affect the risk of stroke over time?" Using diagnosis codes and dated occurrences, one could determine if patients with a diagnosis of Atrial Fibrillation suffered a stroke, at a later date, and stratify by what type of medication the patients were prescribed such as Warfarin vs. Apixaban. This can be done in minutes demonstrating the power and low cost of RWE.

1a : Measures of Association

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

Risk Difference: Risk Difference	Risk Difference: 95 % CI	Risk Difference: z	Risk Difference: p	Risk Ratio: Risk Ratio	Risk Ratio: 95 % CI	Odds Ratio: Odds Ratio	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)

Example: onboard analytics analysis

C2: Exported/Offline Analysis

After a cohort is established/saved, one can request a download of the data. This allows for more specific, dense analyses that would be run by an informatician or statistician using SAS, R, Stata, etc. Unlike Online Analysis, offline analysis requires requesting and downloading data described in Section D1.

D: Getting Data

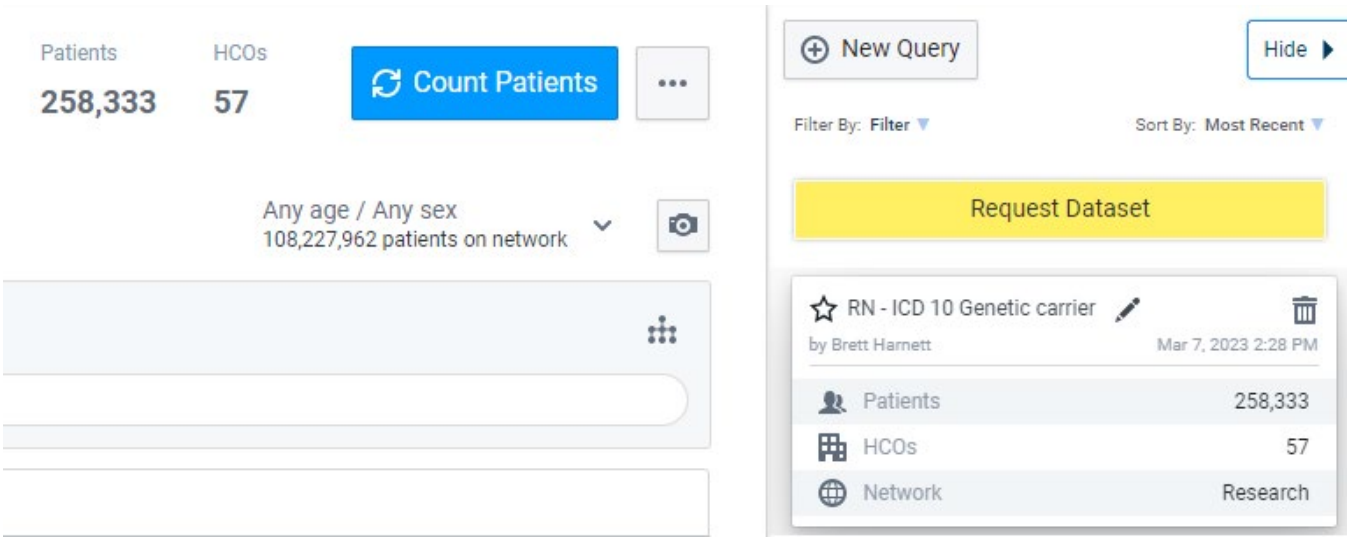
Accessing data from TriNetX is easy but not immediate; there are a few steps outlined below.

D1: Getting Data from the TriNetX Research Network (TRN)

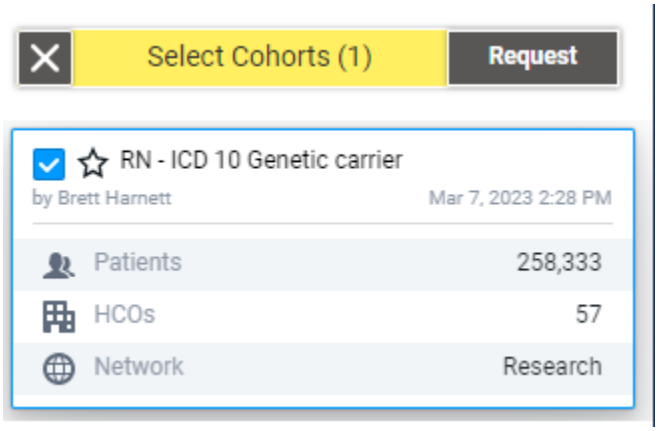
Data requested from queries against the TRN **are de-identified** using the Expert Determination methodology as required by Health and Human Services (HHS) and HIPAA. Because of this, the data is not considered Protected Health Information (PHI) and does not fall under the Privacy Rule, thus does not need IRB approval or oversight.

To request data, click the yellow button, it will ask you to select a query (this is why you should name important queries you create, each time you click "Count Patients", a new query adds to the list in the right-hand panel). This is handy because it allows you to tweak queries over and over until you zero in on what you want. You can delete junk queries if you like.

**Note: Ensure you have named your query using the "pencil" icon. Notice also that if you run a query against the local UC Health population, running it against the Research Network creates another query, we suggest adding the prefix "RN" to these query names.*



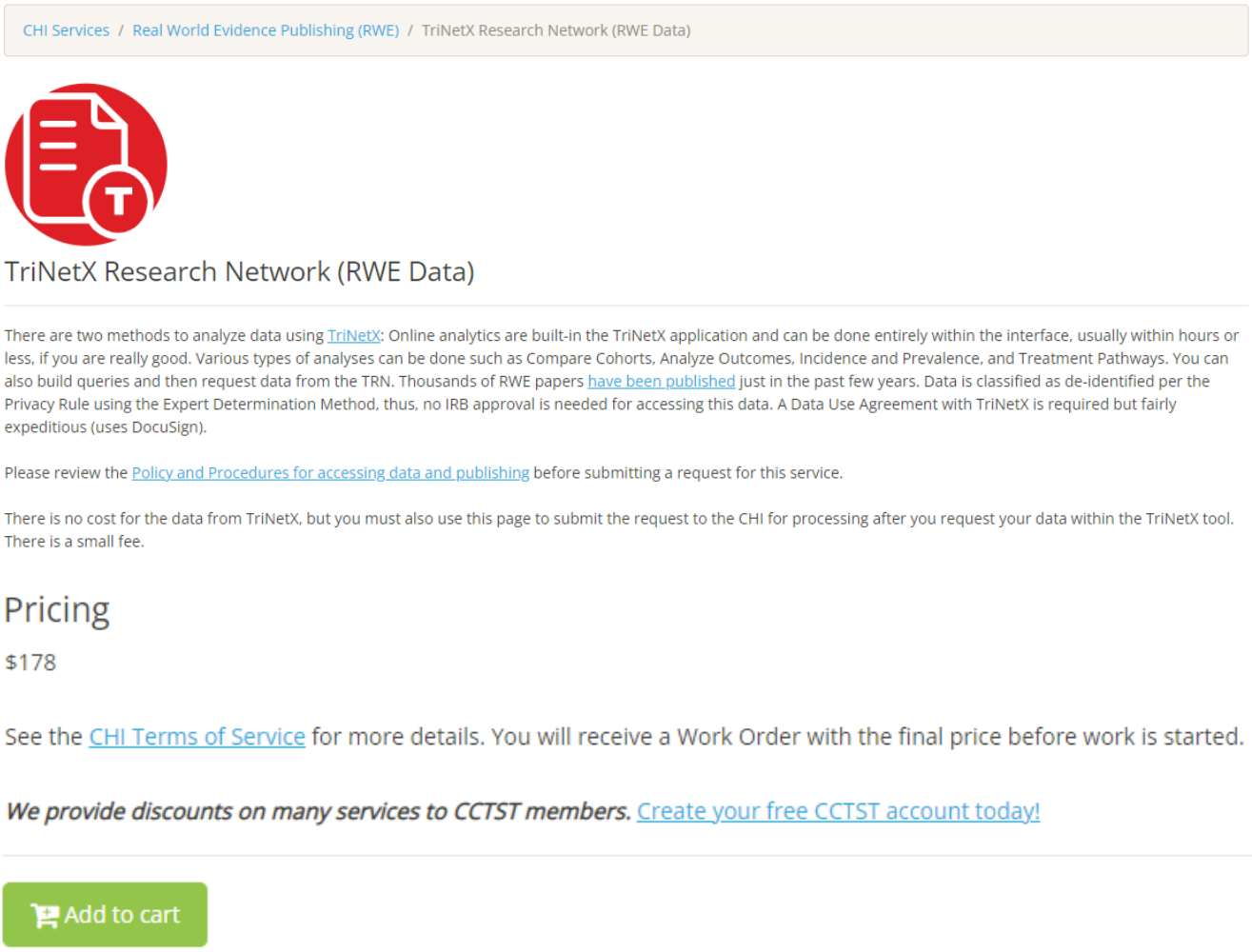
After clicking the yellow "Request Dataset" it will change to "Select Cohorts", and a checkbox appears where you select the query you want (blue checkbox)



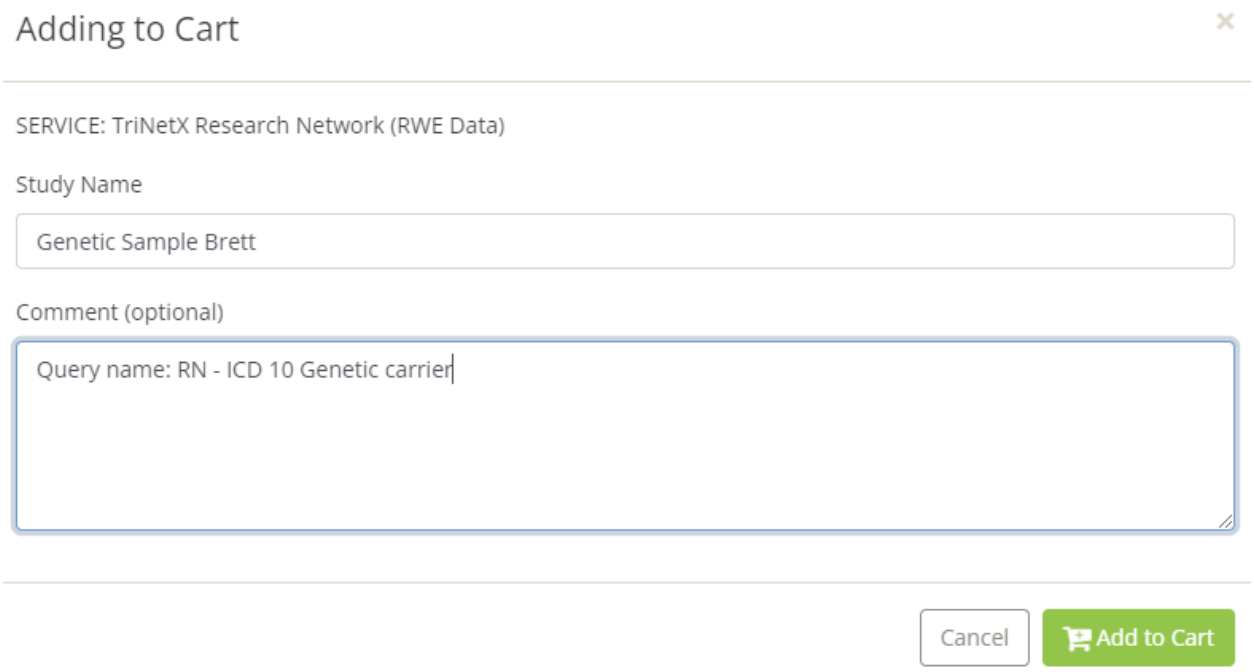
After you request the data within the TriNetX interface, you must submit a request for the CHI to process the order, otherwise, the CHI will not know you requested data and cannot proceed.

- Instructions below -

Go to the CHI services portal
https://chi.uc.edu/customer_portal/extranet/services/chi_services/RWE/deid_tnx



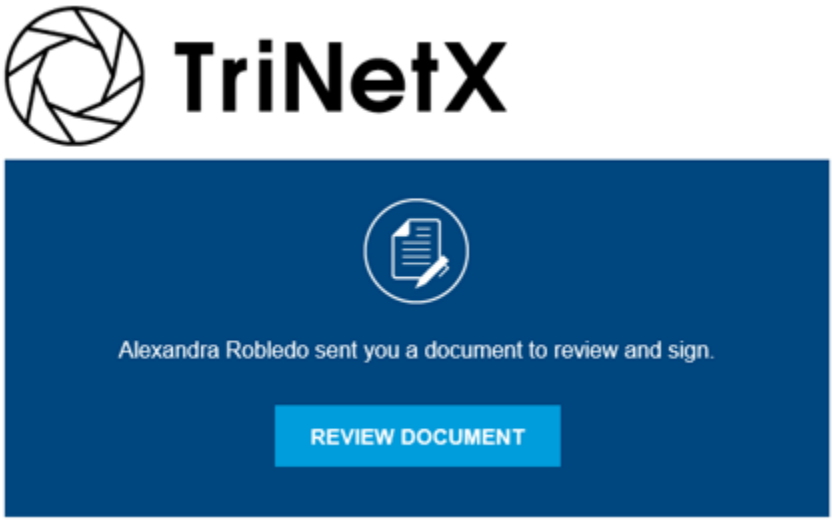
Select “Add to Cart”, include the study name you used in TriNetX, and include your query name in the Comment section.



D2: Submitting the Request to Process the Data

After you submit your request within the TriNetX environment and the internal request to the CHI Portal, within a few days you will receive a "Data Set Order Form" as a **DocuSign** message format that is a simple agreement between TriNetX and you, that includes a Data Use Agreement (DUA). This must be signed off by both the investigator and a UC Health official. The document is first routed to you (the investigator), then it auto-routes to the UC Health Chief Health Digital Officer (Dr. Umberto Tachinardi).

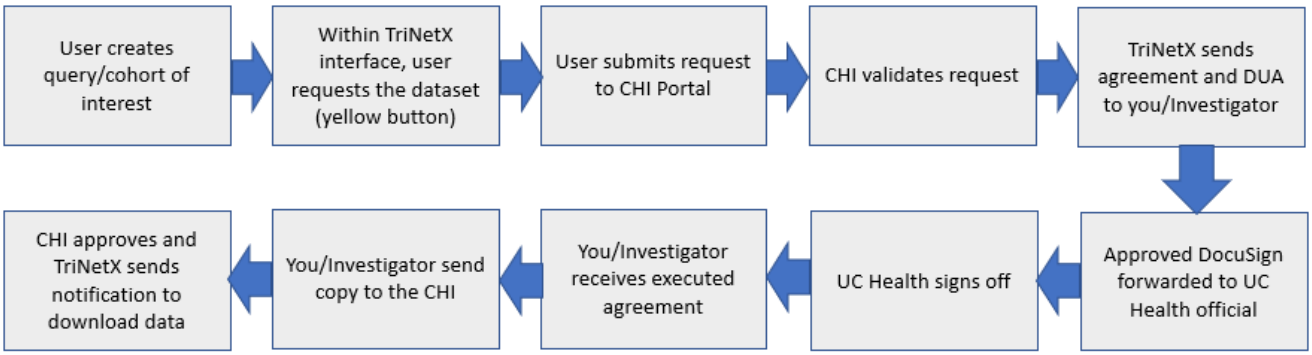
After you receive the completed agreement, you must send a copy to combmichi@ucmail.uc.edu. The CHI will approve the final steps to acquire the data. Once TriNetX processes the data, you will be notified and will be able to download the data to your PC or cluster environment.



After the request is approved by TriNetX, you will receive instructions from TriNetX on how to download the data. This data must follow the guidance from the Data Use Agreement you signed off on including using only encrypted devices to store data.

While there are no costs for the actual data from TriNetX, BMI charges a small fee to process any requests. Per established governance, BMI oversees the distribution of all clinical data for research. This includes validating requests, local approvals, consulting with BMI faculty, processing requests, and data transfer. This fee is $178 for each data request (unless there is a re-request for some reason).

Graphical Process Flow



Note: If you plan to use TriNetX data for a grant submission, there are very different rules for this outside the scope of this document. This involves potential fees from TriNetX if a grant is awarded. Reach out to Brett Harnett if this is the intention.

E: Publishing

Any manuscript you seek to publish using TriNetX data must be sent to and approved by **Brett Harnett**.

E1: Information not to disclose

Unless the publication is initiated and authored by an HCO about their local populations, no HCO-specific data can be shown in any publication, not even in an anonymized way (e.g., "site 1, site 2, site 3, etc."). All results must be shown as aggregated statistics only.

Screenshots of the platform are confidential and shall not be used in any publication without express consent from TriNetX.

We recommend reviewing the TriNetX guides and informative webinars.

The link to the full TriNetX publishing guide is available here.

E2: Citing TriNetX

TriNetX, LLC must be mentioned in the methods section. A suggested general description would read:

"The data used in this study was collected on [INSERT DATE OF ANALYSIS OR DATE OF DATA DOWNLOAD] from the TriNetX [INSERT NETWORK NAME] Network, which provided access to electronic medical records (diagnoses, procedures, medications, laboratory values, genomic information) from approximately [##] million patients from [##] healthcare organizations. TriNetX, LLC is compliant with

the Health Insurance Portability and Accountability Act (HIPAA), the US federal law which protects the privacy and security of healthcare data, and any additional data privacy regulations applicable to the contributing HCO. TriNetX is certified to the ISO 27001:2013 standard and maintains an Information Security Management System (ISMS) to ensure the protection of the healthcare data it has access to and to meet the requirements of the HIPAA Security Rule. Any data displayed on the TriNetX Platform in aggregate form, or any patient-level data provided in a data set generated by the TriNetX Platform, only contains de-identified data as per the de-identification standard defined in Section §164.514(a) of the HIPAA Privacy Rule. The process by which the data is de-identified is attested to through a formal determination by a qualified expert as defined in Section §164.514(b)(1) of the HIPAA Privacy Rule. Because this study used only de-identified patient records and did not involve the collection, use, or transmittal of individually identifiable data, this study was exempted from Institutional Review Board approval."

E3: Citing the CTSA/CCTST

Additionally, the CCTST must be cited in publications. *"The project described was supported by the National Center for Advancing Translational Sciences of the National Institutes of Health (NIH), under Award Number 2UL1TR001425-05A1. The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH."*

Note: All publications must be reviewed and approved by the CHI before submission.

E4: TriNetX Audited Privacy Principles

https://trinetx.com/wp-content/uploads/2021/12/TriNetX-Empirical-Summary-by-Brad-Malin-2020.pdf

E5: Summary of the Research Network

https://trinetx.com/wp-content/uploads/2021/01/TriNetX-HCO-2021.pdf