HART Services to Support Data Management

Research Concierge Services: Ensures appropriate support is leveraged to provide access, acquisition, storage and utilization of research and QA/QI data, including PHI

- Secure Shared Drive
- Epic Research Access
- Data Extracts (EPIC)
- Data Collection and Storage (REDCap)
- Data Analysis: Biostatistical Services
- Data Exploration: TriNetX

Definitions

- Medical records based research is frequently performed as Retrospective Research Studies
  - Data that was originally collected for purposes other than the current research study (i.e. clinical reasons), and which exists at the time of IRB submission.
  - For a study to be considered retrospective by the IRB, all data must be in existence at time of submission.
- Prospective Chart Reviews will share similar benefits and limitations
  - Patients have not yet occurred, may require consent

Medical Records Based Research: Privacy and IT Security Concerns

- Protected Health Information of our patients
- Most frequently requested PHI elements
  - Name
  - MRN, MPI, CSN or any account number
  - Date of Birth
  - SSN (rarely allowed)
  - **All** dates – e.g. procedure, admission, encounter
  - Email, Addresses, phone numbers
  - Zip code that is more specific than first three digits

Medical Records Based Research: Privacy and IT Security Concerns

- Collect only what you need!
- Carilion Secured Shared Directory for limited (no patient names, maybe a date and a zip code) or de-identified datasets (no HIPAA element)
- Anyone with **access to data** must either be on the study team or a Carilion employee whose job duties stipulate access or have another approved agreement (R&D)

Medical Records Based Research: Privacy and IT Security Concerns

- Acquire and **use Epic Research access** if you do chart review
- REDCap **required** for PHI that is manually collected
- Use Carilion or your institution's email, not private
- Obtain IRB approval BEFORE working with identifiable information (consent may be required, if feasible)

Data Management

- Manual chart review vs. data extraction
  - *Long*: data extraction
  - *Wide*: chart review
  - *Notes, free text*: chart review
  - *Field calculated on the fly*: chart review
- Data collection tool indicative of amount of work
- Use **MPI** (master patient index, unique) instead of MRN (not unique)
- PHI and sensitive information: if don't need, don't collect

Data Management

- What data are needed to answer the question? Are the data available?
- Are the data consistently collected? How confident are you in the accuracy?
- Are there inter-rater reliability issues?
- What are exact definitions? (ex/ ICD codes)

Data Management

- What are the other confounding factors?
- Have data instruments changed over the time period? Upgrades to the EMR?
- Are there other initiatives that overlap your timeframe that may also impact the outcomes?
- How to define clean cohorts without bias, attrition, impacts of changing medicine?
- If the project relies on follow-up, how will attrition, discharge status, death, and ongoing Carilion relationship impact your outcomes and measurement?

Data Sources

- **EPIC EMR** (electronic medical record)
  - Most common data categories:

    demographics, encounters, diagnosis, procedures, labs, flowsheets, medications, assessments
  - Most general categories:

    inpatient, outpatient, emergency, operating room…
- **Other data sources: (examples)**
  - Infection Control Susceptabilities
  - Trauma Registry
  - TriNetX data sets
  - All Payers Claim Database (APCD)

Data Source Limitations

- Inconsistent
  - workflow change
- Incomplete
  - medical history, employment/education history
- Inaccurate
  - manual entry

Solution:

- Understand the workflow: how, when, who
- Limit the time frame to consistent documentation
- Eliminate inaccurate data

EPIC Timeline at Carilion

- Incomplete data prior to go live dates
- Paper chart reviews prior dates or may not even be available.

Data Management: Data Extraction

- Most appropriate for large numbers of patient records
- Most appropriate for less variety in data types
- Different types of data (medications versus demographics) may have different sources and become separate extracts
- Requires very complete data sets

Data Management: Data Abstraction

- Most appropriate for fewer numbers of patient records
- Most appropriate for more variety in data types from different parts of medical record
- Essential if data is not stored in extractable fields
- Better technique if data fields frequently incomplete and need review to complete

Data Management: Hybrid

- Data Extract for extractable data points
- File imported into REDCap including patient identifiers
- Additional fields for chart review built into REDCap
- Chart reviewed and data entered into REDCap
- De-identified data set exported from REDCap for analysis

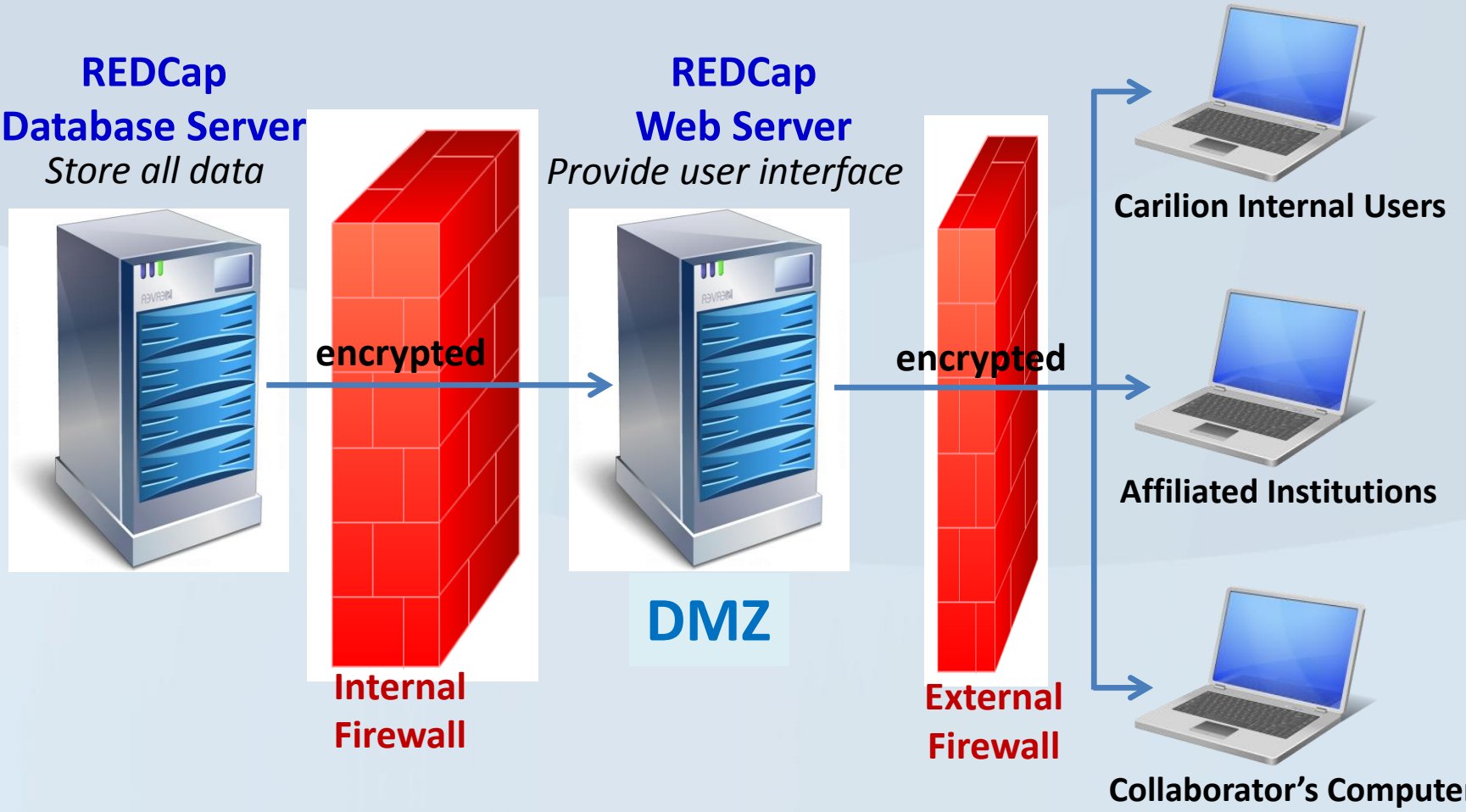
REDCap

- **R**esearch **E**lectronic **D**ata **Cap**ture
- **Secure**, **web-based** application for managing and collection of research data
- Origin: Vanderbilt University, 2004
- >2000 institutions, >100 countries

REDCap at Carilion

- **Go-live** at Carilion 2017
- Open to **Research, QA/QI and Grants**
- Installed and maintained by **HART**
- Free of charge

Carilion REDCap Infrastructure



REDCap Project Types

- **Survey**

  - Forms to collect data from respondents, typically *via* emailed links

- **Traditional project**

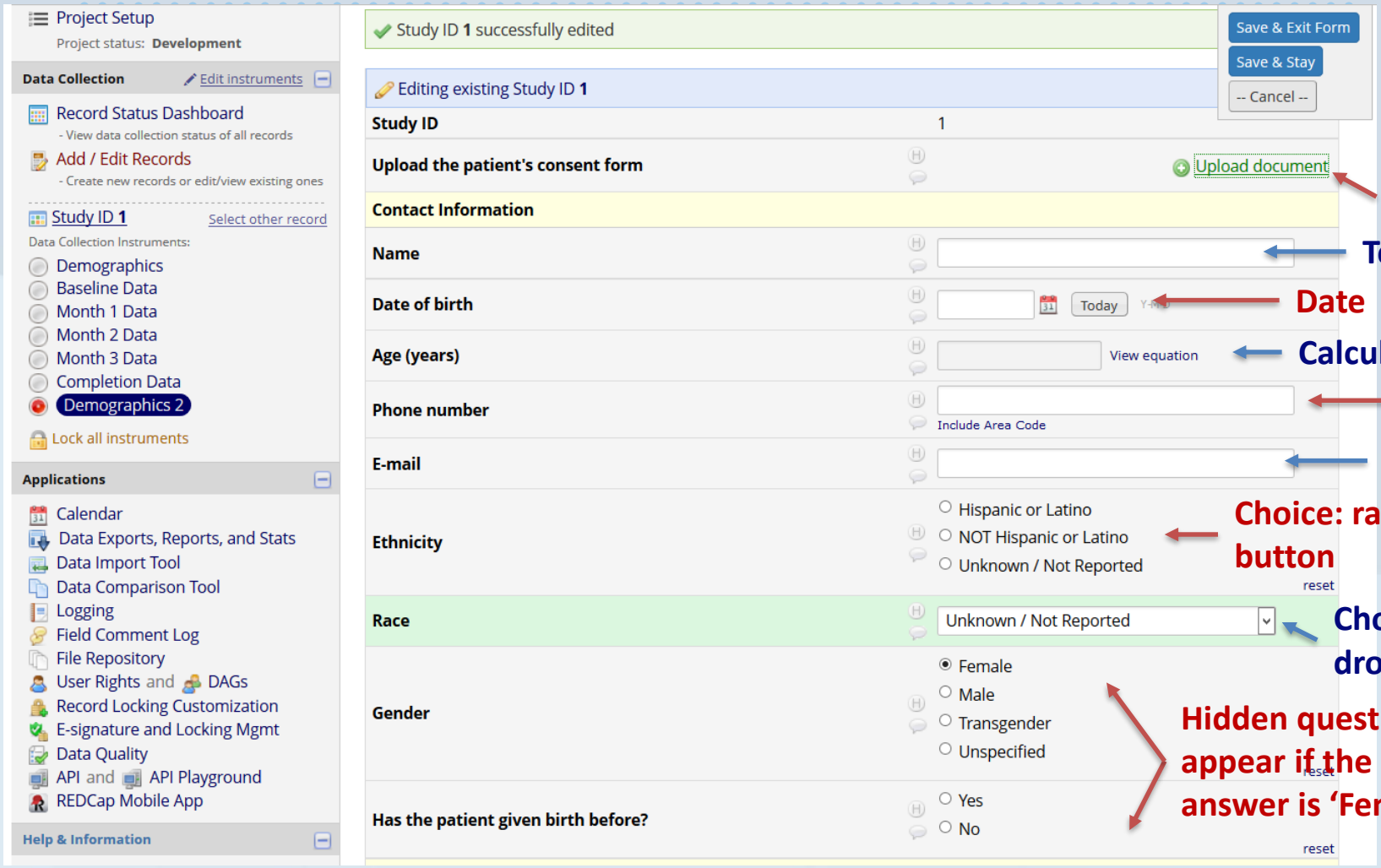
  - Data entry forms for consistent data collection

- **Longitudinal Study**

  - Data gathered for the same subjects over time

- **Combination of the above**

Field Types


Project Setup
Project status: Development
Data Collection
Edit instruments
Record Status Dashboard
- View data collection status of all records
Add / Edit Records
- Create new records or edit/view existing ones
Study ID 1
Select other record
Data Collection Instruments:
Demographics
Baseline Data
Month 1 Data
Month 2 Data
Month 3 Data
Completion Data
Demographics 2
Lock all instruments
Applications
Calendar
Data Exports, Reports, and Stats
Data Import Tool
Data Comparison Tool
Logging
Field Comment Log
File Repository
User Rights and DAGs
Record Locking Customization
E-signature and Locking Mgmt
Data Quality
API and API Playground
REDCap Mobile App
Help & Information
Study ID 1 successfully edited
Save & Exit Form
Save & Stay
-- Cancel --
Editing existing Study ID 1
Study ID
1
Upload the patient's consent form
Upload document
Contact Information
Name
Date of birth
Today
Age (years)
View equation
Phone number
Include Area Code
E-mail
Ethnicity
Hispanic or Latino
NOT Hispanic or Latino
Unknown / Not Reported
reset
Race
Unknown / Not Reported
Gender
Female
Male
Transgender
Unspecified
reset
Has the patient given birth before?
Yes
No
reset
Attachment
Text
Date
Calculated field
Phone #
Email
Choice: radio button
Choice: drop down
Hidden question: only appear if the above answer is 'Female'

Matrix

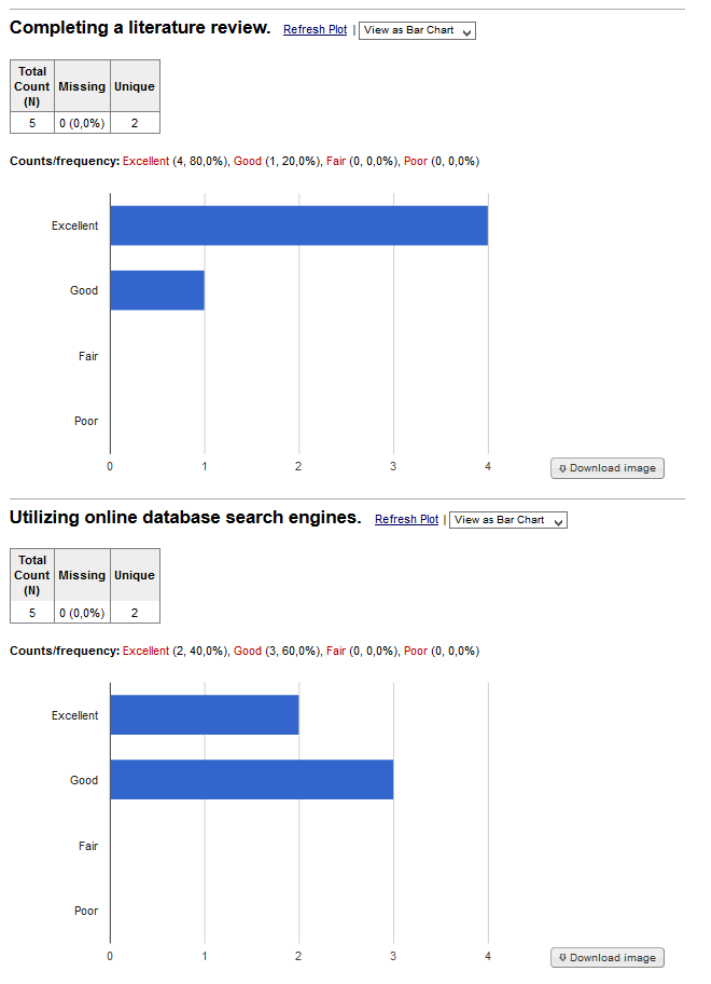
The following qualities are important in my supervisor:							
		Extremely Important	Very Important	Somewhat Important	Slightly Important	Not Important at All	
1)	BELIEVABLE	○	○	○	○	○	reset
2)	APPROACHABLE	○	○	○	○	○	reset
3)	HONEST	○	○	○	○	○	reset
4)	SUCCESSFUL	○	○	○	○	○	reset
5)	QUALIFIED	○	○	○	○	○	reset

Please let us know your weekly schedule for the following:							
		Monday	Tuesday	Wednesday	Thursday	Friday	
6)	Gym (Weight Training)	☐	☐	☐	☐	☐	
7)	Aerobics	☐	☐	☐	☐	☐	
8)	Eat Out (Dinner/Lunch)	☐	☐	☐	☐	☐	
9)	Drink (Alcoholic Beverages)	☐	☐	☐	☐	☐	

Survey Distribution Methods

- Email invite
- Public survey link
- Embed survey on website
- QR code

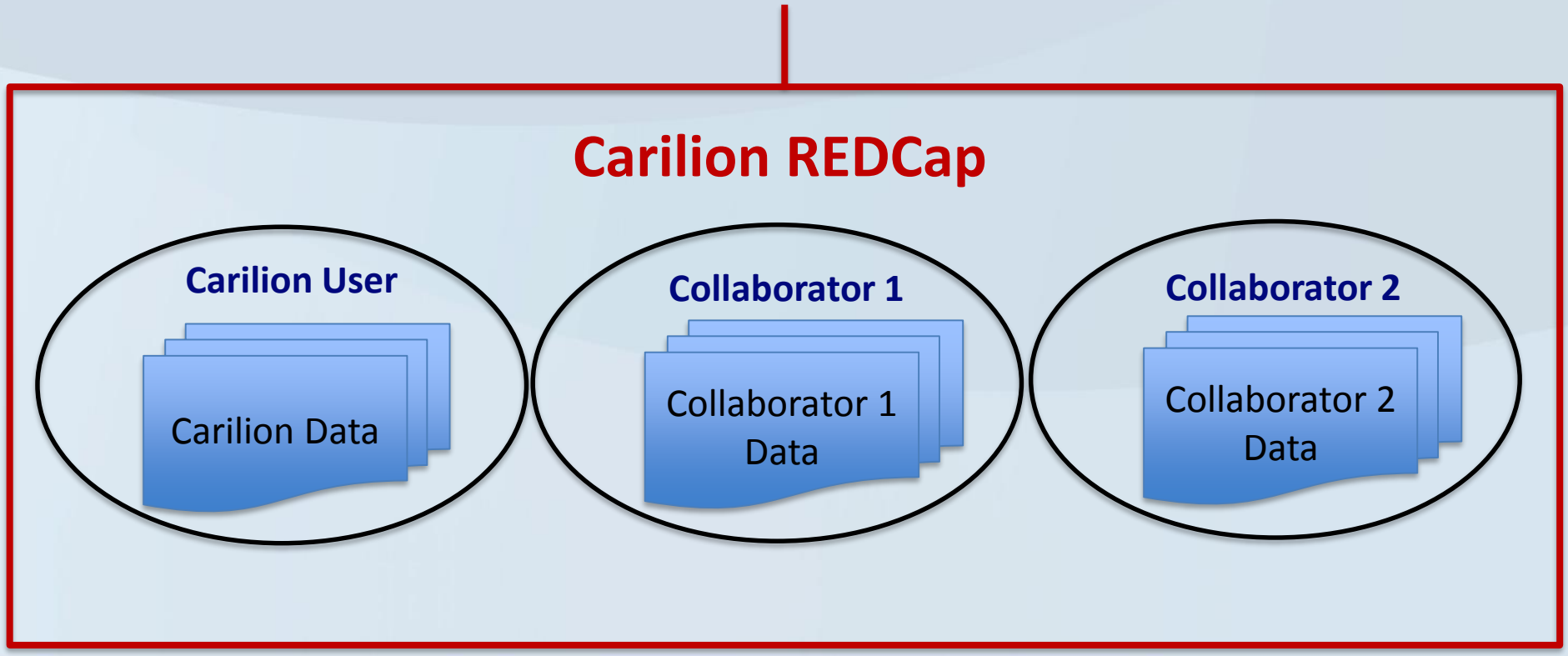
Analyzing Results



- Descriptive
- Export to Excel, R, SAS, SPSS, Stata for further analysis

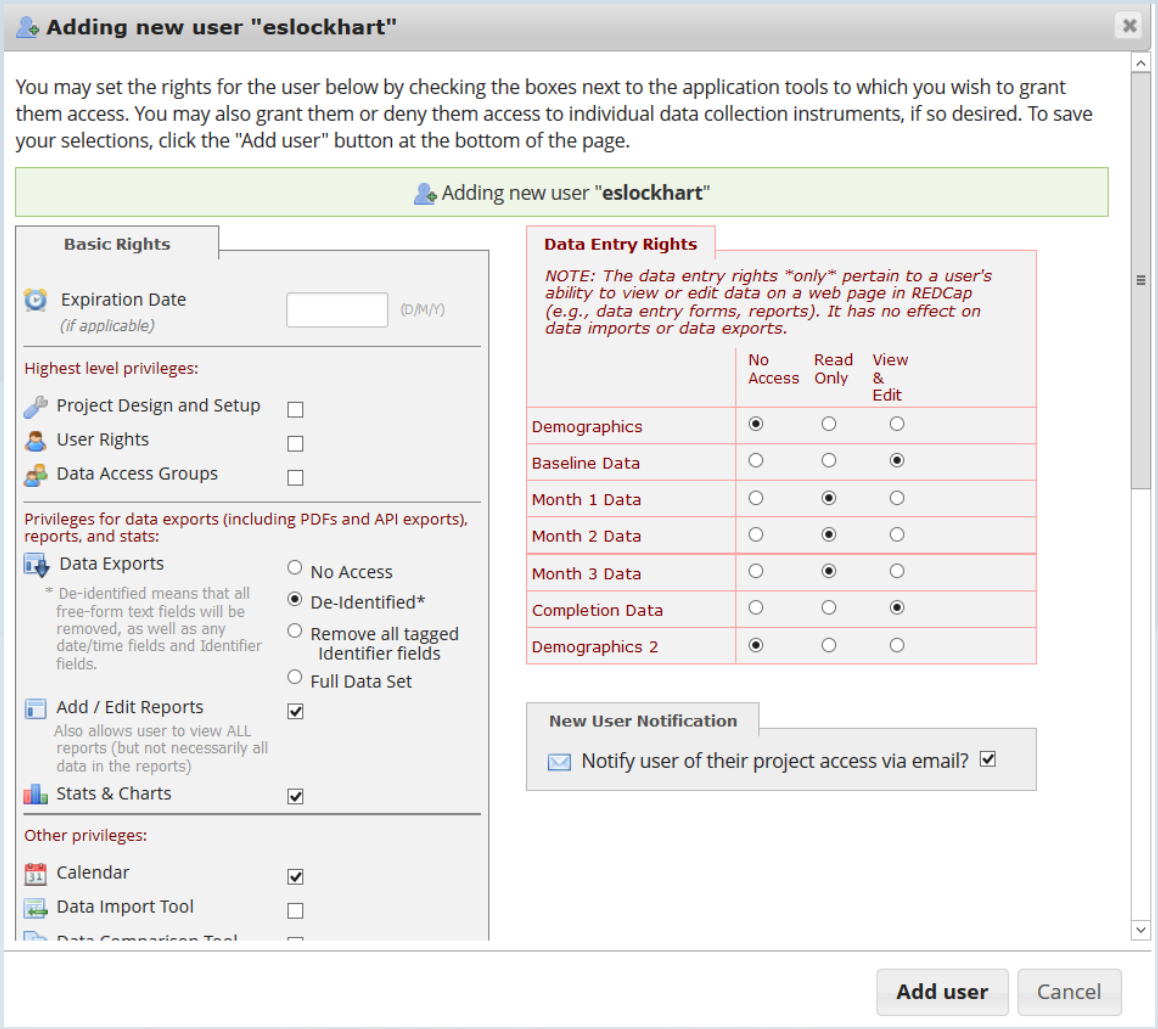
REDCap Data Sharing

- **Multiple Sites**



REDCap Data Sharing

Define each individual user's specific access



Audit Trail

This module lists all changes made to this project, including data exports, data changes, and the creation or deletion of users.

Filter by event: All event types (excluding page views)
Filter by user name: All users
Filter by record: All records
Displaying events (by most recent): 1 - 12
Filter by time range from to

Time / Date	Username	Action	List of Data Changes OR Fields Exported
06/06/2017 6:11pm	mmwang	Manage/Design	Email survey link to self
06/06/2017 6:11pm	mmwang	Manage/Design	Set up survey
29/05/2017 11:14am	mmwang	Updated User mmtenzer	user = 'mmtenzer'
29/05/2017 11:14am	mmwang	Updated User mmwang	user = 'mmwang'
29/05/2017 11:13am	mmwang	Updated User mmwang	user = 'mmwang'
29/05/2017 11:13am	mmwang	Updated User sjbwondara	user = 'sjbwondara'
29/05/2017 11:13am	mmwang	Updated User sjbwondara	user = 'sjbwondara'
29/05/2017 11:12am	mmwang	Created User mmtenzer	user = 'mmtenzer'
29/05/2017 11:11am	mmwang	Created User sjbwondara	user = 'sjbwondara'
29/05/2017 11:09am	mmwang	Manage/Design	Modify project settings
29/05/2017 11:09am	mmwang	Manage/Design	Modify project settings
29/05/2017 11:08am	mmwang	Manage/Design	Create project using REDCap XML file

Exploring Data through The TriNetX Solution

Health Analytics Research Team

TriNetX Background

- 90+ Healthcare Organizations
- 10 out of 15 top Pharma companies
- 5 out of 10 top CROs (clinical research organization)
- 19 countries
- 14.5 billion facts
- 140M patients

TriNetX "Live" Business Model

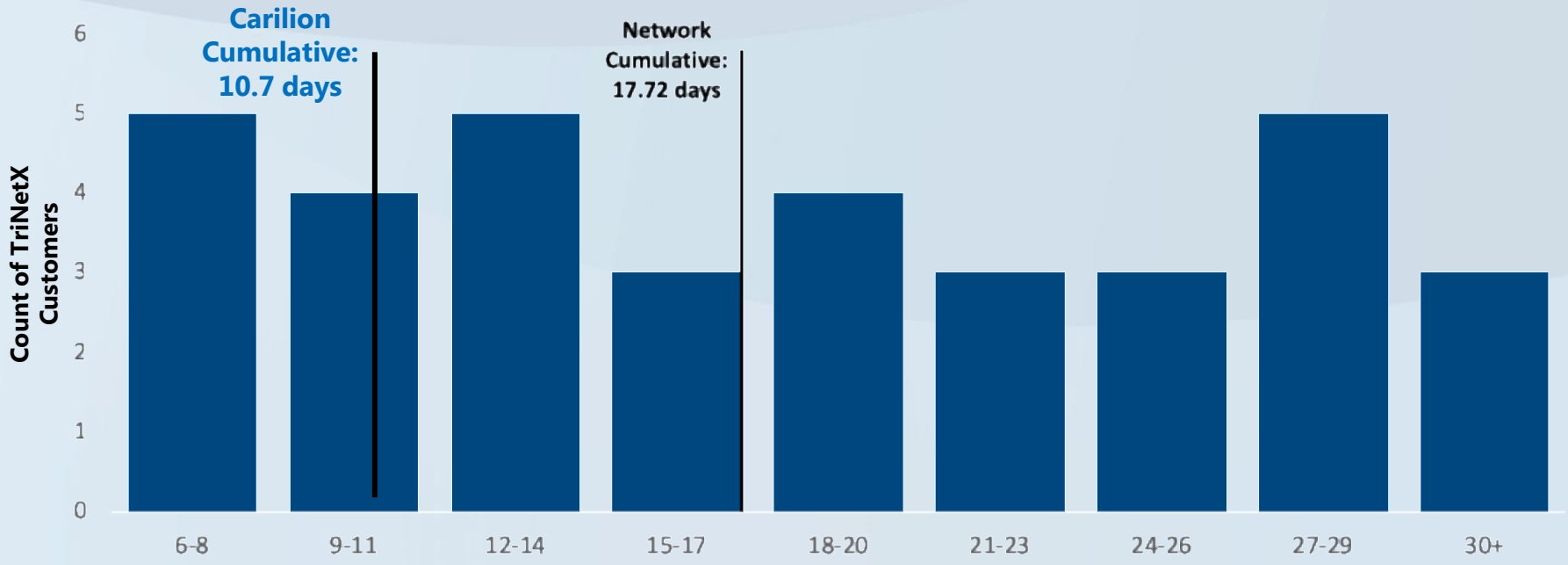
- FREE to Healthcare Organizations (HCO)
- HCO contributes data for two main purposes
  - Increase number of incoming clinical trials
  - Utilize for self-service feasibility for investigator initiated trials
  - Data exploration without need for IRB approval
- HCO queries their own de-identified data, with the ability to re-identify a patient list with appropriate internal HCO approvals

TriNetX “Live” Business Model

- CRO’s and Pharma query aggregated data to determine available study populations for clinical research trials
- CRO’s and Pharma PAY for this service
- HCOs respond to clinical trial queries either accepting or declining the trial request
- Efficient, consistent, timely

TriNetX "Live" Clinical Trial Statistics

- ~ 2000 trials offered; >600 trials accepted
- Turn around time improvement: Industry average 42 days



TIME TO RESPOND TO TRIAL CONNECT REQUESTS: 9/20/2018 – 6/05/2019

TriNetX “Live” Data Set

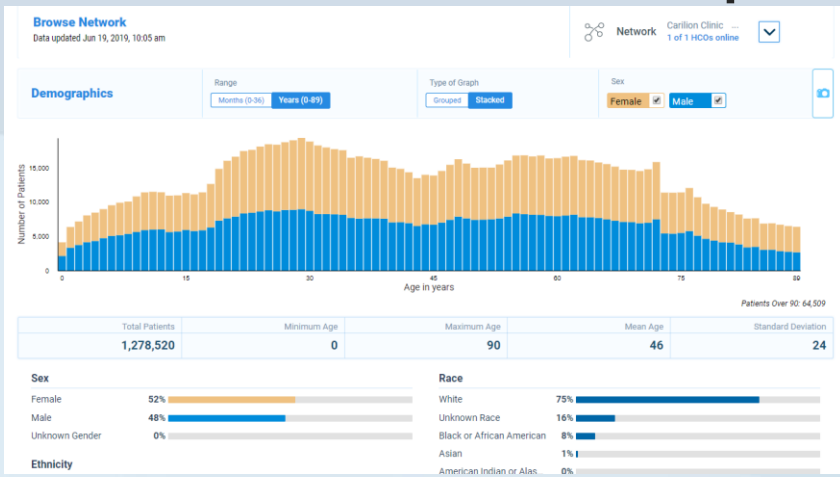
- Demographics
- Encounters
- Diagnoses
- Procedures
- Labs (numeric and positive/negative)
- Medications (outpatient prescription orders)
- Vitals

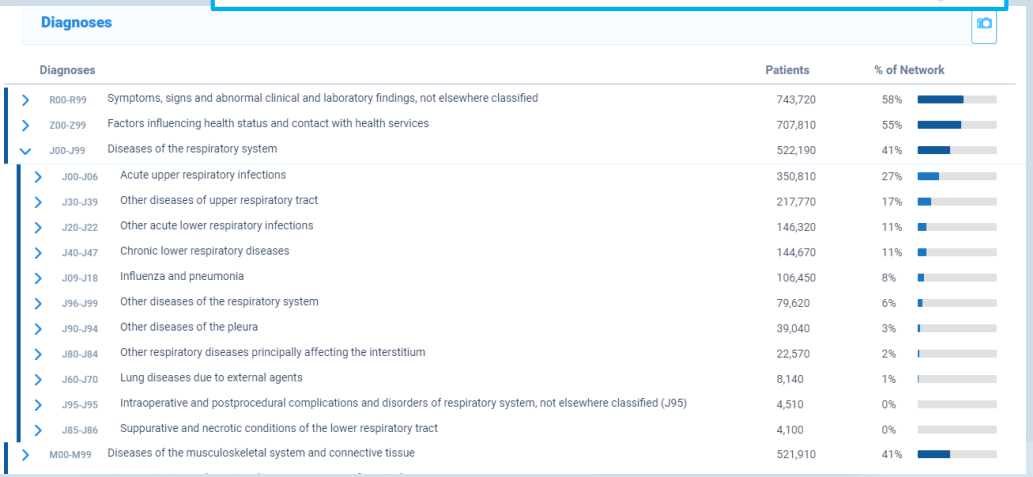
TriNetX “Live” Logic

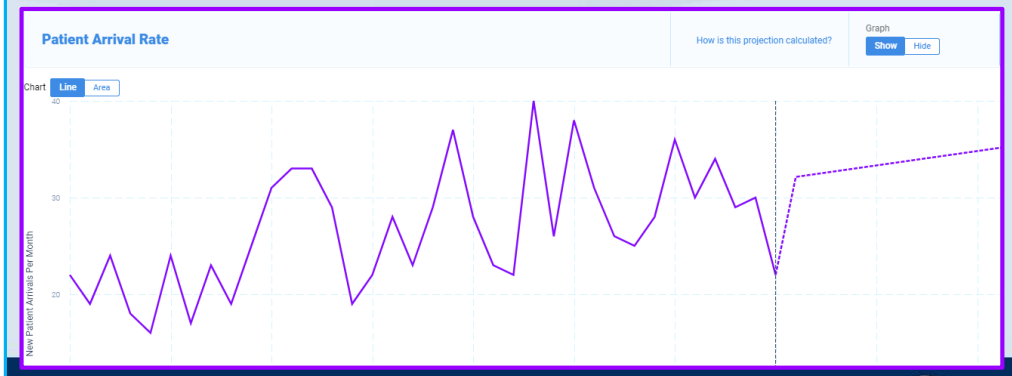
- Search for terms with clear ontologies
  - Can search on “Diabetes” or codes E11.9, 250.*, etc
- Filter for specific values
  - A1C >8
- Apply time logic to events
  - Patients with diabetes with visits between 1/1/2018 and 8/31/2018
- AND / OR logic on every component
  - AND on metformin AFTER visit
  - AND not on metformin BEFORE visit
  - AND Creatinine >=60 BEFORE visit
  - AND patient does not have CHF BEFORE visit
- Can get very complicated. TriNetX provides FREE support

TriNetX “Live” Result

- X number of patients







TriNetX “Live” Result

- Use results to verify sufficient population
- Number is approximate
- De-identified data extracts (free of own data, fee for network-wide)
- Seek approval (R&D, IRB) to re-identify patient list, if needed for study (not necessarily needed for prospective cohorts yet to occur)

TriNetX Advanced Analytics

- Further explore the de-identified cohort
  - Ability to design comparative effectiveness studies by defining one or multiple cohorts
  - Comparisons between groups with outcome analysis and identification of impact weight of other variables
  - Provides statistics on outcomes, including p values, confidence intervals, variable impact, Kaplan-Meier survival curves

TriNetX Advanced Analytics

Advanced Analytics

Analyze Outcomes

How do patients in a cohort experience outcomes?

Index Event

Explore Characteristics | Review Outcomes

Single Cohort

Compare Outcomes

How do outcomes compare between cohorts?

Index Event

Compare Characteristics | Review Outcomes

Two Cohorts

Compare Cohorts

How do patient characteristics compare between cohorts?

Compare Characteristics

Two Cohorts

Treatment Pathways

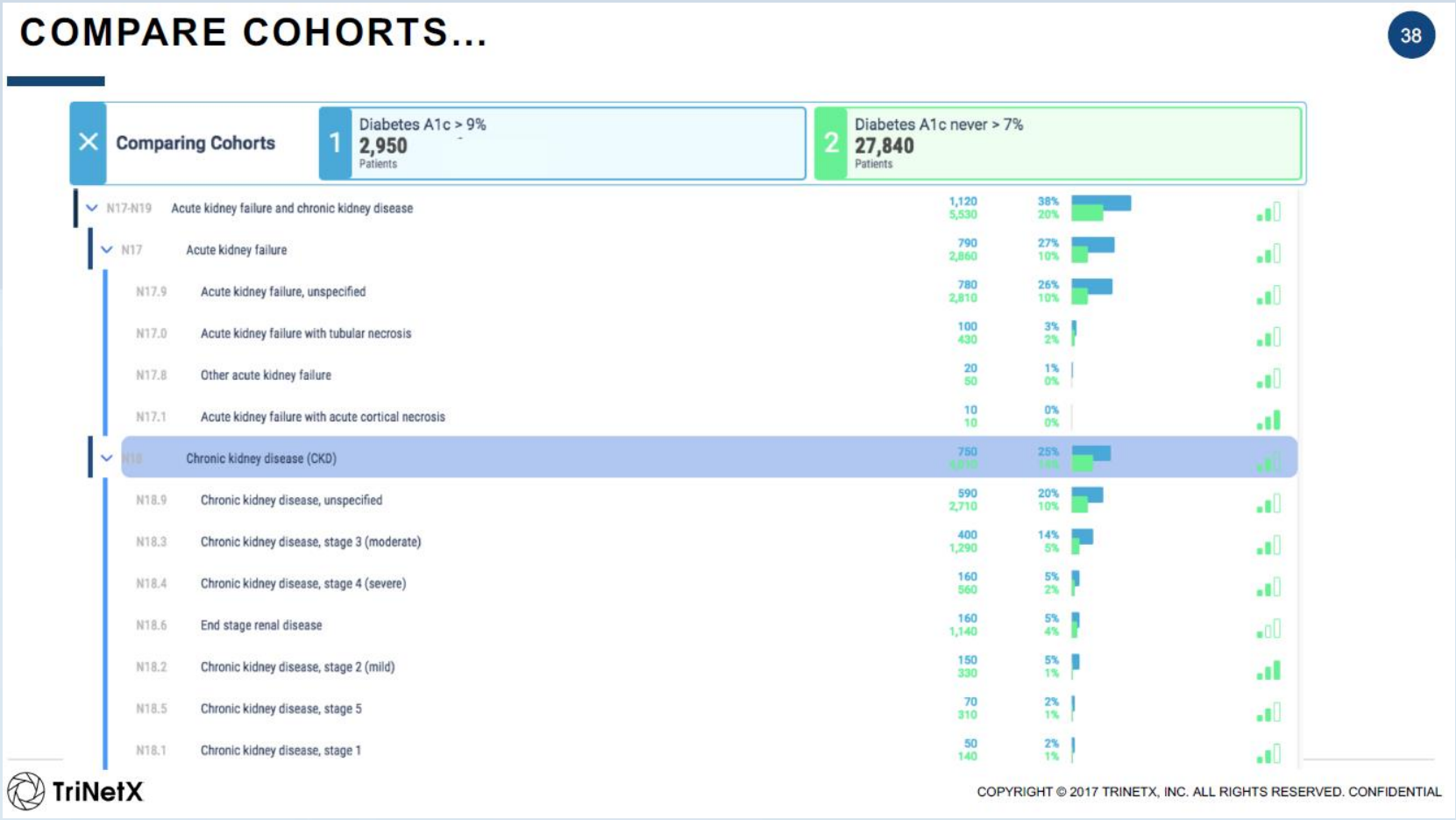
In what order do patients receive treatments following a diagnosis?

Index Event

Review Characteristics | Review Treatment Pathways

Single Cohort

TriNetX Advanced Analytics



TriNetX Advanced Analytics

COMPARE COHORTS...

39

Comparing Cohorts

1 Diabetes A1c > 9%
2,950
Patients

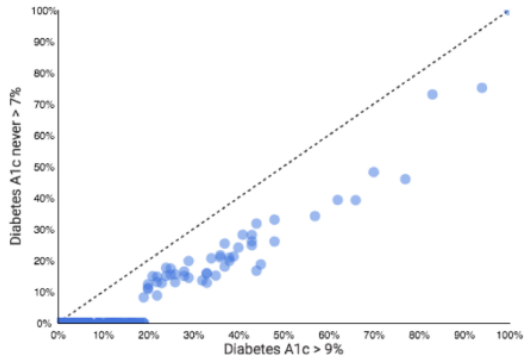
2 Diabetes A1c never > 7%
27,840
Patients

Show Diagnoses Within (Months) What's this?
3M 6M 12M 24M Custom Anytime

Show What's this?
All Acute Chronic

SCATTER PLOT

9,439 Unique Diagnoses

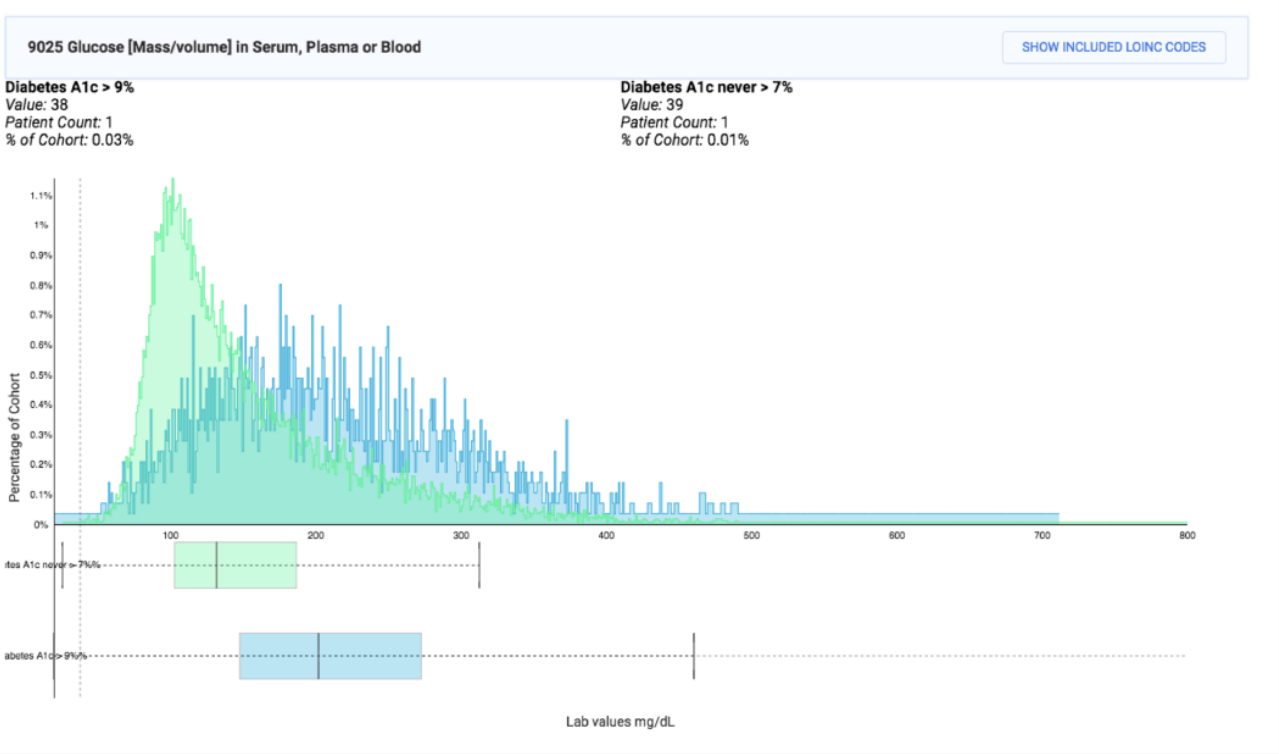


RESET CHART BACK

TriNetX

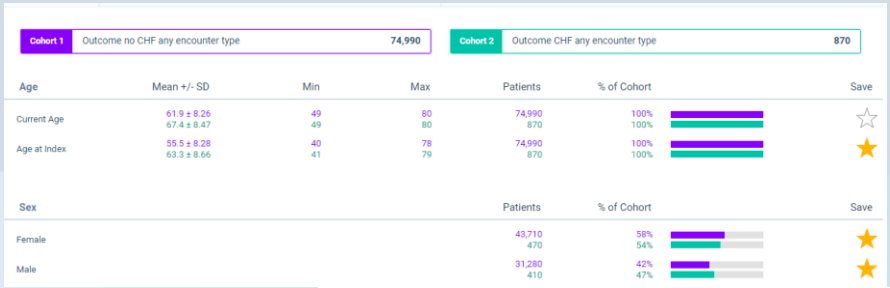
TriNetX Advanced Analytics

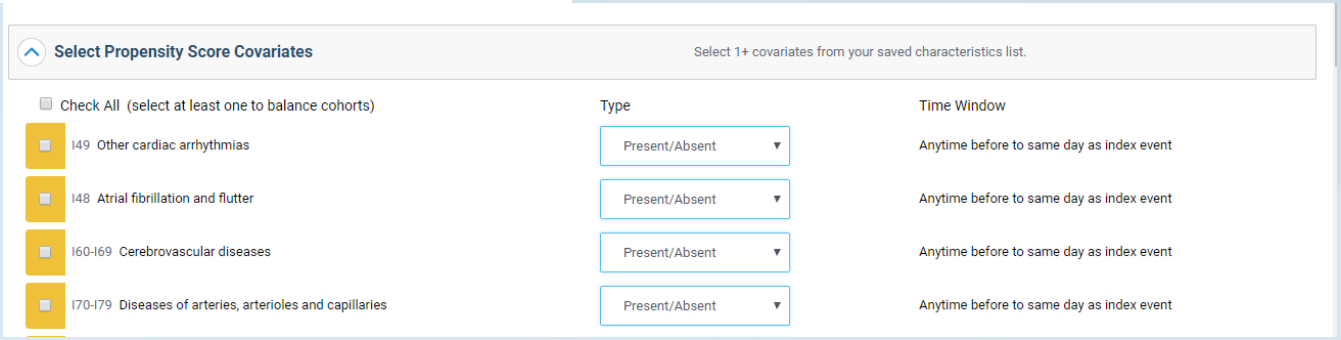
COMPARE COHORTS...



TriNetX Advanced Analytics

- Ability to adjust for confounding factors





- Ability to generate balanced cohorts through propensity score matching

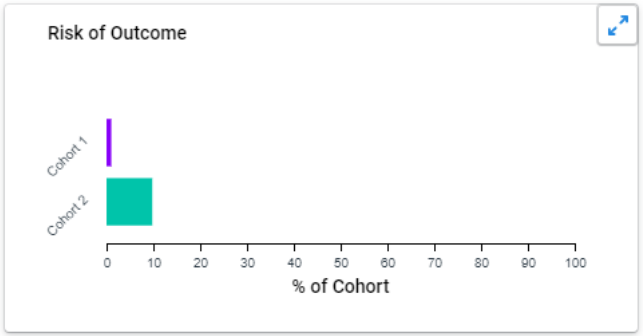
TriNetX Advanced Analytics

2a : Measures of Association Excluding Patients with Outcome Prior to the Time Window

	Cohort	Cohort Statistics: Patients in Cohort	Cohort Statistics: Patients with Outcome	Cohort Statistics: Risk
1	No CHF	2,970	30	1.01%
2	CHF	2,970	290	9.764%

Risk Difference	95 % CI	z	p	Risk Ratio	95 % CI	Odds Ratio	95 % CI
-8.754%	(-9.881%,-7.628%)	-14.943	< 0.0001	0.103	(0.071,0.15)	0.094	(0.065,0.138)

20 patients in Cohort 1 and 10 patients in Cohort 2 were excluded from results because they had the outcome prior to the time window.

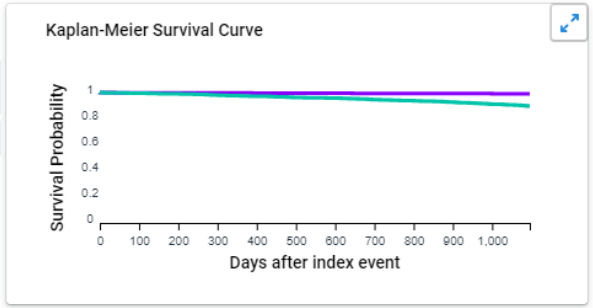


2b : Kaplan-Meier Analysis Excluding Patients with Outcome Prior to the Time Window

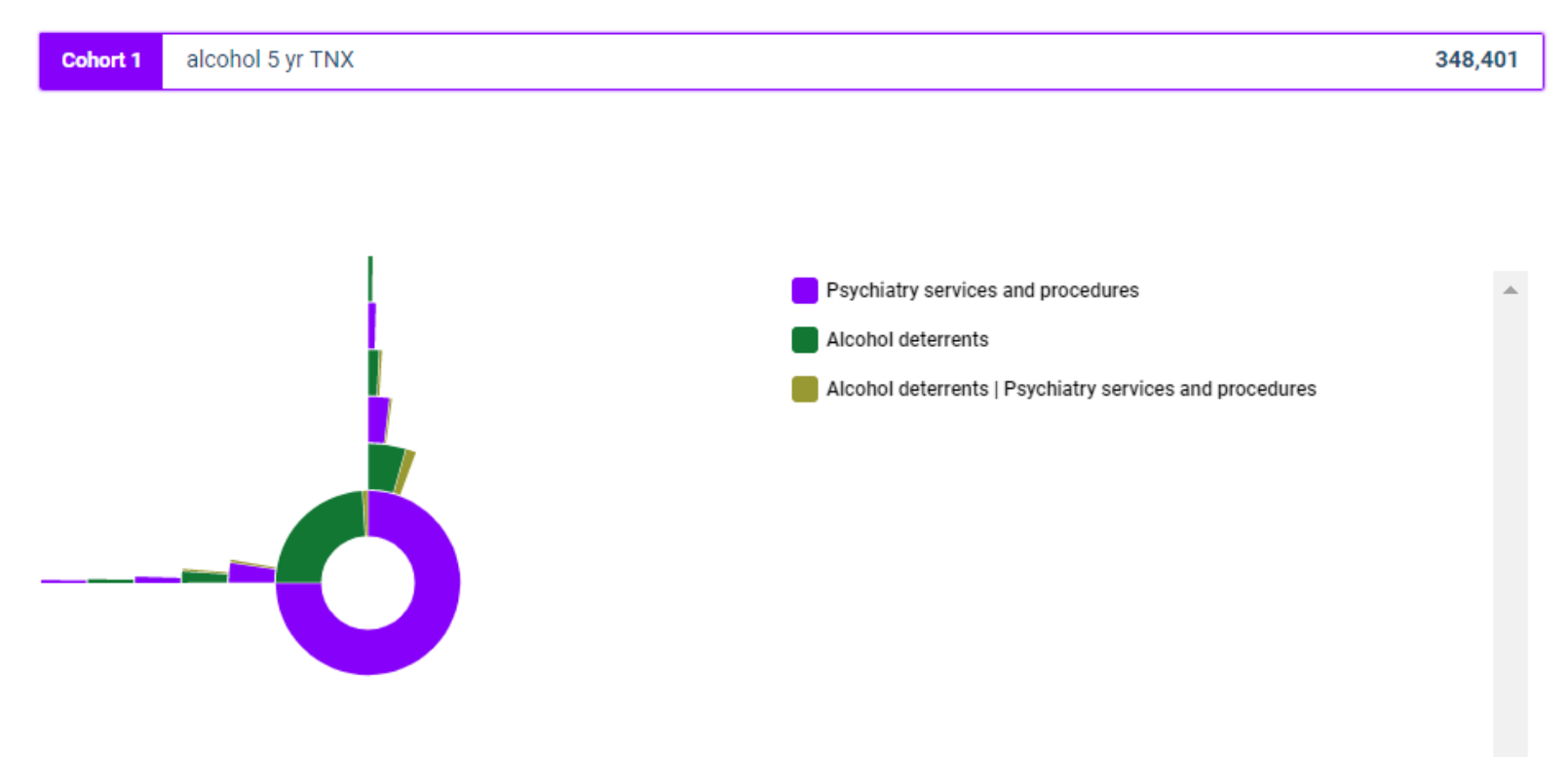
	Cohort	Cohort Statistics: Patients in Cohort	Cohort Statistics: Patients with Outcome	Cohort Statistics: Median Survival (Days)	Cohort Statistics: Survival Probability at End of Time Window
1	No CHF	2,970	30	-	99.17%
2	CHF	2,970	290	-	89.758%

Log-Rank Test: χ^2	df	p
228.939	1	< 0.0001

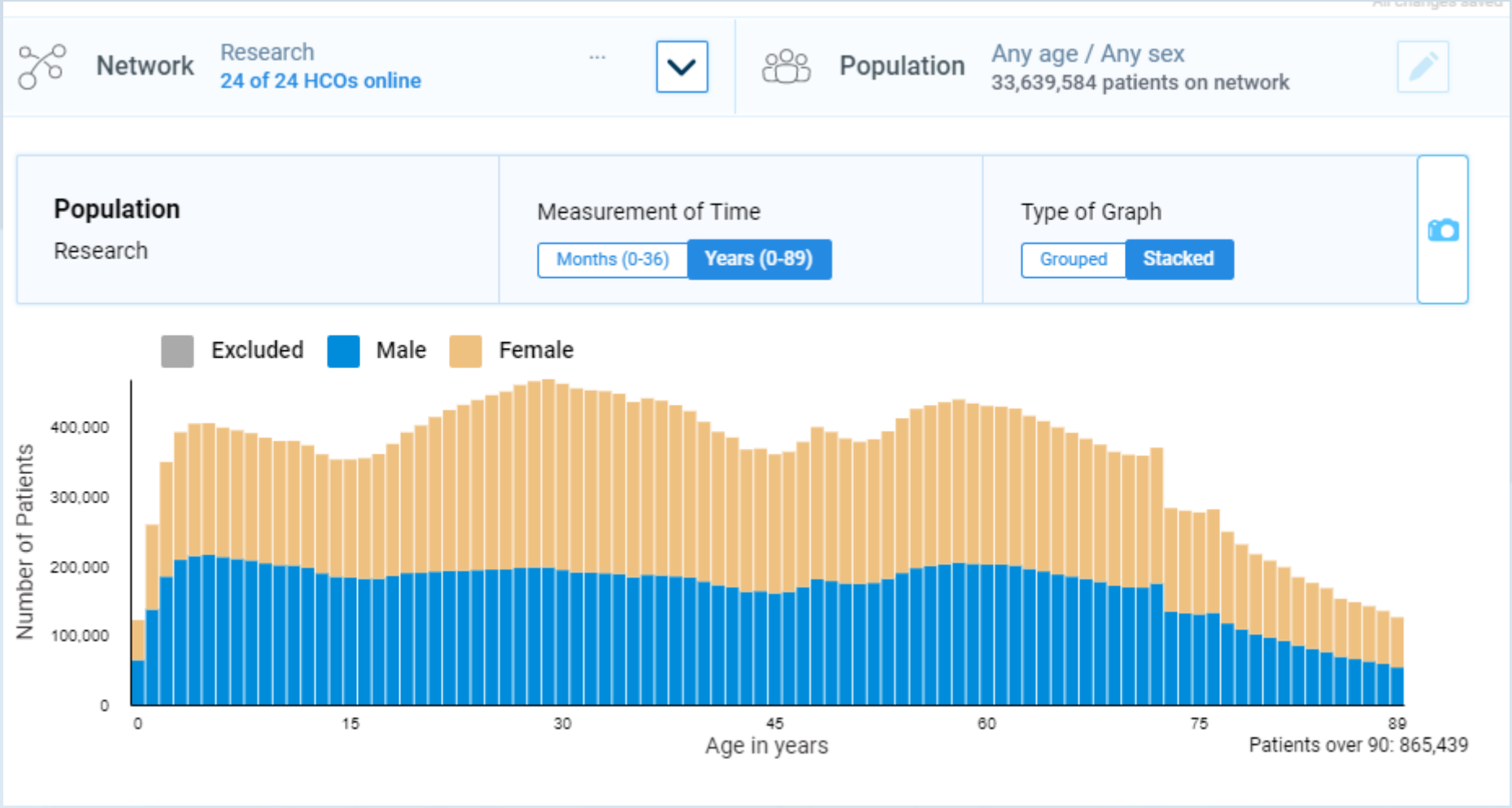
20 patients in Cohort 1 and 10 patients in Cohort 2 were excluded from results because they had the outcome prior to the time window.



TriNetX Advanced Analytics



TriNetX Research Network



Data Management Checklist

- Explore your cohort through TriNetX
- Determine if you need identified or prospective data and its data source
- Determine if data is an extract, chart review, or both (or survey!)
- Determine who will have access, what level of access, and if they need agreements (don’t forget the biostatistician!)
- Write up protocol to include Epic research access, REDCap and secure shared drive

Data Management Process

Post IRB and R&D approval, our concierge services will contact you to submit all necessary requests for:

- Secure Shared Drive
- Epic Research Access
- Data Extracts (EPIC)
- Data Collection and Storage (REDCap)
- Data Analysis: Biostatistical Services
- TriNetX Files or Reidentification

HART Drop-In Office Hours

- *CRMH, 1 South Training Room:*
- Mondays and Wednesdays, 9 a.m. - 5 p.m.
- Other days by appointment

- *3 Riverside, Conference Room 2B:*
- Mondays and Wednesdays, drop-in for Biostatistics support, 9 a.m. - noon
- Tuesdays and Thursdays, drop-in for Solution Developer support, 9 a.m. - noon
- Other days and times by appointment

Contact Information

Mattie Tenzer, Director
mmtenzer@carilionclinic.org

Min Wang, Manager
mmwang@carilionclinic.org

HART@carilionclinic.org

https://carilionclinic.org/health-analytics-research-team

FAQ

Q: I want to just keep my data in an Excel spreadsheet. Can I do that?

A: Only if approved by the IRB, which is typically if the dataset is a limited dataset or fully de-identified. Unless it is fully deidentified and not company confidential, excel spreadsheets must be stored in the secure shared drive set up for your project.

Best practice is to use REDCap, and it is required for fully identified data sets. The patient name is allowed to be stored in REDCap, which facilitates data collection. In addition, REDCap offers protections against corruption and loss that Excel does not. It also enforces consistent data collection.

FAQ

Q: How do I get access to TriNetX and what approvals do I need?

A: Email HART@carilionclinic.org for Carilion Clinic TriNetX End User Agreement. Complete the form and have your chair/manager sign. If you are not a Carilion employee, send to Francis Farrell fxfarrell@carilionclinic.org for approval.

FAQ

Q: How do I get my project built into REDCap? What if I also need a data extract?

A: Once you have IRB approval or exemption, HART is notified. Through our Concierge Services, we will confirm the services you need for your project, enter the requests and assign them out to our team. Our team member will develop the extract and build your REDCap project for you, working closely with you to ensure they meet your project's approved data collection tool. If needed, we will import the extract into REDCap. We will train you on how to use your REDCap project.

FAQ

Q: I think my project is just QA/QI. Do I have to go through all of this?

A: Not necessarily, but it is best practice.

The best QA/QI projects are often similar to research in terms of ensuring sufficient appropriate patient population (TriNetX), data extracts (Epic), data management (REDCap), chart review, and statistics. Often QA/QI projects take as much or more time and resources to accomplish. Therefore, safe storage of data is essential to protect against loss and corruption. When in doubt, consult with the IRB to ensure your project meets QA/QI definitions. In addition, Research takes priority when our workload is too heavy, so your QA/QI project may not get the timely it would if structured as Research.