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Learning Objectives

- To list the services of the Health Analytics Research Team
- To understand how to navigate the research and QA/QI data processes at Carilion
- To apply knowledge gained to access and utilize MyProjectPath
- To describe the uses and applications of TriNetX, REDCap, Epic for Research, Sparc and shared drives

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HART Services

…. provide proper access, acquisition, storage and utilization of research and QA/QI data, including PHI

- Consultation: study design, data management, and stats
- Data Exploration: TriNetX
- Data Extracts (EPIC)
- Data Collection and Storage (REDCap)
- Epic Research Access
- Secure Shared Drive or SPARC
- Data Analysis: Sparc tools and Biostatistical Services

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HART

- 20 team members providing end to end support
- Mix of grant funded / institution supported
- 250+ combined years in healthcare/research
- 165+ combined years at Carilion
- 83% diversity (non-white (33%), female (72%), veteran (5%))
- Full support for Research Informatics, Biostatistics, Data Science, Epidemiology, Research Design, data extraction and research navigation services
- Carilion component of NIH CTSA iTHRIV iBERDI group
- Innovation Department support (app development)

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Please answer a few questions to help you navigate research services at Carilion Clinic.

This tool provides several options to display information, depending on your familiarity of the process and needs. You can choose:

- ○ Interactive PDF: Provides overall process with links to some resources, with no tracking.
- ○ Lite Version: A "lite" version that works best for experienced researchers. Does not provide tracking.
- ○ Full Version: A comprehensive version presenting you with relevant resources tailored to your project, while tracking progress and costs. Great for new investigators and experienced investigators interested in learning about new offerings.

reset

Submit

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Survey Queue

This tool is designed to help you navigate the processes related to Research and QA/QI projects. You may either view an overview or get in depth assistance by answering questions about your project. Each question will provide you with contact information for the resources you may need. In addition, information is provided on approximate project costs to consider and timelines, based on your answers

Do you want to provide an email address and title?

* must provide value

(•) Yes ( ) No

reset

Email mmtenzer@carilionclinic.org

Project Title Testing project for OPCD 3/25/2021

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Save & Return Later

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Your survey responses were saved!

You have chosen to stop the survey for now and return at a later time to complete it. To return to this survey, you will need the survey link to this survey.

Survey link for returning

You have just been sent an email containing a link for continuing the survey. If you do not receive the email soon, please check your Junk Email folder.

Or if you wish, you may continue with this survey again now.

Continue Survey Now

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Project Type

Is your project Research or QA/QI?

○ Research ○ QA/QI ◉ Not sure

reset

Research vs QA/QI Determination

Click above to learn more about Research versus Quality Assurance/Quality Improvement projects.

QA/QI activities are simply to assure known quality. QA activities present no risk to participants. They are typically observational and unobtrusive, and involve the collection and analysis of data to which the investigators have legitimate access through their institutional roles. They do not prevent or hinder standard practices and they do not impose additional risks or burdens on participants. They do not infringe on privacy or breach confidentiality. QI activities determine quality and improve services or clinical care. They are usually applied within a defined institutional setting, often a single department or division. Their intent is to evaluate and alter processes constituting the delivery of care in the near future, with the expectation that the population of patients usually served in that location will benefit.

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Proposal

Would you like a section to organize your thoughts? (Idea, Problem, Background)

(•) Yes ( ) No

reset

Idea / Title

OCPD testing

Understanding of Problem

This is where I would enter the current understanding of the problem I am trying to address.
Everything I type on this page becomes available to copy/paste later into my Research and Development application.

Expand

Background

This section can be extended as large as I need in order to type in a full background

Expand

Time period of data: Prospective or Retrospective?

If Retrospective, what time period (e.g. 2015 - 2017) will the data cover? Please note for retrospective datasets, all data must be in existence (including followup data) at the time of IRB submission

This is a place to organize the type of project and time period.

Expand

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Save & Return Later

Background

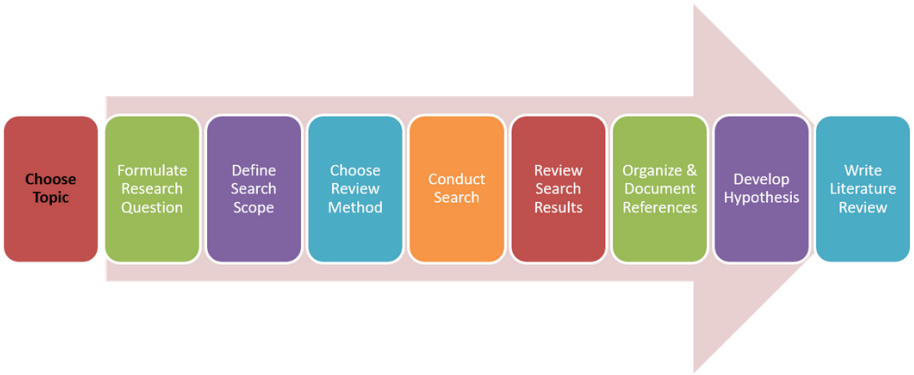
Have you conducted a literature search?

○ Yes ◉ No

reset

Literature review is a process that helps you:

- Learn about what is known.
- See what is missing or what needs to be investigated.
- Build your opinion.
- Ask a research question to contribute to the advancement of knowledge about a topic.
- Discuss the implications of your findings.



Open the attached powerpoint presentation to learn more about how to perform an effective literature search.

Attachment: Literature Review v 12.19.19.pptx (0.73 MB)

Save the attached Literature Search Template Tool and use it in your Lit Search process.

Attachment: Literature Review Table-Template.xlsx (0.01 MB)

Carilion Library Services (library@carilionclinic.org) can provide excellent support for your literature search.

In addition, check out the attached file for a great template.

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Team

Do you have external collaborators?

- ○ No
- ○ VTCSOM only
- ○ 1+ non-Carilion, non VTCSOM person
- ◉ Not sure

reset

Projects with external collaborators will require a contract or an agreement to be put in place. The external collaborator will not be able to take part in the project until all agreements are in place. Please contact research@carilionclinic.org for more information.

In addition, if the external collaborator(s) needs access to Carilion systems, they will need to sign an Access Confidentiality Agreement (attached here), complete a PHI form for the project if applicable, and provide a copy of their driver's license, prior to receiving access.

There may be additional software licensing costs associated with external collaborators.

research@carilionclinic.org and HART@carilionclinic.org will help you through these processes after IRB approval.

Attachment: access confidentiality agreement.pdf (1.23 MB)

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Save & Return Later

Funding

Will you have funding?

- ( ) Yes, External (e.g., Grant, Sponsor, Other Institution, Startup)
- (•) Yes, Internal funding (e.g., RAP, Foundation, Department funds, Research overhead acct)
- ( ) No
- ( ) Not sure

reset

If you want to search for funding opportunities, visit portal.iTHRIV.org to find internal and external funding opportunities that may apply to your project. Login with your Carilion credentials. The Events tab frequently has upcoming funding opportunities and deadlines, or you can navigate to Propose, Funding Resources to browse various grants.

Be sure to acknowledge iTHRIV support with the following in your presentations/manuscripts:

This content was supported, in part, by the National Center For Advancing Translational Sciences of the National Institutes of Health under Award Numbers UL1TR003015 and KL2TR003016. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

Do you want to calculate an estimate for project costs as you compile your project?

Please note that these are just estimates, and your costs may be significantly more or less, or even $0, depending on the circumstances of your project and funding status.

Even if you do not have funding, understanding the costs related to your project will assist you in determining the benefit and value.

(•) Yes ( ) No

reset

If there is external funding for a project, a Conflict of Interest disclosure may need to be completed. Contact researchcompliance@carilionclinic.org with any questions.

Involving Patients/Patient Data

Does your project involve Carilion patients?

(•) Yes ( ) No ( ) Not sure

reset

Would you like to explore patient cohorts to better understand volumes, co-morbidities, outcomes, treatment paths, and other attributes, in a safe, de-identified manner?

(•) Yes ( ) No ( ) Not sure

reset

TriNetX at Carilion provides tools to search criteria related to demographics, diagnostic codes, procedures, laboratory results, medications and vitals. An approximate number of patients matching the search criteria is returned, but does not include any patient identifiers or other clinical data. Investigators can explore the feasibility of patient cohorts and then request assistance from HART@carilionclinic.org to obtain appropriate approvals and subsequently receive detailed clinical data for research, grant and QA/QI purposes.

For more information on TriNetX, please view the attached Powerpoint.

Attachment: CC TriNetX Overview.pptx (1.68 MB)

If you are interested in gaining access, complete the attached End User Agreement. You may return the Agreement to HART@carilionclinic.org.

Attachment: CCTriNetX User Agreement.pdf (0.08 MB)

Would you like to see language to use in your IRB protocol for TriNetX use? ( ) Yes ( ) No

reset

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Save & Return Later

TriNetX Background

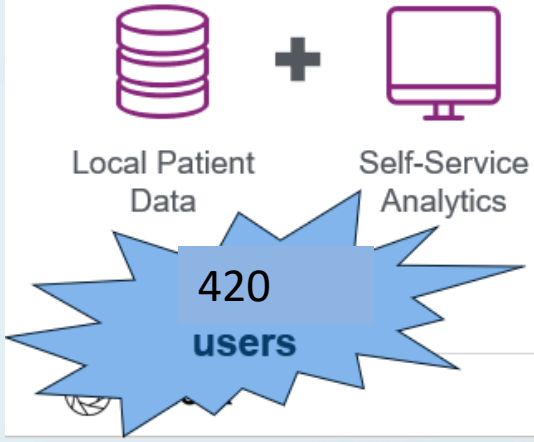
- 120+ Healthcare Organizations (HCO)
- 13 out of 15 top Pharma companies
- 70+ billion facts
- 250M+ patients
- Carilion's data loaded since 2008
- Carilion's data re-identifiable by HART with appropriate permissions

TriNetX Business Model

- FREE to Healthcare Organizations

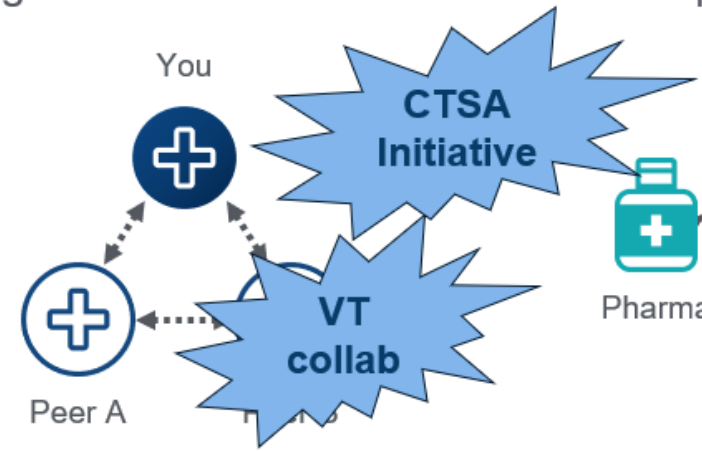
LOCAL RESEARCH

Provide your investigators with data and analytics to develop study protocols and pursue grants



COLLABORATION

Participate in multi-site investigator-initiated trials with peer research organizations



SPONSORED TRIALS

Attract industry-sponsored clinical trials and funding for local research and development

Carilion Data in TriNetX

- Inpatient, emergency and outpatient
- Demographics & Encounters
- Diagnoses & Procedures
- Labs (numeric and positive/negative)
- Medications & Vitals
- Oncology data from Cancer Registry
- Integrated Claims and Mortality data
- NEW: Integrated data from NLP (natural language processing)

Would you like to see language to use in your IRB protocol for TriNetX use? (●) Yes ( ) No reset

Copy and paste the relevant language here into your IRB protocol.

If using a volume of patients generated by TriNetX:
A feasibility query run through TriNetX with available inclusion and exclusion criteria generated an approximate volume of __ patients of ____ time period.

If you plan to re-identify these patients in order to do chart review or patient outreach:

The TriNetX cohort will be re-identified by the Health Analytics Research Team, and a list of MPIs (with or without other relevant data points) will be generated. The list may be used to generate Epic extracts and/or imported to REDCap for further chart review.

Refine as appropriate for your protocol.

Citing TriNetX
TriNetX should be mentioned in the methods section.

A suggested adequate general description would read like:

If a TriNetX platform with browser-based real-time analytical features was used:
"....We used TriNetX, a global federated health research network providing access to electronic medical records (diagnoses, procedures, medications, laboratory values, genomic information) from approximately xy Million patients in yz large Healthcare Organizations. The TriNetX platform only uses aggregated counts and statistical summaries of de-identified information. No Protected Health Information (PHI) or Personal Data is made available to the users of the platform..."

If a dataset, downloaded from TriNetX, was used:
"....TriNetX, a global health research network provided a de-identified dataset of electronic medical records (diagnoses, procedures, medications, laboratory values, genomic information) from xy patients with [cohort definition]. The data is de-identified based on standard defined in Section §164.514(a) of the HIPAA Privacy Rule. The process by which Data Sets are 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. Protected Health Information (PHI) or Personal Data is made available to the users of the platform..."

This general description should be followed by a description of the actual methods used including the date of the data download or when the analytics were performed.

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Study Design / Methodology

Contact HART@carilionclinic.org for a consultation about your project.

We have expert biostatisticians and research data engineers who can help you design your project including determining how to acquire, manage and analyze your data. We can also assist with survey design, secure data collection tools, and defining patient cohorts.

Our Carilion Clinic Health Analytics Research Team has the expertise and access to Epic data, in addition to other Carilion data sources. Because it is part of our job responsibilities, HART does not need to be included on your protocol, unless the HART member significantly contributed to study design. No additional agreements, contracts or statements of work are required.

All HART members have completed CITI training in case they do need to be included on your protocol. In addition, HART members have access to project shared drives and SPARC folders in order to facilitate the analysis of your datasets.

Click here to visit our website and explore our end-to-end support of your project!

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

Do you need advice about your study design, what data you can collect, how you will analyze the data, and/or if you have enough subjects to do the project?

(•) Yes ( ) No ( ) Not sure

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Additional Resources

Does your project involve a human factors approach to address different aspects of a work "system" including the design of equipment, the physical environment, and the actual tasks that individual caregivers do on a daily basis?

(•) Yes ( ) No ( ) Not sure

reset

Visit the SIMI web page by clicking here.

Does your project involve potential intellectual property, new ideas or patents?

(•) Yes ( ) No ( ) Not sure

reset

Contact the innovation@carilionclinic.org for more information.

Does your project involve the use of the Basic Science Research Lab at Roanoke Community Hospital? (e.g. specimen collection, storage and processing)

(•) Yes ( ) No ( ) Not sure

reset

Visit our website by clicking here: https://www.carilionclinic.org/research/lab#research-lab

If you have specific project needs beyond what is covered here, visit portal.iTHRIV.org to find internal and external resources that may apply to your project.

Login with your Carilion credentials. Navigate to Conduct, to browse various resources.

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Save & Return Later

Data Sources

Understanding what data are available and limitations is critical to the success of your project, whether your project is Research or QA/QI, Retrospective or Prospective, and regardless of Data Source.

If you would like to learn more about what data are available, data extracts, chart review and data management, please review the attached Powerpoint.

Attachment: DataManagementOverview.pptx (0.23 MB)

What is your data source(s)?

Epic

Expand

Epic is our most frequent source of data for research projects. Are you planning on a HART member acquiring an Epic data extract for your project?

○ Yes ○ No

reset

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 Susceptibilities
  - Trauma Registry
  - TriNetX data sets
  - All Payers Claim Database (APCD)

DATA - 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 Study:
  - 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

- 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 documentation issues?
- What are exact definitions? (ex/ ICD codes and cut-offs)

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?

Epic is Carilion's vendor for the patient electronic medical record. **www.epic.com**

We have almost all of Epic's modules except the ones in RED.

We are not an insurance company, so we do not have Tapestry.

We use Quest labs, so we do not have Beaker. Lab results are fed into Epic via a real time interface.

Epic Applications and Modules

Core Clinicals	ASAP EpicCare Ambulatory Clin Doc Orders	Ancillary Clinicals	Anesthesia Beacon Clinical Case Management Cupid Home Health Infection Control OpTime Phoenix Radiant Research Stork Willow Ambulatory Willow Inpatient Beaker (Lab system)
Access	Grand Central Cadence Prelude Health Information Management Identity		
Revenue	Hospital Billing Professional Billing Claims Tapestry (insurance payor)		

Different Epic modules were brought live at different times at Carilion.

Therefore, the completeness of the Epic medical record is dependent on the type of data required and when that module went live.

EPIC Timeline at Carilion

Ambulatory	CMC	NRV	Optime	Radiant
Started 2/2008	8/2008	4/2009	10/2010	6/2012

Cardiant	Stork	Beacon	Anesthesia	Home Health
5/2013	5/2013	10/2014	11/2016	2/2017

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

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Save & Return Later

Data Storage

Retaining your data in a secure location for analysis is critical, both for privacy and security reasons, but also to prevent data loss. Data should never been transferred off of Carilion's network until and unless the exact dataset(s) are specified and approved in the IRB protocol, and all appropriate agreements are in place with Research and Development.

If you have external collaborators who will need access to data to analyze, Carilion offers a secure research environment named SPARC. Powerful analytic tools are available within the environment, where your data will reside.

If your project is entirely internal (no external collaborators), you may use a Carilion shared drive which is set up specifically for your project. You may also choose to use SPARC to leverage the analytics tools.

QA/QI is not required to use network folders or SPARC, but may choose to leverage these options.

Some sponsored trials do not require the retention of local data in an electronic format, so a secure Carilion location may not be necessary.

If you are interested in learning more about Sparc, please review the attached presentation.

Attachment: SparcOverview.pptx (0.87 MB)

Will you be performing chart review or collecting patient information?

- (●) Yes
- ( ) No
- ( ) Not sure

reset

Any Carilion dataset used for research purposes that is NOT fully identified will be stored on a secure Carilion environment. This access will be set up for you after IRB approval.

Which environment do you anticipate needing for storage of your data?

- ( ) Neither a shared drive on the network or SPARC are needed
- ( ) Secure shared drive on Carilion's network
- ( ) SPARC Secure Research Environment
- ( ) Both

reset

Data Storage

- Data should be stored securely where only the research team can access
  - Secure shared drive (S: drive)
  - Secure Research Environment:

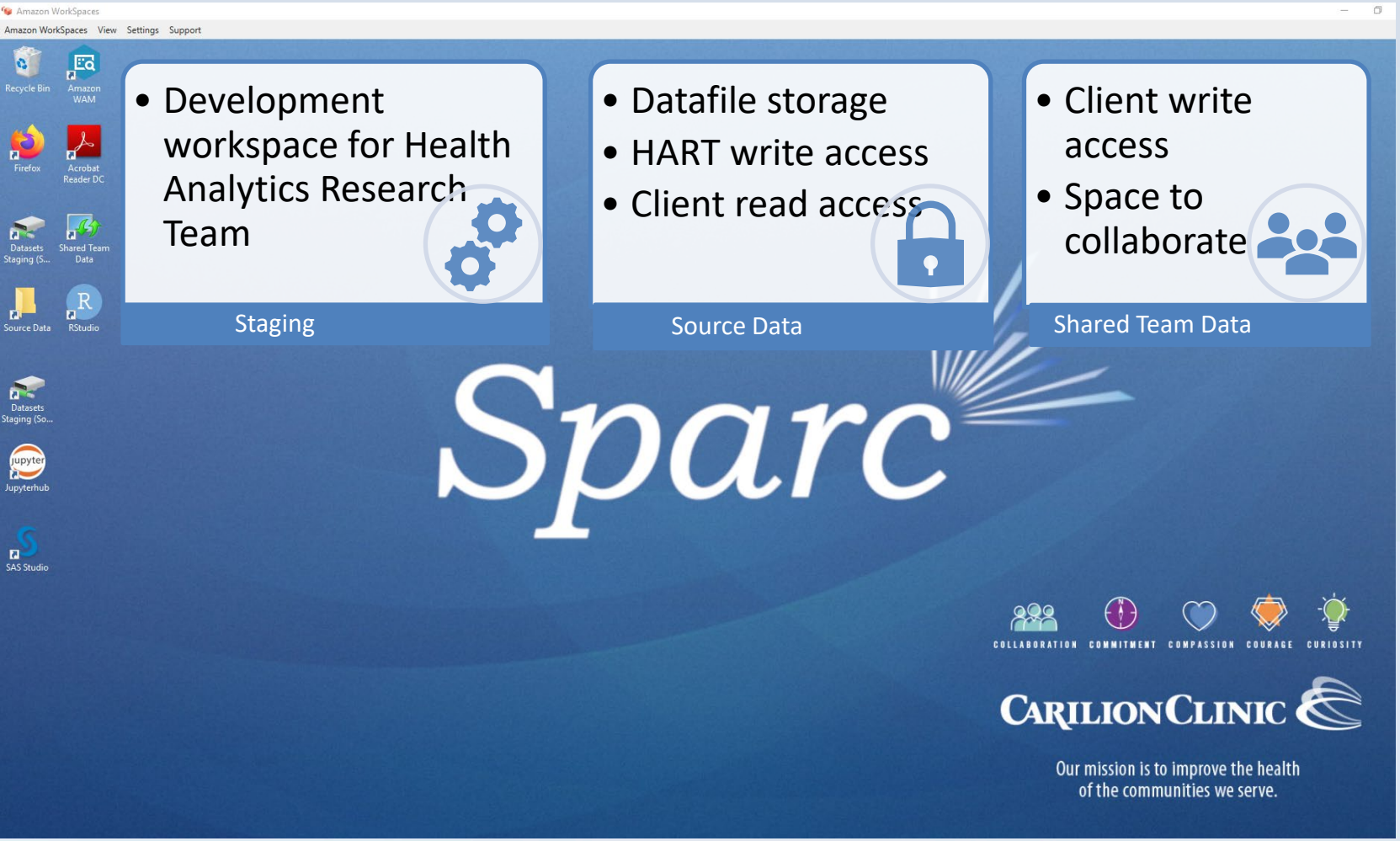
  Storage and Programs Accelerating Research Collaborations (SPARC)

Sparc
CARILION CLINIC

Environment

- Cloud-based. Accessible through any internet connection, but with the applied security of our firewall and account verification
- SAS Viya and statistics, JupyterNotebook, R & R Studio, Python, NVIVO to meet our internal and collaborators analytics needs.
- Approved for all data (de-identified, limited and identified), but must be specified in IRB protocol
- Will provide the platform to integrate with the iTHRIV Data Commons for ease of launch

AWS S3 Bucket Structure



Which environment do you anticipate needing for storage of your data?

- ( ) Neither a shared drive on the network or SPARC are needed
- ( ) Secure shared drive on Carilion's network
- (•) SPARC Secure Research Environment
- ( ) Both

reset

Use the following language in your IRB protocol if you will be using Carilion's SPARC environment for data storage and analysis.

Carilion Clinic's SPARC secure research environment will be used to store and analyze datasets for analysis. SPARC (Storage and Programs Accelerating Research Collaborations) is Carilion's web-based, secure research environment, that provides accessible storage of research project files in addition to advanced analytics programs to apply to those files for analysis. Current product offerings are SAS Viya and Statistics, integrated with R and Python, in addition to Microsoft Excel, Powerpoint and Word. AWS offerings may be possible to implement, depending on the needs of the project. Once access is authorized through an IRB approved protocol and a signed end user agreement, the clients utilize their institution's credentials to sign in. Data are prevented from download from the environment, without appropriate permissions and managed by the Health Analytics Research Team (HART). Folders are set up specifically for each approved project, with access limited to the research team, as specified on the protocol. This mitigates most of the minimal risk of privacy breach.

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Data Management

If you are collecting patient information or doing a survey, you will need to use Carilion's REDCap environment to keep it secure and safe.

If you would like to learn more about REDCap, please review the attached Powerpoint.

Attachment: REDCapOverview.pptx (1.26 MB)

Will you be surveying participants?

(•) Yes ( ) No ( ) Not sure

reset

Will you be using REDCap? Select Yes, and we will provide you with language to use in your IRB protocol.

(•) Yes ( ) No ( ) Not sure

reset

Use the following language in your IRB protocol if you will be using Carilion's REDCap for data storage or surveys.

Carilion Clinic's REDCap software will be used as the central location for data collection. REDCap (research electronic data capture) provides a secure, web-based application designed to support data management and collection for research/QA/QI studies. Carilion's REDCap servers are securely housed on site in a limited access data center, and all data are stored on Carilion's firewall protected network. The Health Analytics Research Team supports the proper development of projects and surveys in REDCap, observing appropriate change control and enforcing appropriate security controls. Data collection projects are built with a study-specific data dictionary, enforcing intuitive, accurate, consistent and complete data entry. REDCap also provides a survey tool for building and managing online surveys. Health Analytics Research team restricts user access to the IRB-approved project research team utilizing the approved processes and standards of TSG. REDCap is HIPAA compliant and provides audit trails. Data can be easily exported in several formats to a secure network directory for combination with extracted data, if appropriate, and analysis with common statistical packages.

Use the following language in your manuscripts and presentations if you will be using Carilion's REDCap for data storage or surveys.

Study data were collected and managed using REDCap electronic data capture tools hosted at Carilion Clinic. REDCap (Research Electronic Data Capture) is a secure, web-based software platform designed to support data capture for research studies, providing 1) an intuitive interface for validated data capture; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for data integration and interoperability with external sources.

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

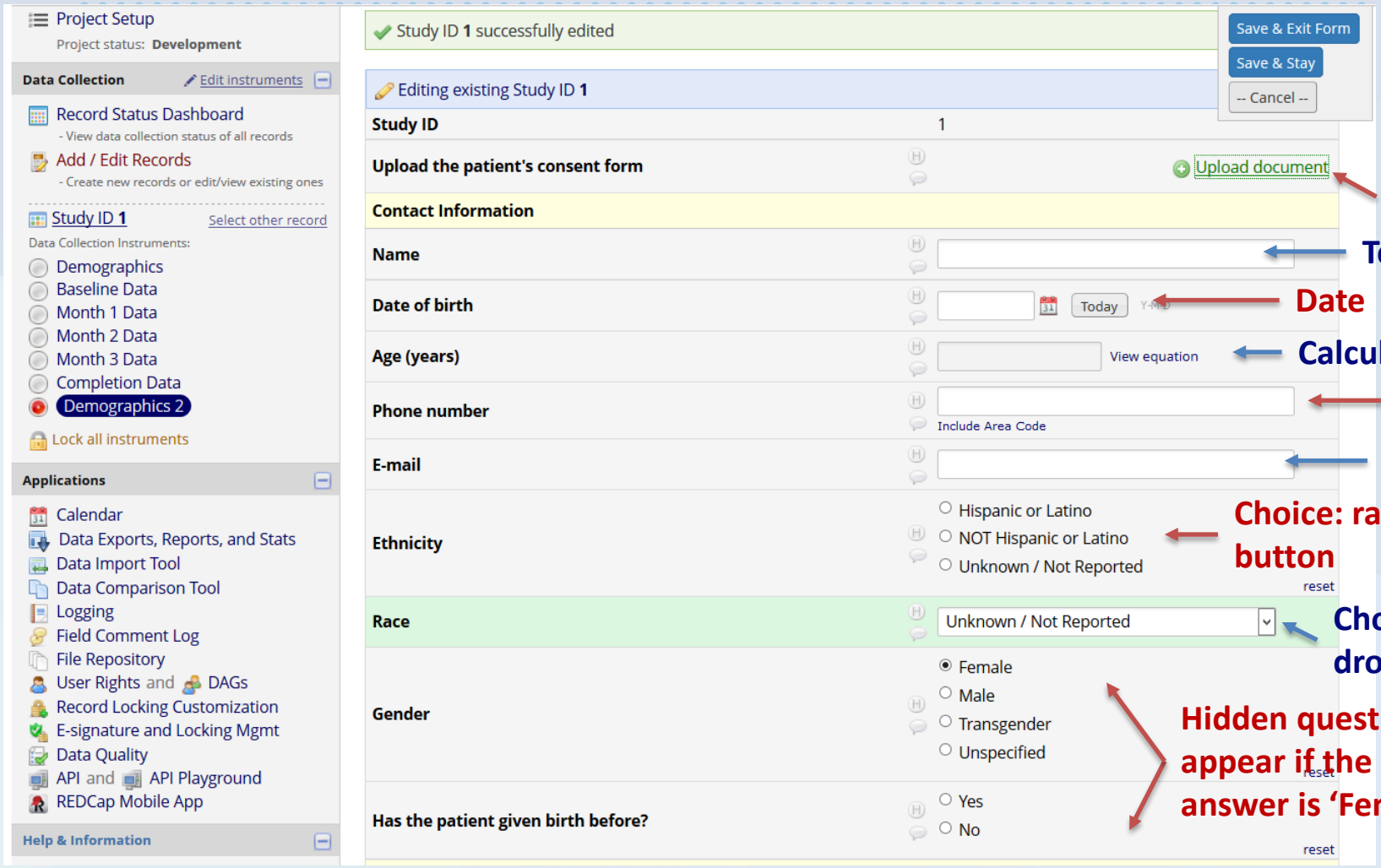
REDCap at Carilion

- HIPAA compliant processes with stringent change control
- CFR Part 11 Compliant Ready
- eConsent process available
- Data Collection Tools
- Surveys via email, text, URL, or QR code
- COMING SOON: EPIC/REDCap integration!

REDCap Project Types

- **Survey**
  - Forms to collect data from respondents
    - Email invite
    - Public survey link
    - Embed survey on website
    - QR code
- **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'

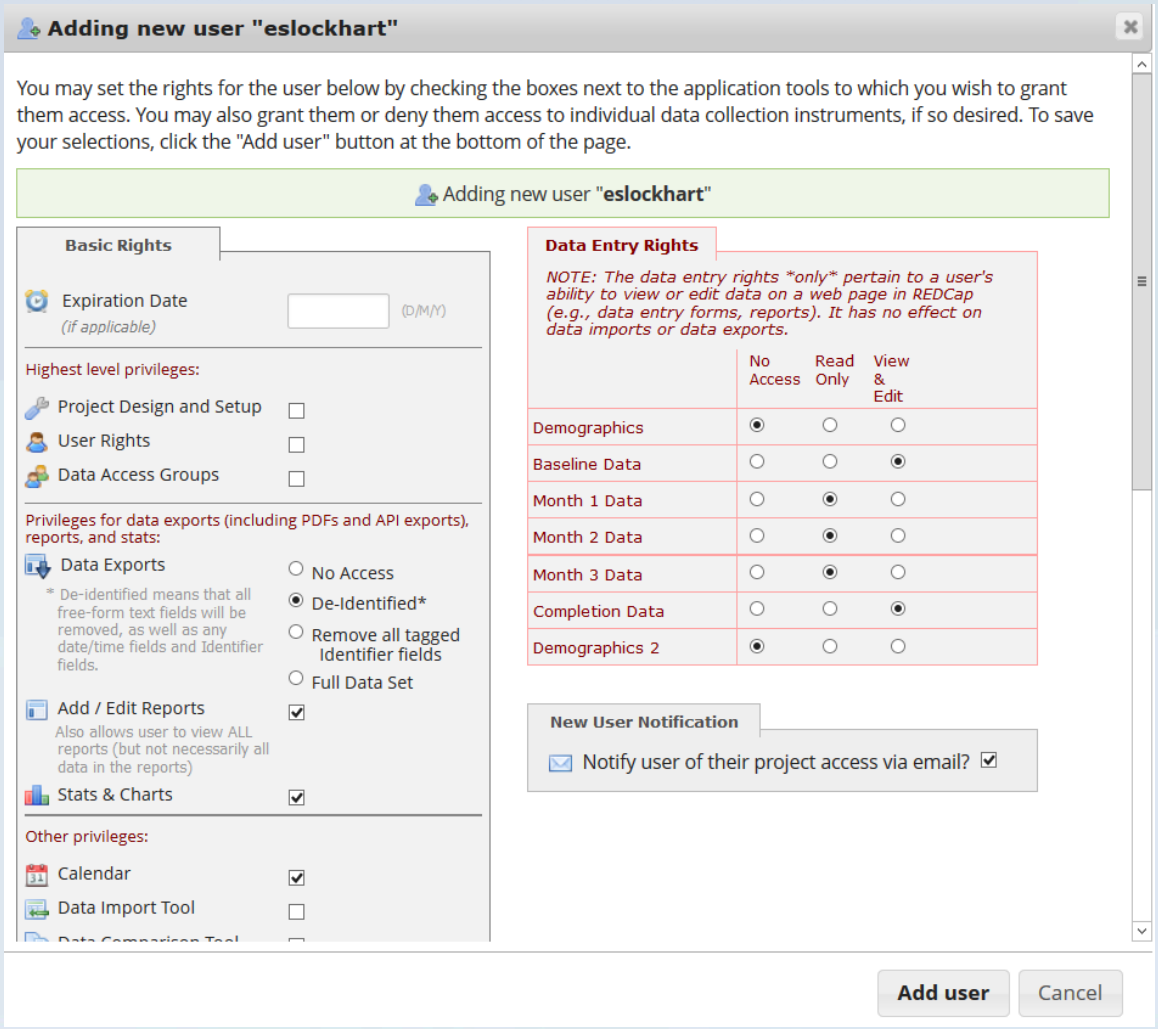
Matrix

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)	☐	☐	☐	☐	☐	

REDCap Data Sharing

Define each individual user's specific access



Data Management Checklist

- Explore your cohort through TriNetX
- Determine data points and 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/SPARC

MyProjectPathwayFull

https://redcap.link/MyProjectPath

Complexity Estimates

How "big" and "complicated" is your data collection tool? Estimate based on number of fields to be collected, variety of fields to be collected, and complexity of data collection. If you don't know how to estimate, contact HART@carilionclinic.org for a consult.

○ Small ◉ Medium ○ Large ○ Extra Large ○ This is a survey only

reset

How "big" and "complicated" is your survey tool? Estimate based on length of survey, frequency of collection, number of participants, complexity of build. If you don't know how to estimate, contact HART@carilionclinic.org for a consult.

○ Small ◉ Medium ○ Large ○ Extra Large ○ This is a data extract only

reset

If you will need statistical support for analysis of your data, once complete, estimate the size of your project. If you don't know how to estimate, contact HART@carilionclinic.org for a consult.

Please note that for most projects, the IRB will require a biostatistician to review and approve your statistical analysis plan to ensure the success of your project as designed. Rarely, if you are planning on simple descriptive statistics, or if performing the statistics yourself is a requirement of your program, you may not need biostatistical support.

○ Small ◉ Medium ○ Large ○ Extra Large ○ I will not utilize biostat services

reset

Estimated Costs

Would you like to document additional costs? (•) Yes ( ) No

reset

Extra cost additional amount (dollars) 500

Extra cost descriptive detail

gift cards for participants

Expand

Estimated Total Cost.
This is a general estimation only. There may be additional costs such as research coordinator/assistant, biorespository costs, IRB submission fees, dedicated researcher time, or other costs.

6000

Breakdown of costs:

REDCap storage (Yes): $ 500
Data extract (Medium): $ 2000
Survey setup (Medium): $ 1000
Biostat support (Medium): $ 1000
Epic Research Build (_____): $ 500
Carilion network storage/Sparc: $ 500

Extra costs: $ 500

Extra Description: gift cards for participants

Research and Development

Does your department require submission to R&D and/or a chair approval for QA/QI projects?

(•) Yes ( ) No ( ) Not sure

reset

You indicated that your project may involve external collaborators. Be sure to include them on your Research and Development application, including what roles they play in the project and what access they will need. This will help facilitate the necessary agreements and access.

Contact research@carilionclinic.org with questions.

To submit to Research and Development, click on the link below.

This will open a new window that you can copy / paste into.

https://is.gd/Research_Application

A summary of your information is provided here for your convenience.

Title: Testing project for OPCD 3/25/2021
Idea: OCPD testing
Problem: This is where I would enter the current understanding of the problem I am trying to address. Everything I type on this page becomes available to copy/paste later into my Research and Development application.

Expand

Project submitted to Research and Development

(•) Yes ( ) No

reset

Research and Development Approval received

(•) Yes ( ) No

reset

<< Previous Page Next Page >>

Save & Return Later

Human Research Protections Office (IRB)

You indicated that your project may involve external collaborators. Be sure to include them on your IRB protocol, including what roles they play in the project and what access they will need.

To submit to the IRB, click here.

https://carilionclinic.imedris.net/

Project submitted to IRB

(•) Yes ( ) No

reset

IRB Approval received

(•) Yes ( ) No

reset

https://redcap.link/MyProjectPath

Analyze and Present

For assistance with statistics, contact HART@carilionclinic.org

For poster and presentation templates, Carilion employees can access them here.
https://insidecarilion.org/hub/marketing-and-communications/resources

Don't forget to consider authorship and acknowledgements to your team and contributors. Click here for guidelines

If you used iTHRIV support (including Carilion Clinic REDCap), include the following citation in your presentations/manuscripts:

This content was supported, in part, by the National Center For Advancing Translational Sciences of the National Institutes of Health under Award Numbers UL1TR003015 and KL2TR003016. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

If you used TriNetX, TriNetX should be mentioned in the methods section.

A suggested adequate general description would read like:

If a TriNetX platform with browser-based real-time analytical features was used:
"....We used TriNetX, a global federated health research network providing access to electronic medical records (diagnoses, procedures, medications, laboratory values, genomic information) from approximately xy Million patients in yz large Healthcare Organizations. The TriNetX platform only uses aggregated counts and statistical summaries of de-identified information. No Protected Health Information (PHI) or Personal Data is made available to the users of the platform..."

If a dataset, downloaded from TriNetX, was used:
"....TriNetX, a global health research network provided a de-identified dataset of electronic medical records (diagnoses, procedures, medications, laboratory values, genomic information) from xy patients with [cohort definition]. The data is de-identified based on standard defined in Section §164.514(a) of the HIPAA Privacy Rule. The process by which Data Sets are 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. Protected Health Information (PHI) or Personal Data is made available to the users of the platform..."

This general description should be followed by a description of the actual methods used including the date of the data download or when the analytics were performed.

If you used REDCap, use the following language in your manuscripts and presentations.

Study data were collected and managed using REDCap electronic data capture tools hosted at Carilion Clinic. REDCap (Research Electronic Data Capture) is a secure, web-based software platform designed to support data capture for research studies, providing 1) an intuitive interface for validated data capture; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for data integration and interoperability with external sources.

https://redcap.link/MyProjectPath

Close survey

Thank you for using our tool. We hope it is helpful to you to navigate these processes.

To get a link sent to you to edit in the future, click on Get link to my survey queue. Enter your email address if it is not there already. Click Send.

Please provide feedback to HART@carilionclinic.org

Download your survey response (PDF): Download

Survey Queue

Get link to my survey queue

Listed below is your survey queue, which lists any other surveys that you have not yet completed.
To begin the next survey, click the 'Begin survey' button next to the title.

Status	Survey Title	
Completed	MyProjectPathwayFull	Edit response

MyProjectPath

Record ID	33
Email	mmtenzer@carilionclinic.org
Project Title	Testing project for OPCD 3/25/2021

Project Type

Is your project Research or QA/QI?

◯ Research ◯ QA/QI ⊗ Not sure

Current Project Time	0

How long (in months) do you anticipate the project to take, from the time of IRB approval to the end of data collection?

This information will be used to estimate the completion time of your project from start to finish.

_____

Idea / Title

OCPD testing

Understanding of Problem

This is where I would enter the current understanding of the problem I am trying to address.
Everything I type on this page becomes available to copy/paste later into my Research and Development application.

Background

This section can be extended as large as I need in order to type in a full background

Time period of data: Prospective or Retrospective?

If Retrospective, what time period (e.g. 2015 - 2017) will the data cover? Please note for retrospective datasets, all data must be in existence (including followup data) at the time of IRB submission

This is a place to organize the type of project and time period.

Background

Have you conducted a literature search?

◯ Yes ⊗ No

Data Management Process

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

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

Contact Information

HART@carilionclinic.org

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

https://redcap.link/MyProjectPath

QUESTIONS?