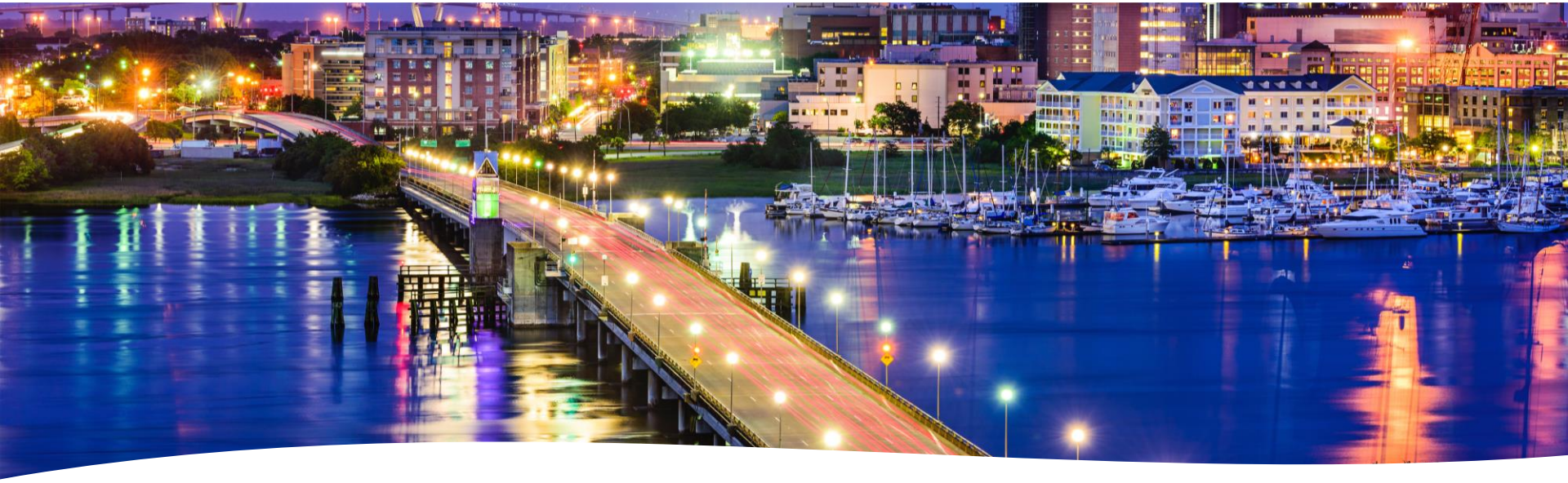

Research Professionals Network

Investigator-Initiated Lead Site Responsibilities: Oversight, Feasibility and Communications

June 29th, 2021

SCTR MUSC Medical University of South Carolina | South Carolina Clinical & Translational Research Institute

Disclosure

The Presenters for today's session are:

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We have no relevant financial relationships in connection with this educational activity.

Investigator-Initiated Lead Site Responsibilities: Oversight, Feasibility and Communications

Objectives

1) Discuss the differences in oversight, responsibilities, and scopes of work for investigator-initiated multisite trials versus single site studies
2) Determine factors to consider while assessing feasibility
3) Provide strategies to enhance communications as the lead site

How would you best describe your role?

- Clinical Research Coordinator/ Nurse
- Data Manager
- Investigator
- Monitor/ Clinical Research Associate (CRA)
- Program Manager
- Regulatory Expert
- Other

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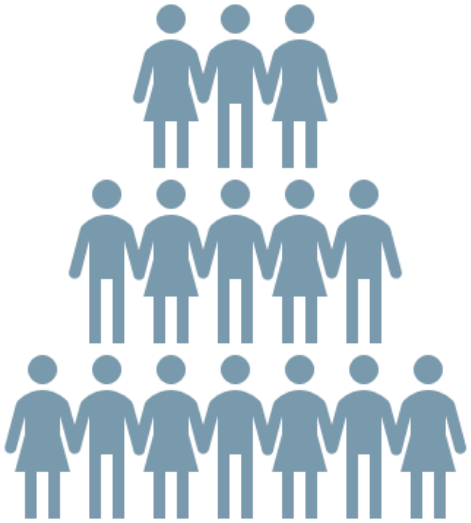
What do you do next?



Planning/Oversight

Feasibility

Communication

Planning/Oversight- Gather Subject Matter Experts

Planning/ Oversight

- Documentation of training and qualifications
- Monitoring
- Adapting procedures for a multisite trial
  - Protocol
  - Data capture
  - AE Reporting
- Difference between a clarification and workflow development vs IRB amendment
- Randomization tools
- IRB
  - Local vs central

IRB Considerations

- Local
  - Do sites have staff sufficiently qualified to navigate IRB submission?
  - Who will review site modifications to ICFs?
  - How will you collect documentation of IRB approval from sites?
- Single
  - Which single IRB should you use?
  - Who will be designated to complete study-wide submissions?
  - Who will assist sites with site submission process?

Monitoring Considerations

- What type of monitoring will be done?
  - On-site, remote, central
- Who will perform monitoring?
  - How will they be trained? What are their qualifications?
- What is the frequency and extent of monitoring?
- How will findings be documented and communicated?

Adapting procedures from single site to multisite

- Is protocol too specific or not specific enough?
  - May encourage or require local SOPs for site specific operational details.
- How will AE reporting be handled?
  - How will sites be trained on reporting requirements?
- How will sites report data?

Activity Time!

Method of subject reimbursement

Site Standard Operating Procedure (SOP)

Protocol

Method of maintaining blind

Site Standard Operating Procedure (SOP)

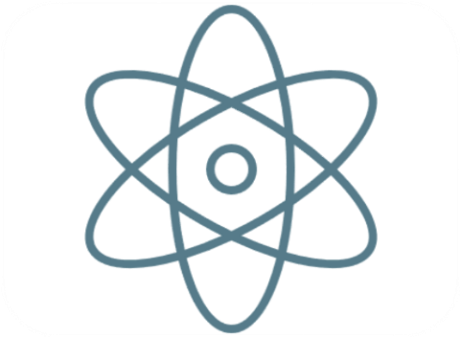
Protocol

Role of staff who can perform clinical scales

Site Standard Operating Procedure (SOP)

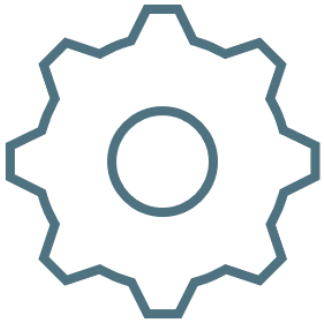
Protocol

Components of a Feasibility



Initial Interest

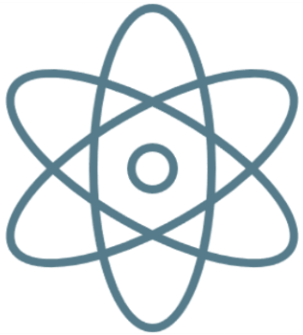
Assess Patient Population



Operational Ability

Financial Viability

Initial Interest



- Established research networks
  - Trial Innovation Network
    - https://ncats.nih.gov/ctsa/projects/network
  - PCORnet
    - https://pcornet.org/front-door/
- Social Media
  - Twitter
  - Facebook
- Collaboration platforms
  - https://covidcp.org/
- Existing relationships
  - CTSI meeting
  - Direct PI to PI contact

Assess Patient Population

- Can interested sites meet the recruitment goals?
- How are sites pulling projected recruitment numbers?
  - Self-Service Feasibility Tools
    - SlicerDicer, TriNetX, i2b2
  - Manual Chart Reviews
  - Previous Enrollment Metrics
  - PI Estimates
- Leverage larger Networks
  - Trial Innovation Network- EHR Based Cohort Assessment
  - PCORnet- The National Patient Centered Clinical Research Network- Submit a front door application

Trial Innovation Network (TIN)- EHR Based Cohort Assessment

EHR-Based Cohort Assessment	This resource helps investigators consider ways to use Electronic Health Record (EHR) data to inform study design and potential site selection. Expect expert clinical and technical review of a study's goal recruitment population and high-level assessment of computable phenotyping. Funded projects may also request support to organize the distribution of phenotype algorithms to potential CTSA sites and collate results.

Case 1:

Include:

ICD Codes (one or more occurrences between 7/1/2017-6/30/2020):

ICD-9	ICD-10	Description
480.0	J12.0	Pneumonia due to adenovirus/ Adenoviral pneumonia
480.1	J12.1	Pneumonia due to respiratory syncytial virus/ Respiratory syncytial virus pneumonia
480.2	J12.2	Pneumonia due to parainfluenza virus/ Parainfluenza virus pneumonia
480.8		Pneumonia due to other virus not elsewhere classified
	J12.3	Human metapneumovirus pneumonia
480.9	J12.9	Viral pneumonia, unspecified
	J12.89	Other viral pneumonia
481	J13	Pneumococcal pneumonia [Streptococcus pneumoniae pneumonia]
	J18.1	Lobar pneumonia, unspecified organism
482.0	J15.0	Pneumonia due to Klebsiella pneumoniae
482.30	J15.4	Pneumonia due to Streptococcus, unspecified
482.41	J15.21	Methicillin susceptible pneumonia due to Staphylococcus aureus
482.42	J15.212	Methicillin resistant pneumonia due to Staphylococcus aureus
482.83	J15.6	Pneumonia due to other gram-negative bacteria
482.89	J15.8	Pneumonia due to other specified bacteria
482.9	J15.9	Bacterial pneumonia, unspecified
483.8	J16.8	Pneumonia due to other specified organism/ Pneumonia due to other specified infectious organisms
484.3		Pneumonia in whooping cough
	A37.01	Whooping cough due to Bordetella pertussis with pneumonia
	A37.11	Whooping cough due to Bordetella parapertussis with pneumonia
	A37.81	Whooping cough due to other Bordetella species with pneumonia
	A37.91	Whooping cough, unspecified species with pneumonia
485	J18.0	Bronchopneumonia, organism unspecified
486	J18.9	Pneumonia, organism unspecified
	J18.8	Other pneumonia, unspecified organism
487.0		Influenza with pneumonia
	J10.00	Influenza due to other identified influenza virus with unspecified type of pneumonia
	J10.01	Influenza due to other identified influenza virus with the same other identified influenza virus pneumonia
	J10.08	Influenza due to other identified influenza virus with other specified pneumonia
	J11.00	Influenza due to unidentified influenza virus with unspecified type of pneumonia
	J11.08	Influenza due to unidentified influenza virus with specified pneumonia

WHERE

(
Age at ICD Code is between 6 months and 18 years

https://trialinnovationnetwork.org/

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PCORnet

Data Network Request

Data Network Requests generally provide preliminary data to help design proposals or assess study feasibility.

- The Front Door team contacts you to schedule a consultation and understand your data needs
- If appropriate, the team will partner to develop your query for the PCORnet Common Data Model, and securely distribute the query to PCORnet data partners. PCORnet data partners will choose whether or not to execute the query and will send back results.
- Once data are returned to the Front Door, the team will meet with you to review your data report and answer any questions

Queries can take from weeks to months depending on the complexity of the request, availability of the requestor to address questions, and number of other queries in the queue. Simple Data Network Requests are generally completed without charge. More complex queries, including those as part of research projects are supported by those research funds.

Network Collaborator Request

The Front Door team can connect you with collaborators within the Network. You can seek sites for funded studies, partners to co-design research leveraging PCORnet, or find people with specific expertise.

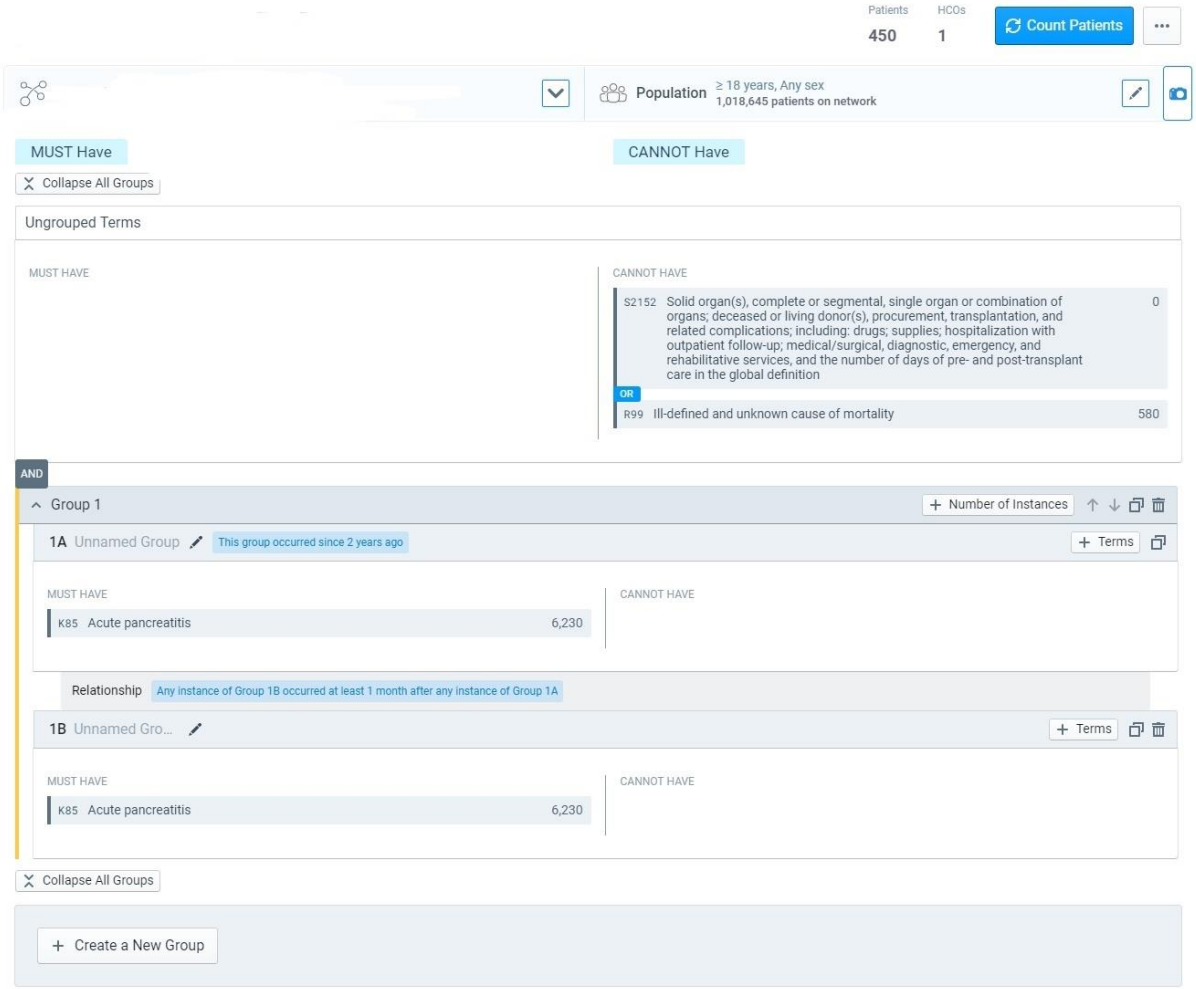
- The Front Door team shares your request by hosting an informational webinar to the Network
- The team sends information to each network; each network then disseminates internally
- The team collects questions and contact information and shares it with you.

The Front Door can advise you on site scope of work and budget parameters, however the requestor will generally execute any study-specific agreements with the sites that participate.

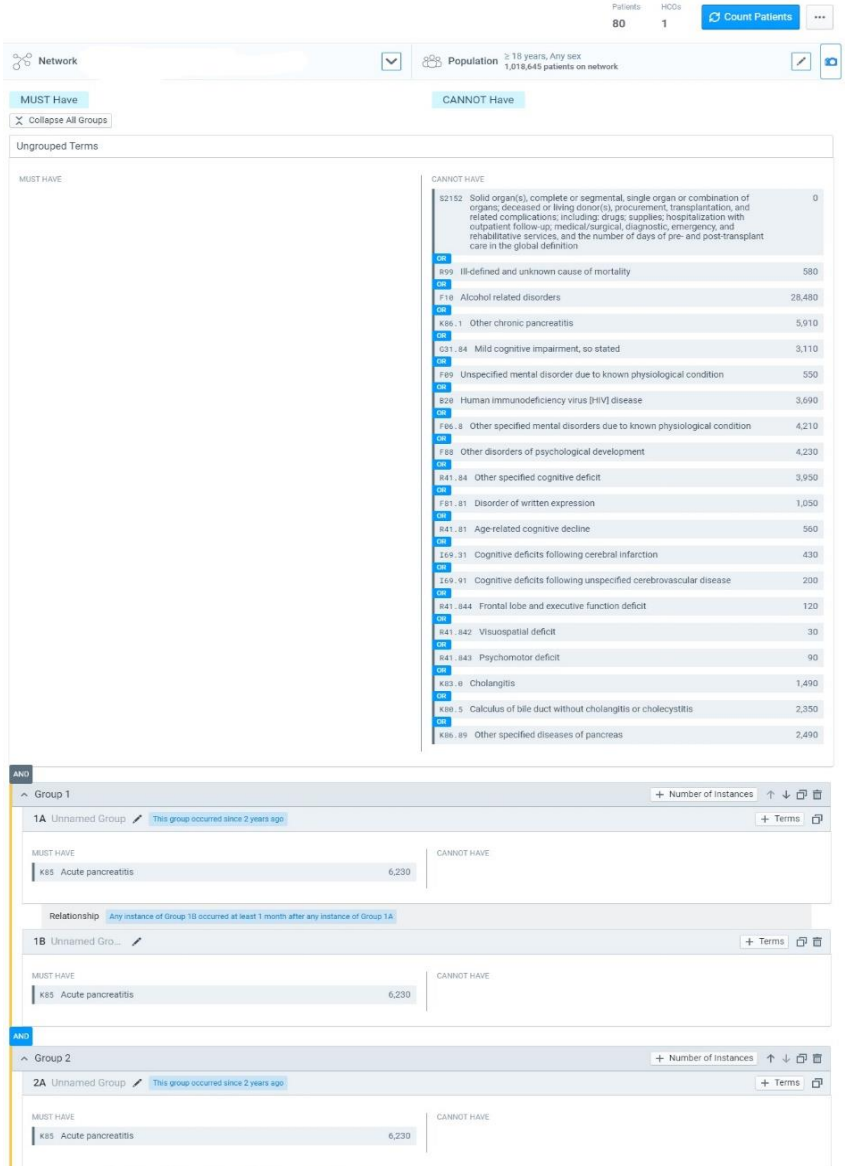
https://pcornet.org/front-door/

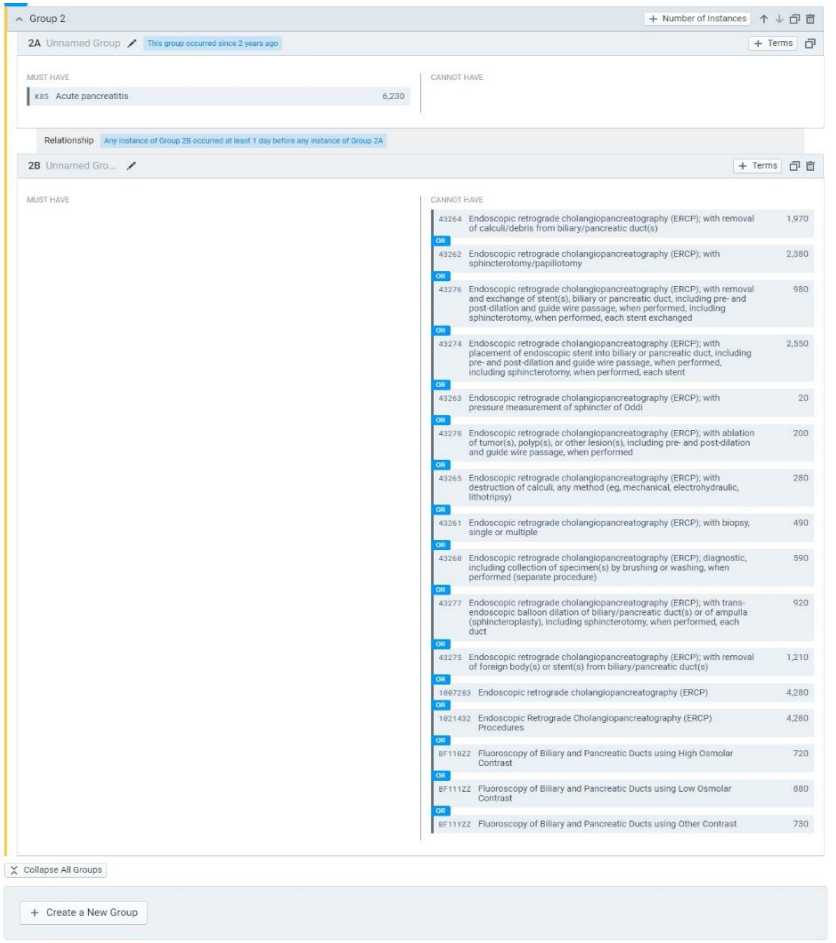
Activity Time!

Which EHR Query is Best for Feasibility - A



Which EHR Query is Best for Feasibility - B





Generated by TriNetX

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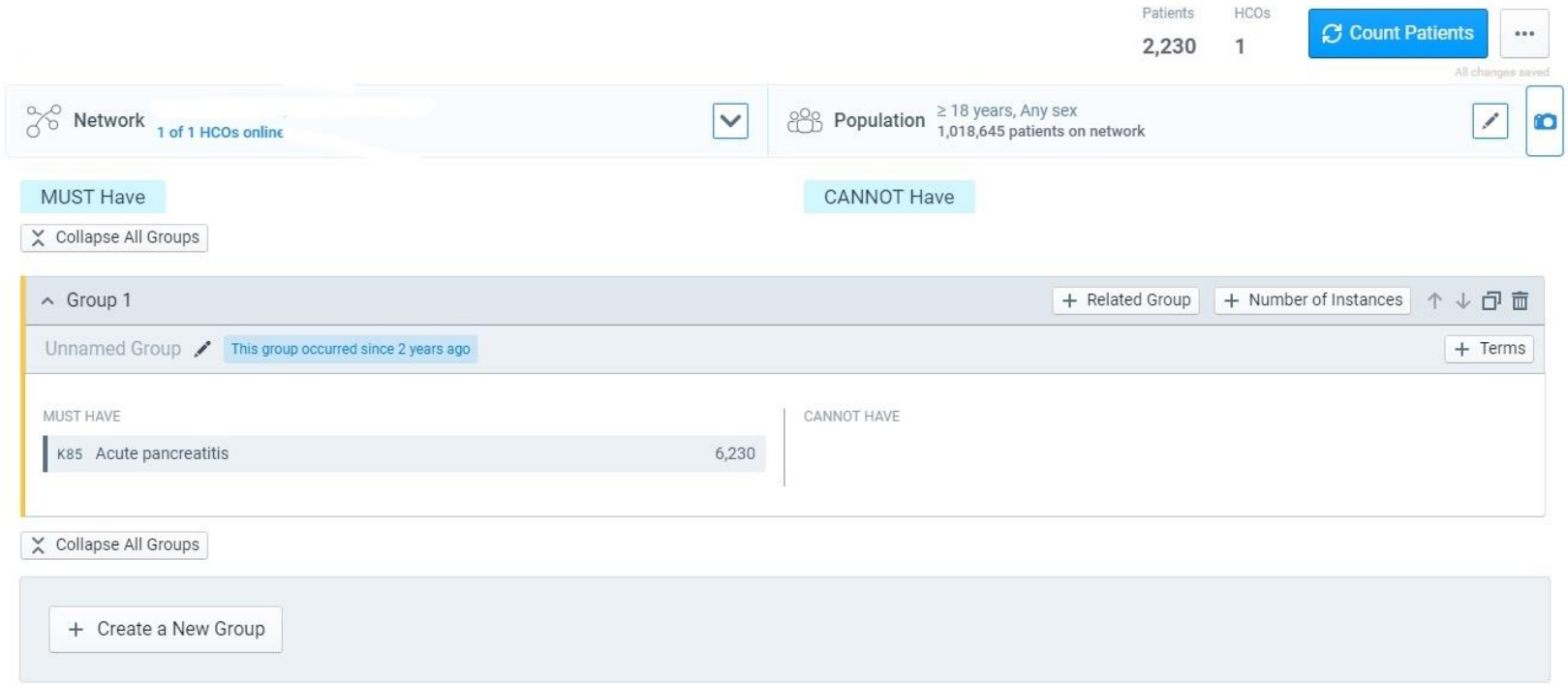
Which EHR Query is Best for Feasibility - C



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EHR Query Summary

A	B	C
Medium complexity query that is specific on the patient population: • Patients who have not had a transplant, had an acute pancreatitis in the past 2 years and then had another acute pancreatitis at least 1 month later • **450 patients**	Complex query that details much of the inclusion/ exclusion: • patients who have not had a transplant, no alcohol abuse disorder, no history of HIV, no history of cognitive impairment, no inflammation of the bile duck, no other pancreas diseases. • AND has had a had an acute pancreatitis in the past 2 years and then had another acute pancreatitis at least 1 month later. • AND since the acute pancreatitis has not had an endoscopic retrograde. • **80 patients**	Simple query • patients over 18 and have had an acute pancreatitis • **2230 patients**

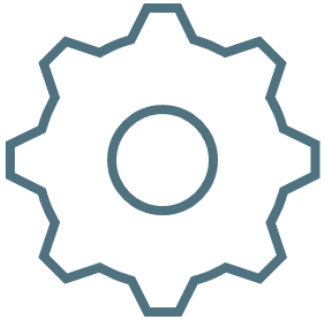
Which EHR Query is Best for Feasibility?

A

B

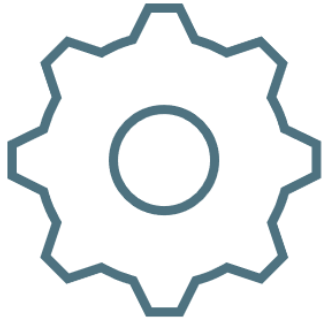
C

Operational Ability



- Research team availability/capacity
- Space to conduct study
- Who/how will consent patients?
- Start up timelines?
- Experience with study specific assessments
- Monitoring space
  - Onsite location or will the study be monitored remotely?
- Is this a blinded study? If so, can sites keep the blind?

Operational Ability



- Drug Management
  - Where will it be stored?
  - Does that storage location meet requirements for classification of drug?
  - Will you be shipping drug?
  - SOP in place?
- Processing Lab Specimens
  - Trained staff?
  - Freeze or Refrigerator ?
  - Dry ice accessibility?
  - Centrifuge machines and are they calibrated?
  - Skills needed to process samples?
  - Processing complexity?

Components of Protocol Feasibility

- Financial Viability
  - At this stage think high-level
  - Is this budget negotiable?
  - Is the site able to participate with the given budget?

Discussion

Preferred Method of Communication?

Communications

- Leadership
- Set expectations early on in conversations
  - Request deadlines
  - Discuss authorship
  - Ensure transparency
- Newsletters
- Standing Meetings
  - Who is most appropriate to include in meetings
- Consistency

Communications

- Ensure sites know who to contact for questions
  - Central Contact vs Subject Matter Experts
  - Clinical vs Non-Clinical
- Account for different time zones
- Who will answer questions on the weekend, afterhours, holidays?
- Expectations on timely responses

Resources for example SOPs and Policy/procedures

- BUMC/BMC:
  - http://www.bumc.bu.edu/crro/
  - http://www.bumc.bu.edu/ohra/hrpp-policies/hrpp-policies-procedures/#2.5.3.2
  - http://www.bumc.bu.edu/ohra/hrpp-policies/hrpp-policies-procedures/#2.5.4
- UF:
  - https://www.ctsi.ufl.edu/research/research-support/multisite-studies/
  - https://irb.ufl.edu/sirb-2.html
- UVM:
  - https://www.uvm.edu/rpo/irb-policies-and-procedures
- MUSC:
  - https://research.musc.edu/resources/ori/irb/policies

It Takes a Village! Reach Out for Help!

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Questions?


clinical
monitors
sites
conducts
protocol
supervises
evaluates
coordinates
safety
certified
standard
ensures
sponsors
requirements
human
study
procedures
subject
communicates
practice
integrity
trains
regulatory
management
data
research
best-practices
implements
approved
operating
good
compliance
liaison
enrollment
subjects
agencies
adverse
visits
financial
metrics
designs
manages
develops
policies
staff
events
reviews

Speaker Contact Information

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