

# Research Professionals Network

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

June 29<sup>th</sup>, 2021

# Disclosure

The Presenters for today's session are:

**Amanda Fortelney, MPH, CPH, CCRP**

**Erin Klintworth, BA, CCRA**

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

When poll is active, respond at **pollev.com/amandacamero594**

Text **AMANDACAMERO594** to **37607** once to join

# How would you best describe your role?

Clinical Research Coordinator/ Nurse

Data Manager

Investigator

Monitor/ Clinical Research Associate (CRA)

Program Manager

Regulatory Expert

Other

Powered by  **Poll Everywhere**

Start the presentation to see live content. For screen share software, share the entire screen. Get help at [pollev.com/app](https://pollev.com/app)





## What do you do next?

Powered by  **Poll Everywhere**

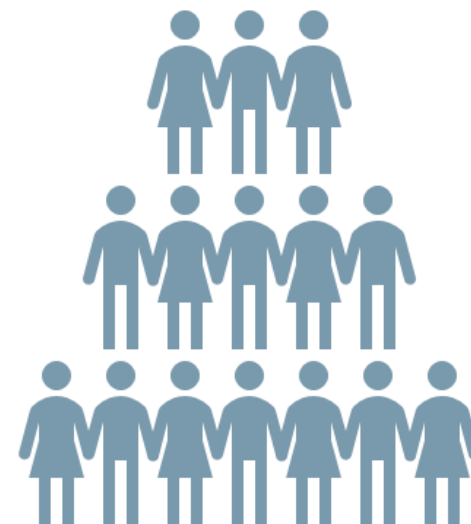
Start the presentation to see live content. For screen share software, share the entire screen. Get help at [pollev.com/app](https://pollev.com/app)



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

Powered by  **Poll Everywhere**

Start the presentation to see live content. For screen share software, share the entire screen. Get help at [pollev.com/app](https://pollev.com/app)

# Method of maintaining blind

---

Site Standard  
Operating  
Procedure (SOP)

Protocol

Powered by  **Poll Everywhere**

Start the presentation to see live content. For screen share software, share the entire screen. Get help at [pollev.com/app](https://pollev.com/app)



# Role of staff who can perform clinical scales

---

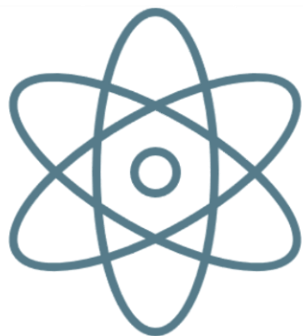
Site Standard  
Operating  
Procedure (SOP)

Protocol

Powered by  **Poll Everywhere**

Start the presentation to see live content. For screen share software, share the entire screen. Get help at [pollev.com/app](https://pollev.com/app)

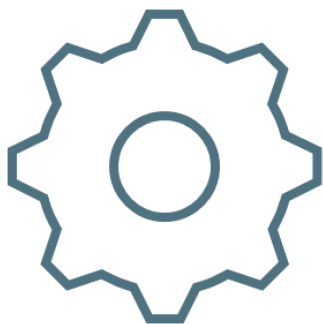
# Components of a Feasibility



Initial Interest



Assess Patient  
Population

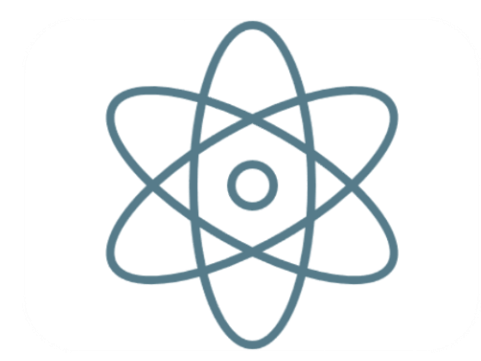


Operational Ability



Financial Viability

# Initial Interest



- Established research networks
  - Trial Innovation Network
    - <https://ncats.nih.gov/ctsa/projects/network>
  - PCORnet
    - <https://pcornt.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

<https://trialinnovationnetwork.org/>

WHERE

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

## 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.

# Activity Time!






# Which EHR Query is Best for Feasibility - A


Patients  
450


HCOs  
1


Count Patients


...





 Population ≥ 18 years, Any sex  
1,018,645 patients on network





MUST Have

CANNOT Have

✕ Collapse All Groups

Ungrouped Terms

MUST HAVE

CANNOT HAVE

S2152 Solid organ(s), complete or segmental, single organ or combination of organs; deceased or living donor(s), procurement, transplantation, and related complications; including: drugs; supplies; hospitalization with outpatient follow-up; medical/surgical, diagnostic, emergency, and rehabilitative services; and the number of days of pre- and post-transplant care in the global definition

0

OR

R99 Ill-defined and unknown cause of mortality


580

AND


^ Group 1

+ Number of Instances

↑ ↓




1A Unnamed Group



This group occurred since 2 years ago

+ Terms



MUST HAVE

CANNOT HAVE


k85 Acute pancreatitis

6,230


Relationship

Any instance of Group 1B occurred at least 1 month after any instance of Group 1A

1B Unnamed Gro...



+ Terms



MUST HAVE

CANNOT HAVE

k85 Acute pancreatitis

6,230

✕ Collapse All Groups

+ Create a New Group

# Which EHR Query is Best for Feasibility - B

Patients: 80 HCOs: 1 [Count Patients](#) ...

Network ☐ Population ☒ ≥ 18 years, Any sex 1,018,645 patients on network

**MUST Have** **CANNOT Have**

☒ Collapse All Groups

Ungrouped Terms

**MUST HAVE**

**CANNOT HAVE**

S2152 Solid organ(s), complete or segmental, single organ or combination of organs; deceased or living donor(s), procurement, transplantation, and related complications; including: drugs, supplies, hospitalization with outpatient follow-up, medical/surgical, diagnostic, emergency, and rehabilitative services, and the number of days of pre- and post-transplant care in the global definition	0
<input checked="" type="checkbox"/> S099 Ill-defined and unknown cause of mortality	580
<input checked="" type="checkbox"/> F10 Alcohol related disorders	28,480
<input checked="" type="checkbox"/> K86.1 Other chronic pancreatitis	5,910
<input checked="" type="checkbox"/> G31.84 Mild cognitive impairment, so stated	3,110
<input checked="" type="checkbox"/> F69 Unspecified mental disorder due to known physiological condition	550
<input checked="" type="checkbox"/> B20 Human immunodeficiency virus [HIV] disease	3,690
<input checked="" type="checkbox"/> F69.8 Other specified mental disorders due to known physiological condition	4,210
<input checked="" type="checkbox"/> F10 Disorders of psychological development	4,230
<input checked="" type="checkbox"/> R41.84 Other specified cognitive deficit	3,950
<input checked="" type="checkbox"/> F81.81 Disorder of written expression	1,050
<input checked="" type="checkbox"/> R41.81 Age-related cognitive decline	560
<input checked="" type="checkbox"/> I69.31 Cognitive deficits following cerebral infarction	430
<input checked="" type="checkbox"/> I69.91 Cognitive deficits following unspecified cerebrovascular disease	200
<input checked="" type="checkbox"/> R41.844 Frontal lobe and executive function deficit	120
<input checked="" type="checkbox"/> R41.842 Visuospatial deficit	30
<input checked="" type="checkbox"/> R41.843 Psychomotor deficit	90
<input checked="" type="checkbox"/> K83.0 Cholangitis	1,490
<input checked="" type="checkbox"/> K86.5 Calculus of bile duct without cholangitis or cholecystitis	2,350
<input checked="" type="checkbox"/> K86.89 Other specified diseases of pancreas	2,490

**AND**

**Group 1** [+ Number of Instances](#) [↑ ↓](#) [Copy](#)

**1A Unnamed Group** [+ Terms](#) [Copy](#)

**MUST HAVE** **CANNOT HAVE**

☒ K85 Acute pancreatitis 6,230

**Relationship** [Any instance of Group 1B occurred at least 1 month after any instance of Group 1A](#)

**1B Unnamed Gro...** [+ Terms](#) [Copy](#)

**MUST HAVE** **CANNOT HAVE**

☒ K85 Acute pancreatitis 6,230

**AND**

**Group 2** [+ Number of Instances](#) [↑ ↓](#) [Copy](#)

**2A Unnamed Group** [+ Terms](#) [Copy](#)

**MUST HAVE** **CANNOT HAVE**

☒ K85 Acute pancreatitis 6,230

**Group 2** [+ Number of Instances](#) [↑ ↓](#) [Copy](#)

**2A Unnamed Group** [+ Terms](#) [Copy](#)

**MUST HAVE** **CANNOT HAVE**

☒ K85 Acute pancreatitis 6,230

**Relationship** [Any instance of Group 2B occurred at least 1 day before any instance of Group 2A](#)

**2B Unnamed Gro...** [+ Terms](#) [Copy](#)

**MUST HAVE** **CANNOT HAVE**

<input checked="" type="checkbox"/> 43264 Endoscopic retrograde cholangiopancreatography (ERCP), with removal of calculi/debris from biliary/pancreatic duct(s)	1,970
<input checked="" type="checkbox"/> 43262 Endoscopic retrograde cholangiopancreatography (ERCP), with sphincterotomy/papillotomy	2,380
<input checked="" type="checkbox"/> 43276 Endoscopic retrograde cholangiopancreatography (ERCP), with removal and exchange of stent(s), biliary or pancreatic duct, including pre- and post-dilation and guide wire passage, when performed, including sphincterotomy, when performed, each stent exchanged	980
<input checked="" type="checkbox"/> 43274 Endoscopic retrograde cholangiopancreatography (ERCP), with placement of endoscopic stent into biliary or pancreatic duct, including pre- and post-dilation and guide wire passage, when performed, including sphincterotomy, when performed, each stent	2,550
<input checked="" type="checkbox"/> 43263 Endoscopic retrograde cholangiopancreatography (ERCP), with pressure measurement of sphincter of Oddi	20
<input checked="" type="checkbox"/> 43278 Endoscopic retrograde cholangiopancreatography (ERCP), with ablation of tumor(s), polyp(s), or other lesion(s), including pre- and post-dilation and guide wire passage, when performed	200
<input checked="" type="checkbox"/> 43265 Endoscopic retrograde cholangiopancreatography (ERCP), with destruction of calculi, any method (eg, mechanical, electrohydraulic, lithotripsy)	280
<input checked="" type="checkbox"/> 43261 Endoscopic retrograde cholangiopancreatography (ERCP), with biopsy, single or multiple	490
<input checked="" type="checkbox"/> 43268 Endoscopic retrograde cholangiopancreatography (ERCP), diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)	590
<input checked="" type="checkbox"/> 43277 Endoscopic retrograde cholangiopancreatography (ERCP), with trans-endoscopic balloon dilation of biliary/pancreatic duct(s) or of ampulla (sphincteroplasty), including sphincterotomy, when performed, each duct	920
<input checked="" type="checkbox"/> 43275 Endoscopic retrograde cholangiopancreatography (ERCP), with removal of foreign body(s) or stent(s) from biliary/pancreatic duct(s)	1,210
<input checked="" type="checkbox"/> 1007283 Endoscopic retrograde cholangiopancreatography (ERCP)	4,280
<input checked="" type="checkbox"/> 1021432 Endoscopic Retrograde Cholangiopancreatography (ERCP) Procedures	4,280
<input checked="" type="checkbox"/> BF11022 Fluoroscopy of Biliary and Pancreatic Ducts using High Osmolar Contrast	720
<input checked="" type="checkbox"/> BF11122 Fluoroscopy of Biliary and Pancreatic Ducts using Low Osmolar Contrast	880
<input checked="" type="checkbox"/> BF11122 Fluoroscopy of Biliary and Pancreatic Ducts using Other Contrast	730

☒ Collapse All Groups

[+ Create a New Group](#)

Generated by TriNetX

# Which EHR Query is Best for Feasibility - C


Patients  
2,230


HCOs  
1


Count Patients


...

All changes saved

 Network 1 of 1 HCOs online


 Population ≥ 18 years, Any sex  
1,018,645 patients on network





MUST Have

CANNOT Have


 Collapse All Groups

^ Group 1

+ Related Group

+ Number of Instances

↑ ↓ □ ✕

Unnamed Group 

This group occurred since 2 years ago


+ Terms

MUST HAVE

CANNOT HAVE

K85 Acute pancreatitis

6,230

 Collapse All Groups

+ Create a New Group

Generated by TriNetX

# EHR Query Summary

A	B	C
<p>Medium complexity query that is specific on the patient population:</p> <ul style="list-style-type: none"><li>• 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</li><li>• <b>450 patients</b></li></ul>	<p>Complex query that details much of the inclusion/exclusion:</p> <ul style="list-style-type: none"><li>• 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 duct, no other pancreas diseases.</li><li>• AND has had a had an acute pancreatitis in the past 2 years and then had another acute pancreatitis at least 1 month later.</li><li>• AND since the acute pancreatitis has not had an endoscopic retrograde.</li><li>• <b>80 patients</b></li></ul>	<p>Simple query</p> <ul style="list-style-type: none"><li>• patients over 18 and have had an acute pancreatitis</li><li>• <b>2230 patients</b></li></ul>

Respond at [pollev.com/amandacamero594](https://pollev.com/amandacamero594)

Text **AMANDACAMERO594** to **37607** once to join, then **A, B, or C**

# Which EHR Query is Best for Feasibility?



**A**



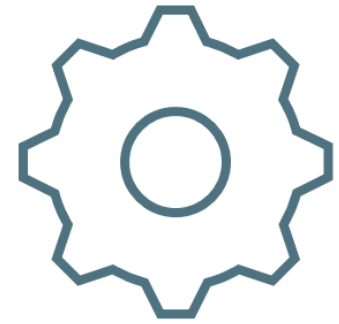
**B**



**C**

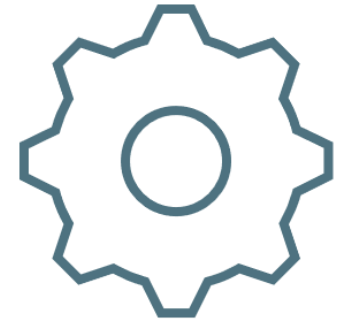
Powered by  **Poll Everywhere**

Start the presentation to see live content. For screen share software, share the entire screen. Get help at [pollev.com/app](https://pollev.com/app)



## 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?

Powered by  **Poll Everywhere**

Start the presentation to see live content. For screen share software, share the entire screen. Get help at [pollev.com/app](https://pollev.com/app)

# 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/crrro/>
- <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!







# Speaker Contact Information

**Amanda Fortelney, MPH, CPH, CCRP**  
Trial Innovation Network Program Manager  
[cameroa@musc.edu](mailto:cameroa@musc.edu)

**Erin Klintworth, BA, CCRA**  
RCM Quality Assurance Program Manager  
[klintwor@musc.edu](mailto:klintwor@musc.edu)