PCORnet ADAPTABLE
Data Strategy Discussion

Friday, January 29, 2016
Hosted by Lesley Curtis, PhD and Schuyler Jones, MD
Facilitated by Shelley Rusincovitch and Lisa Eskenazi

Adaptable
The Aspirin Study
Welcome & Overview
Where to find materials from prior meetings

❖ Phenotype working session on September 4, 2015
  ▪ Slides, recording, and summary:
    https://pcornet.centraldesktop.com/p/ZgAAAAAAAZgS3

❖ Data strategy session on September 25, 2015
  ▪ Slides, recording, and summary:
    https://pcornet.centraldesktop.com/p/ZgAAAAAAAZn7T

❖ Data strategy session on October 30, 2015
  ▪ Slides, recording, and summary:
    https://pcornet.imeetcentral.com/p/ZgAAAAAAAaMVO

❖ Data strategy session on December 11, 2015
  ▪ Slides, recording, and summary:
    https://pcornet.imeetcentral.com/p/ZgAAAAAAAa76Y
Average of 38 attendees per session

Four sessions between September - December 2015
The study website is now live!

- Public-facing
- Dual branded with PCORnet
- Mirrors PCORnet’s visual style in order to provide a seamless experience for visitors
- Relevant content, rich media, and milestones will be shared as the study progresses

theaspirinstudy.org

ADAPTABLE, the Aspirin Study – A Patient-Centered Trial

ADAPTABLE (Aspirin Dosing: A Patient-centric Trial Assessing Benefits and Long-Term Effectiveness) will compare the effectiveness of two daily doses of aspirin, widely used to prevent heart attacks and strokes in individuals living with heart disease. What we learn from the ADAPTABLE study will improve care and outcomes for patients with heart disease and could prevent as many as 88,800 deaths per year around the world.

Adaptable is considered a pragmatic trial. Pragmatic trials are designed to reflect “real-world” medical practice, with the actual work of the study taking place in a variety of clinical settings.
CMS Linkage Pilot presentation on February 1

Why it may be of interest to this group:

• Update on the PCORnet CMS Linkage Pilot Project, including discussion of transformation of Medicare datasets into the CDM v3.0

PCORnet: DRN Operations Center Meeting (CDRNs)
February 1, 2016 from 11 am – 12 pm ET

Online Component: https://dukemed.webex.com/dukemed/j.php?MTID=m673a55da642446e051031e5ec3813340

Call-in toll-free number (US/Canada): 1-855-244-8681
Call-in toll number (US/Canada): 1-650-479-3207
Access code: 735 866 908
Design and Architecture of a Distributed Network Pragmatic Clinical Trial: The PCORnet ADAPTABLE Study

Lesley H. Curtis, PhD¹, Shelley Rusincovitch¹, Jenny Ibarra¹, Bradley G. Hammill, DrPH¹, Laura G. Qualls¹, Debra F. Harris¹, W. Schuyler Jones, MD¹, Russell L. Rothman, MD², Matthew Roe, MD¹, Adrian F. Hernandez, MD¹

¹Duke University, Durham, North Carolina, ²Vanderbilt University, Nashville, Tennessee

Abstract

The ADAPTABLE (Aspirin Dosing: A Patient-Centric Trial Assessing Benefits and Long-term Effectiveness) study will be the first randomized clinical trial to be executed within PCORnet, the National Patient-Centered Clinical Research Network. Design of the ADAPTABLE data architecture incorporates features of the Distributed Research Network, including innovative use of the PCORnet Common Data Model. The ADAPTABLE study database will amalgamate multiple data sources into an integrated data ecosystem.

Podium for March 24, 2016
Track: CRI: Clinical And Research Data Collection; Curation; Preservation; Or Sharing
Where to find the ADAPTABLE protocol and informed consent

Publically posted on [http://theaspirinstudy.org/](http://theaspirinstudy.org/)

Setting the stage for today’s meeting

Our scope for today:

- Discuss the current status of development for the ADAPTABLE data components
- Outline considerations and areas needing further assessment
We’ll be talking today about the *current* state of development.

These details may change during the iterative design, development, and implementation of the project.

Today is the last strategy-focused session!

These sessions will continue with a focus transition from strategy to implementation.
Items from December 11 session

Question about network-acquired claims data
  - For ADAPTABLE, claims-based datamarts are entirely appropriate to include

Generalizability for data completeness
  - Important area of assessment, especially in analysis stage

Plus, question during Dan Vreeman LOINC Best Practices session this past Wednesday (January 27)
  - The CDM v3.0 common lab result categories will be used for ADAPTABLE analysis
Eligibility Phenotype Development
Patients meeting eligibility

Patients who are invited

Patients who visit portal

Patients who choose to participate

Patients Enrolled in ADAPTABLE

Managed at site and/or network level

This is where the phenotype is situated

The patient answers a few basic questions to check for those unsafe to participate, but full eligibility criteria was determined at the site level
ADAPTABLE eligibility criteria

ADAPTABLE Protocol Final Version 1.0, October 22, 2015, section III.A.1., pages 16-17 (PDF pages 20-21).

1. Known atherosclerotic cardiovascular disease (ASCVD), defined by a history of prior myocardial infarction, prior coronary angiography showing ≥75% stenosis of at least one epicardial coronary vessel, or prior coronary revascularization procedures (either PCI or CABG)
2. Age ≥ 18 years
3. No known safety concerns or side effects considered to be related to aspirin, including
   a. No history of significant allergy to aspirin such as anaphylaxis, urticaria, or significant gastrointestinal intolerances
   b. No history of significant GI bleed within the past 12 months
   c. Significant bleeding disorders that preclude the use of aspirin
4. Access to the Internet. In the event that the CDRNs are notified that a cohort of patients without internet access can be included, then patient agreement will be obtained during the consent process to provide follow-up information by telephone contact with the DCRI Call Center.
5. Not currently treated with an oral anticoagulant – either warfarin or a novel anticoagulant (dabigatran, rivaroxaban, apixaban, edoxaban) – and not planned to be treated in the future with an oral anticoagulant for existing indications such as atrial fibrillation, deep venous thrombosis, or pulmonary embolism.
6. Not currently treated with ticagrelor and not planned to be treated in the future with ticagrelor.
7. Female patients who are not pregnant or nursing an infant
8. Estimated risk of a major cardiovascular event (MACE) > 8% over next 3 years as defined by the presence of at least one or more of the following enrichment factors:
   a. Age > 65 years
   b. Serum creatinine > 1.5 mg/dL
   c. Diabetes mellitus (Type 1 or Type 2)
   d. 3-vessel coronary artery disease
   e. Cerebrovascular disease and/or peripheral arterial disease
   f. Left ventricular ejection fraction (LVEF) < 50%
   g. Current cigarette smoker
Base phenotype customization is expected

**III.A.3.b. Cohort Identification**

Local site investigators within the CDRNs will be asked to endorse the protocol. They will then be asked to give their permission for the CDRN, through its integrated health system members, to identify and contact potentially eligible patients. In the latter case, patients who meet criteria for secondary prevention after a cardiovascular event will be identified using search algorithms developed by the DCRI Coordinating Center (based on the trial inclusion criteria) and customized by the CDRN for their own EHR systems. Broad agreement from both cardiovascular specialists and primary care physicians will be sought. In this trial, we believe that most systems will agree that prior approval of the relevant clinician will be needed and useful since these patients will be at high-risk for death or a major disabling event. Although it is unlikely that a medical reason for ineligibility will be found, most of these patients are close to their clinicians, whose confidence in and support of the trial will be important for patient engagement, both in terms of participation as well as promoting adherence to the study medication and treatment of the inevitable clinical events.
Where to find the ADAPTABLE base phenotype code on GitHub

https://github.com/ADAPTABLETRIAL
Increasing traffic and activity on GitHub
(2-week view)

“forking” is an important activity in GitHub
The coordinating center has completed development of the base phenotype

- Released in December 2015
- With appreciation to Brad Hammill!

https://github.com/ADAPTABLETRIAL/PHENOTYPE

The next set of discussion questions are intended to help facilitate CDRNs sharing experiences
Discussion Questions (1 of 3)

How are your plans shaping up for programming and implementation of your site’s customized eligibility phenotype?

- Are you planning to use NLP in your phenotype implementation?
- Are you planning to run your site’s phenotype in SAS, SQL, or something else?
Discussion Questions (2 of 3)

What are your plans for workflow of the invites?
- Do you plan to automate the invitations?
- What are your plans for activity now (prior to IRB approval)?
Discussion Questions (3 of 3)

Are you interested in collaborations with other CDRNs?

- One CDRN is interested in creating SQL code from the base phenotype posted on GitHub, and opportunities for sharing code – does this interest your network?

- Do you have other areas of development where you’d like to ask to connect with others?
Logistics of collaboration: a few potential options

- Collaborative space on iMeetCentral (within PCORnet-authenticated space)
- GitHub
  - Both public-facing repositories and private repositories
- Institution-hosted solutions, such as protected Box.com sharing
- Many other options exist!
Collaborative space on iMeetCentral:
https://pcornet.imeetcentral.com/p/ZgAAAAAAAAYfoecwAAAAAAAABihp
Patient Portal Development
Our next topic takes place here

**Figure 1.** The ADAPTABLE study database will amalgamate multiple data sources in an integrated ecosystem.
Walk-through of portal development
Discussion and questions
Next steps

⚠️ Materials from this meeting to be shared
  - We post updates on the DRNOC blog: https://pcornet.centraldesktop.com/drnoc-workgroups/blog/

⚠️ Contracting, site operations, and startup
  - Biweekly CDRN Calls, Mondays at 2 PM
Supplemental Slides: Reference
Abbreviations


DCRI = Duke Clinical Research Institute, the ADAPTABLE Coordinating Center

DRN = Distributed Research Network

DSMB = Data and Safety Monitoring Board

DSSNI = Data Standards, Security, and Network Infrastructure

LTFU = Lost to Follow-up

RDBMS = Relational Database Management System (for example, Oracle, SQL Server, PostgreSQL, MySQL)
The ADAPTABLE trial is based upon the foundation of the PCORnet DRN data infrastructure. PCORnet trials and studies form a continuous cycle of improvement in data infrastructure development.
SCREENING
Site-specific screening processes and data
Includes crosswalk between PATID and PARTICIPANTID

CDRN’s PCORnet Datamart
Common Data Model (CDM), including PCORNET_TRIAL table

Enrolled participants are populated

PARTICIPANT PORTAL
Web-based electronic data capture; also used by call center

Portal data transfers, including all study variables

PCORNet query to identify and send study data (via PopMedNet)

Portal sends patient-level status reports to site

STATUS REPORTING
All participants
Blinded

ADAPTABLE STUDY DATABASE:
All participants with status of enrolled
Unblinded

Coordinating Center

Potential External Data Sources
National Death Index (NDI)
Medicare
Private Insurer Claims

Figure 2. Data flows for the ADAPTABLE trial. Data stores are indicated in red, and data exchange processes are indicated in gray.
PCORnet Common Data Model v3.0

The PCORnet CDM lives at
http://pcornet.org/pcornet-common-data-model/

Bold font indicates fields that cannot be null due to primary key definitions or record-level constraints.

Data captured from healthcare delivery, direct encounter basis

Data captured from processes associated with healthcare delivery, registry activity, or directly from patients
The PCORNET_TRIAL table serves as a connector and filter for CDM data within the parameters of a given trial protocol:

- **PATID**: Which patient?
- **TRIALID**: Which trial?
- **PARTICIPANTID**: Which person?
- **TRIAL_SITEID**: Which site? (may be trial-specific)
- **TRIAL_ENROLL_DATE**
- **TRIAL_END_DATE**
- **TRIAL_WITHDRAW_DATE**
- **TRIAL_INVITE_CODE**: If used by trial

Any given PCORnet datamart may contain data from a large number of patients. The PCORNET_TRIAL table assists the ADAPTABLE Data Core in knowing which of these patients have consented and been enrolled in the ADAPTABLE trial for querying purposes.

Small modifications from the slide used with the CDM v3.0 Stakeholder meetings on April 28 and 29, 2015. The CDM v3.0 was released on June 1, 2015.
Implementation of v3.0

- v3.0 expected to be in place at beginning of Phase II, per PFA
- Phase II expectations for CDM versioning are in development, and not part of this current discussion

Page 13 of the Phase II PFA (highlight added)
www.pcori.org/sites/default/files/PCORI-PFA-CDRN.pdf

Slide from CDM v3.0 Stakeholder meetings on April 28 and 29, 2015.
Supplemental Slides: Selected sets from prior sessions
Data Sharing in ADAPTABLE
(slides from December 11 session)
6. We will get some information from other places. Taking part in ADAPTABLE does not require any special study visits or trips to your doctor. But to be sure we get a complete picture of your health:

- **We will get certain information from your medical records.** Examples include information about your health problems, health care visits, hospital stays, medical procedures, and lab results. In some cases, we might need you to sign a form saying it is okay for us to get the information we need for the study.

- **We will ask for the last 4 digits of your Social Security number and health insurance ID numbers.** We need these to check other sources (such as health insurance claims) for information about your health.

We will get these kinds of information from time to time for as long as you are in the study.
Two areas of consideration

- **External linkage projects for ADAPTABLE** (which may include Medicare, private health claims with partners, and National Death Index) will be managed by the Coordinating Center.
  - Patient-level linkage between ADAPTABLE patients and these external sources will also be performed by the Coordinating Center.

- Transmitting information about **subject recruitment status** is a different process and will be covered in operational updates.
Review of Phenotype Context
(slides from December 11 session)
Patients meeting eligibility

Patients who are invited

Patients who visit portal

Patients who choose to participate

Patients Enrolled in ADAPTABLE

Managed at site and/or network level
This is where the phenotype is situated

The patient answers a few basic questions to check for those unsafe to participate, but full eligibility criteria was determined at the site level
ADAPTABLE eligibility criteria

ADAPTABLE Protocol Final Version 1.0, October 22, 2015, section III.A.1., pages 16-17 (PDF pages 20-21).

6. Not currently treated with ticagrelor and not planned to be treated in the future with ticagrelor.

---

Ticagrelor criterion was added as a result of protocol comment cycle
ADAPTABLE eligibility criteria contain both inclusions and exclusions

There will be no exclusions for any upper age limit, comorbid conditions, or concomitant medications other than oral anticoagulants and ticagrelor that are used at the time of randomization, or are planned to be used during the study follow-up.

Simple, inclusive eligibility criteria will make enrollment easier, and will render study results more generalizable to a broader population of patients. We will exclude pregnant or lactating women (because of concern for the fetus or child), patients taking oral anticoagulants or likely to require an oral anticoagulant during trial follow-up (because of complex drug interactions and a projected excessive risk of bleeding), and patients at relatively low risk for cardiovascular events (i.e., no enrichment factor because of the large number of outcomes needed to detect a clinically meaningful difference with the available sample size).
Screening and recruitment development

Sites and/or networks are heterogeneous, and expected to have different processes for identifying, contacting, and inviting potential trial participants.

- “Base phenotype” (to be developed by ADAPTABLE CC) will be modified by individual sites to best suit their processes.
Base phenotype customization is expected

III.A.3.b. Cohort Identification

Local site investigators within the CDRNs will be asked to endorse the protocol. They will then be asked to give their permission for the CDRN, through its integrated health system members, to identify and contact potentially eligible patients. In the latter case, patients who meet criteria for secondary prevention after a cardiovascular event will be identified using search algorithms developed by the DCRI Coordinating Center (based on the trial inclusion criteria) and customized by the CDRN for their own EHR systems. Broad agreement from both cardiovascular specialists and primary care physicians will be sought. In this trial, we believe that most systems will agree that prior approval of the relevant clinician will be needed and useful since these patients will be at high-risk for death or a major disabling event. Although it is unlikely that a medical reason for ineligibility will be found, most of these patients are close to their clinicians, whose confidence in and support of the trial will be important for patient engagement, both in terms of participation as well as promoting adherence to the study medication and treatment of the inevitable clinical events.
In summary:

The ADAPTABLE eligibility phenotype will not be executed by the Coordinating Center.

Each network will run their phenotype at the local level, against their own data sources, and using logic that best fits their local workflows and governance for potential participant identification.
Phenotype Feedback Cycle
(slides from December 11 session)
Feedback cycle for base phenotype specification

Feedback cycle November 3-20

89 discreet comments received from 6 networks

- With many thanks!

Comments classified into 16 thematic categories, responses added, and posted:

- https://pcornet.imeetcentral.com/adaptabletrial/file/43196859/
16 thematic categories

<table>
<thead>
<tr>
<th>Tag</th>
</tr>
</thead>
<tbody>
<tr>
<td>AGE</td>
</tr>
<tr>
<td>ALLERGY</td>
</tr>
<tr>
<td>AUTHORITATIVE_SOURCE</td>
</tr>
<tr>
<td>BLEED</td>
</tr>
<tr>
<td>COHORT_BASIS</td>
</tr>
<tr>
<td>ENRICHMENT</td>
</tr>
<tr>
<td>FUTURE_TX</td>
</tr>
<tr>
<td>GLOBAL</td>
</tr>
<tr>
<td>LOOK_BACK</td>
</tr>
<tr>
<td>MEDS</td>
</tr>
<tr>
<td>MI</td>
</tr>
<tr>
<td>MORTALITY</td>
</tr>
<tr>
<td>NET_ACCESS</td>
</tr>
<tr>
<td>PREGNANCY</td>
</tr>
<tr>
<td>SITE_PLANNING</td>
</tr>
<tr>
<td>SMOKING</td>
</tr>
</tbody>
</table>
Only **“one or more”** enrichment factor is required

Some networks expressed concern about reliability of certain factors in their data (such as current smoking status).

However, the “one or more” requirement means that sites have discretion about which enrichment factor(s) to implement.
In the portal, the potential participant will answer a few basic questions to check for those unsafe to participate.

The basic questions are expected to include:
1. Aspirin allergy
2. History of severe bleeding
3. Oral anticoagulant use
4. Pregnancy

- Known atherosclerotic cardiovascular disease (ASCVD), defined by a history of prior myocardial infarction, prior coronary angiography showing ≥75% stenosis of at least one epicardial coronary vessel, or prior coronary revascularization procedures (either PCI or CABG)
- Age ≥ 18 years
- No known safety concerns or side effects considered to be related to aspirin, including
  a. No history of significant allergy to aspirin such as anaphylaxis, urticaria, or significant gastrointestinal intolerances
  b. No history of significant GI bleed within the past 12 months
  c. Significant bleeding disorders that preclude the use of aspirin
- Access to the Internet. In the event that the CDRNs are notified that a cohort of patients without internet access can be included, then patient agreement will be obtained during the consent process to provide follow-up information by telephone contact with the DCRI Call Center.
- Not currently treated with an oral anticoagulant – either warfarin or a novel anticoagulant (dabigatran, rivaroxaban, apixaban, edoxaban) – and not planned to be treated in the future with an oral anticoagulant for existing indications such as atrial fibrillation, deep venous thrombosis, or pulmonary embolism.
- Not currently treated with ticagrelor and not planned to be treated in the future with ticagrelor.
- Female patients who are not pregnant or nursing an infant
- Estimated risk of a major cardiovascular event (MACE) > 8% over next 3 years as defined by the presence of at least one or more of the following enrichment factors:
  a. Age > 65 years
  b. Serum creatinine > 1.5 mg/dL
  c. Diabetes mellitus (Type 1 or Type 2)
  d. 3-vessel coronary artery disease
  e. Cerebrovascular disease and/or peripheral arterial disease
  f. Left ventricular ejection fraction (LVEF) < 50%
  g. Current cigarette smoker
Known Atherosclerotic Cardiovascular Disease

1. Known atherosclerotic cardiovascular disease (ASCVD), defined by a history of prior myocardial infarction, prior coronary angiography showing ≥75% stenosis of at least one epicardial coronary vessel, or prior coronary revascularization procedures (either PCI or CABG).
Other important areas (1 of 2)

- Cohort basis, including consideration of “loyalty cohorts”
- Practices of date obfuscation within a datamart (such as shifting all birth dates by a random number of days)
- Concern for reliability of smoking data (enrichment factor)
Other important areas (2 of 2)

- Does the presence of an e-mail address serves as a proxy measure for Internet access
- Confirmation of future treatment issue
- Global: Development processes
ADAPTABLE RDBMS and SAS Platform Basis

(slides from October 30 session)
Modules of the data landscape amalgamate into the study database

Data sources

- Healthcare Delivery Data in Common Data Model
- External Linkage Projects: Claims Data Partnerships with Trial, National Death Index, and Others
- Participant Portal
- Call Center

ADAPTABLE Study Database
Recommended setup* for ADAPTABLE data partners - DRAFT

* Please note that data partners are known to be heterogeneous in their technical configurations and processes.
Data Flow Development between Patient Portal and Sites

(slides from October 30 session)
Steps to Randomize Participants

1. Potential Participant Logs into Portal and enters Golden Ticket
2. Watches Video
3. Information Sheet Review
4. Answers I/E Questions
5. Answers Review Questions (comprehension)
6. CDRN Specific ICF Review (and print)
7. Creates ADAPTABLE Account
8. Signs ICF
9. Randomized
CDRN Responsibilities

- CDRNs request “Golden Ticket” codes through Mytrus
- CDRNs invite potential participants and provide each a “Golden Ticket”
- CDRNs track “Golden Ticket” assignments
- Mytrus provides “Golden Ticket” status for those entered into Mytrus
- CDRNs reconcile “Golden Ticket” to patient identifiers
- CDRNs update PCORNET_TRIAL (including the PARTICIPANTID and TRIAL_INVITE_CODE)
## Participant Identifiers

<table>
<thead>
<tr>
<th>ID</th>
<th>Origin</th>
<th>Trigger</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Golden Ticket</td>
<td>Mytrus</td>
<td>CDRNs request through Mytrus</td>
<td>CDRNs request as bulk and receive download that can be used for mail merges</td>
</tr>
<tr>
<td>Mytrus Subject ID</td>
<td>Mytrus</td>
<td>Upon randomization</td>
<td>Unique system generated study number assigned at randomization and sequential</td>
</tr>
<tr>
<td>PATID</td>
<td>PCORNET CDM</td>
<td>Present in the CDM</td>
<td>The unique subject identifier in the PCORNET CDM that CDRNs populate in PCORNET_TRIAL</td>
</tr>
<tr>
<td>PARTICIPANTID</td>
<td>PCORNET_TRIAL</td>
<td>CDRN Populates</td>
<td>The ADAPTABLE randomized participant identifier that links the Mytrus randomized participants to the PCORNET CDM</td>
</tr>
<tr>
<td>TRAIL_INVITE_CODE</td>
<td>PCORNET_TRIAL</td>
<td>CDRN Populates</td>
<td>The ADAPTABLE invited participant identifier captured in PCORNET_TRIAL</td>
</tr>
</tbody>
</table>
Mytrus Reports

- Entered “Golden Ticket” Codes
- I/E Dropped Out *(aggregate)*
- Completed Account Creation
- Signed Consent
- Randomized
- Key Participant Identifiers (e.g. Name, DOB, Gender, Race)
- Other fields needed for PCORNET_TRIAL

Adaptable
Drilling Down into Individual Modules

(slides from September 25 session)
Module #1: CDRN CDM data

Data sources

- Healthcare Delivery Data in Common Data Model
- External Linkage Projects: Claims Data Partnerships with Trial, National Death Index, and Others
- Participant Portal
- Call Center

ADAPTABLE Study Database
#1: CDM development notes

- The ADAPTABLE trial will use CDM v3.0
- ADAPTABLE trial DRN activity will be performed in SAS
- DRN OC data characterization processes will be the primary mechanism for determining datamart “analysis-ready” state
- ADAPTABLE Site PIs will receive request to confirm ADAPTABLE datamart concordance with ADAPTABLE clinical sites
Why are “sites” different from “datamarts”?

Working definitions:

Sites = **Organization of people** for clinical and patient-facing purposes.

Datamarts = **Organization of data** for distributed querying activity.

- Existing CDRNs have different network typologies (ie, different configurations for their datamarts)
  - One datamart may include more than one site
- Sites participating in ADAPTABLE will likely be smaller components of larger networks
Not all PCORnet datamarts will receive ADAPTABLE queries.

Only analysis-ready datamarts will populate the ADAPTABLE study database.

ADAPTABLE queries will be performed in SAS.

Network topology is used to direct ADAPTABLE queries to ADAPTABLE-participating datamarts.
Module #2: External Linkage Projects

Data sources:
- Healthcare Delivery Data in Common Data Model
- External Linkage Projects: Claims Data Partnerships with Trial, National Death Index, and Others
- Participant Portal
- Call Center

ADAPTABLE Study Database
#2: External Linkage development notes

- Current pilot projects with GPC’s Kansas University Med Ctr and Mid-South’s Vanderbilt
  - Important work for developing efficient processes

- All ADAPTABLE sites will be expected to contribute patient-level identifiers for external linkage
  - These identifiers will not be exposed through the CDM; instead this will be a separate process
  - Exact details will be based upon experiences with the pilot projects
Module #3: Participant Portal and Call Center

ADAPTABLE Study Database

Data sources:

- Healthcare Delivery Data in Common Data Model
- External Linkage Projects: Claims Data Partnerships with Trial, National Death Index, and Others

Participant Portal

Call Center
The Participant Portal is direct patient self-report; sites are not expected to enter clinical data.

The Call Center will use the Participant Portal for follow-up of non-respondents. Therefore, data collection design for the Portal is consistent.

Development is underway.
Module #4: Study Database

Data sources:
- Healthcare Delivery Data in Common Data Model
- External Linkage Projects: Claims Data Partnerships with Trial, National Death Index, and Others
- Participant Portal
- Call Center

ADAPTABLE Study Database
Important determinations in protocol for endpoint definitions, hierarchy of data sources, and planned analyses

Data Safety & Monitoring Board (DSMB) reports and reviews are important process
Phenotyping Objectives and Criteria

(slides from September 4 session)
Open Discussion: Process Related

Broadly, how has your network considered the use of EHR data for potential participant identification with ADAPTABLE?

What can we all learn from your experiences from generating prep to research metrics for ADAPTABLE?

What can we all learn from your experiences and lessons learned from other projects?
A lesson learned

- It may be helpful to consider how results will be triaged or filtered.
- Techniques for filtering down thousands (or tens of thousands) of results may benefit from non-clinical elements.
- May also assist in responsiveness to enrollment foci and targeted recruitment groups.
Ideas for non-clinical data elements

Are they a “current” patient? Do they receive their routine care here?

- If not an explicit flag in the system, are there potential indirect indicators?
  - For example: do they live in this state?
  - When was their last encounter?
  - When is their next scheduled appointment?
Ideas for non-clinical data elements (2)

How are they receiving their care?
- Does the patient have a PCP?
- Specialty care association?
- Registry flag?

Are they alive?
- If mortality data are known to be incomplete, can last encounter data be helpful?
Open Discussion: Phenotype Criteria

What **clinical** data domains and elements do you feel are most important for your ADAPTABLE phenotyping?

What components of the ADAPTABLE inclusion/exclusion criteria may be difficult to translate for your network?

What **non-clinical** data domains and elements do you feel may be important for your processes?
Possible Considerations

Potential data sources may include:
- Data transformed to CDM
- Other non-CDM sources

Logistics may include:
- Latency of source data
- Frequency of refreshes
- Tracking previously contacted patients, including those who decline
Open Discussion: Phenotype Logistics

What logistics do you think will be most important for your processes? Some examples may include:

- Selection of potential data sources
- Considering structured data elements vs. unstructured/narrative content
- Latency considerations of source data and also associated refreshes and transformation processes