Leveraging Informatics in Pragmatic Research: Initial Experience in PCORnet

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Disclosures

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• **Disclosures:** EdLogics (Advisory Board), Boehringer Ingelheim
PCORI Initiative: PCORnet

• Patient Centered Outcomes Research Institute (PCORI) created PCORnet with:
  – 13 sites as Clinical Data Research Networks (CDRN)
  – 20 sites as Patient Powered Research Networks (PPRN)

• Goals
  – Each CDRN engages 1 million or more patients across 2 or more health systems
  – Build infrastructure to share data, build novel informatics tools, engage key stakeholders
  – Perform comparative effectiveness research and pragmatic clinical trials.
PCORnet Reaches Across the Nation

This map depicts the number of PCORI-funded Patient-Powered or Clinical Data Research Networks that have coverage in each state.
Pragmatic Research: Use Cases

1. De-identified data/HIPAA Limited data for prep to research or observational research
2. Fully-identified data for observational research
3. Contact patients for observational (survey or cohort) research
4. Pragmatic intervention studies at patient, clinic, or system level to answer practical clinical questions and improve patient care
5. Health system innovation and population health efforts
Principal Investigators:
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Trent Rosenbloom MD MPH, Vanderbilt University Medical Center
Paul Harris PhD, Vanderbilt University Medical Center
Tim Carey MD MPH, University of North Carolina at Chapel Hill
Les Lenert MD, Health Sciences of South Carolina
Over **9 million patients** in the Mid-South Region. The Mid-South Clinical Data Research Network includes **clinical records** of patients **since 2004** and is updated on a quarterly basis. Our partnership with **Greenway Health** adds over **16 million** patients nationwide.
Data Aggregation Across CDRN

1. Queries and Analytic Software Packages from PCORI
2. CDRN returns Counts and Aggregate resulting data

PopMedNet

PCORNet

> 110 million patients!
PCORI Common Data Model V 3.0

**CONDITION v2.0**
A condition represents a patient’s diagnosed and self-reported health conditions and diseases. The patient’s medical history and current state may both be represented.

**DEATH v3.0**
Reported mortality information for patients.

**DEATH_CAUSE v3.0**
The individual causes associated with a reported death.

**DEMOGRAPHIC v1.0**
Demographics record the direct attributes of individual patients.

**DIAGNOSIS v1.0**
Diagnosis codes indicate the results of diagnostic processes and medical coding within healthcare delivery.

**DISPENSING v2.0**
Outpatient pharmacy dispensing, such as prescriptions filled through a neighborhood pharmacy with a claim paid by an insurer. Outpatient dispensing is not commonly captured within healthcare systems.

**ENROLLMENT v1.0**
Enrollment is a concept that defines a period of time during which all medically-attended events are expected to be observed. This concept is often insurance-based, but other methods of defining enrollment are possible.

**ENCOUNTER v1.0**
Encounters are interactions between patients and providers within the context of healthcare delivery.

**HARVEST v3.0**
Attributes associated with the specific PCORnet datamart implementation.

**LAB_RESULT_CM v2.0**
Laboratory result Common Measures (CM) use specific types of quantitative and qualitative measurements from blood and other body specimens. These standardized measures are defined in the same way across all PCORnet networks.

**PCORNET_TRIAL v3.0**
Patients who are enrolled in PCORnet clinical trials.

**PRESCRIBING v3.0**
Provider orders for medication dispensing and/or administration.

**PRO_CM v2.0**
Patient-Reported Outcome (PRO) Common Measures (CM) are standardized measures that are defined in the same way across all PCORnet networks. Each measure is recorded at the individual item level: an individual question/statement, paired with its standardized response options.

**PROCEDURES v1.0**
Procedure codes indicate the discreet medical interventions and diagnostic testing, such as surgical procedures, administered within healthcare delivery.

**VITAL v1.0**
Vital signs (such as height, weight, and blood pressure) directly measure an individual’s current state of attributes.
## PCORI Common Data Model V 3.0

<table>
<thead>
<tr>
<th>Site</th>
<th>Sites in CDM</th>
<th>Patients in CDM</th>
<th>Encounters in CDM</th>
<th>CDM Dates</th>
<th>Production CDM Refresh Rate*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vanderbilt</td>
<td>Vanderbilt University Health System</td>
<td>1,683,921</td>
<td>27,164,268</td>
<td>1/09 - 03/17</td>
<td>Quarterly update</td>
</tr>
<tr>
<td>VHAN</td>
<td>Williamson Medical Center, Maury Regional Medical Center, West TN Health</td>
<td>386,015</td>
<td>1,305,116</td>
<td>12/13 - 03/16</td>
<td>Quarterly update</td>
</tr>
<tr>
<td>Greenway Health</td>
<td>952 sites</td>
<td>16,754,670</td>
<td>103,984,550</td>
<td>1/10 - 12/15</td>
<td>Quarterly Update</td>
</tr>
<tr>
<td>UNC at Chapel Hill</td>
<td>UNC Health Care System</td>
<td>2,138,696</td>
<td>20,817,024</td>
<td>6/04 – 4/17</td>
<td>Quarterly update</td>
</tr>
<tr>
<td>Duke University</td>
<td>Duke University</td>
<td>2,254,461</td>
<td>39,788,694</td>
<td>1/05 – 3/17</td>
<td>Quarterly update</td>
</tr>
<tr>
<td>HSSC</td>
<td>Greenville Health System (GHS), MUSC Health (MUSC), Palmetto Health (PH), and Spartanburg Regional Healthcare System (SRHS)</td>
<td>3,105,315</td>
<td>31,837,251</td>
<td>SRHS: 1/11 – 12/16, PH: 1/11-12/16, MUSC: 1/07 – 12/16</td>
<td>Quarterly update</td>
</tr>
<tr>
<td>Meharry Medical College</td>
<td>Meharry Medical College and Nashville General Hospital</td>
<td>137,147</td>
<td>751,870</td>
<td>1/04 – 04/17</td>
<td>Quarterly update</td>
</tr>
</tbody>
</table>

* Production tables are updated after data characterizations have been approved by the Coordinating Center.
Additional Linkage for “Complete” Data

**TN State Health Data**
- Includes statewide hospital discharge data and vital statistics (death) data. Approved for 1998-2015 data
- Agreements in place; Will purchase 2015 once ready
- Currently have 2011-2014 data, Linkage in process!

**TennCare Data**
- Includes health claims data derived from approx. 1,480,430 individuals covered under the state's Medicate coverage
- Agreements in place, linkage/pipeline in process of being built
- Received Data, Linkage in process!

**CMS Data (RESDAC, CMMI data)**
- Reuse application in process – waiting on IRB approval and original DUA extension from CMS
- CDRN-wide linkage plan in development

**Vanderbilt Health Plan (Aetna)**
- Includes health claims data derived from approx. 19,600 employees and dependents covered. Years 2011-2016 available
- Agreements in place, data linkages in process

**Linkage to NC BC/BS Data and NC Medicaid Data**
- Data Use Agreements complete;
- Linkage approved on a case by case basis

**Linkage to SC Claims Data**
- Data Use Agreement Complete
- Linkages available on a per project basis
Novel Informatics Tools

- Tools for quickly running queries and analyzing electronic health data
- Tools for identifying and contacting patients
  - Email, Text, Phone (> 400K emails at VUMC)
  - My Research at Vanderbilt (~30K)
  - Epic MyChart (MUSC)
- New electronic consent process
- Expanded survey tools for collection of patient reported outcomes (via web/mobile platforms, automated phone, embedded video/audio, etc.)
- Integration of PROMIS measures into REDCAP
- Electronic payment processes for study participation
- Potential integration of patient survey data into the EHR for clinical use
- Expansion of clinical decision support tools
Weight Cohort Example

- Email blast to >10,000 Vanderbilt patients with over 30% response rate!
- Surveyed > 10,000 patients across multiple health systems/clinic sites in < 6 months
Mobile Data Collection

- 396 enrolled participants
- 11,189 meals
- Mean of 28.3 (17.6) meals/person
### BMI by Eating Clusters

<table>
<thead>
<tr>
<th></th>
<th>Adjusted β</th>
<th>95% CI</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healthy</td>
<td>Ref</td>
<td>Ref</td>
<td>Ref</td>
</tr>
<tr>
<td>Healthy Emotional</td>
<td>1.9</td>
<td>1.5, 2.3</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Unhealthy</td>
<td>2.4</td>
<td>2.0, 2.8</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Unhealthy Emotional</td>
<td>5.1</td>
<td>4.7, 5.6</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Adjusted for age, gender, race/ethnicity, income, and physical activity.

Heerman, B. *J Nutr Educ Behav*. 2017
Identifying Eligible CHD Patients

• Case 1: 2 outpatient visits billed for MI or CHD
  – N=27,194

• Case 2: 1 or more revascularization procedure codes
  – N=3,637 additional

• 26,343 of 30,831 pts (85.4%) had encounter in last 2 yrs

<table>
<thead>
<tr>
<th></th>
<th>CHD Disease Positive</th>
<th>CHD Disease Negative</th>
<th>TOTALS</th>
</tr>
</thead>
<tbody>
<tr>
<td>CHD algorithm detected</td>
<td>192</td>
<td>3</td>
<td>195</td>
</tr>
<tr>
<td>CHD algorithm NOT detected</td>
<td>11</td>
<td>264</td>
<td>275</td>
</tr>
<tr>
<td>TOTALS</td>
<td>203</td>
<td>267</td>
<td>470</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Positive Predictive Value</th>
<th>192/195</th>
<th>98.5%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative Predictive Value</td>
<td>264/275</td>
<td></td>
<td>96.0%</td>
</tr>
<tr>
<td>Sensitivity (true positives)</td>
<td>192/203</td>
<td></td>
<td>94.6%</td>
</tr>
<tr>
<td>Specificity (true negatives)</td>
<td>264/267</td>
<td></td>
<td>98.9%</td>
</tr>
</tbody>
</table>

Available in Phenotype Knowledge Base:
Roumie CL, Shirey-Rice J, Kripalani S. MidSouth CDRN – Coronary Heart Disease algorithm. PheKB (a knowledgebase for discovering phenotypes from electronic health records). Available at: https://phekb.org/phenotype/midsouth-cdrn-coronary-heart-disease-algorithm
CHD “Personome”

- 70% married
- 12% divorced
- 12% widowed
- 21% live alone

- 26% missed their meds at least once in the last week
- 9% not high school graduate
- 35% make ≤ $35k

- 17% disabled

- Self-rated health
- Excellent, Very Good, Good, Fair

- Emotional Support
- All of the time, Most of the time, Some of the time, A little of the time, None of the time

- Fatigue
- Not at all, A little bit, Somewhat, Quite a bit, Very much

- Difficult to Pay Bills
- Not at all, Not very, Somewhat, Very
### Response Rates for Different Recruitment Approaches

<table>
<thead>
<tr>
<th></th>
<th>Face-to-face</th>
<th>Phone call</th>
<th>Letter with URL</th>
<th>Mailed survey</th>
<th>Email from physician</th>
<th>Email from researcher</th>
<th>Research Match</th>
<th>Two-step screening</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Eligible</strong></td>
<td>2,443</td>
<td>874</td>
<td>1,430</td>
<td>1,276</td>
<td>23,572</td>
<td>33,733</td>
<td>447</td>
<td>12,468</td>
</tr>
<tr>
<td><strong>Consented</strong></td>
<td>2,305</td>
<td>331</td>
<td>520</td>
<td>370</td>
<td>1,451</td>
<td>5,008</td>
<td>340</td>
<td>3,845</td>
</tr>
<tr>
<td><strong>Completed</strong></td>
<td>2,248</td>
<td>320</td>
<td>504</td>
<td>369</td>
<td>1,356</td>
<td>4,383</td>
<td>335</td>
<td>3,682</td>
</tr>
<tr>
<td><strong>Response rate</strong></td>
<td>94.3%</td>
<td>37.8%</td>
<td>36.3%</td>
<td>28.9%</td>
<td>6.1%</td>
<td>14.8%</td>
<td>76.0%</td>
<td>30.8%</td>
</tr>
</tbody>
</table>

Heerman, *Contemporary Clinical Trials*, 2017
AR-POWER Collaboration

~21K emailed (MRAV and Clinics) and 256 patients joined AR-POWER

To

If there are problems with how this message is displayed, click here to view it in a web browser.

Message

ArthritisPower_flyer.pdf (9 MB)

Please disregard if you have already joined the ArthritisPower network.

Hello,

In a survey sent to My Health at Vanderbilt users you agreed to be contacted directly to receive information about research studies. Below is a description of a possibly match your health profile.

We are excited to introduce you to ArthritisPower, a new online resource and smart phone app for patients with arthritis and other bone, joint and autoimmune diseases.

This resource is free and allows you to help keep track of your symptoms and take control of your condition with your computer or smart phone.

In addition, you can volunteer to participate in this patient research network and join in studies to learn about the safety and effectiveness of various medications, exercise and medication. If you decide to join ArthritisPower, you can elect to share your Vanderbilt electronic health records with the registry for scientific studies.

By joining ArthritisPower you will be joining thousands of others and give patients a much needed voice in comparing treatments to each other as well as identify cures.

ArthritisPower is the first ever patient centered research registry for arthritis and related conditions and is completely voluntary. If you decide not to participate, we hope you’ll consider downloading this app or using it online. Visit www.ArthritisPower.org or see the attached flyer to learn more.

Please let your rheumatologist know if you have any questions.

Best wishes,

Leslie J. Crofford, MD
Professor of Medicine
Director, Division of Rheumatology & Immunology
Stakeholder Engagement

• **Governance:**
  - Co-Investigator – 1 member
  - Stakeholders at Oversight Committee – 2 members
  - Stakeholder Advisory Council – 4 members (3 VU, 1 Carolinas)

• **Stakeholder input:**
  - Surveys
    - 480 Providers - (30% racial/ethnic minorities, 16% Community Health Centers)
    - >5,000 consumers – completed
  - Provider Interviews
    - 59 (44.1% Physician)
  - Community Engagement studios – 58 stakeholders

• **Proposal Review:**
  - Stakeholder Engagement Review Process
Regulatory Efficiencies

• **SMART IRB (Central IRB)**
  – 100% of Mid-South sites have signed on

• **Data Sharing Agreements: DSA 2.0**
  – Includes Indemnification/Liability options, network participation institutional/state requirements
  – All sites have signed the DSA

• **Contract Share**
  – Shared templating for contracts
Process for accessing resources

https://midsouthcdrn.mc.vanderbilt.edu/

Welcome to the Mid-South Clinical Data Research Network

The Southern US has the highest rates of obesity, diabetes, cardiovascular disease, and significant rates of health disparities. The Mid-South Clinical Data Research Network (CDRN) centered at Vanderbilt University (VU) focuses on health systems in the Southern United States, but will include the capacity to reach a national population.
PCORnet Examples

• Preliminary data from national weight cohort
• ADAPTABLE pragmatic clinical trial
### Weight Cohort across PCORnet

<table>
<thead>
<tr>
<th></th>
<th>All DataMarts</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adult</td>
<td></td>
</tr>
<tr>
<td>2010-2014</td>
<td>10,174,030</td>
</tr>
<tr>
<td>2014</td>
<td>5,043,643</td>
</tr>
<tr>
<td>2013</td>
<td>4,365,744</td>
</tr>
<tr>
<td>2012</td>
<td>3,480,730</td>
</tr>
<tr>
<td>2011</td>
<td>2,271,557</td>
</tr>
<tr>
<td>2010</td>
<td>1,755,450</td>
</tr>
<tr>
<td>Child</td>
<td></td>
</tr>
<tr>
<td>2010-2014</td>
<td>4,366,777</td>
</tr>
<tr>
<td>2014</td>
<td>1,665,083</td>
</tr>
<tr>
<td>2013</td>
<td>1,483,721</td>
</tr>
<tr>
<td>2012</td>
<td>1,242,143</td>
</tr>
<tr>
<td>2011</td>
<td>884,348</td>
</tr>
<tr>
<td>2010</td>
<td>705,056</td>
</tr>
</tbody>
</table>

**NHANES 2011-2012:**

- **5,211**

- **3,999**
## PCORnet Weight Cohorts vs. NHANES

<table>
<thead>
<tr>
<th></th>
<th>PCORnet Adults</th>
<th>NHANES Adults</th>
<th>PCORnet Children</th>
<th>NHANES Children</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Underweight</strong></td>
<td>1.8%</td>
<td>1.7%</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Normal weight</strong></td>
<td>29.2%</td>
<td>29.0%</td>
<td>67.2%</td>
<td>68.0%</td>
</tr>
<tr>
<td><strong>Overweight</strong></td>
<td>31.9%</td>
<td>34.0%</td>
<td>15.1%</td>
<td>15.0%</td>
</tr>
<tr>
<td><strong>Obesity</strong></td>
<td>29.6%</td>
<td>35.0%</td>
<td>17.7%</td>
<td>17.0%</td>
</tr>
<tr>
<td><strong>Severe Obesity</strong></td>
<td>7.6%</td>
<td>6.0%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Patients with known ASCVD + ≥ 1 “enrichment factor”*

Identified through EHR (computable phenotype) by CDRNs
(PPRN patients that are already a part of a CDRN are eligible to participate.)

Patients contacted with trial information and link to e-consent;†
Treatment assignment will be provided directly to patient

ASA 81 mg QD
ASA 325 mg QD

Electronic follow-up: Every 3–6 months
Supplemented with EHR/CDM/claims data

**Duration:** Enrollment over 24 months;
maximum follow-up of 30 months

**Primary endpoint:**
Composite of all-cause mortality, hospitalization for MI, or
hospitalization for stroke

**Primary safety endpoint:**
Hospitalization for major bleeding

† Participants without internet access will be consented and
followed via a parallel system.
# Disrupting the Norm

## Traditional Trials vs. ADAPTABLE

<table>
<thead>
<tr>
<th></th>
<th>Traditional</th>
<th>ADAPTABLE</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>I/E Criteria Reviewed</strong></td>
<td>Sample via CRA Visit</td>
<td>CDM</td>
</tr>
<tr>
<td><strong>Representative Cohort</strong></td>
<td>Narrow</td>
<td>Broad</td>
</tr>
<tr>
<td><strong>Consent</strong></td>
<td>Facilitated</td>
<td>Patient Directed</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>Paper</td>
<td>e-consent</td>
</tr>
<tr>
<td><strong>Data Collection</strong></td>
<td>Patient Reported</td>
<td>Patient Reported</td>
</tr>
<tr>
<td></td>
<td>Site Recorded</td>
<td>CDM</td>
</tr>
<tr>
<td></td>
<td>Only seen by Site</td>
<td>Received via CDM</td>
</tr>
<tr>
<td><strong>Source Documents</strong></td>
<td></td>
<td>CDM, EHR data</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Protocol design, Committee, Analyses, Dissemination</td>
</tr>
<tr>
<td><strong>Endpoint Adjudication</strong></td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Participants Only</td>
<td></td>
</tr>
<tr>
<td><strong>Patient Involvement</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Costs</strong></td>
<td>+++++</td>
<td>+</td>
</tr>
</tbody>
</table>
Let’s get started!
Thank you for taking the time to find out more details about the ADAPTABLE aspirin study. With your help, we hope to find out what is the right dose of aspirin for people with heart disease.

Got a code?
Please enter in the special code that was included in your invitation:
AX3BN

No code? No problem!
You can still learn more about this study even if you have not been asked to participate.
There are 5 steps to join the study!

The time on each card is an estimate of how long it will take you to complete each section. There are no time limits, so please go at your own pace.

Watch
Watch the ADAPTABLE short video
5 min

Read
Read more details about participating in ADAPTABLE
15 min

Answer
Answer a few questions about the study
5 min

Join
Join the ADAPTABLE study
3 min

Inform
Inform us about your current health
5 min

Let’s get started
Web-Based, Electronic Informed Consent

- Text and video review of the consent is completed on the web portal
- Simplified common consent form with selected local adaptations
- Focused questions to confirm patient comprehension for informed consent and eligibility for randomization after consent is obtained
- Direct patient feedback and user testing for the development of the consent form and process as well as the comprehension questions
ADAPTABLE Information

Aspirin Dosing: A Patient-Centric Trial Assessing Benefits and Long-term Effectiveness (ADAPTABLE)

We are asking you to join a research study called ADAPTABLE. The information below explains the study so you can decide if you want to take part or not. Please read it carefully and take all the time you need to decide. Feel free to talk it over with your family, friends, and doctor. If there is anything you do not understand, be sure to ask questions.

WHY IS THIS STUDY BEING DONE?

For more than 40 years, doctors have been telling patients with heart disease to take aspirin. For these patients, taking aspirin every day can lower the risk of heart attacks and strokes.

Millions of Americans who have heart disease already take either regular (325 mg) or low-dose (81 mg) aspirin. Many studies have shown that both doses work and both are generally safe. The most common side effect of aspirin is an upset stomach. Aspirin can also make you bleed more easily. In rare cases (about 5 in 1,000 people), it can cause dangerous bleeding in the stomach, brain, or other places.

Even though both doses of aspirin are widely used, no one knows which is better. Regular aspirin has a higher risk of bleeding than low-dose aspirin. But no one knows if low-dose aspirin is both safer and works just as well as regular aspirin to prevent heart and blood vessel problems.

The goal of ADAPTABLE is to try to find out which dose of aspirin is better for patients like you who have heart disease. Patients who join this study will take either low-dose or regular aspirin every day. That way, we can learn which is better in terms of reducing the risk of heart attacks, strokes, bleeding, and death.

We expect 20,000 patients will take part in ADAPTABLE.
ADAPTABLE is a research study. The main reason for doing this study is because, for patients who have heart disease, no one knows:

- whether taking aspirin has any side effects.
- which of two commonly-used doses of aspirin is better.
- if a new, experimental alternative to aspirin is safe.

You must select one answer to continue.
Thanks for joining, Allison!
You’re now a member of the Adaptable Community!

Thanks to you we are one step closer to finding out what is the right dose of aspirin for people with heart disease.

What’s next?

Start taking your aspirin dosage.
Starting tomorrow, please take 325 mg of aspirin each day and stop taking your previous aspirin dose if it is different.

Early Check In
In about a week, we will be reaching out to you by email.

Regular Follow-ups
Every 3 months from today, we will send you an email or text reminder to come back here to complete your survey.

Look for your Welcome Packet
Please check your email for a Welcome Packet that includes your signed informed consent. You may also print it here.
## Site Approach & Enrollment Update (8/28)

<table>
<thead>
<tr>
<th>CDRN</th>
<th>Site</th>
<th>Total Number Eligible</th>
<th>Total Number Approached</th>
<th>% of Eligible Approached</th>
<th>Golden Tickets Entered</th>
<th>% Golden Tickets entered per Approached</th>
<th>Total Enrolled</th>
<th># Non-internet Enrolled</th>
<th>% Enrolled Per Approached</th>
<th>% Enrolled Per Golden Ticket Entered</th>
<th>Enrolled last week</th>
</tr>
</thead>
<tbody>
<tr>
<td>MidSouth</td>
<td>Vanderbilt</td>
<td>22,271</td>
<td>17,970</td>
<td>81%</td>
<td>1,896</td>
<td>11%</td>
<td>992</td>
<td>49</td>
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Initial Approach Metrics

Contacts Metrics
- Approached Participants
  - 1 Contact: 75.5%
  - 2 Contacts: 25.9%
  - 3 Contacts: 12.2%
  - >3 Contacts: 3.8%

- Randomized Participants
  - 1 Contact: 50.9%
  - 2 Contacts: 27.0%
  - 3 Contacts: 16.6%
  - >3 Contacts: 5.6%

41,315 Total Approached
1,313 Total Randomized
Invitation Methods
Golden Tickets Entered vs Randomized

- Electronic Communication: 1347 Golden Tickets Entered, 513 Randomized
- Letter: 903 Golden Tickets Entered, 397 Randomized
- In-Clinic/Tablet: 585 Golden Tickets Entered, 438 Randomized
- Telephone: 393 Golden Tickets Entered, 208 Randomized
- Other: 68 Golden Tickets Entered, 6 Randomized

Conversion Rate:
- e-Communication: 38%
- Letter: 44%
- In-Clinic/Tablet: 75%
- Telephone: 53%
Phase 2: Recruitment Strategies (Mid-South)

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* CP2 eligibility numbers as of Mar 1, 2017

**Approach 1**
- **Eligible by CP**
- Meet and present to local providers to generate support and practice-level buy-in

**Approach 2**
- **Local Clinician Engagement**
- In-clinic approach along with 200 mail-outs per week

**Approach 3**
- **1st Approach**
- Phone and Email follow up approximately 1 week after 1st contact

**Approach 4**
- **2nd Approach**
- Electronic messaging via email

**Approach 5**
- **3rd Approach**
- Phone follow up approximately 2 weeks after 1st contact

**Approach 6**
- **4th+ Approach**
- Phone follow up approximately 3 weeks after 1st contact

*Vanderbilt utilizes email as 1st contact*
*Duke utilizes In-Clinic approach as 1st contact*
Retention: Visit Status for Eligible Patients

As of May 22, 2017

Percent of Expected Complete

- Early Check-In
- 3 Month
- 6 Month

Legend:
- Complete
- Late
- >90 days Late
Lessons Learned to Date

- Significant variation by CDRN/Recruitment Site
- Needed to expand Computable Phenotype to expand eligible patient pool
- Percent enrolled vs percent approached is very low
- Recruitment and retention needs to be multimodal
  - Email contact
  - Phone Call
  - Face-to-Face
- Recruitment needs to engage clinicians/patients/stakeholders
- Some patients need to be recruited with non-internet approaches
- Keep an eye on retention!

Adaptable
Summary

• PCORnet is a powerful network for pragmatic research
• Informatics approaches can help to identify, recruit, retain, and follow patients
• Informatics alone is insufficient to conduct pragmatic trials.
Acknowledgements

• Vanderbilt/ Meharry/VHAN
  – Paul Harrris MD
  – Trent Rosenbloom MD
  – Keri Wolfe MS, Megan Cook MS, Mellisa Basford MS
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  – Christianne Roumie MD
  – Gordon Benard MD, Robert Dittus MD MPH
  – Dan Munoz MD
  – Bill Heerman MD, Ken Wallston PhD. David Schlundt PhD, David Crenshaw
  – Jonathan Schildcroudt PhD
  – Christina Eskew, Lesa Black PhD
  – Bobo Tanner MD
  – Wayne Jenkins MD
  – Marino Bruce PhD, Rowena Dolor MD
  – Yvonne Joosten MPH
  – Consuelo Wilkins MD
  – Duane Smoot MD
  – Sidd Pratha PhD

• PCORnet
  – Ben Nowell (AR-Power)
  – Jason Block MD (Partners)

• Duke
  – Ian Sanderson MD
  – Ebony Boulware MD
  – Adrian Hernandez MD
  – Matt Roe MD
  – Gene Oddone MD
  – Lauren Cohen
  – Meg Welch
  – Janice Curtis
  – ADAPTABLE TEAM

• UNC
  – Tim Carey MD MPH
  – Jacque Halladay MD
  – Darren DeWalt MD MPH
  – John Buse MD PhD CDE

• Health Sciences of South Carolina
  – Christy Turley MD
  – Katrina Friar Riley
  – Les Lenert MD (MUSC)
  – Jihad Obeid PhD

• Greenway Health
  – Sarah Pesko
Questions