Real World Data for Clinical Research: A PCORnet Workshop with the Pharmaceutical and Biologics Industry

March 30, 2015
9:00 AM – 5:00 PM
Morning Agenda

- 9:00 – Welcome
- 9:15 – Introductions and Purpose of the Workshop
- 9:30 – PCORnet in Brief
- 10:00 – Examples and Insights from the Networks
- 10:30 – Q&A on PCORnet Structure, Plans, Network Activities
- 10:45 – Break
- 11:00 – Open Discussion, Continued Q&A
Afternoon Agenda

12:00 – Lunch Presentation: PCORnet in Use for Interventional and Observational Studies

1:00 – Breakout Sessions
  ▪ Randomized Trials
  ▪ Observational Studies

3:00 – Break

3:20 – Reports from Breakout Sessions: Opportunities, Areas for Further Exploration

4:10 – Open Discussion

4:45 – Observations and Next Steps

5:00 – Closing Remarks and Adjournment
PCORnet in Brief
Enabling PCORnet Collaborations with Industry

Rachael Fleurence, PhD
Program Director CER Methods and Infrastructure, PCORI

Industry Workshops March 30&31 2015
Overview

- PCORnet and Industry
- PCORnet Brief Overview
- PCORnet Emerging Operational Model
- Role and Access for External Funders
- Key Take Away Messages
PCORnet and Industry

- **Partnerships** with industry are critical to PCORnet’s sustainability.
- PCORnet is being set up so as to enable these partnerships to be **successful**.
- Your participation and feedback today will be critical to ensure that we enable these **successful** partnerships.
Vision for PCORnet

PCORnet brings together the expertise, populations, resources, and data of its participating organizations to create a national infrastructure that enables more efficient, patient-centered research

“Research Infrastructure Done Differently”
Touch points between PCORnet and industry

Industry faces expensive and inefficient **trials** with low recruitment:
- Large, cost-effective interventional trials leveraging electronic health data and utilizing streamlined contracting and IRB processes

Industry needs access to increasingly large samples of **real-world data**
- Rapid observational studies leveraging a distributed research network and a common data model

Industry needs to respond to emerging regulatory requirements of **patient-preferences** and **patient engagement** in general
- 18 PPRNs governed by patients
- 11 CDRNs with patient governance
- Patient Council involved in launching PCORnet
Hallmarks of PCORnet’s success

1. Highly **engaged** patients, clinicians, health systems, researchers and other partners
2. A **collaborative community** supported by robust governance
3. Analysis-ready **standardized data** with strong privacy protections
4. Oversight that **protects patients**, supports the timely conduct of research, and builds trust in the research enterprise
5. Research that is **sustainably integrated** into care settings and with communities of patients
Pivotal $100M Infrastructure Investment

11 Clinical Data Research Networks (CDRNs)
System-based networks, such as integrated delivery systems, academic medical centers, federally qualified health centers,

18 Patient-Powered Research Networks (PPRNs)
Participants/patients working together to discover, propose, and answer relevant research questions. Building the tools to engage people more broadly in research from end to end.

Coordinating Center
Provides technical and logistical assistance under the direction of a steering committee and PCORI program staff.
Parts of PCORnet are still under construction
Spring 2015: Coming Into View

PCORnet’s infrastructure built to:

- To leverage rich clinical **electronic health data** linking EHR data with private and public claims data (incl. CMS)
- Support both large **observational studies** and embedded **randomized clinical trials**
- Support novel models of **participant-led research**, integrate patient-preference science, and build robust patient-participation
- Involve **patients, clinicians, and health systems leaders** in governance and use of the network
Each CDRN Network will have 1-10 DataMarts

Total anticipated DataMarts: 75

Annotated Data Dictionaries received: 62

Software installation completed: 30

Nine of 11 CDRNs have transformed data for at least one million individuals
## CDRNs Disease Cohorts

<table>
<thead>
<tr>
<th>Organization</th>
<th>Common Cohort</th>
<th>Rare Cohort</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADVANCE</td>
<td>Diabetes</td>
<td>Co-infection with HIV and hepatitis C virus</td>
</tr>
<tr>
<td>CAPriCORN</td>
<td>Anemia; Asthma</td>
<td>Sickle cell disease; Recurrent C. Difficile colitis</td>
</tr>
<tr>
<td>Great Plains Collaborative</td>
<td>Breast Cancer</td>
<td>Amyotrophic Lateral Sclerosis (ALS)</td>
</tr>
<tr>
<td>Louisiana Clinical Data Research Network</td>
<td>Diabetes</td>
<td>Sickle Cell Disease, Rare Cancers</td>
</tr>
<tr>
<td>NYC-CDRN</td>
<td>Diabetes</td>
<td>Cystic fibrosis</td>
</tr>
<tr>
<td>Mid-South CDRN</td>
<td>Coronary Heart Disease (CHD)</td>
<td>Sickle Cell Disease (SCD)</td>
</tr>
<tr>
<td>PEDSNet</td>
<td>Inflammatory bowel disease</td>
<td>Hypoplastic left heart syndrome</td>
</tr>
<tr>
<td>PORTAL</td>
<td>Colorectal Cancer</td>
<td>Severe Congenital Heart Disease</td>
</tr>
<tr>
<td>pSCANNER</td>
<td>Congestive Heart Failure</td>
<td>Kawasaki Disease</td>
</tr>
<tr>
<td>P2ATH</td>
<td>Atrial Fibrillation</td>
<td>Idiopathic Pulmonary Fibrosis</td>
</tr>
<tr>
<td>SCIHLS</td>
<td>Osteoarthritis</td>
<td>Pulmonary arterial hypertension</td>
</tr>
</tbody>
</table>
Coming Into View – Funded PCORnet Demonstration Projects

RCT: A Patient-centric Trial Assessing Benefits and Long-term Effectiveness (ADAPTABLE) Trial
- Comparative effectiveness of 81 vs 325 mg of aspirin for secondary prevention of cardiac events and serious bleeding

Observational CER in the Weight Cohort – one or two large observational studies
- Compare bariatric surgery procedures on weight loss, regain, and other outcomes
- Comparative effect of different antibiotics in children under 2 years on BMI, patterns of growth, and rates of obesity by ages 3-5 years

PPRN Demonstration Projects
- PCORI will fund CER projects generated by patient communities of the PPRNs
PCORnet Phase I: 2014 – 2015

- Jan: Phase I Kick-Off, Washington DC
- Mar:
- May:
  - Common Data Model version 1.0 Released
  - PCORnet Patient Council Announced
  - Patient Data and Privacy Roundtable
- July:
  - Aspirin Clinical Trial Topic Approved by Board of Governors
  - Test Queries Performed by the PCORnet Coordinating Center
- Sep:
- Nov:
  - Phase II RFP Released
- Dec:
  - Governance Policies Under Review
  - Common Data Model 2.0 Released
  - Aspirin Clinical Trial Review
- Jan:
- Apr:
- May:
- July:
- Aug:
- Sep:
- Oct:
- Nov:
  - Observational Weight Cohort Application Due
  - PPRN demos application due
  - Strategic planning with key funding partners
  - Phase II Begins
- Dec:
  - Partnerships with key external funders begin
PCORnet uses a privacy protecting distributed data network.
PCORnet Operational Model: Key Points

PCORnet as a National Resource and Utility

- The use of the **PCORnet Distributed Research Network (DRN)** leverages the network data organized in the **common data model**
- All networks will be contractually required in **Phase II** to participate in a minimum number of research queries using the DRN (mix between type of studies may be negotiable)
- Networks **always** have the right to **decline** participation in any specific study
- Networks can participate in other types of research not leveraging the **DRN**

Planned volume of research in Phase II:

<table>
<thead>
<tr>
<th>Phase II Year</th>
<th>Pre-Research Questions per CDRN</th>
<th>Observational Studies per CDRN</th>
<th>Clinical Trials per CDRN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Year 1</td>
<td>50</td>
<td>10</td>
<td>5</td>
</tr>
<tr>
<td>Year 2</td>
<td>100</td>
<td>10</td>
<td>5</td>
</tr>
<tr>
<td>Year 3</td>
<td>200</td>
<td>20</td>
<td>5</td>
</tr>
</tbody>
</table>
PCORnet needs to collaborate with external funders for sustainability

- **External funders** include: NIH, pharmaceutical, device, diagnostic industry, patient organizations, foundations etc.

- **Pre-Research Queries for External Funders:**
  1. The CC will be the “front door” to PCORnet and will triage requests to the Executive Steering Committee. Prioritization process is under development
  2. PCORI will allocate pre-research questions to interested funders in Year 1

- **Externally-funded studies:**
  1. CDRNs and PPRNs and their investigators will be working with external funders to ensure their sustainability
  2. These studies may apply for a PCORnet study designation which has some higher requirements

- **External funders may fund studies using the PCORnet Distributed Research Network (DRN):**
  1. CDRNs and PPRNs can work with external funders on queries using the DRN. The terms and conditions are described in the policies
**“PCORnet Study” Designation: Level of Requirements**

<table>
<thead>
<tr>
<th>Requirements for “PCORnet Study” Designation</th>
<th>Requirements for using PCORnet without “PCORnet study” designation</th>
<th>Pre-Research Queries</th>
</tr>
</thead>
<tbody>
<tr>
<td>PCORI-funded High Requirements</td>
<td>High Requirements</td>
<td>Low Requirements</td>
</tr>
<tr>
<td>Externally-funded High Requirements</td>
<td>Lower Requirements</td>
<td>Low Requirements</td>
</tr>
</tbody>
</table>
Key Take-Away Points

- Providing easy access to PCORnet to external funders from industry is critical to the sustainability of the network.

- Understanding industry perspectives and constraints is critical to being able to address them in the emerging governance model.

- A concrete process, possibly a work group, to address industry feedback in collaboration with PCORI will be essential.
# Requirements for “PCORnet study” status by type of funder

<table>
<thead>
<tr>
<th>PCORI-funded</th>
<th>Summary of Requirements for PCORnet Study Designation</th>
<th>Summary Requirements for using PCORnet without PCORnet study designation</th>
<th>Pre-Research Queries *</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PCORI-funded</strong></td>
<td>Patient-centeredness; Patient engagement; Advisory Panels; Methodology Standards; Peer review and release of findings; Open Science; no CEA (PCORI requirements)</td>
<td>Not applicable (all PCORI-funded research through PCORnet must qualify for a PCORnet study designation)</td>
<td>No cost-effectiveness questions Patient-centered question</td>
</tr>
</tbody>
</table>

A site PI is included in study for studies involving patient level data for that participating CDRN or PPRN (CDRN/PPRN requirements)

<table>
<thead>
<tr>
<th>Externally-funded</th>
<th>Summary of Requirements for PCORnet Study Designation</th>
<th>Summary Requirements for using PCORnet without PCORnet study designation</th>
<th>Pre-Research Queries *</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Externally-funded</strong></td>
<td>As above, except for loosening PCORI requirements that involve PCORI resources (e.g. peer review)</td>
<td>Lower requirements. Requirement for peer-review for RCTs under discussion.</td>
<td>No cost-effectiveness questions Patient-centered question</td>
</tr>
</tbody>
</table>

*Pre-Research Query a question intended to inform the development of research questions such as assessing the feasibility of a study within the network. Pre-Research Questions can generally be executed outside an IRB.*
CDRN Progress Snapshot (March 2015)

- 9 of 11 have transformed data for at least 1 million patients into the PCORnet CDM
- Progress varies with respect to completing linkage of EHR and claims data at each network, although all 11 have identified claims data sources for these linkages (e.g., CMS, Medicaid, vendors such as IMS Health)
- All CDRNs have established architecture to support distributed querying; architecture varies based on each CDRN’s data governance preferences
- All CDRNs have made significant progress on their internal governance policies and data use agreements
- 6 of 11 are participating in the ADAPTABLE (aspirin) trial, and all are developing the requisite trial infrastructure, including approaches to engaging clinicians and systems
- All have 2+ significant collaborations with one or more PPRNs
- 9 of 11 have identified patients for a cohort using computable phenotypes
- 7 of 11 will have surveyed at least one of their three named cohorts by Summer 2015
PPRN Progress Snapshot (Rare Conditions & CENA PPRN)

- 8 of 9 actively enrolling patients, 2 have achieved target enrollment
- 8 of 9 have completed governance documents
- 9 of 9 have IRB approval for the development of their network
- Data sources include patient registries (some new, some expansions of existing registries), surveys, CRFs, biospecimens
- All 9 have the ability to contact their patients about trial participation, and are working closely with patients to co-create and prioritize research questions of interest
- Data querying capabilities vary, however all should have ability to run simple queries by end of Phase I, and some will be able to run more complex queries
PPRN Progress Snapshot  (Common Conditions)

- 9 of 9 actively enrolling patients, 1 has achieved target enrollment
- 9 of 9 have IRB approval for the development of their network
- Data sources include patient registries (some new, some expansions of existing registries), surveys including patient reported outcomes, and biospecimens
- All 9 have the ability to contact their patients about trial participation, and are working closely with patients to co-create and prioritize research questions of interest
- Data querying capabilities vary, however all have ability to run simple queries, and will be able to run more complex queries over the course of Phase I & II
- 8 of 9 include clinicians as active members of the research team
Patient Engagement in PCORnet

Sue Sheridan, MBA, MIM, DHL
Director, Patient Engagement
What Does Patient Engagement Look Like In PCORnet?

• Network Partners – CDRNs and PPRNs
• Governance of PCORnet
• Future PCORnet Studies
  – Patient centeredness and patient engagement requirements
Why Engage Patients in Infrastructure Development and Research?

- Greater likelihood of trust and participation in research networks when patients are involved in the development and governance of research network.

- Greater likelihood of uptake of research findings when patients are involved as partners in the design, conduct, and dissemination of the research.
Patient Engagement in PCORnet Network Partners

**Governance**
- Development of network governance structure, roles and responsibilities
- Development of procedures, bylaws and policies for the network
- Patients are partners in decision making about research priorities

**Enrollment and Diversity**
- Increasing size of the network
- Increasing the diversity of the network
- Retention of network members

**Data Collection**
- The development of data collection tools
- Identification of Patient Reported Outcomes (PROs) for inclusion in database
- Registry development

**Consent, Data Sharing and Privacy**
- The development of consent processes and policies
- Development of data sharing agreements
Governance of PCORnet

- Patients engaged at Coordinating Center level and on Executive Committee of Steering Committee

- Patients engaged in PCORnet task forces and policy development

- PCORnet Patient Council, a national deliberative body of patient leaders, provides feedback and recommendations on key PCORnet policies to ensure full consideration of both the highest patient engagement standards and issues related to protection of patient privacy, consent and autonomy

- Patients are involved in choosing in which research studies to participate
Patient-Centerededness and Patient and Stakeholder Engagement In PCORnet Studies

Patient-Centerededness:
Does the project aim to answer questions or examine outcomes that matter to patients/caregivers?

Patient and Stakeholder Engagement:
Are patients/caregivers and other stakeholders involved as partners in research, as opposed to study participants?
Elements of Patient Engagement in PCORnet Study

- Planning the Study
- Conducting the Study
- Disseminating the Study Results
- PCOR Engagement Principles
Planning the Study

Potential Activities Include

- Identifying the topic and developing the research question to be studied
- Identifying the intervention or comparators to be studied
- Defining the characteristics of study participants

Real-World Examples:
- Epilepsy study: The patients and parents of patients with epilepsy pose the question: Which anti-epileptic drugs best preserve sufficient cognition to go to work or school and to function normally, while still preventing seizures adequately?
- Diabetes study: Clinicians who reviewed the initial study design indicated that clinical practice is quite variable and suggested that a three-arm approach would be more appropriate for the study. The study design was revised accordingly.
Conducting the Study

Potential Activities Include:

- Participating in and monitoring the conduct of the project
- Assisting with the recruitment of study participants
- Assisting with data analysis

Real-World Examples:

- **Chronic pain study:** The informed consent document is developed with patient partners to make it understandable to study participants.
- **Depression study:** Patient advocacy groups assist with recruitment through their patient networks—the “book club” model.
Disseminating the Study Results

3. DISSEMINATING THE STUDY RESULTS: Describe how patient and stakeholder partners will be involved in plans to disseminate study findings, and ensure that findings are communicated in understandable, usable ways.

Potential activities include:

Potential Activities Include:

- Identifying partner organizations for dissemination
- Planning dissemination efforts
- Participating in dissemination efforts, such as the authoring of manuscripts and the presentation of study findings

- Cardiac study: A Patient Dissemination Board is helping to craft the dissemination plan and advise the research team on how to best share study findings.
- Chronic pain study: Patient partners co-author manuscripts, present at scientific and lay conferences, and share study findings through their networks.
The Vasculitis Patient-Powered Research Network
an Example for Potential PCORnet-Industry Partnership

Patient-Centered Outcomes Research Institute (PCORI)
March 30, 2015

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Vasculitis is a family of rare, complex, severe/life-threatening, multi-organ system diseases that involve inflammation of blood vessels.
The Vasculitides

- **Immune Complex Small Vessel Vasculitis**
  - Cryoglobulinemic Vasculitis
  - IgA Vasculitis (Henoch-Schönlein)
  - Hypocomplementemic Urticarial Vasculitis (Anti-C1q Vasculitis)

- **Medium Vessel Vasculitis**
  - Polyarteritis Nodosa
  - Kawasaki Disease

- **Anti-GBM Disease**

- **ANCA-Associated Small Vessel Vasculitis**
  - Microscopic Polyangiitis
  - Granulomatosis with Polyangiitis (Wegener’s)
  - Eosinophilic Granulomatosis with Polyangiitis (Churg-Strauss)

- **Large Vessel Vasculitis**
  - Takayasu Arteritis
  - Giant Cell Arteritis
The Vasculitis Clinical Research Consortium

The VCRC is an international, multicenter research infrastructure for conducting clinical and translational investigation in various types of vasculitis

Part of the NIH Rare Diseases Clinical Research Network
Vasculitis Clinical Research Consortium
North American Clinical Sites

Many additional VCRC partner sites in EU, Asia, Australia
Patient Engagement in Vasculitis Research: Evolution Over a Decade

- Vasculitis Clinical Research Consortium & Vasculitis Foundation: >10 year partnership
  - Support/promotion → advice/review → co-investigators → co-governance
  - Steadily accelerated
  - Promotion, recruitment, awareness
  - Steering Committee and research working groups

- PCORI Vasculitis Outcomes Initiative: 2012--present
  - Patients on Steering Committee and engaged in researchers

- Vasculitis Patient-Powered Research Network: 2014
  - Patients and physicians are co-investigators (including co-PIs)
  - Rapid growth of Network clearly due to patient engagement
The Vasculitis Patient-Powered Research Network
Blueprint for Innovative Research

The Challenges

- All types of vasculitis are rare diseases making it difficult to find enough patients for research studies.
- Patients are spread out geographically.
- It is hard to get health information from physicians to researchers.
- Getting the attention of funding agencies for research is hard.

The Solutions

- Enroll patients and collect data on-line to break down geographic barriers.
- Involve patients so that health information is easily shared with researchers.
- Work within PCORnet so the V-PPRN will have a much larger pool of patients and data and can collect electronic health records.
- Build a strong, vibrant Network and we will get funders’ attention.
Agreement to Participate in the Vasculitis Patient-Powered Research Network (V-PPRN)

The V-PPRN seeks to transform how clinical research in vasculitis is conducted by directly engaging patients, investigators, care providers, and health systems to develop research methods to electronically collect health records and patient-reported data on a large number of patients with various forms of vasculitis. The goal of the V-PPRN research program is to conduct high-quality studies that will improve the care and the health of patients with vasculitis by exploring research questions that matter most to patients and advance medical knowledge about vasculitis.

When you join the V-PPRN, you will be asked to...
("You" means you, your child or the person for whom you are providing care)

Tell us about yourself
- Provide information about yourself, your diagnosis and treatment, and how vasculitis impacts your life.

Agree to let us contact you
- We plan to give you opportunities to participate in studies that may lead to improved care and outcomes for patients with vasculitis.
- By joining the V-PPRN, you will automatically be enrolled in the Vasculitis Clinical Research Consortium (VCRC) Patient Contact Registry which connects patients with opportunities to participate in clinical research trials and experts in vasculitis.

Check-In
- We will need you to periodically update your information so that we have your latest data and contact information.

Stick Around
- Participation is completely voluntary and you may choose to withdraw at any time. We hope that you choose to stay an active participant in the research to help improve care for people with vasculitis.

The V-PPRN will...

Respect Your Privacy
- The information you provide us will be kept confidential and secure to the extent permitted by law. The V-PPRN will never sell, rent, or lease your contact information. Please see the V-PPRN privacy policy for additional information.
- The V-PPRN follows all federal, state, and local guidelines regarding patient protection, including HIPAA.

Keep You Informed
- We will give you feedback and share what we learn about vasculitis. All the information you provide may help us learn more about vasculitis.
- We will also keep you informed about new research opportunities that arise within the Network.

Make Participation Easy
- Updates may be entered directly by you or, with your permission, directly from your healthcare provider.
- There are no costs or any unanticipated risks associated with participation in the V-PPRN.

☐ I confirm that I am at least 18 years of age and I live in the United States (including US territories and commonwealths).

Accept  Decline

By clicking “Accept” you consent to participate in the V-PPRN.
By clicking “Decline” you do not consent to participate but wish to help in another way.

Questions? Contact the V-PPRN Network Manager
Kalen Young, V-PPRN Network Manager
VCRC-V-PPRN-NIAMS DSMB

• NIAMS recognized need for Consortium-specific DSMB with expertise in vasculitis and independence from investigators

• The NIAMS-VCRC-V-PPRN DSMB oversees all projects
  – Efficient review and approval of new studies given familiarity with diseases and investigators
  – Shorter start-up since DSMB formed and processes in place
  – Independence well maintained
  – Institute retains control/oversight

• Model for Rare Diseases Research
  – High level of satisfaction by program officials, DSMB members, and investigators
  – Acceptance and appreciation by industry/funders
IRB of Record Within the V-PPRN

• The University of Pennsylvania has a progressive IRB willing to take the lead as the IRB of Record
• NIH and PCORI strongly urges this to happen
• Currently in place in three VCRC clinical trials conducted in collaboration with industry
• V-PPRN-Penn has substantial experience with this process
### VCRC & V-PPRN Protocols

#### Clinical Cohorts and Biospecimens

<table>
<thead>
<tr>
<th>Number</th>
<th>Protocol Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>02</td>
<td>Longitudinal Protocol for GCA</td>
</tr>
<tr>
<td>03</td>
<td>Longitudinal Protocol for TAK</td>
</tr>
<tr>
<td>04</td>
<td>Longitudinal Protocol for PAN</td>
</tr>
<tr>
<td>05</td>
<td>Longitudinal Protocol for GPA/MPA</td>
</tr>
<tr>
<td>06</td>
<td>Longitudinal Protocol for EGPA</td>
</tr>
<tr>
<td>06</td>
<td>Longitudinal Protocol for IA (proposed)</td>
</tr>
<tr>
<td>10</td>
<td>Genetic Repository (One-Time DNA)</td>
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</tbody>
</table>

#### Outcome Measures

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<th>Number</th>
<th>Protocol Description</th>
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<tbody>
<tr>
<td>15</td>
<td>Imaging Protocol for MRI and PET in TAK</td>
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<tr>
<td></td>
<td>OMERACT Vasculitis Working Group</td>
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<tr>
<td></td>
<td>Validation of PROMIS in Vasculitis</td>
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<tr>
<td></td>
<td>Development of an AAV-Specific PRO</td>
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<tr>
<td></td>
<td>International Classification of Function</td>
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#### Clinical Trials

<table>
<thead>
<tr>
<th>Number</th>
<th>Study Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>22</td>
<td>Pilot Study: Abatacept in Mild GPA</td>
</tr>
<tr>
<td>23</td>
<td>RCT: Abatacept for GCA/TAK (AGATA)</td>
</tr>
<tr>
<td>24</td>
<td>RCT: Plasma Exchange for AAV (PEXIVAS)</td>
</tr>
<tr>
<td>25</td>
<td>RCT: Rituximab vs. Azathioprine for AAV (RITAZAREM)</td>
</tr>
<tr>
<td>26</td>
<td>RCT: Tapering of Prednisone in GPA (TAPIR)</td>
</tr>
<tr>
<td>27</td>
<td>RCT: Abatacept for Mild/Mod GPA (ABROGATE)</td>
</tr>
<tr>
<td></td>
<td>Several others under development</td>
</tr>
</tbody>
</table>

#### Contact Registry/V-PPRN Studies

<table>
<thead>
<tr>
<th>Number</th>
<th>Study Description</th>
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</thead>
<tbody>
<tr>
<td>31</td>
<td>Reproductive Health in Vasculitis</td>
</tr>
<tr>
<td>32</td>
<td>Vasculitis Pregnancy Registry (V-PREG)</td>
</tr>
<tr>
<td>33</td>
<td>Vasculitis Illness Perception Study (VIP)</td>
</tr>
<tr>
<td>34</td>
<td>Vasculitis Educational Needs Study</td>
</tr>
<tr>
<td>35</td>
<td>Vasculitis Diagnostic Confirmation Study</td>
</tr>
<tr>
<td>36</td>
<td>Work Disability Survey (VascWorks)</td>
</tr>
<tr>
<td>37</td>
<td>Validation of PROMIS in Vasculitis</td>
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</table>
The V-PPRN/PCORnet Greatly Expands the Reach and Capabilities of the VCRC-VF Partnership
The V-PPRN is Research-Ready

The V-PPRN is able to conduct the following:

- Comparative Effectiveness Research
- Cross-Sectional & Longitudinal Studies
- Randomized Clinical Trials
How PPRNs Add to Industry-Partnered Clinical Studies

- Access to a large number of patients with target condition
  - Wide geographic catchment—well beyond usual centers
  - Rapid/efficient ability to select patients with specific criteria

- Capacity for collection of extensive clinical data for CER and RCTs
  - Links to CDRNs and electronic health records (EHR)
  - On-line portals to collect PROs and other types of data

- Established & organized collaborators
  - Immediate/inherent patient “buy-in” and collaboration
  - Imbedded group of expert investigators, data managers

- Ability to leverage PCORnet infrastructure and PPRN resources
  - Established use of single/central IRBs, DSMBs, data coordination

- Flexibility
  - Opportunities for novel designs of RCTs
    e.g.: screen/collect data on-line with treatment at selected CTSA sites
GRANT/FUNDING SUPPORT

- NIH
  - National Institute of Arthritis and Musculoskeletal and Skin Diseases
  - National Center for Advancing Translational Sciences
- pcori
- CTSA Clinical & Translational Science Awards
- National Heart, Lung, and Blood Institute
- National Institute for Health Research
- Immune Tolerance Network
- NHS
- Vascularitis Foundation

Companies:
- Genentech/Roche
- Bristol-Myers Squibb
- TerumoBCT
Questions/Comments
PCORI/Industry Workshop

March 30 – March 31, 2015

Russell Rothman MD MPP
Professor, Internal Medicine, Pediatrics, Health Policy
Director, Vanderbilt Center for Health Services Research
PI, Mid-South CDRN
Vanderbilt University
Key Milestones for Phase I

- Patient and stakeholder engagement
- Large scale enrollment
- Standardized data
- De-identified data sharing & regulatory processes
- Capability to implement clinical trials
- Efficient biospecimen banking
- Three specific cohorts populated
Our Mission

• Support comparative effectiveness and pragmatic research that is robust, efficient, and impactful.
Mid-South CDRN Has Local & National Reach

Vanderbilt Medical Center: hospitals, >100 clinics engaging 2 million patients

VHAN: 7 health systems, 34+ hospitals, 350+ clinics engaging >3 million patients

Greenway: 1600 clinics engaging 14 million patients
Vanderbilt Data & Research Tools

CLINICAL ENTERPRISE
- clinic notes/forms
- meds
- demographics
- labs
- registries
- vitals
- billing codes
- outpatient encounters

INFORMATICS METHODS DEVELOPMENT
- Examples: Natural Language Processing
- Pattern Recognition
- Automated Phenotyping
- Automated Study Recruitment Eligibility
- End User Research Integration Methods
- Anonymization and Reidentifiability

RESEARCH ENTERPRISE
- RECORD COUNTER
- SD SYNTHETIC DERIVATIVE
- SUBJECT LOCATOR
- RD RESEARCH DERIVATIVE

CLINICAL ENTERPRISE 
- Identified (RD)
- De-identified (SD)

RESEARCH DATA WAREHOUSE
Data Aggregation Across CDRN

EHR and Pt Data

VU RDW

RED cap

RD RC

CDM

PopMedNet

EHR and Pt Data

VHAN RDW

RED cap

RD RC

CDM

PopMedNet

EHR and Pt Data

Greenway RDW

CDM

PopMedNet

Shared Results
Additional Linkage for “Complete” Data

- Linkage to TN State Health Data (hospitalizations, birth/death data)
- Linkage to Tenncare Data
- Linkage to CMS Data (Virtual Research Data Center, RESDAC, CMMI data)
- Linkage to Vanderbilt Health Plan (Aetna) health data (claims and PBM data)
- Surescripts
- Linkage to VU Home Health Data
- Linkage to Nursing Home data
Novel Informatics Tools

- Tools for quickly running queries and analyzing electronic health data
- Tools for identifying and contacting patients
- New electronic consent process
- Expanded survey tools for collection of patient reported outcomes (via web/mobile platforms, automated phone, 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
Current Cohorts

• Weight Cohort
  • Electronic cohort of >300,000 at VUMC
  • Identifying cohort at Greenway
  • Surveyed 4800 patients to date

• CHD Cohort
  • Electronic cohort of >30,000 at VUMC
  • Surveyed 800 patients to date

• Sickle Cell Cohort
  • Identified ~ 400 families in TN
  • Surveyed > 40 families

Collaborations with St. Judes, Cincinnati, Northwestern
Obesity Cohort

PCORI Pre-screening

What is your first name? [ ]
What is your last name? [ ]
What is your date of birth? [ ] [ ] [ ]
In the past 5 years, have you received treatment at a Vanderbilt health clinic or hospital? [ ]
SCREENER: Which study are you screening for? [ ]

Determine Eligibility

Email blast to >10,000 Vanderbilt patients with over 30% response rate!
Stakeholder Engagement

- Stakeholders at Oversight Committee
- Stakeholder Advisory Council meeting
- Community Engagement Studios
- Stakeholder Surveys
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.
Services Provided

- Development and validation of computable phenotypes
- Prep-to-research and simple queries of CDM
- Observational research of de-identified data
- Observational research of identifiable data
- CER and Pragmatic interventions at patient or system (clinic, hospital, etc) level
- Informatics, IRB, Regulatory support
- Access to patients and sites in CDRN
- Stakeholder Engagement
Collaborations

• Over 30 collaborations to date
  • Local investigator initiated grants
    • PCORI pragmatic trials x 4
    • NIH and AHRQ Grants
    • CDC grant (Autism)
  • Academic centers
    • UAB (EDGE Trial)
    • Duke (Transform Trial)
    • Wisconsin/Harvard (Flu Vaccine Study)
  • Industry
    • Diabetes trials
  • PPRNS (CCFA, AR-POWER, SAP-CON, Health eHeart, ABOUT, Vasculitis)
  • PCORI funded trials in Coronary Heart Disease and Obesity
Rapid Queries for “Pre-Research”
Observational Research

• Identify patients electronically
• Perform analyses based on robust electronic data
• Contact patients for survey or cohort studies through electronic means, face-to-face, or phone.
• Novel tools for data collection (mobile tools, patient portal, etc)
Intervention Studies

• Rapid identification of eligible patients
• Electronic consent processes
• Studies embedded into clinical care (inpatient and/or outpatient)
• Can track long-term outcomes through patient surveys and extraction of electronic data
Advantages of PCORnet Research

• Access to robust electronic health record data and claims data
• Informatics tools to rapidly identify, contact, recruit, and survey patients
• Ability to embed research into clinical care
• Ability to collect long-term outcomes
• Rapid research at modest costs
Questions
Distributed Data Model

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

PCORNet

mid-south clinical data research network
Q&A on PCORnet Structure, Plans, and Network Activities
Break
Open Discussion, Continued Q&A
PCORnet’s Demonstration Projects

Rich Platt, MD, MSc, PCORnet Executive Committee
Adrian Hernandez, MD, MHS, PCORnet Executive Committee
PCORnet’s goal

Conduct widely generalizable observational and interventional research quickly and at low cost
Guiding principle: Make research easier

- Analysis ready data
  - Standard format
  - Harmonized definitions
  - Quality checked in advance
- Reusable analysis tools
- Efficient clinical trial enrollment and follow up mechanisms
- Simple, pragmatic studies integrated into routine care
- Administrative simplicity
Goal of demonstration observational and interventional studies

- Address questions important to patients and clinicians that require multi-site evaluation
- Facilitate collaboration between PCORnet’s networks
- Guide further development of PCORnet policies, procedures, infrastructure
- Evaluate the readiness of PCORnet’s data and networking capabilities
- Assess PCORnet’s privacy protecting data infrastructure and analysis capabilities
- Develop efficient methods for identifying potential clinical trial participants, reaching out to them, enrolling, and obtaining follow up
- Assess end-to-end functionality, from protocol development through implementation, analysis, and reporting
Observational Studies in PCORnet’s Weight Cohort
PCORnet’s weight cohort

- Entire PCORnet CDRN population
- The Weight Cohort: Weight and height/length measurements
- Weight-related studies
Short- and Long-Term Outcomes related to Bariatric Surgery
There is an ongoing major shift in bariatric procedures in the United States

N=43,732, Michigan, Reames, JAMA 2014
Outcomes of Bariatric Surgery (in development)

Compare three bariatric surgical procedures
- Roux-en-Y gastric bypass
- Sleeve gastrectomy
- Adjustable gastric banding

Outcomes under consideration:
- Weight loss and regain
- Obesity-related outcomes
  - Resolution of type 2 diabetes
  - Incidence or recurrence of type 2 diabetes
- Adverse outcomes: hospitalization, reoperation, death
Potential Secondary Aim

Engage patient communities through surveys, interviews, focus groups, etc. to

- Elicit patient preferences around the risks and benefits of the study treatments
- Collect patient-reported outcomes meaningful to patients with obesity
Principal Investigators

- David Arterburn, clinical investigator [lead PI]
  - Bariatric surgery researcher

- Kathleen McTigue, clinical investigator
  - Obesity researcher

- Neely Williams, patient investigator
  - Community engagement leader
  - Bariatric surgery patient
Short- and Long-Term Effects of Antibiotics on Childhood Growth
Association of Antibiotics in Infancy with Early Childhood Obesity

Short- and Long-Term Effects of Antibiotics on Childhood Growth

Compare different antibiotics used during the first 2 years of life

Outcomes

- Weight-related outcomes during 3rd to 5th years of life
  - Body mass index and
  - Risk of being overweight or obese
- Growth trajectories through preschool ages
Antibiotic Use and Childhood Obesity: Unresolved Issues (in development)

Is there a sensitive exposure age? If yes, does it matter
- How large the exposure is (#doses)?
- Broad v. narrow spectrum?
- Class of antibiotic?

Timing of outcome?
- Early v. late
- Growth trajectories could help

Is there potentiation by chronic steroid use?

How much does confounding play a role in observed effects?

To what extent will information about this association change practice?
Potential Secondary Aim

Investigate attitudes of pediatric clinicians and parents of infants/toddlers regarding

- Potential impact of information about obesity risk on antibiotic prescribing
- How the risk of obesity compares with other potential risks to individuals (e.g., allergy) or society (e.g., resistance) in relation to antibiotic decision-making
Principal Investigators

Matt Gillman, clinical investigator, lead PI
- Research focus on early life prevention of chronic disease
- Lead, PCORnet Obesity Task Force

Chris Forrest, clinical investigator
- Academic investigator in childhood obesity research for the Healthy Weight Program

Douglas Lunsford, patient investigator
- Parent Member, Nationwide Children’s Hospital Healthy Weight Program
Guiding principle: Make research easier

- Analysis ready data
  - Standard format
  - Harmonized definitions
  - Quality checked in advance

- Reusable analysis tools

- Administrative simplicity

- Simple, pragmatic studies integrated into routine care
Requirements for Network Participation in Observational Studies

- Work with a single IRB of record (1 per project)
- Complete contracting and data use agreements quickly
- Have analysis ready data (Common Data Model v2.1)*
- Use PCORnet’s networking querying capabilities*
- Execute supplied QC and analytical programs (SAS) without modification*
- Share relevant data and documentation

* Clinical data research networks
Requirements for Network Participation in Observational Studies

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- Share relevant data and documentation

*Clinical data research networks*
PCORnet Common Data Model v2.1

**DEMOGRAPHIC**
- PATID
- BIRTH_DATE
- BIRTH_TIME
- SEX
- HISPANIC
- RACE
- BIOBANK_FLAG

**VITAL**
- PATID
- ENCOUNTERTID (optional)
- MEASURE_DATE
- MEASURE_TIME
- VITAL_SOURCE
- HT
- WT
- DIASTOLIC
- SYSTOLIC
- ORIGINAL_BMI
- BP_POSITION

**ENCOUNTER**
- PATID
- ENCOUNTERTID
- SITEID
- ADMIT_DATE
- ADMIT_TIME
- DISCHARGE_DATE
- DISCHARGE_TIME
- PROVIDERID
- FACILITY_LOCATION
- ENC_TYPE
- FACILITYID
- DISCHARGE_DISPOSITION
- DISCHARGE_STATUS
- DRG
- DRG_TYPE
- ADMITTING_SOURCE

**LAB_RESULT**
- PATID
- ENCOUNTERTID (optional)
- LAB_NAME
- SPECIMEN_SOURCE
- LAB_LOINC
- STAT
- RESULT_LOC
- LAB_PW
- LAB_PW_TYPE
- LAB_ORDER_DATE
- SPECIMEN_DATE
- SPECIMEN_TIME
- RESULT_DATE
- RESULT_TIME
- RESULT_QUAL
- RESULT_NUM
- RESULT_MODIFIER
- RESULT_UNIT
- NORM_RANGE_LOW
- MODIFIER_LOW
- NORM_RANGE_HIGH
- MODIFIER_HIGH
- ABN_IND

**CONDITION**
- PATID
- ENCOUNTERTID (optional)
- REPORT_DATE
- RESOLVE_DATE
- CONDITION_STATUS
- CONDITION
- CONDITION_TYPE
- CONDITION_SOURCE

**DIAGNOSIS**
- PATID
- ENCOUNTERTID
- ENC_TYPE (replicated)
- ADMIT_DATE (replicated)
- PROVIDERID (replicated)
- DX
- DX_TYPE
- DX_SOURCE
- PDX

**PROCEDURE**
- PATID
- ENCOUNTERTID
- ENC_TYPE (replicated)
- ADMIT_DATE (replicated)
- PROVIDERID (replicated)
- PX_DATE
- PX
- PX_TYPE

**ENROLLMENT**
- PATID
- ENR_START_DATE
- ENR_END_DATE
- CHART
- ENR_BASIS

**DISPENSING**
- PATID
- RX_DATE
- NDC
- RX_SUP
- RX_AMT

**PRESCRIBING**
associated with healthcare delivery

Data captured from healthcare delivery, direct encounter
Data Quality Assurance review process

1. Perform Data Update
2. Execute data quality program package
3. Review output; identify and resolve issues
4. Deliver summary output to MSOC
5. Review #1 of data quality output
6. Prepare initial report of findings
7. Review #2 of data quality output
8. Annotate initial report of findings
9. Review and finalize report
10. Review report; resolve issues, respond to MSOC
11. Review Data Partner’s response to report; send additional questions if needed
12. Approve Data Update

Data Partner
MSOC
Glycosylated hemoglobin (HBA1c) units

| % HEMOGLOBIN | %T.HGB | % TL HGB | % HGB PERCENT |
| % HB | %T.Hgb | % OF TOTAL | Percent |
| % OF T | % NGSP | % of Hgb | HbA1c% |
| % A1C | % TOTAL HGB | % of total | %HbA1c |
| MG/DL | % NGSP | %THb | % A1C |
| % A1C | % TOTAL HGB | %NGSP | Blank |
| NULL | % Hgb | mmol/mol | g/dL |
| % THb | | |

Raebel  Pharmacoepi and Drug Safety 2014; DOI:10.1002
Data Visualization: After 7th refresh, partner A
Data Visualization: After 8\textsuperscript{th} refresh, partner A

New data problem in old time period
Data Visualization: After 8th refresh fixed
PCORnet Operational Model

**Funders:**
- PCORI
- NIH
- Industry, patient organizations etc.

**Research queries**

- Pre-research queries (from funders)
- Coordinating Center
- Investigators

**Pre-research queries (from investigators)**

**Independent Queries**

- Query distributed to network
- Secure Portal
- DataMart

**Coordinating Center**

- PCORnet investigators
- PPRN
- CDRN

**PCORnet Operational Model Diagram**

- Q Question submitted
- C Question converted to query
- R Response
- P Query Processed
1. User creates and submits query (a computer program)

2. Individual CDRNs/PPRNs retrieve query

3. CDRNs/PPRNs review and run query against their local data

4. CDRNs/PPRNs review results

5. CDRNs/PPRNs return results via secure network

6. Results are aggregated
Aspirin Dosing: A Patient-Centric Trial Assessing Benefits and Long-term Effectiveness (ADAPTABLE) Trial

PCORnet’s First Proposed Pragmatic Clinical Trial
What if a choice made over the counter prevented...

19,000 Deaths & Heart Attacks
Or
Prevented Thousands of Bleeds Annually in the United States
Aspirin: A “wonder” drug

- Proven clinical benefit in reducing ischemic vascular events
- Cost effective
- Benefit with combination antiplatelet therapies

But there are issues:

- Emerging evidence for dose modifiers (ASA resistance, genetics, P2Y12 inhibitors)
- Equal efficacy across patients?
- Intolerance

Most effective dose uncertain
Risks of aspirin therapy

**ADVERSE REACTIONS**

<table>
<thead>
<tr>
<th>MMR VACCINE</th>
<th>ASPIRIN</th>
</tr>
</thead>
<tbody>
<tr>
<td>SERIOUS ALLERGIC REACTION</td>
<td>INTRACEREBRAL HEMORRHAGE</td>
</tr>
<tr>
<td>LESS THAN 1 OUT OF 1 MILLION DOSES</td>
<td>12 EVENTS PER 10,000 PEOPLE</td>
</tr>
</tbody>
</table>

**MEASLES OUTBREAK**

102 CASES REPORTED IN 14 STATES
Aspirin Dosing: Equipoise?
Distribution of aspirin dosing at discharge

- **81 mg**: 36%
- **325 mg**: 61%
- **162 mg**: 3%
- **Other**: 0.01%

Hall et al. Circulation Cardiovascular Quality and Outcomes 2014
High (25 -fold) Variation Across Hospitals on Use of High Dose (325mg) Aspirin

>440 US Hospitals
Main objectives of the ADAPTABLE Trial

- To compare the effectiveness and safety of two doses of aspirin (81 mg and 325 mg) in high-risk patients with coronary artery disease.
  - **Primary Effectiveness Endpoint:** Composite of all-cause mortality, nonfatal MI, nonfatal stroke
  - **Primary Safety Endpoint:** Major bleeding complications

- To compare the effects of aspirin in subgroups of patients:
  - Women vs men
  - Older vs younger
  - Racial and ethnic minorities vs. whites
  - Diabetics vs. nondiabetics
  - Chronic kidney disease (CKD) vs. not
  - Internet users vs. not
  - P2Y12 inhibitor users vs. not

- To develop and refine the infrastructure for PCORnet to conduct multiple comparative effectiveness trials in the future
ADAPTABLE Leadership

- Robert Harrington, clinical investigator [Study Chair]
  - Cardiovascular trialist

- Russell Rothman, clinical investigator [Study Co-Chair]
  - Health services researcher

- Matthew Roe, clinical investigator [CC PI]
  - Cardiovascular trialist

- Sana Al-Khatib, clinical investigator [CC-PI]
  - Cardiovascular health services researcher

- Bray Patrick-Lake, patient investigator
  - Community engagement leader
  - ADAPTORs leader
Study design

Patients with known coronary artery disease (MI, or CAD or Revasc) + ≥1 “enrichment factor”*

Identified through EHR/direct pt. consenting in clinics and hospitals through CDRNs/PPRN (PPRN pts. would need to connect through a CDRN to participate)

Pts. contacted electronically with trial information and eConsent; treatment assignment will be provided directly to patient

ASA 81 mg QD

ASA 325 mg QD

Electronic F/U Q 4 months; supplemented with EHR/CDM/claims data

Duration: Enrollment over 24 months; maximum f/u of 30 months

Primary Endpoint: Composite of all-cause mortality, nonfatal MI, nonfatal stroke

Primary Safety Endpoint: Major bleeding complications

*Enrichment factors
- age > 65 years
- creatinine > 1.5
- diabetes
- known 3-vessel coronary artery disease
- current cerebrovascular disease and/or peripheral artery disease,
- known ejection fraction <50%
- current smoker
Trial Logistics: Leveraging PCORnet Infrastructure
Screening, Enrollment & Data Flow

**SCREENING**
Site-specific screening processes and data
Includes crosswalk between PATID and STUDYID

- ENROLLED participants are populated in CDM STUDY table
- CDRN’s PCORnet Datamart
  - Common Data Model (CDM), including STUDY table

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

- Portal sends patient-level status reports to site
- Portal data transfers, including all study variables
  - PCORnet query to identify and send study data (via PopMedNet)

**STATUS REPORTING**
- All participants
- Blinded

**ADAPTABLE STUDY DATABASE**
- Participants with status of ENROLLED
- Unblinded

Potential External Data Sources
- National Death Index (NDI)
- CMS
- Sentinel
Computable phenotype

History of CAD
• Past MI
  OR
• Past cath showing significant CAD
  OR
• Revascularization (PCI/CABG)

At least one of the following:
• age > 65 years
• Creatinine > 1.5
• Diabetes,
• Known 3 vessel coronary artery disease
• Current cerebrovascular disease and/or peripheral artery disease
• Known ejection fraction <50%,
• Current smoker

Getting consent
Getting Informed Consent

Clinician reviews and decides on participation

Email to potential patient with trial introduction and link to consent

Letter to potential pt. with trial intro and paper consent for non-Internet accessible pt.

Consent Form Contacts:
- Local contact info for any site issues
- Local contact info for withdrawal from trial
- Contact info for questions about the trial
- Contact info for reporting adverse events

Randomization & ASA dose assignment
Centralized follow-up

**ADAPTABLE Enrollee**

**Baseline Data**

**DCRI FOLLOW-UP**
- Patient Reported Outcomes
- Medication use
- Health outcomes

**HeH FOLLOW-UP**
- Patient Reported Outcomes
- Medication use
- Health outcomes

**PCORnet Coordinating Center FOLLOW-UP**
- Via Common Data Model
- Longitudinal health outcomes

**CMS Virtual Data Warehouse FOLLOW-UP**
- Longitudinal health outcomes
Meeting Objectives of PCORnet: ADAPTABLE
Achieving a single functional research network

- **Create** infrastructure, tools, and policies to support rapid, efficient comparative effectiveness research

- **Utilize** multiple electronic health records, insurance claims data, data reported directly by patients, and other data sources

- **Engage** patients, clinicians, and health system leaders throughout
Summary

- Atherosclerotic CV disease is a major cause of death and disability.
- Getting the dose of aspirin right could save up to tens of thousands of lives or heart attacks in the US alone annually (or prevent thousands major bleeding episodes).
  - And multiple times that number globally
- The ADAPTABLE Research Community & “ADAPTORS” will be pioneers working together
  - To solve the challenge and demonstrate the value of a reusable infrastructure
  - Launch a new era for pragmatic clinical trials to answer questions with high impact on population health
PCORnet’s advantages

- Many networks – large pool of engaged participants, patients, practice settings, investigators
- Robust distributed data network capable of supporting a wide array of observational and interventional studies
- Ability to supplement routinely collected electronic health data with patient reported information
- Reusable clinical trial infrastructure
- Administrative simplicity:
  - Single IRB of record for each demonstration study
  - Uniform contracting mechanism
  - Centralized data collection and follow-up
Questions?
Reports from Breakout Sessions: Opportunities, Areas for Further Exploration
Open Discussion

pcornet
The National Patient-Centered Clinical Research Network
Observations and Next Steps

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The National Patient-Centered Clinical Research Network
Closing Remarks and Adjournment