Real World Data for Clinical Research: A PCORnet Workshop with the Devices and Diagnostics Industry

March 31, 2015

9:00 AM – 5:00 PM

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The National Patient-Centered Clinical Research Network

Internet

- Connect to SSID: **HYATT-MEETING**
- Your Conference Code: **PCORI15**

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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

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Afternoon Agenda

- 12:00 – Lunch Presentation: PCORnet in Use for Interventional and Observational Studies
- 1:00 – Breakout Sessions
  - Registry-Related Research
  - Other Topics
- 3:00 – Break
- 3:20 – Reports from Breakout Sessions
- 4:10 – Open Discussion
- 4:45 – Observations and Next Steps
- 5:00 – Closing Remarks and Adjournment

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PCORnet in Brief

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The National Patient-Centered Clinical Research Network

Enabling PCORnet Collaborations with Industry

Rachael Fleurence, PhD

Program Director CER Methods and Infrastructure, PCORI

Industry Workshops March 30&31 2015

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The National Patient-Centered Clinical Research Network

Overview

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

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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

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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"

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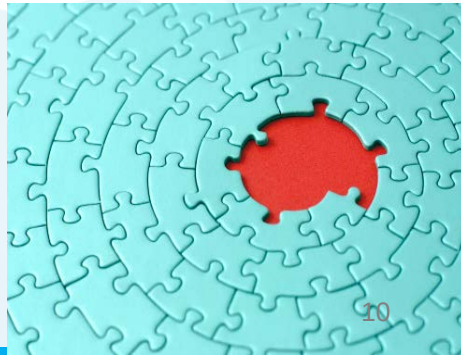
Touch points between PCORnet and industry

- 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



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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

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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

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Parts of PCORnet are still under construction

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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

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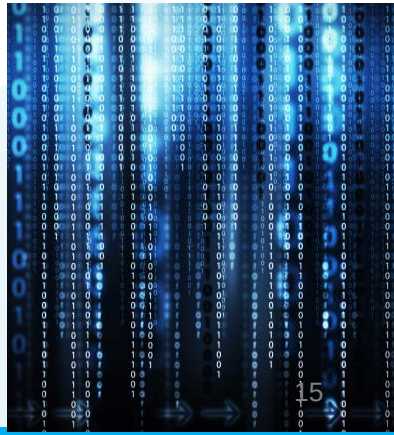
DataMarts leveraging the CDRNs Electronic Health Data

- 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



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CDRNs Disease Cohorts

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

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

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PCORnet Phase I: 2014 – 2015

2014

- **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**

2015

- ►Governance Policies Under Review
  ►Common Data Model 2.0 Released
- **Jan** ►Aspirin Clinical Trial Review
- **Apr** ►Observational Weight Cohort Application Due
- **May** ►PPRN demos application due
- **July** ►Strategic planning with key funding partners
- **Sep**
- **Nov** ► Phase II Begins
  ►Partnerships with key external funders begin

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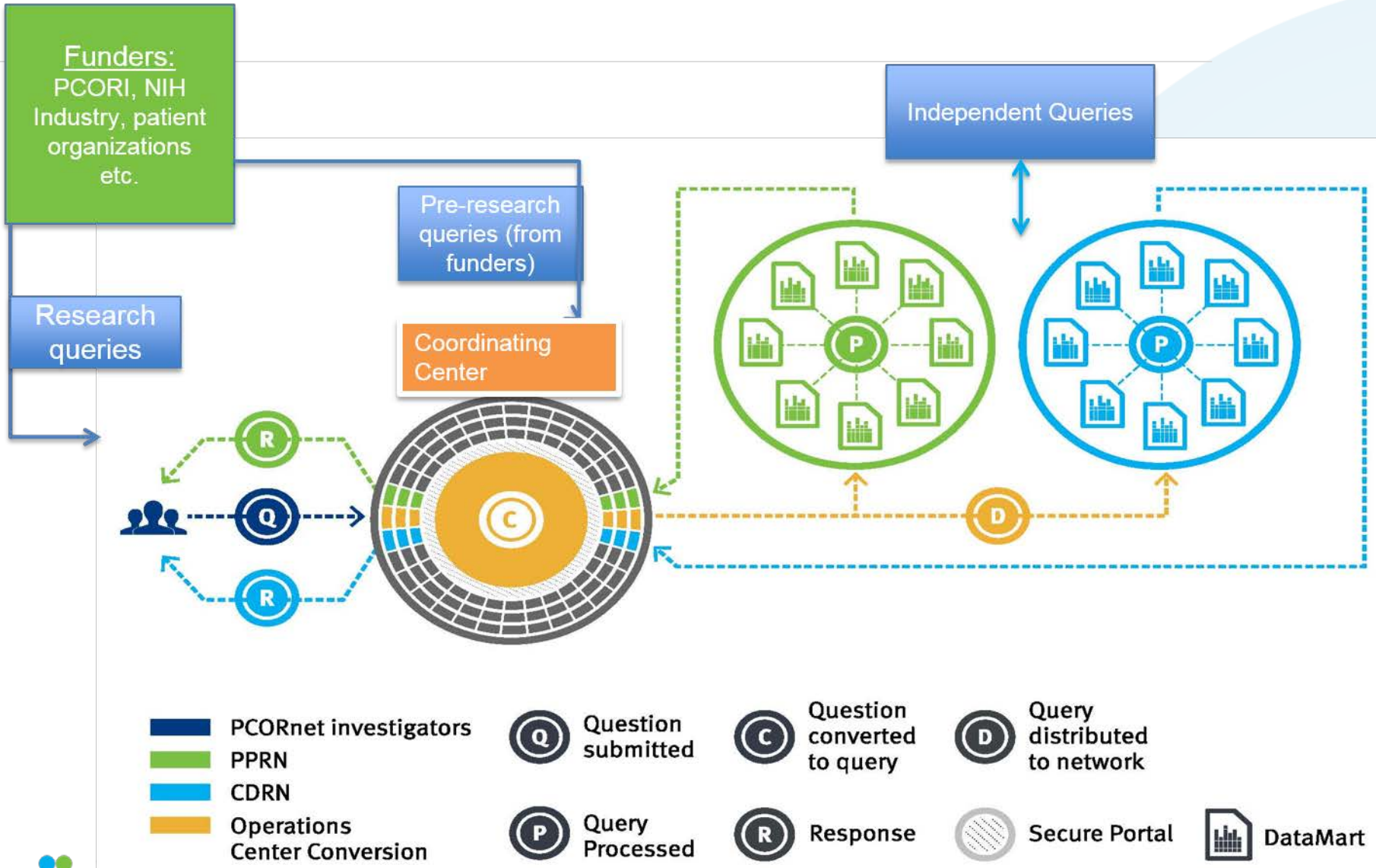
PCORnet uses a privacy protecting distributed data network



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:

Phase II Year	Pre-Research Questions per CDRN	Observational Studies per CDRN	Clinical Trials per CDRN
Year 1	50	10	5
Year 2	100	10	5
Year 3	200	20	5

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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

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“PCORnet Study” Designation: Level of Requirements

	Requirements for “PCORnet Study” Designation	Requirements for using PCORnet without “PCORnet study” designation	Pre-Research Queries
PCORI-funded	High Requirements	High Requirements	Low Requirements
Externally-funded	High Requirements	Lower Requirements	Low Requirements

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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

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Informational Slides

Requirements for “PCORnet study” status by type of funder

	Summary of Requirements for PCORnet Study Designation	Summary Requirements for using PCORnet without PCORnet study designation	Pre-Research Queries *
PCORI-funded	Patient-centeredness; Patient engagement; Advisory Panels; Methodology Standards; Peer review and release of findings; Open Science; no CEA (PCORI requirements) A site PI is included in study for studies involving patient level data for that participating CDRN or PPRN (CDRN/PPRN requirements)	Not applicable (all PCORI-funded research through PCORnet must qualify for a PCORnet study designation)	No cost-effectiveness questions Patient-centered question
Externally-funded	As above, except for loosening PCORI requirements that involve PCORI resources (e.g. peer review)	Lower requirements. Requirement for peer-review for RCTs under discussion.	No cost-effectiveness questions Patient-centered question

*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

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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

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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

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Patient Engagement in PCORnet

Sue Sheridan, MBA, MIM, DHL

Director, Patient Engagement

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The National Patient-Centered Clinical Research Network

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

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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.

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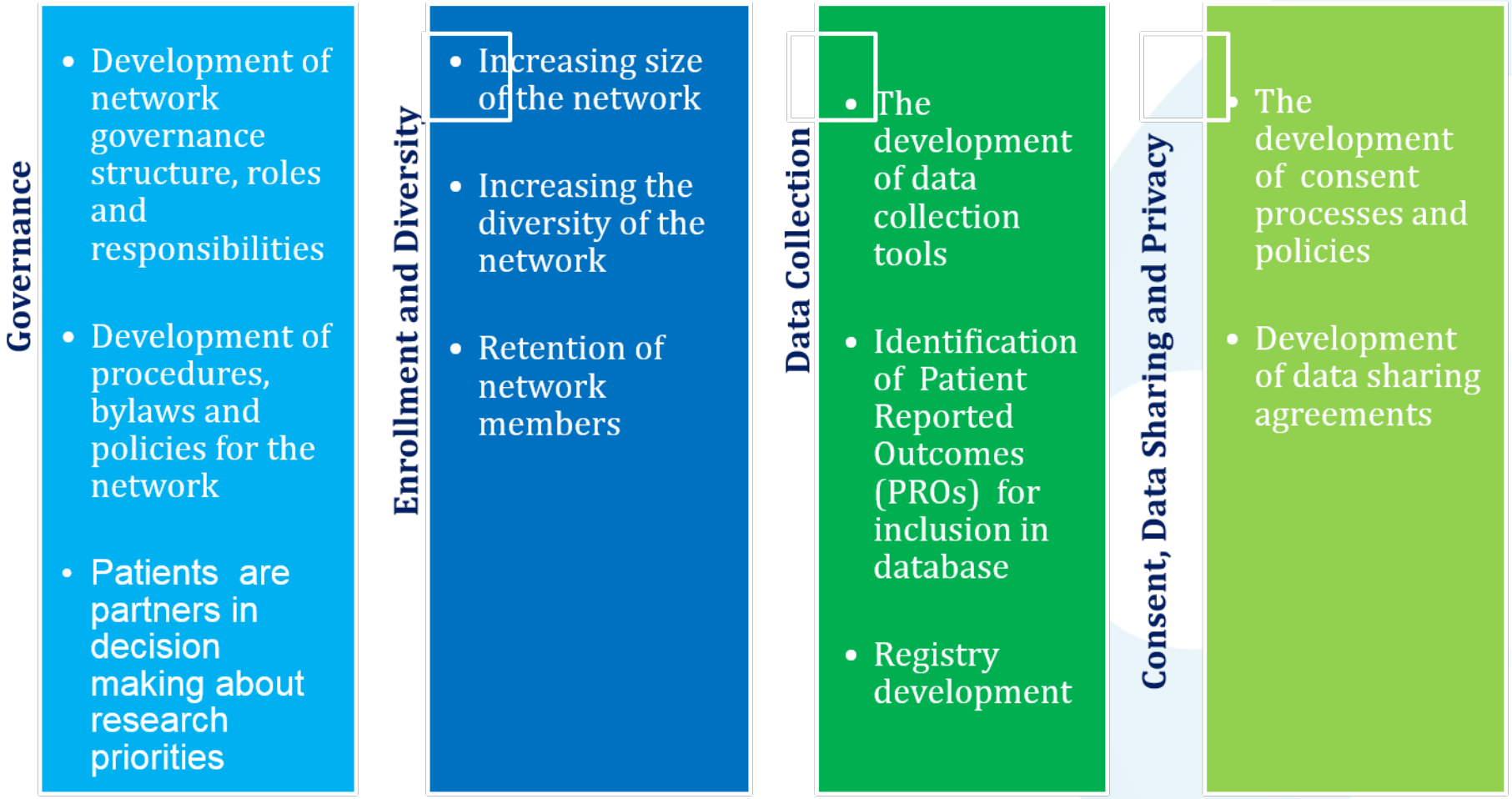
Patient Engagement in PCORnet Network Partners



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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

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Patient-Centeredness and Patient and Stakeholder Engagement In PCORnet Studies

- Patient-Centeredness:

  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?

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Elements of Patient Engagement in PCORnet Study

Planning the Study

Conducting the Study

Disseminating the Study Results

PCOR Engagement Principles

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Planning the Study

1. PLANNING THE STUDY: Describe how patient and stakeholder partners will participate in study planning and design.

Potential activities include:

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

partners in the planning of your study, and include key guidance on study design offered by your patient and stakeholder partners.

- Discuss how the engagement of patients and other stakeholders helped to refine your study's research question, outcomes, and comparators.

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.*

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Conducting the Study

2. CONDUCTING THE STUDY: Describe how patient and stakeholder partners will participate in the study conduct.

Potential activities include:

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.*

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Patient Powered Research Networks

Sharon F. Terry, MA
CEO, Genetic Alliance

Patient-Centered Outcomes Research Institute

Adrenoleukodystrophy
Adult congenital heart disease
Aicardi syndrome
Alpha-1 antitrypsin deficiency (Alpha-1)
Alström syndrome
ANCA-associated vasculitis
Ankylosing spondylitis
Arthritis
Arylsulfatase A deficiency
Atrial fibrillation
Austin disease
Becker muscular dystrophy
Behçet's disease
Bipolar disorder
Breast cancer
Bronchiectasis
CDKL5 disorder
Celiac disease
Central nervous system (CNS) vasculitis
Childhood systemic lupus erythematosus (childhood SLE)
Chronic bronchitis
Chronic obstructive pulmonary disease
Churg-Strauss syndrome (CSS)
Cogan's syndrome
Cogan-type oculomotor apraxia
Crohn's disease
Cryoglobulinemic vasculitis
Dekaban-Arima syndrome
Depression
Dravet syndrome
Duchenne muscular dystrophy
Dup15q syndrome
Dyskeratosis congenita
Emphysema
Eosinophilic granulomatosis with polyangiitis (EGPA)
Familial pulmonary fibrosis
Focal segmental glomerulosclerosis (FSGS)
Gaucher disease
Giant cell arteritis (GCA)
Granulomatosis with polyangiitis (GPA, Wegener's)
Heart disease
Henoch-Schonlein purpura (HSP, IgA vasculitis)
Hepatitis
High blood pressure
High cholesterol
Hypocomplementemic vasculitis
Hypothalamic hamartoma
Inflammatory breast cancer
Inherited bone marrow failure
Jacobs syndrome
Joubert syndrome
Juvenile idiopathic arthritis (JIA)
Juvenile nephronophthisis
Juvenile rheumatic disease
Klinefelter syndrome
Large vessel vasculitis
Lennox-Gastaut syndrome
Lupus
Lyme disease
Meckel-Gruber syndrome
Membranous nephropathy (MN)
Metachromatic leukodystrophy (MLD)
Microscopic polyangiitis (MPA)
Minimal change disease (MCD)
Mucosulfatidosis
Multiple sclerosis
Multiple sulfatase deficiency
Musculoskeletal disorders
Nephrotic syndrome
Ohtahara syndrome
Osteoporosis
Ovarian cancer
PCDH19 female epilepsy
Inflammatory bowel disease
Phelan-McDermid syndrome
Polyarteritis nodosa (PAN)
Primary immunodeficiency diseases
Primary nephrotic syndrome
Pseudoxanthoma elasticum (PXE)
Psoriatic arthritis
Refractory (non-reversible) asthma
Rheumatoid arthritis
Saposin B deficiency
Scleroderma
Senior-Loken syndrome
Sex chromosome aneuploidy
Sleep apnea
Spondyloarthritis
Sudden arrhythmia death syndrome (SADS)
Takayasu's arteritis (TAK)
Telomere biology disorder/syndrome
Trisomy X
Tuberous sclerosis complex
Ulcerative colitis
Urticarial vasculitis
Varadi-Papp syndrome
Vasculitis
X and Y chromosome variations

18 PPRN
Covering ~100 conditions
Participant, Clinician and Researcher-led

Elizabeth and Ian diagnosed with pseudoxanthoma elasticum (PXE)

1994

2015

Elizabeth:
Teach for America

Ian:
Organic Farmer

Needles in Haystacks

…the haystack is made of needles.

Terry SF, Shelton R, Biggers G, Baker D, Edwards K. The haystack is made of needles. Genet Test Mol Biomarkers 2013;17:175-7.

Engaging Research Participants

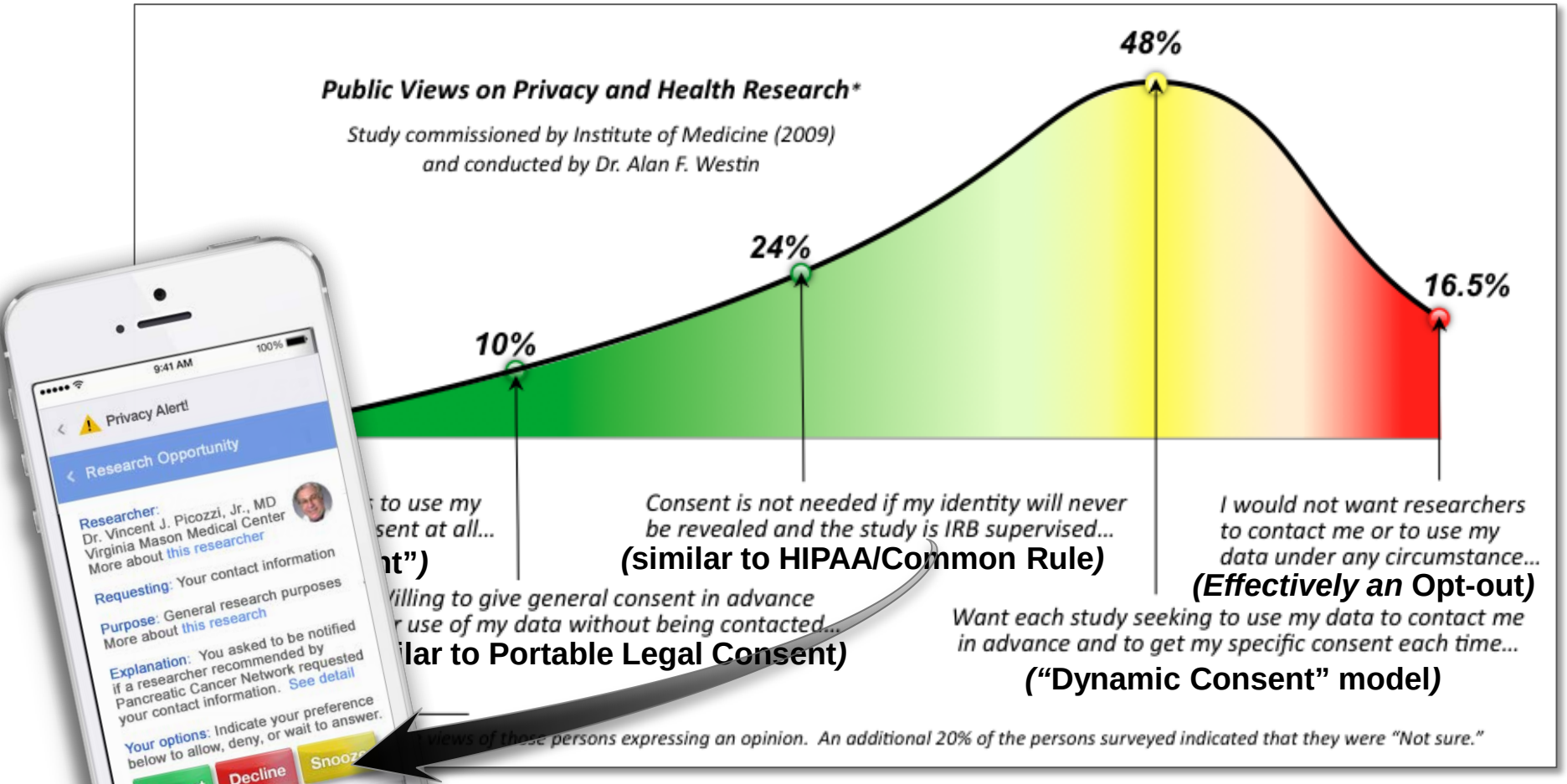
- Partners
  - Not patients, co-investigators
  - Not ‘at the table’, planning the meal
- Frictionless
  - In communities, with community leaders
  - Where we live and play, in our path
- Relevance/Value/Benefit
  - Our questions, meet needs
  - Results are visible and tangible
  - Solve my problems (kid’s immunizations to school, mother’s health record to Minute Clinic)
- Beyond advocates and advocacy to affinity

Community Engaged Network for All

Genetic Alliance (29 yr old advocacy umbrella) as lead

- 11 Disease Advocacy Organizations (chosen from dozens of app)
  - Alström Syndrome International
  - AXYS (sex chromosome differences, Klinefelter's, Turners)
  - Celiac Disease Foundation
  - Dyskeratosis Congenita Outreach
  - Inflammatory Breast Cancer Research Foundation
  - Hepatitis Foundation International
  - Joubert Syndrome and Related Disorders Foundation
  - LymeDisease.org
  - MLD Foundation (metachromatic leucodystrophy)
  - National Gaucher Foundation
  - PXE International (pseudoxanthoma elasticum)
- 2 Universities
  - University of California, San Francisco
  - University of California, Davis
- 1 Technology Partner
  - Private Access, Irvine, CA

Platform for Engaging Everyone Responsibly (PEER)



... Adjust **dynamic and granular** settings as values and priorities change over time

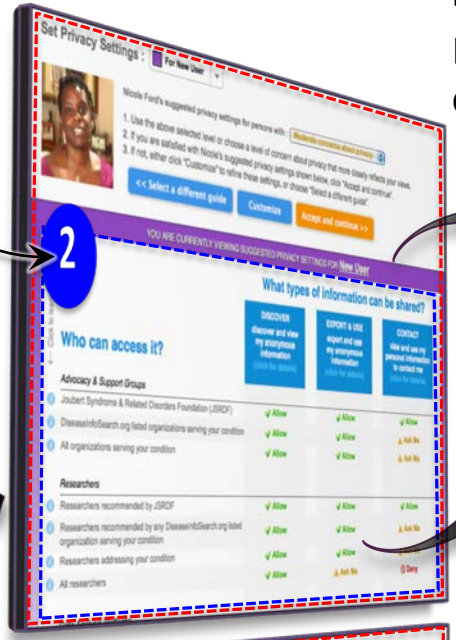
PEER: Creating an environment of trust

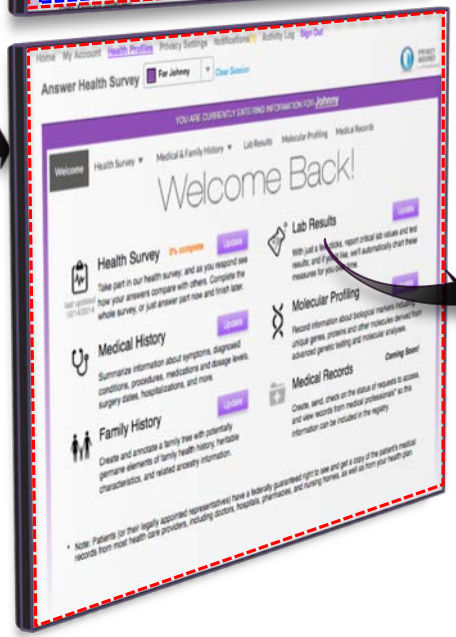
Privacy Set Up:

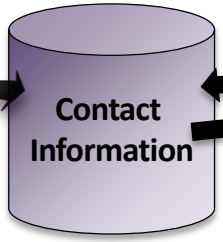
Individual registers and sets privacy preferences using PrivacyLayer®

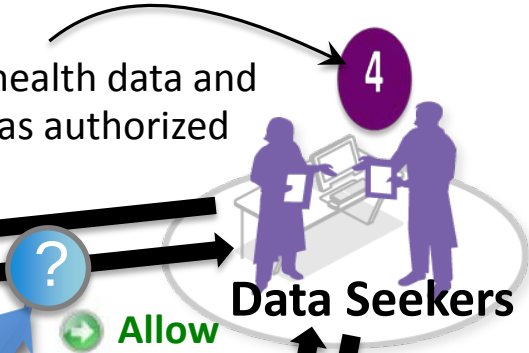
Data Access:

Data Seekers access health data and contact information, as authorized



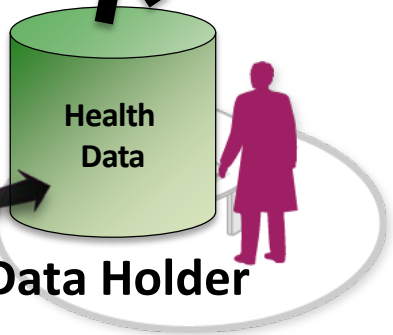






Allow
Prohibit
Ask Me

Allow
Prohibit
Ask Me



Set-up:

Trusted organization simply embeds a PEER entry point into its website

Data Capture (or Order):

Individual provides health data through survey questions (or, in future, from their EHR)

Set privacy settings

PRIVACY ASSURED with PrivateAccess

Privacy settings have not been set for this profile!

▼ Select **Bob's** preferred privacy settings...

What's this?

Sharon suggested settings for persons with: Low concerns about privacy

1. Choose a level of concern about privacy that more closely reflects your views.
2. To accept Sharon's suggested privacy settings shown below, click 'Accept and continue'.
3. If not, either click 'Customize' to refine these settings, or 'Go Back' to choose a different guide.

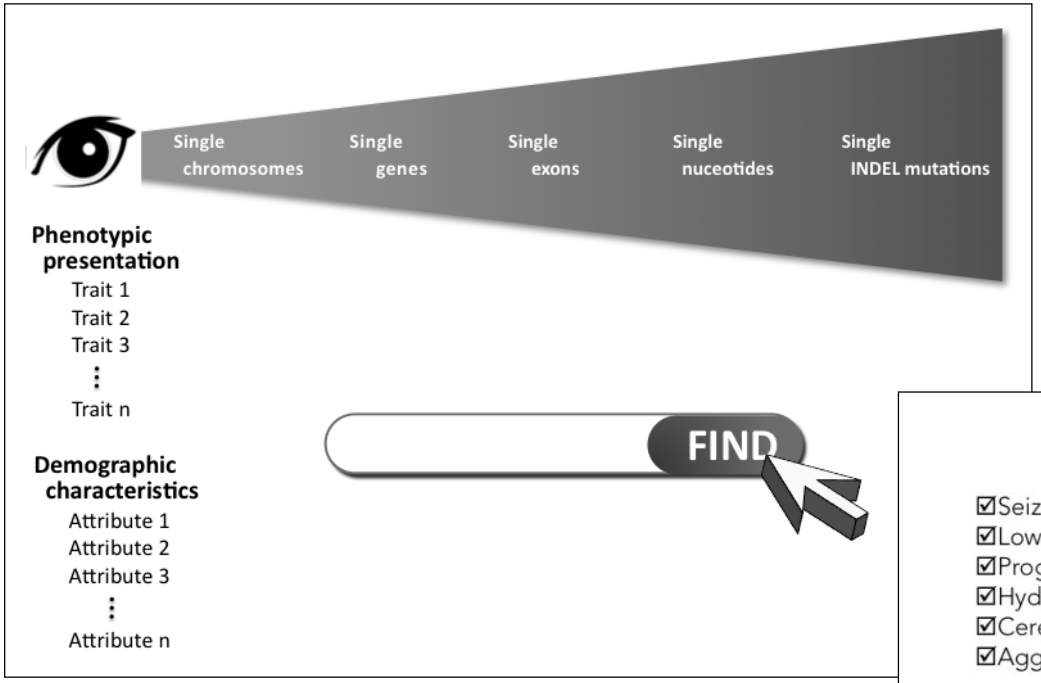
<< Go Back | Customize | Accept and continue >>

Who can access your data and for what purpose... Click any column or row name for more information	Find/Analyze except for name and contact details	Export/Link except for name and contact details	Get Contact find, view, use and export contact details
▼ PanCAN			
Pancreatic Cancer Action Network (PanCAN)	✓ Allow	✓ Allow	✓ Allow
Researchers recommended by PanCAN	✓ Allow	✓ Allow	✓ Allow
▼ Other Researchers			
Researchers addressing your condition	✓ Allow	✓ Allow	✓ Allow
All researchers	✓ Allow	⚠ Ask Me	⚠ Ask Me
▼ Data Analysis Platforms			
Patient-Centered Outcomes Research Network	✓ Allow	⚠ Ask Me	NA
Newly-Released Data Analysis Platforms	⚠ Ask Me	⚠ Ask Me	NA

<< Go Back | Customize | Accept and continue >>

▶ Choose a guide or manually create **Bob's** privacy settings...

Matchmaking
on Genotype and Phenotype



You (your child) match with:

☑Seizures, grand mal, age 5 onset
☑Low tone
☑Progressive cognitive disability
☑Hydrocephalus
☑Cerebral palsy
☑Aggressive behavior

Filters:
☑Age 10 to 20
☑United States

Found: 24 individuals
17 have enabled sharing (ALLOW), 7 have indicated ASK ME
4 with exomes, 1 with genome, 15 extensive panels, 4 no testing

Patient Focused Drug Development

	FDA Docket	Sickle Cell Communities
# of Respondents	25	130
# of Questions Answered	~250	20,438
Race	Unknown	90% African American 10% Caucasian
Age	Unknown	14-19: 14% 20-24: 12% 25-29: 12% 30-34: 12% 35-39: 12% 40-44: 6% 45-49: 8% 50-54: 2% 55-59: 14% 60-64: 8%
Genotype	Unknown	HbAS: 37% HbSS: 43% HbS/B Th: 6% HbSC: 11% HbEE: 1% HbSE: 1% HbSF: 1%

I am interested in taking part in research…

92.7%

Medical Devices

Expanding the work of CDRH
Partnership with
Duke Clinical Research Institute
to assess patient preferences and
real world data

OBESITY

LEADING THE FIGHT TO END DUCHENNE

June 25, 2014

Guidance Document Submission
Division of Dockets Management (HFA-305)
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Dr. Janet Woodcock
Center for Drug Evaluation and Research
Food and Drug Administration

Guidance for Industry
Duchenne Muscular Dystrophy Developing Drugs for Treatment over the Spectrum of Disease

concluded with an agreem
the first draft guidance on

After an intensive five mo
working groups composed
by a community advisory
muscular dystrophy comm
Dystrophy: Developing Dr
patient advocacy-initiated
development and review
(Duchenne).

Our submission is preface
studies, summarizes the d
key imperatives — what v
the sponsors, the academi
importance of the develop
may choose not to formall
inform FDA's deliberation

Parent Project Muscular Dystrophy

PPMD STAFF

My BRAVE Story: Please help us find hope

Posted by PPMD on April 21, 2014 at 2:34pm

Send Message View Blog

I grew up right in the middle of a Duchenne family. My two cousins had it at the time as well as my brother, my best friend. Early on all I knew was that my brother could not walk, little did I know that was the very least of it. Duchenne slowly and brutally made me an only child at 15. Duchenne made it so my brother could not run, skate, walk, or play with other kids. Duchenne made my brother feel lonely, depressed, and unloved. Duchenne took my brothers ability to breathe on his own, it robbed hi. Of the ability to hug, to what without a tube. Finally it took my brothers life due to heart failure.

Throughout his short 18 years, Duchenne sent him to the hospital countless times. He had 13 surgeries, long and painful

Clinical Therapeutics/Volume 36, Number 5, 2014

A Community-Engaged Approach to Quantifying Caregiver Preferences for the Benefits and Risks of Emerging Therapies for Duchenne Muscular Dystrophy

Holly L. Peay, MS[1]; Ilene Hollin, MPH[2]; Ryan Fischer, BA[1]; and John F.P. Bridges, PhD[2]

[1]*Parent Project Muscular Dystrophy, Hackensack, New Jersey; and* [2]*Department of Health Policy Hopkins Bloomberg School of Public Health, Baltimore, Maryland*

rowing agreement that reg-
risk evaluations should take
ferences into consideration.
Development Initiative at the
istration offers patients and
portunity to contribute to

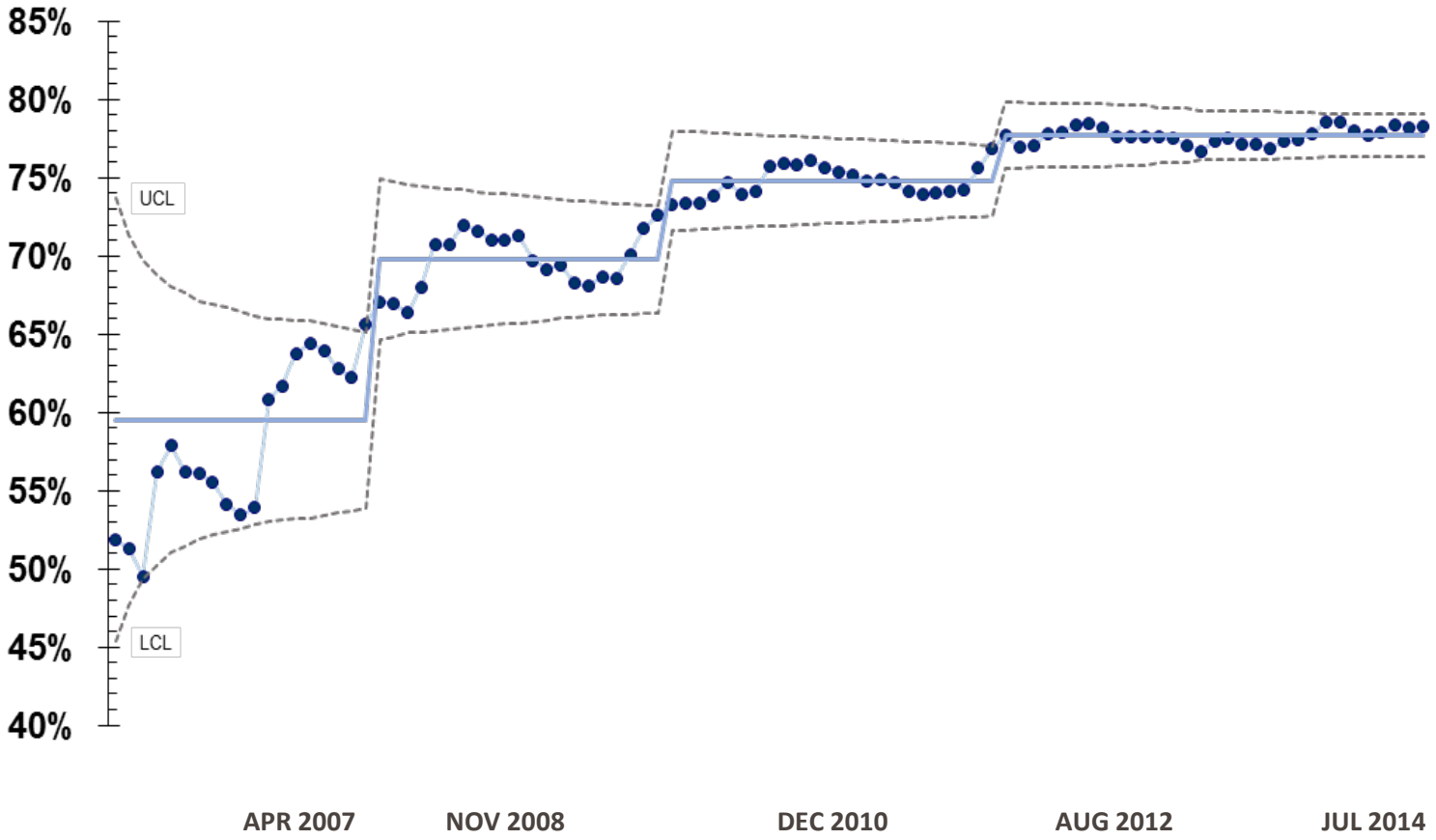
profile. Preference weights were estimated by calculating the relative number of times a feature was chosen as best and as worst, which were then used to estimate relative attribute importance.

Results: A total of 119 DMD caregivers completed the BWS instrument; they were predominately biological mothers (67.2%), married (89.9%), and white (91.6%).

Stakeholder Treatment Preferences: Meaningful Benefits and Risk Tolerance

Remission rate in CD and UC

PGA = Inactive (Physician Global Assessment)



Centers >75% registered

What do 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
- **Link to CDRNs and extensive clinical data for CER**
- **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

Courtesy of Peter Merkel

PCORI/Industry Workshop

March 30 – March 31, 2015

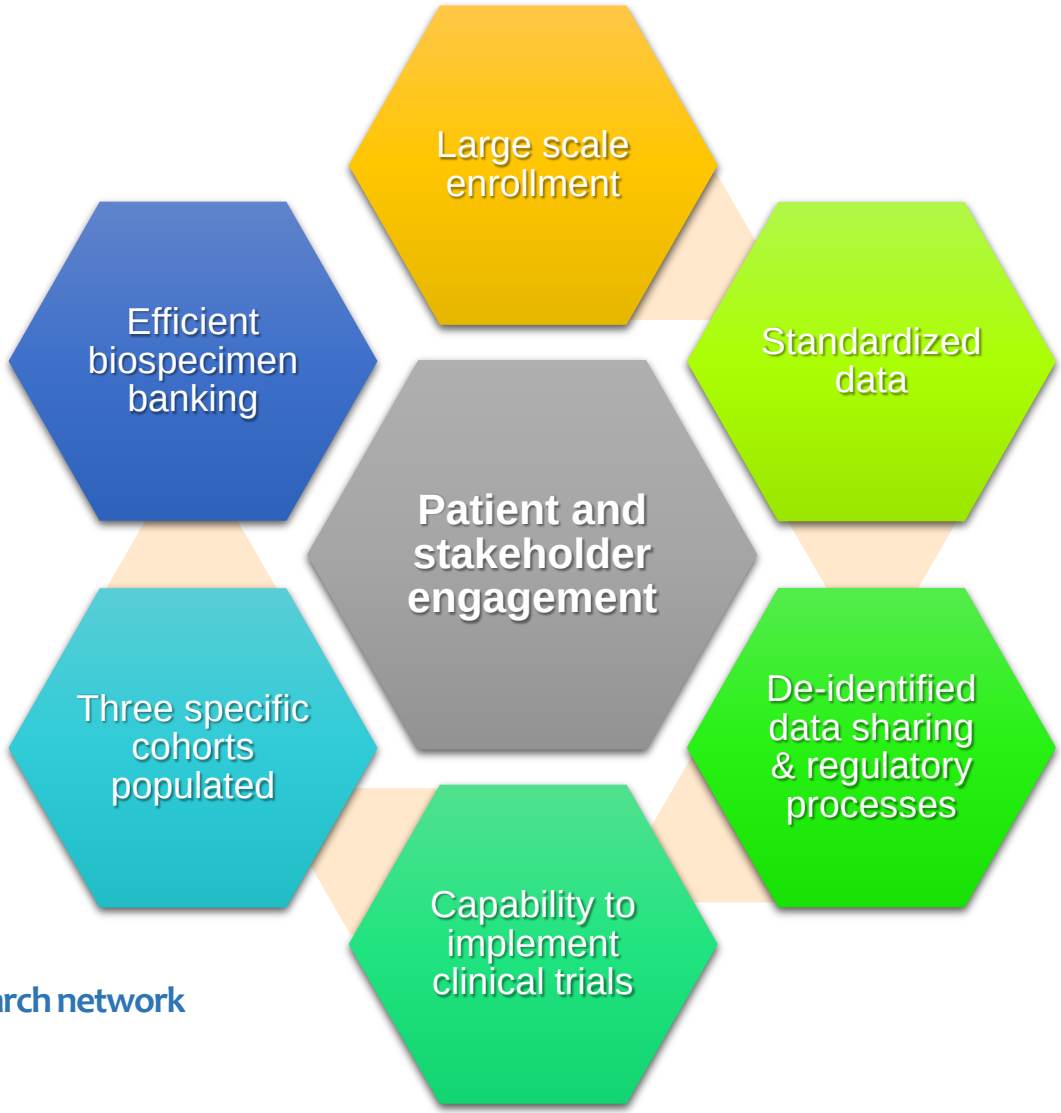
Russell Rothman MD MPP

Professor, Internal Medicine, Pediatrics, Health Policy
Director, Vanderbilt Center for Health Services Research
PI, Mid-South CDRN
Vanderbilt University

mid-south clinical data research network

VANDERBILT UNIVERSITY MEDICAL CENTER

Key Milestones for Phase I



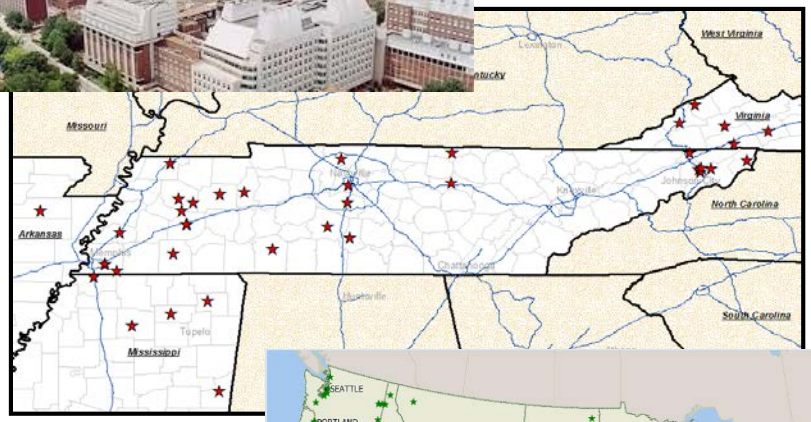
mid-south clinical data research network

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

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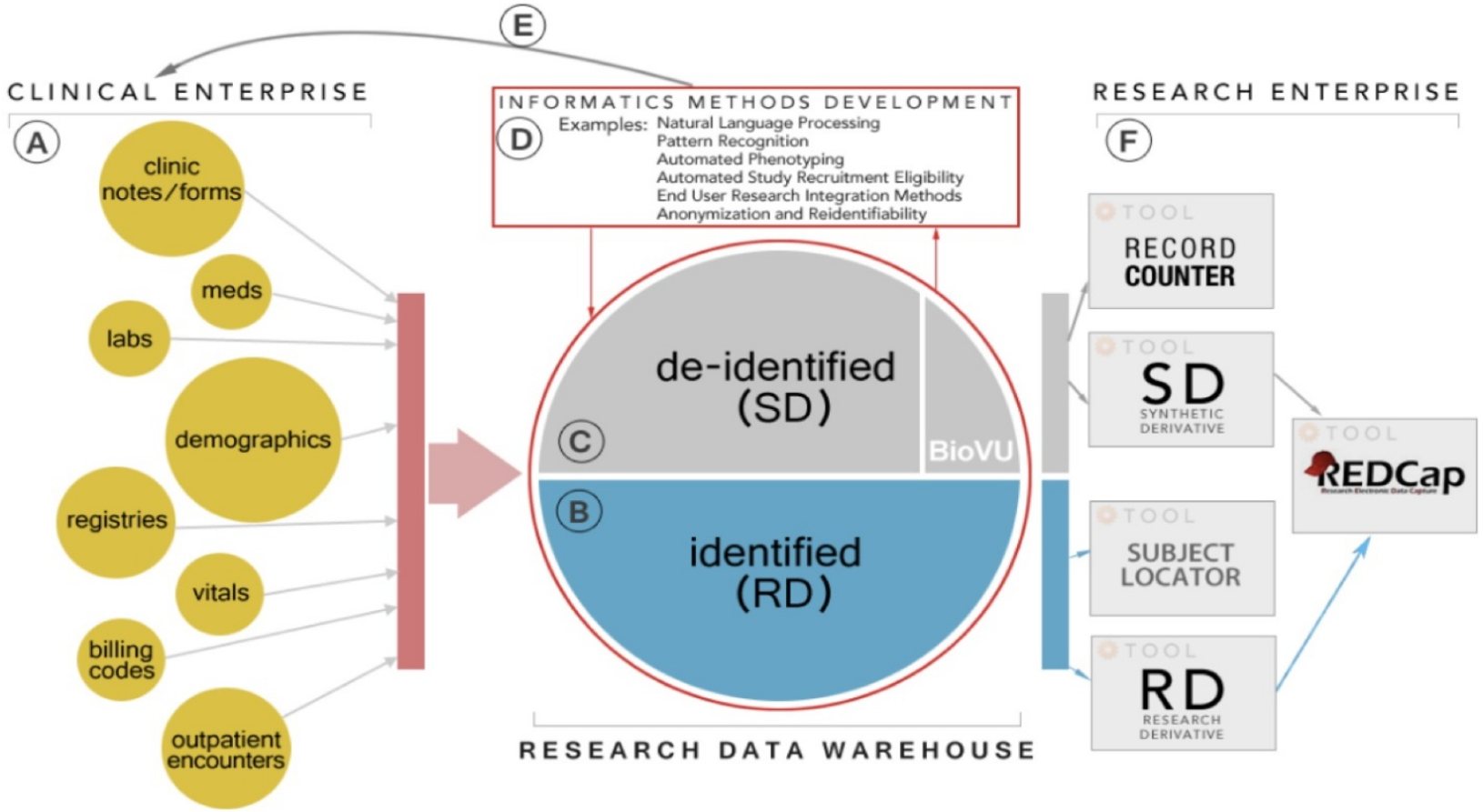
Vanderbilt Data & Research Tools



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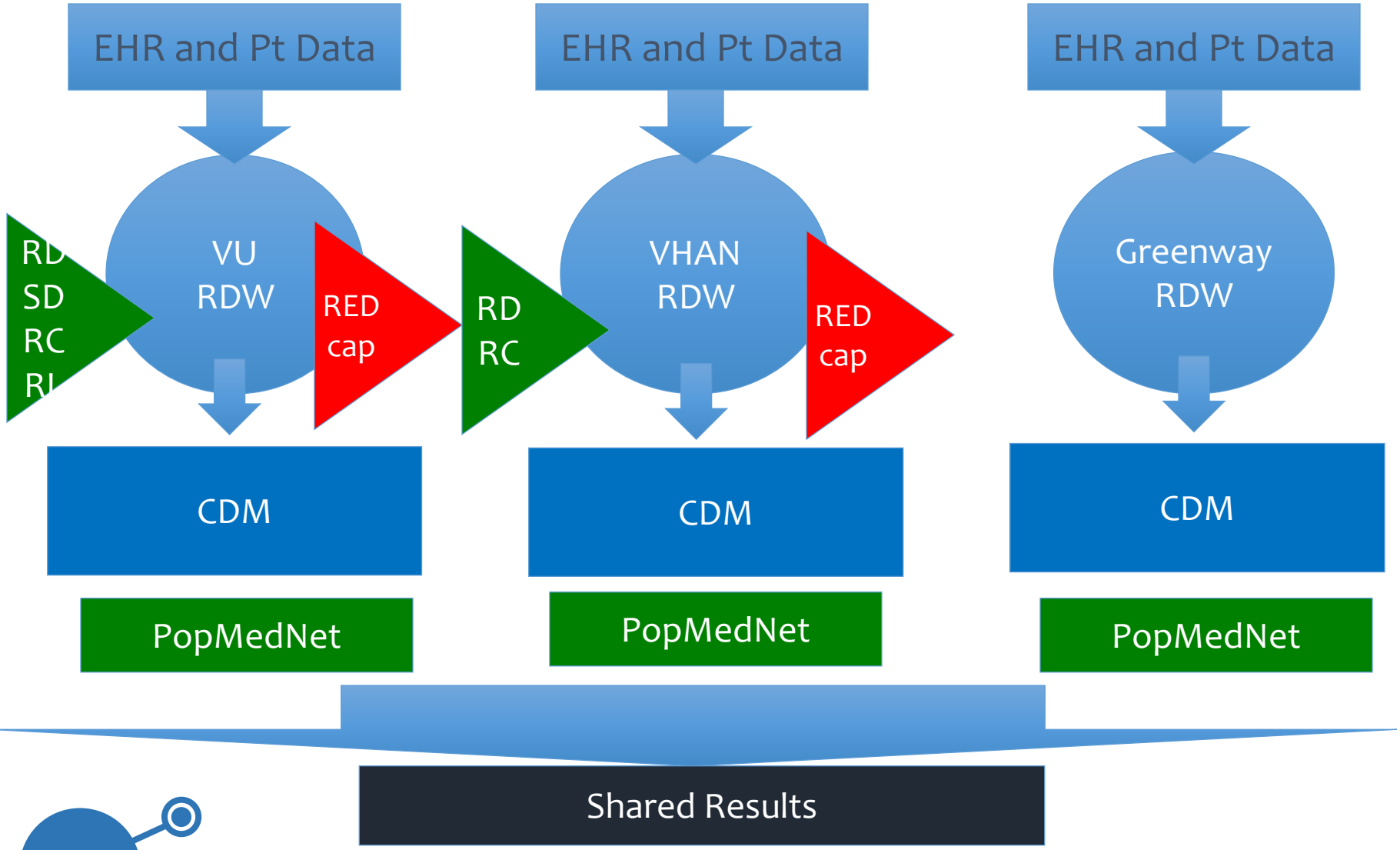
Data Aggregation Across CDRN



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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, Nwestern

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

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NETWORK OF HOSPITALS AND CLINICAL PRACTICES THROUGHOUT THE SOUTHEAST AND THE NATION

Patient Centered Outcomes Research

Vanderbilt University Medical Center is conducting research to help understand what factors influence decisions you make about your health. We invite you to take part in this survey because you have received care at Vanderbilt or other affiliated medical centers.

This survey includes questions about:

- Your background
- Your health habits
- Your willingness to participate in certain types of research studies in the future

Your participation in this survey is totally voluntary. If you choose not to participate, it will not affect your health care or opportunity to participate in future research. Your responses will be kept private. With your permission, we may contact you about future studies you may be interested in. If you participate, we would like to collect some information from your medical chart, such as your height, weight, blood pressure, lab test results, and other health information now and in the future.

There is very little risk involved in this survey. The main risk is that some questions may make you feel uncomfortable. You may choose not to answer any of the questions.

The survey will take about 15-20 minutes and you will receive $10 for your time and participation. If you have any questions or comments regarding the survey, feel free to contact:

David Crenshaw, Study Coordinator
HealthyWeightStudy@Vanderbilt.edu
(615) 343-1765

Thank you!

Date of Birth month day year

By checking this box and entering my birthdate, I agree to participate in this survey and I give permission to have the research team link my answers to my health information that is stored electronically by my doctor

By checking this box, I am refusing to participate in this survey.

Start Survey

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

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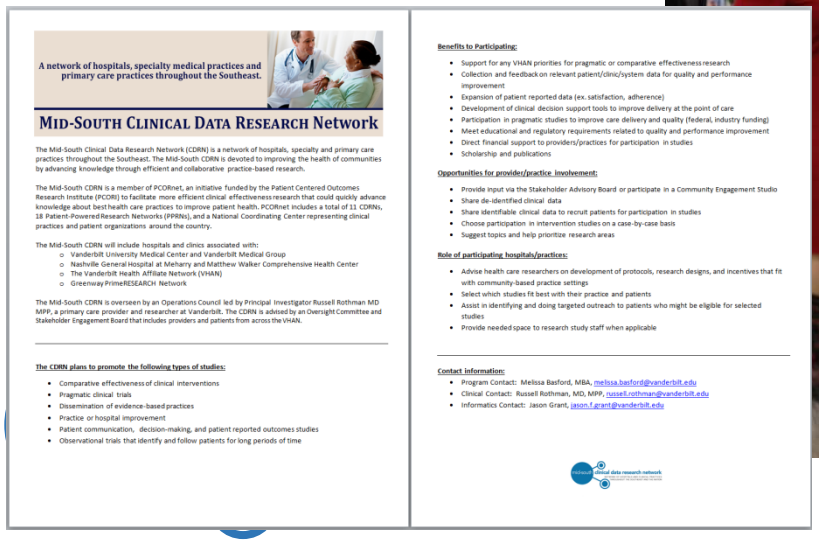
Stakeholder Engagement

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



A network of hospitals, specialty medical practices and primary care practices throughout the Southeast.

MID-SOUTH CLINICAL DATA RESEARCH NETWORK

The Mid-South Clinical Data Research Network (CDRN) is a network of hospitals, specialty and primary care practices throughout the Southeast. The Mid-South CDRN is devoted to improving the health of communities by advancing knowledge through efficient and collaborative practice-based research.

The Mid-South CDRN is a member of PCORnet, an initiative funded by the Patient Centered Outcomes Research Institute (PCORI) to facilitate more efficient clinical effectiveness research that could quickly advance knowledge about best health care practices to improve patient health. PCORnet includes a total of 11 CDRNs, 18 Patient-Powered Research Networks (PPRNs), and a National Coordinating Center representing clinical practices and patient organizations around the country.

The Mid-South CDRN will include hospitals and clinics associated with:

- Vanderbilt University Medical Center and Vanderbilt Medical Group
- Nashville General Hospital at Meharry and Matthew Walker Comprehensive Health Center
- The Vanderbilt Health Affiliate Network (VHAN)
- Greenway PrimeRESEARCH Network

The Mid-South CDRN is overseen by an Operations Council led by Principal Investigator Russell Rothman MD MPP, a primary care provider and researcher at Vanderbilt. The CDRN is advised by an Oversight Committee and Stakeholder Engagement Board that includes providers and patients from across the VHAN.

The CDRN plans to promote the following types of studies:

- Comparative effectiveness of clinical interventions
- Pragmatic clinical trials
- Dissemination of evidence-based practices
- Practice or hospital improvement
- Patient communication, decision-making, and patient reported outcomes studies
- Observational trials that identify and follow patients for long periods of time

Benefits to Participating:

- Support for any VHAN priorities for pragmatic or comparative effectiveness research
- Collection and feedback on relevant patient/clinic/system data for quality and performance improvement
- Expansion of patient reported data (ex. satisfaction, adherence)
- Development of clinical decision support tools to improve delivery at the point of care
- Participation in pragmatic studies to improve care delivery and quality (federal, industry funding)
- Meet educational and regulatory requirements related to quality and performance improvement
- Direct financial support to providers/practices for participation in studies
- Scholarship and publications

Opportunities for provider/practice involvement:

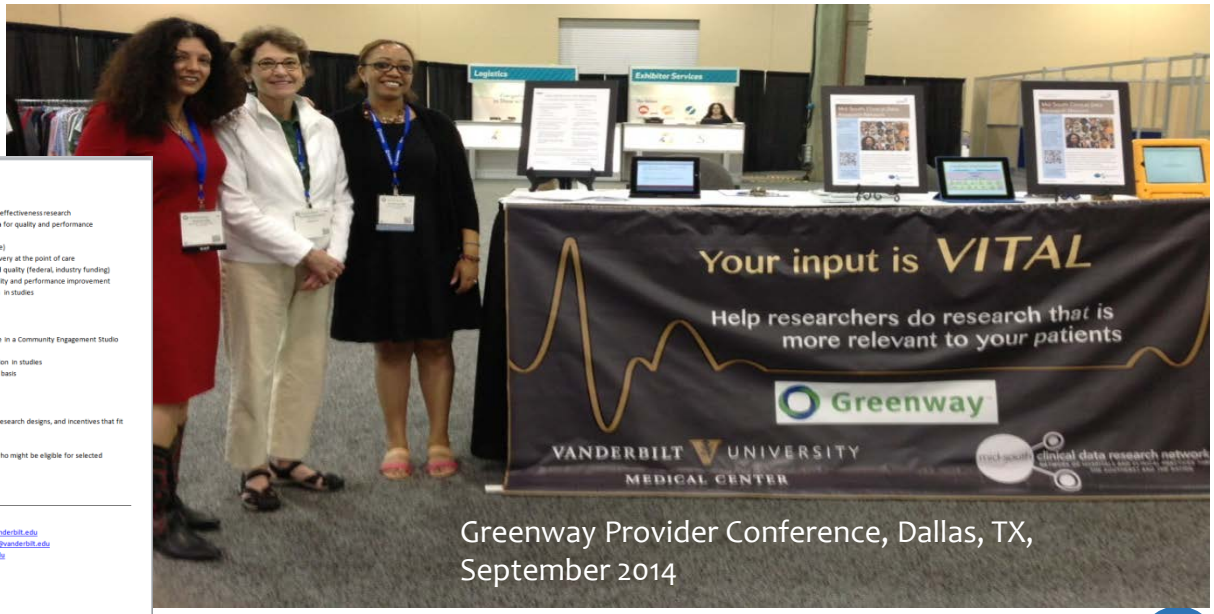
- Provide input via the Stakeholder Advisory Board or participate in a Community Engagement Studio
- Share de-identified clinical data
- Share identifiable clinical data to recruit patients for participation in studies
- Choose participation in intervention studies on a case-by-case basis
- Suggest topics and help prioritize research areas

Role of participating hospitals/practices:

- Advise health care researchers on development of protocols, research designs, and incentives that fit with community-based practice settings
- Select which studies fit best with their practice and patients
- Assist in identifying and doing targeted outreach to patients who might be eligible for selected studies
- Provide needed space to research study staff when applicable

Contact information:

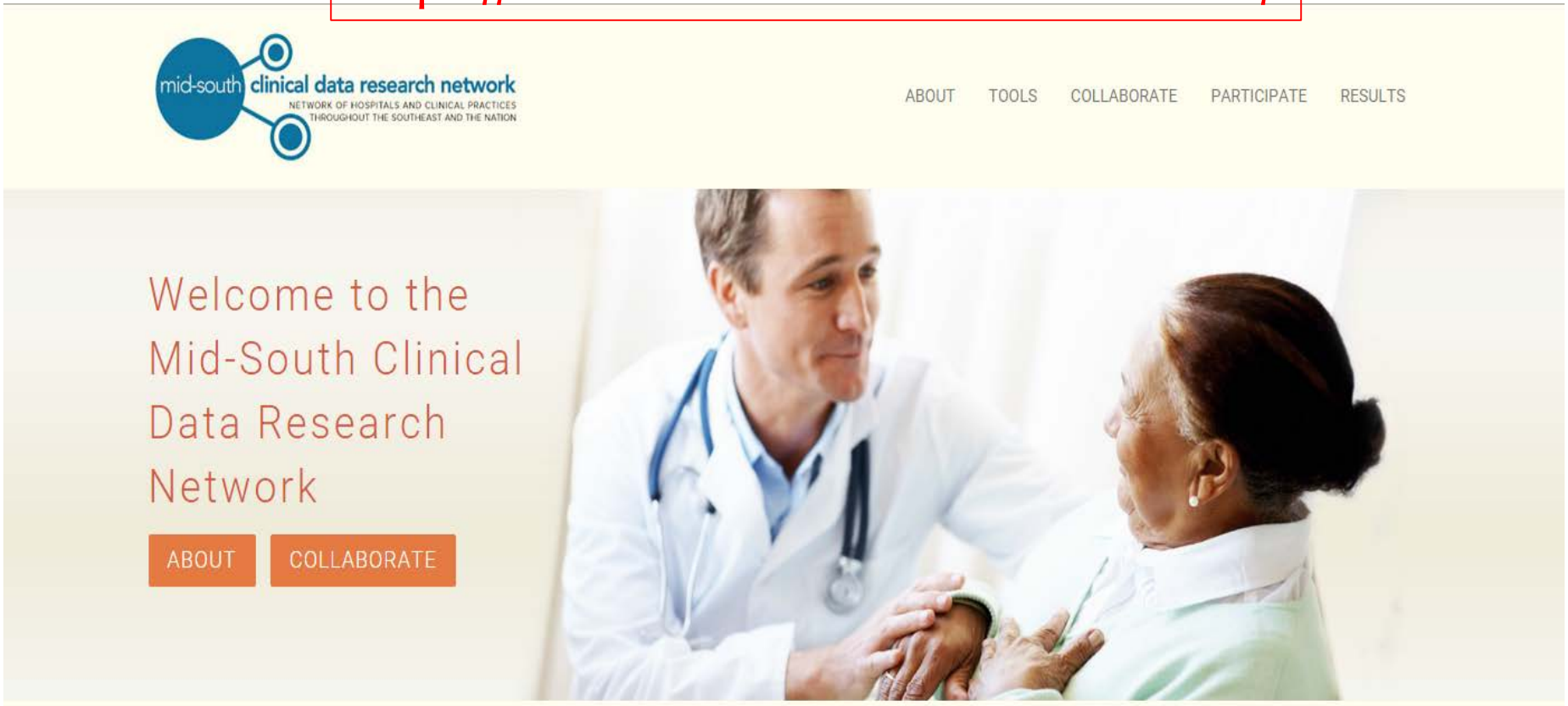
- Program Contact: Melissa Basford, MBA, melissa.basford@vanderbilt.edu
- Clinical Contact: Russell Rothman, MD, MPP, russell.rothman@vanderbilt.edu
- Informatics Contact: Jason Grant, jason.f.grant@vanderbilt.edu



Greenway Provider Conference, Dallas, TX, September 2014

Process for accessing resources

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



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

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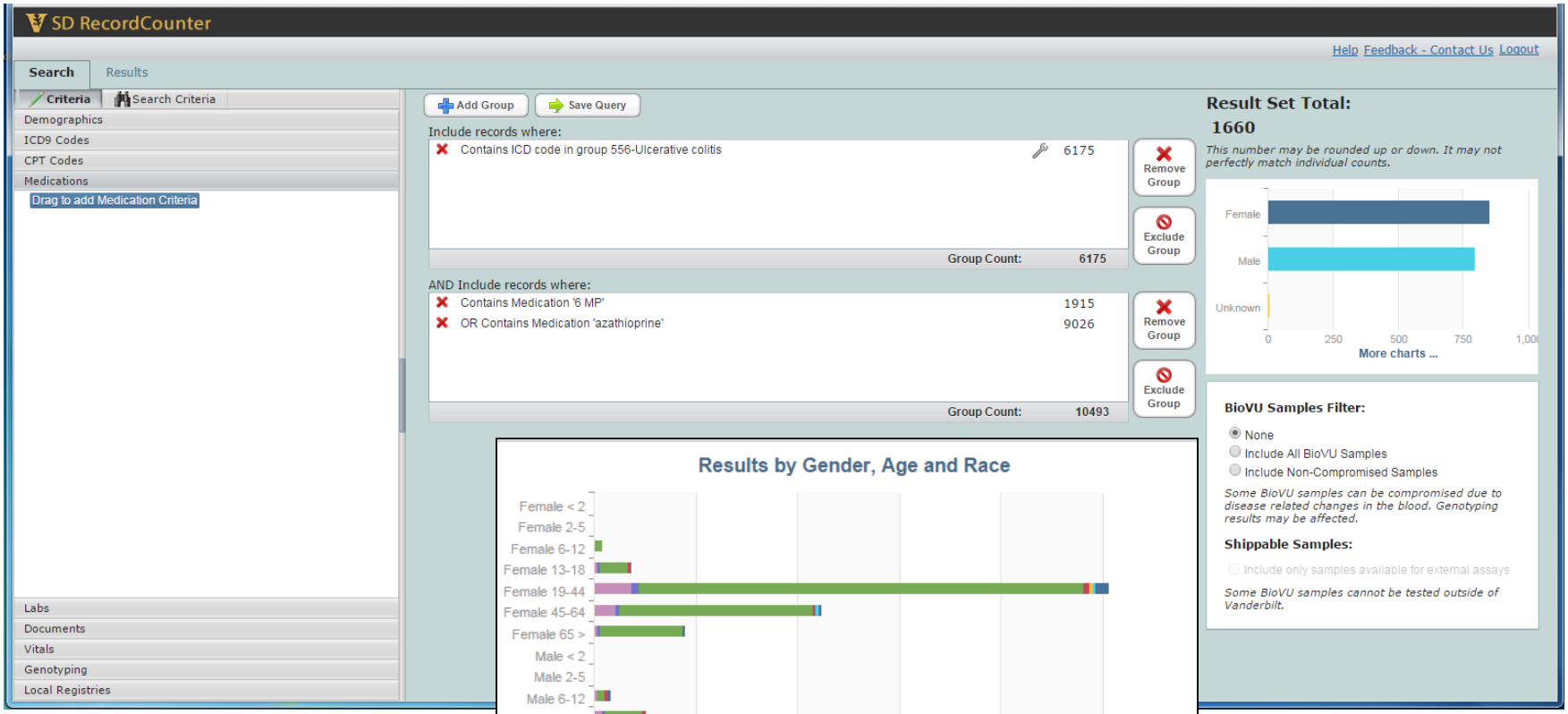
Collaborations

- 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”



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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

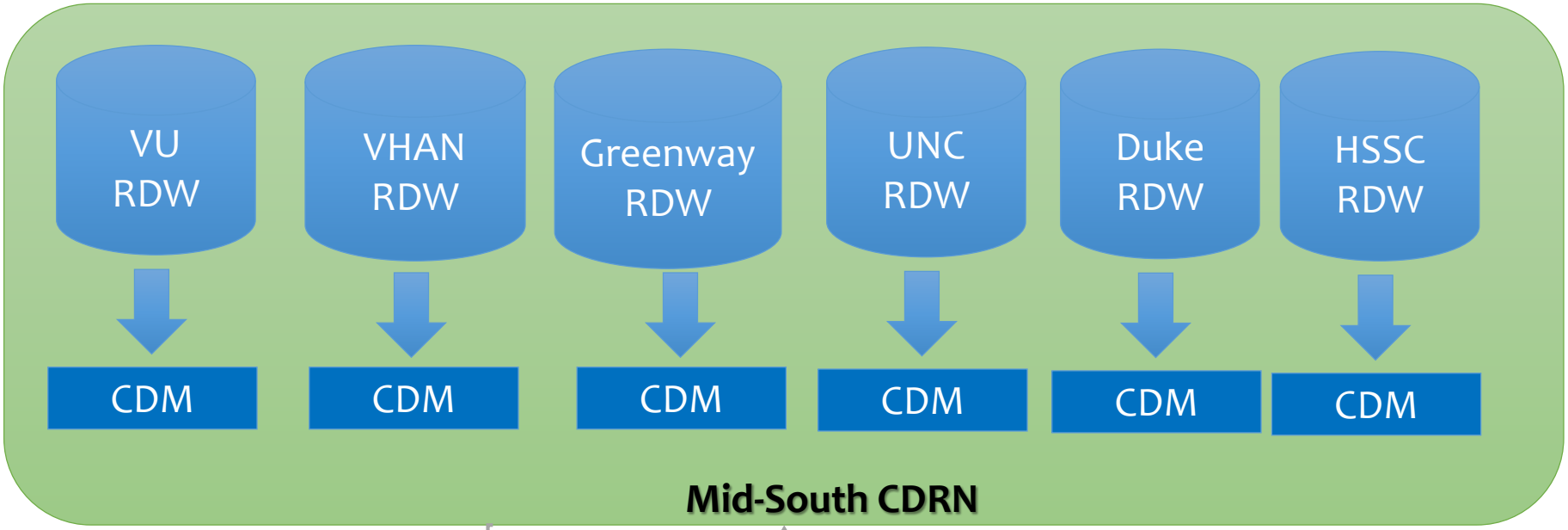
- Rapid identification of eligible patients
- Electronic consent processes
- Studies embedded into clinical care (inpatient and/or outpatient)
- Can track long-term outcomes through patient surveys and extraction of electronic data

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

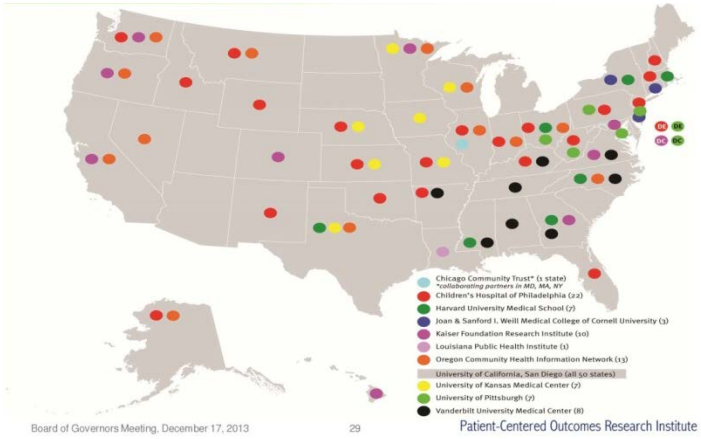


1. Queries and Analytic Software Packages from PCORI

2. CDRN returns Counts and Aggregate resulting data

PopMedNet

PCORNet



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Q&A on PCORnet Structure, Plans, and Network Activities

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The National Patient-Centered Clinical Research Network

Break – visit www.pcornet.org

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The National Patient-Centered Clinical Research Network

Open Discussion, Continued Q&A

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The National Patient-Centered Clinical Research Network

PCORnet's Demonstration Projects

Rich Platt, MD, MSc, PCORnet Executive Committee

Adrian Hernandez, MD, MHS, PCORnet Executive Committee

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The National Patient-Centered Clinical Research Network

PCORnet's goal

Conduct widely generalizable observational and interventional research quickly and at low cost

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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

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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

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Observational Studies in PCORnet's Weight Cohort

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The National Patient-Centered Clinical Research Network

PCORnet's weight cohort

Entire PCORnet CDRN population

The Weight Cohort: Weight and height/length measurements

Weight-related studies

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Short- and Long-Term Outcomes related to Bariatric Surgery

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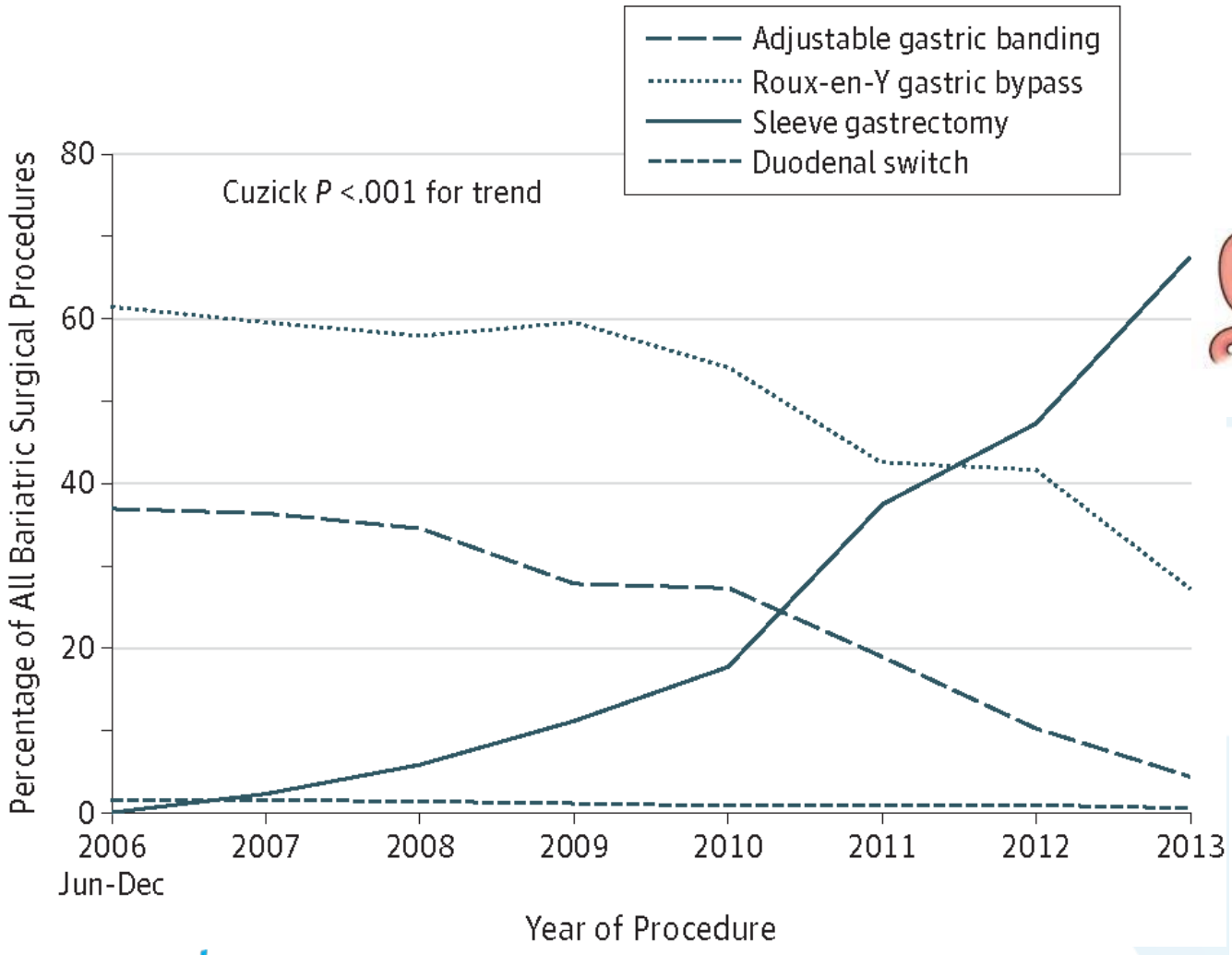
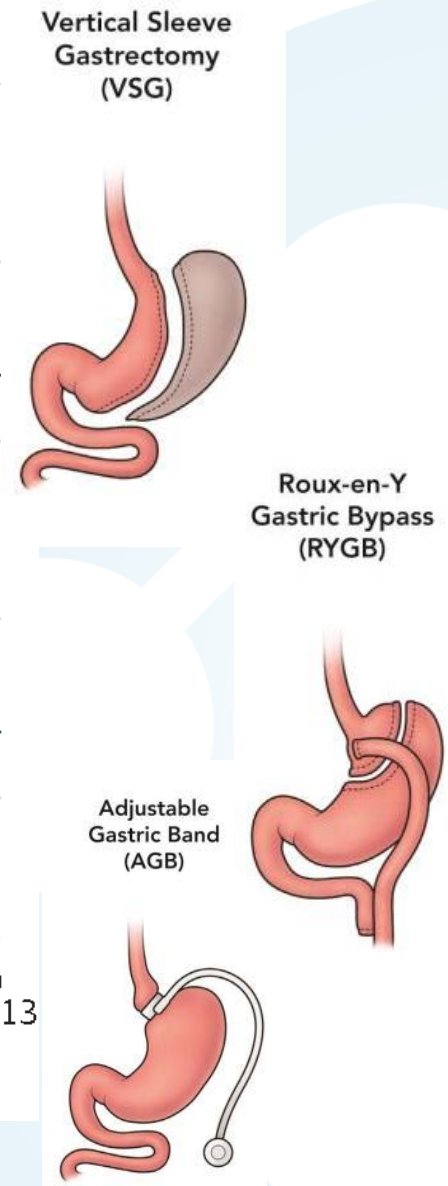
The National Patient-Centered Clinical Research Network

There is an ongoing major shift in bariatric procedures in the United States





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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

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

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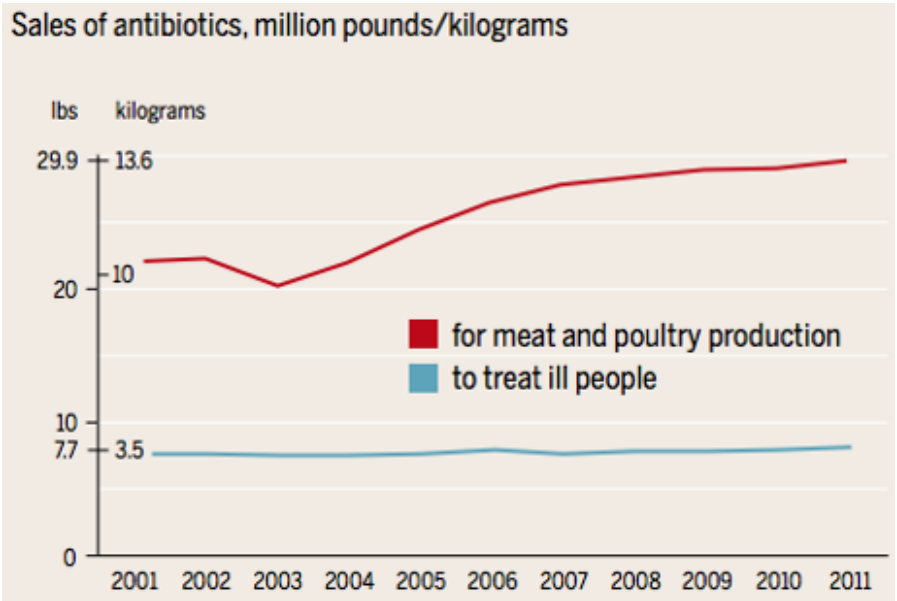
The National Patient-Centered Clinical Research Network


UNiMiX
GROWTH PROMOTER
1 Kg
LINCOMYCIN Feed Additive
POULTRY FEED SUPPLEMENT
NOT FOR MEDICINAL USE


Sales of antibiotics, million pounds/kilograms
lbs
kilograms
29.9
13.6
20
10
10
7.7
3.5
0
for meat and poultry production
to treat ill people
2001
2002
2003
2004
2005
2006
2007
2008
2009
2010
2011

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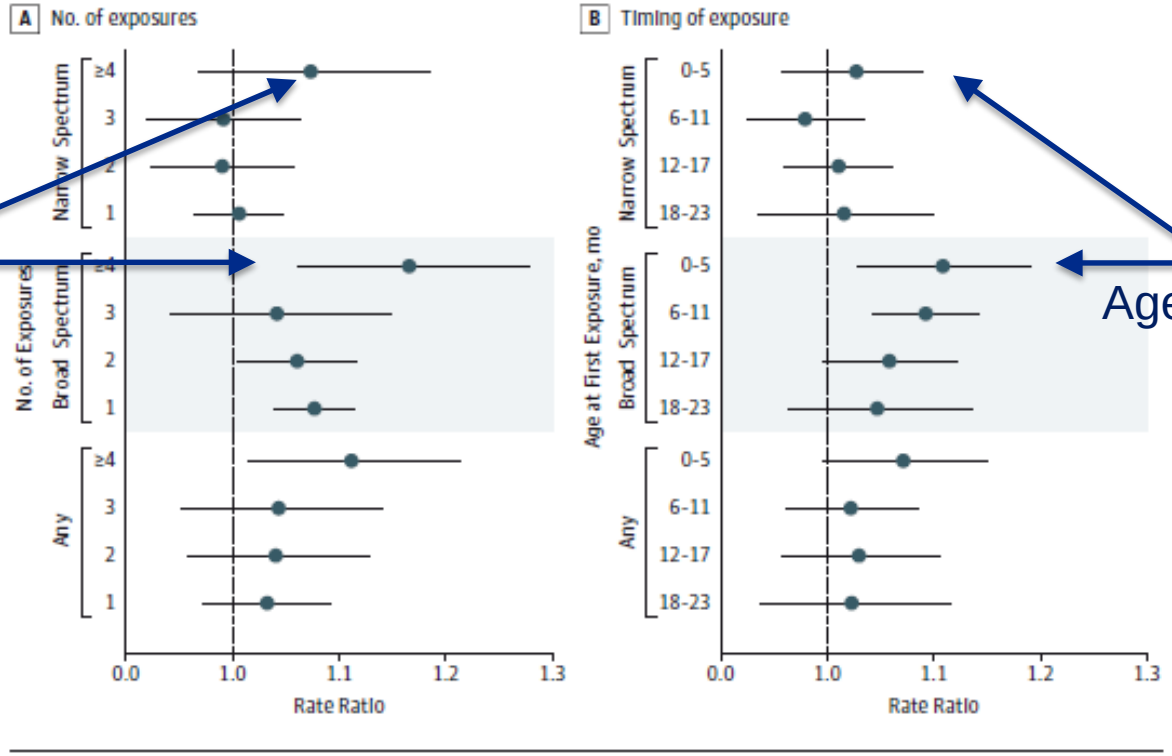
Association of Antibiotics in Infancy with Early Childhood Obesity



Dose effect

Age effect

Bailey et al., *JAMA Pediatr*. doi:10.1001/jamapediatrics.2014.1539;
N ~ 65.000 primary care visits

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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

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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?

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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

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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

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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

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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*

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Requirements for Network Participation in Observational Studies

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** Clinical data research networks*

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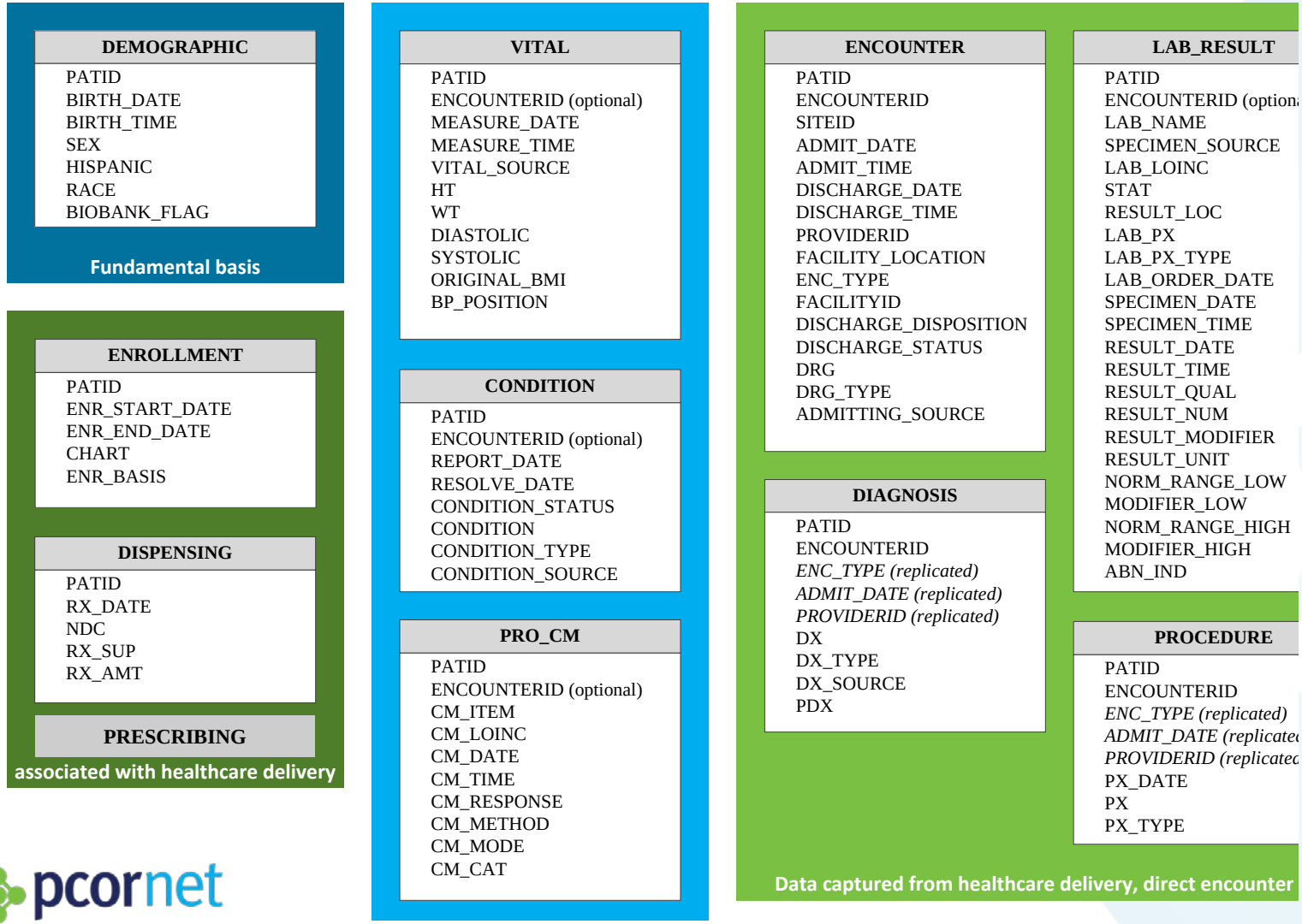
PCORnet Common Data Model v2.1



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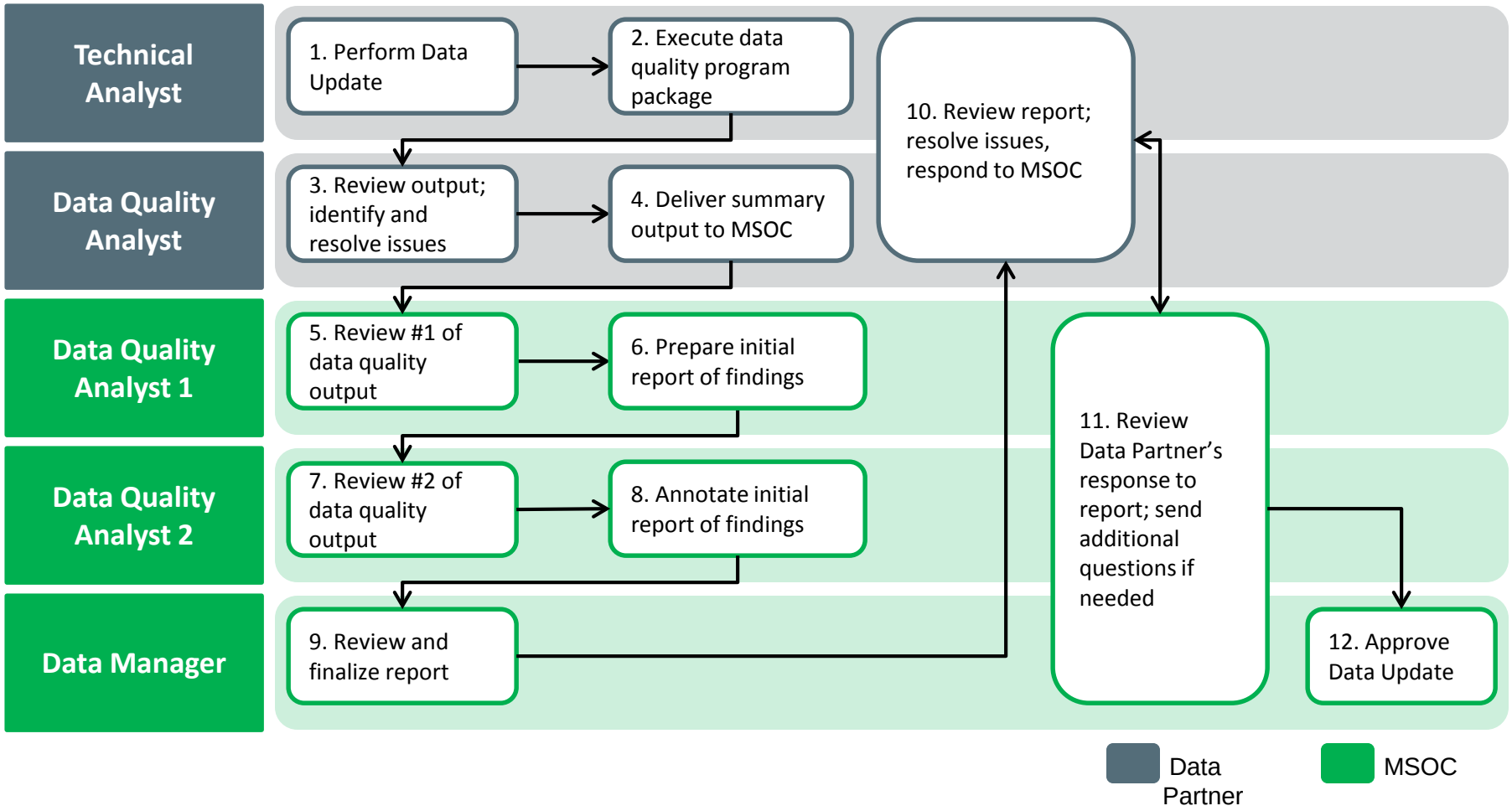
Data Quality Assurance review process

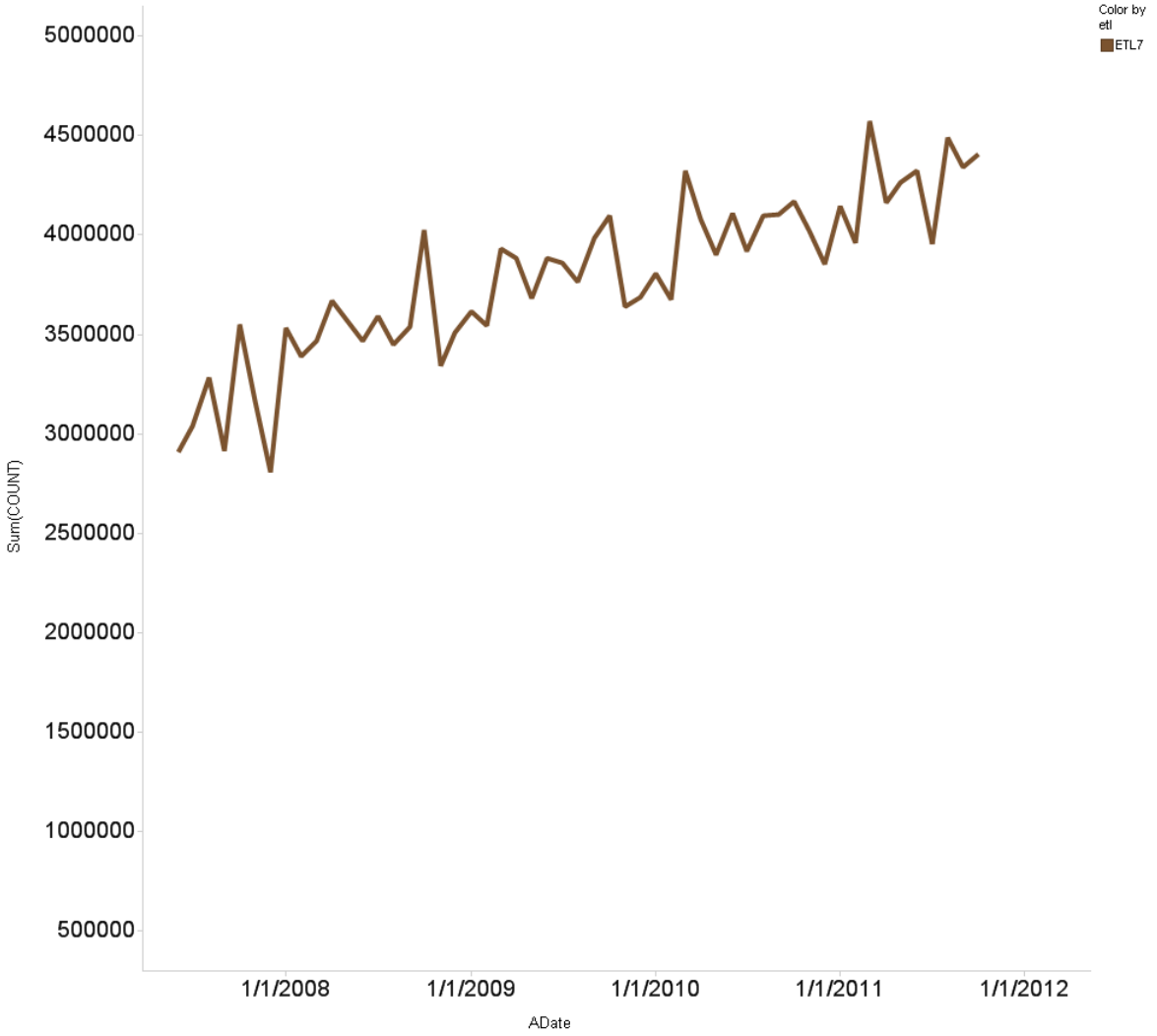


Glycosylated hemoglobin (HBA1c) units

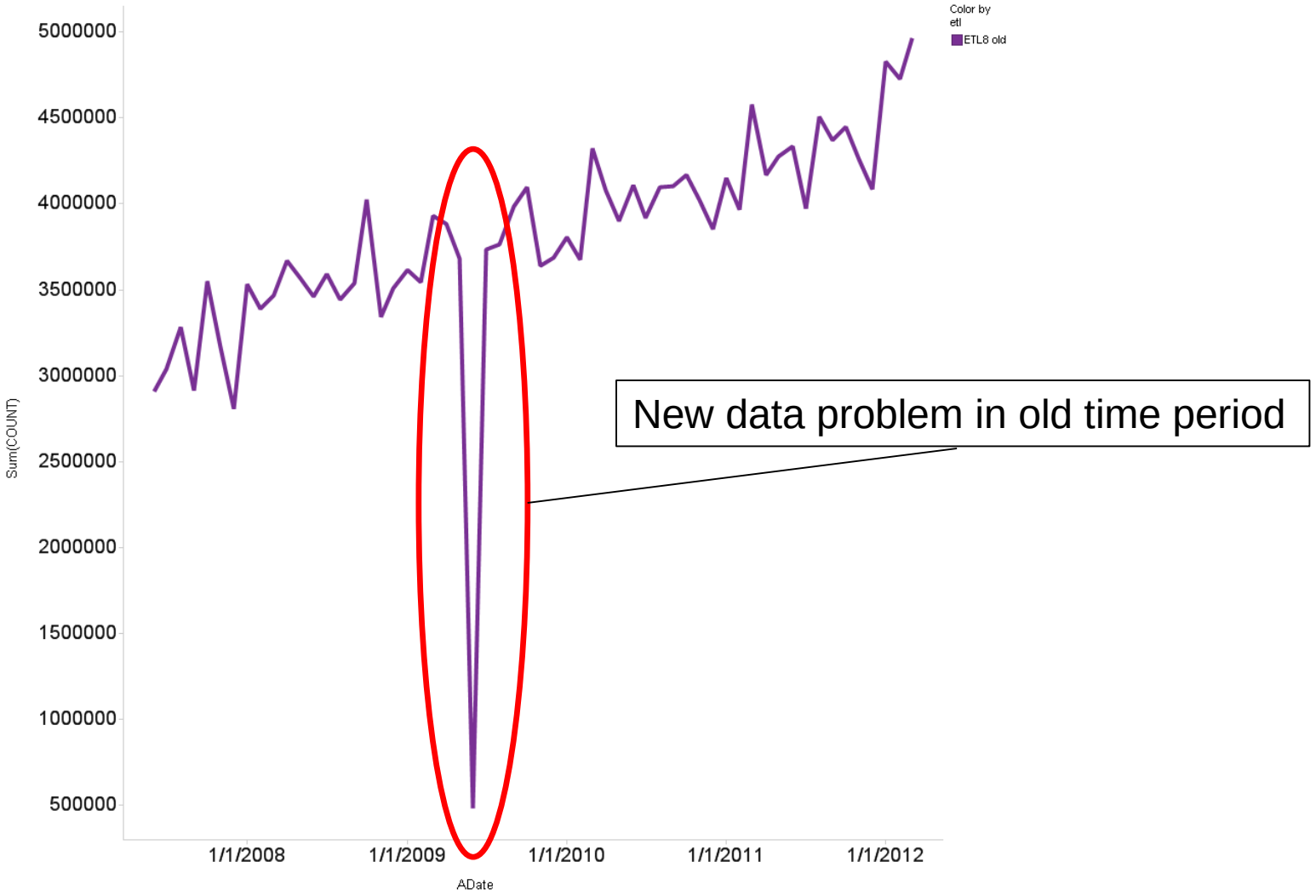
%	%T.HGB	% TL HGB	% HGB
HEMOGLOBIN	%T.Hgb	% OF TOTAL	PERCENT
U	%T.Hgb	% of Hgb	Percent
%HB	% NGSP	% of total	HbA1c%
% OF T	%NGSP	%THb	%HbA1c
%AIC	% TOTAL HGB	%NGSP	% A1C
MG/DL	G/DL	mmol/mol†	Blank
% A1C	% A1c	%Hb	g/dL
NULL	%THb		

Raebel Pharmacoepi and Drug Safety 2014; DOI:10.1002

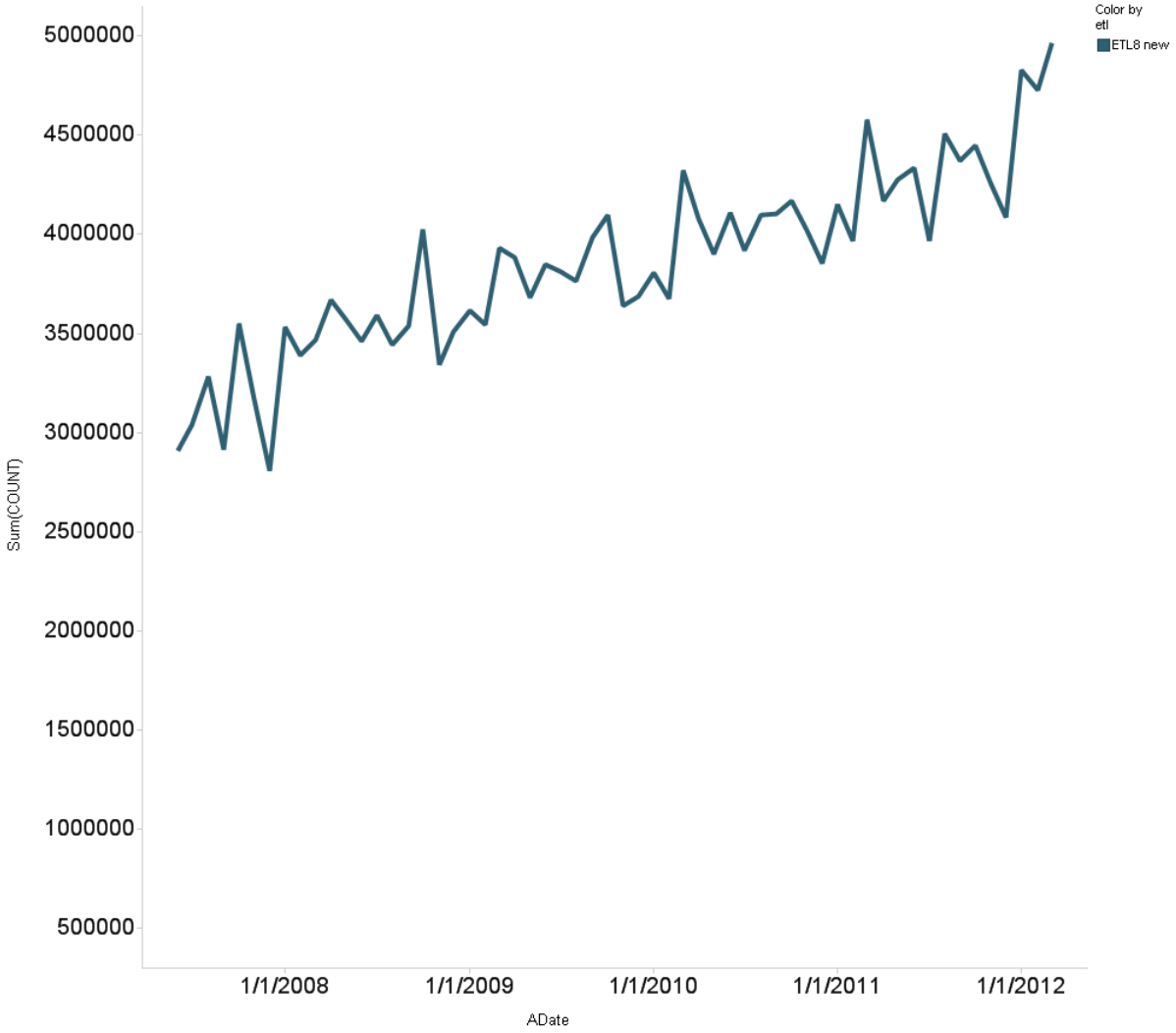
Data Visualization: After 7th refresh, partner A



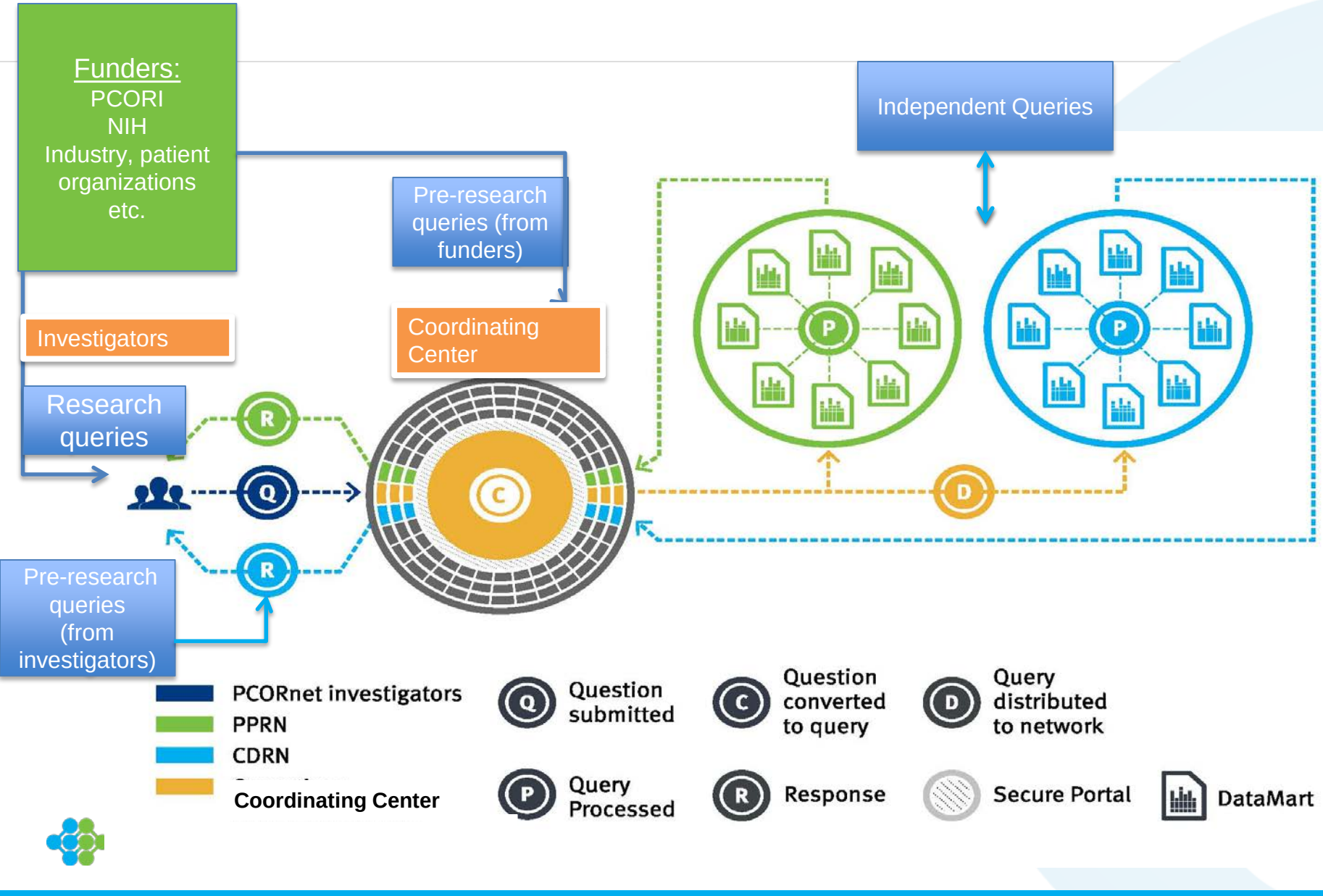
Data Visualization: After 8th refresh, partner A

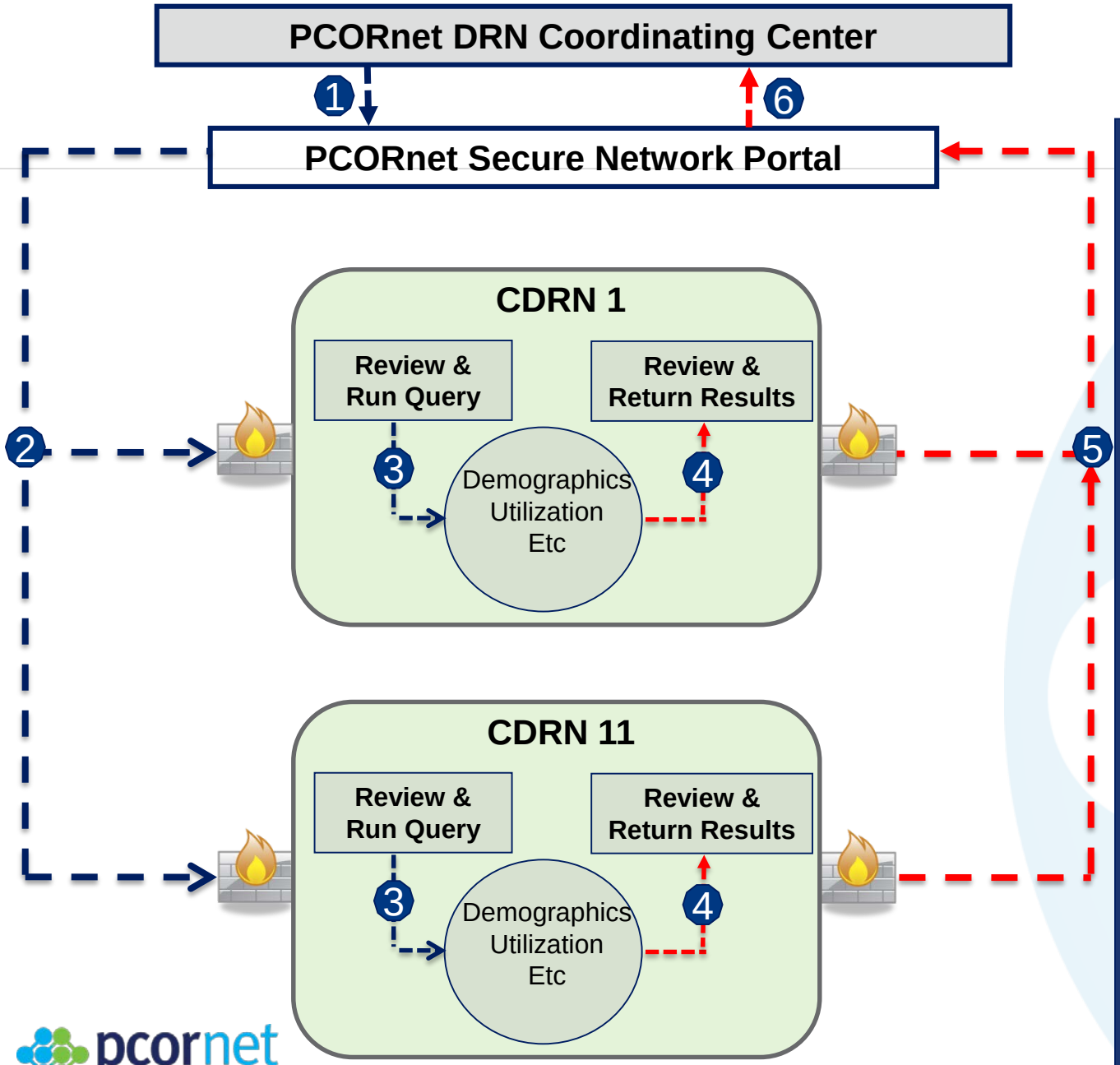


Data Visualization: After 8th refresh fixed



PCORnet Operational Model





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

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

PCORnet's First Proposed Pragmatic Clinical Trial

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The National Patient-Centered Clinical Research Network

What if a choice made over the counter prevented…

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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

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Risks of aspirin therapy

Sanjay Gupta; CNN

Aspirin Dosing: Equipoise?

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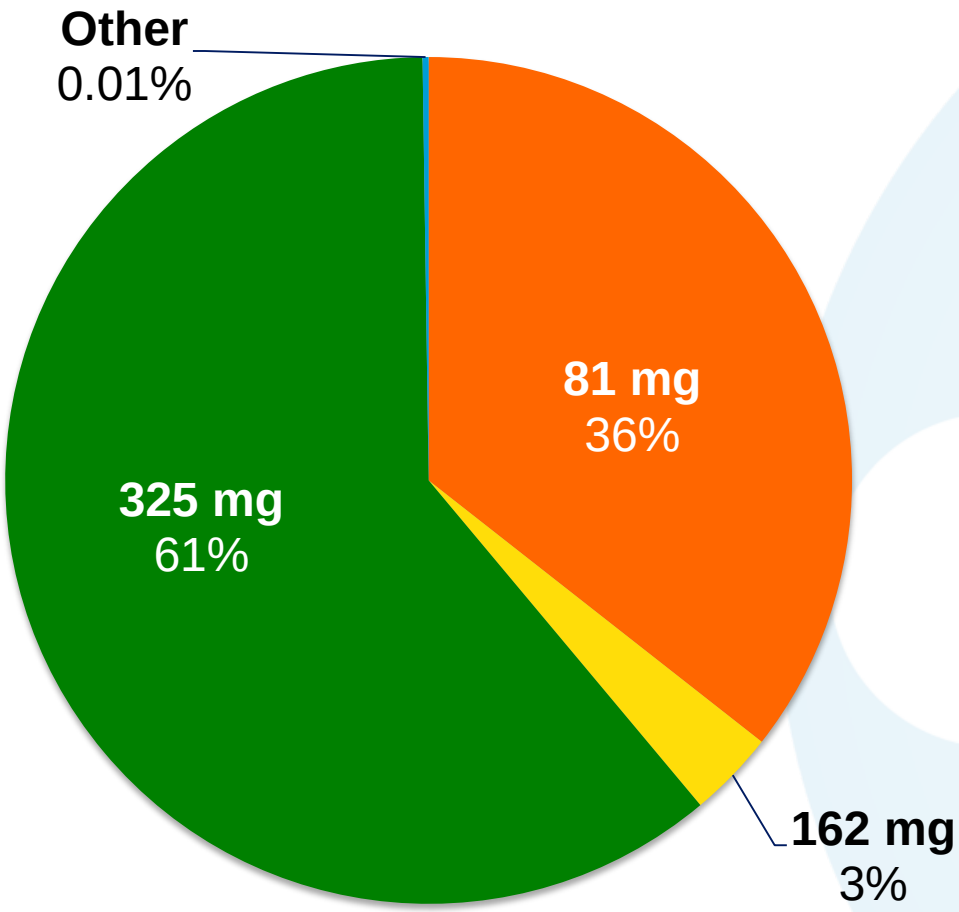
Distribution of aspirin dosing at discharge



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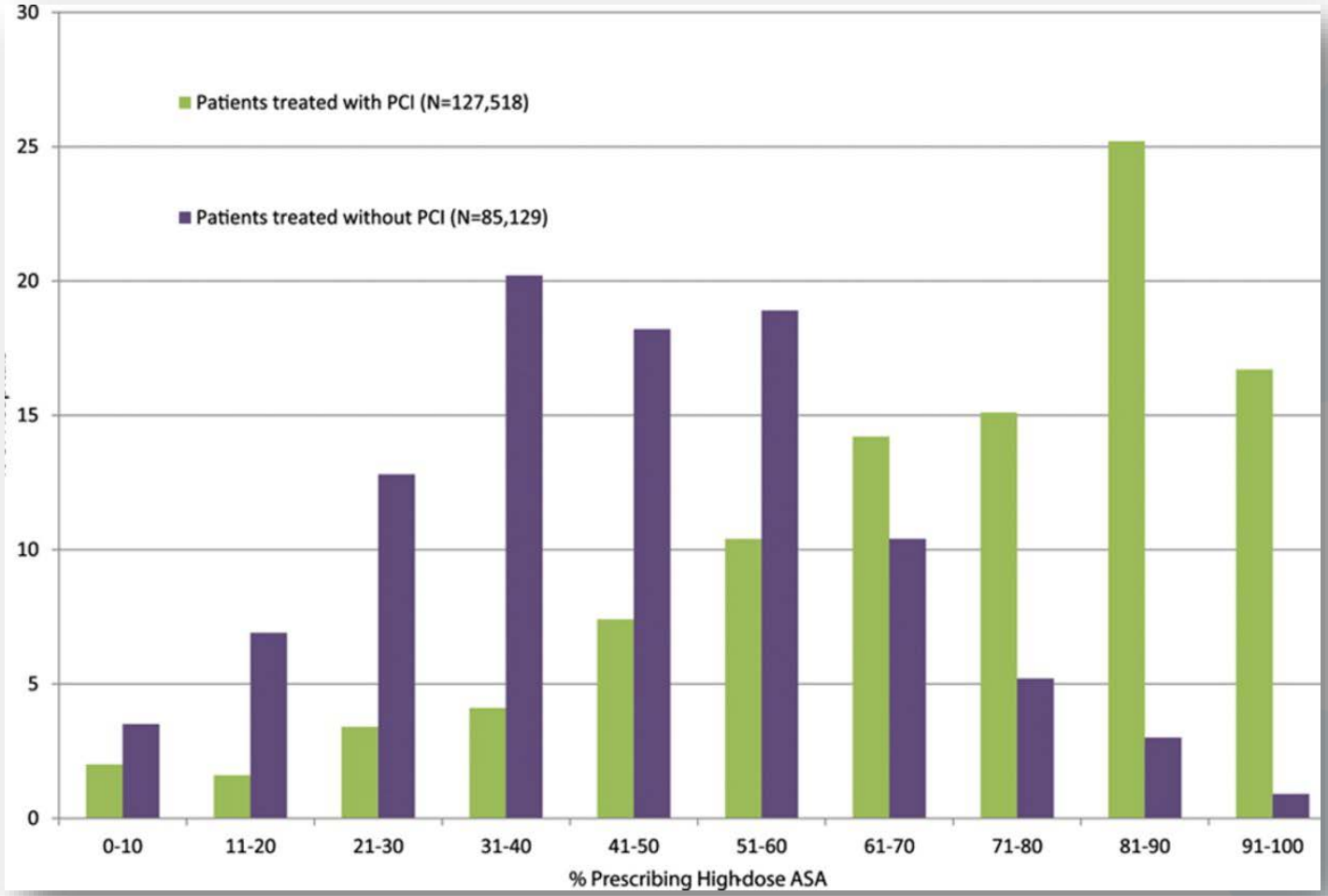
Hall et al. Circulation Cardiovascular Quality and Outcomes 2014

High (25 -fold) Variation Across Hospitals on Use of High Dose (325mg) Aspirin



>440 US Hospitals

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Hall et al. Circulation Cardiovascular Quality and Outcomes 2014

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

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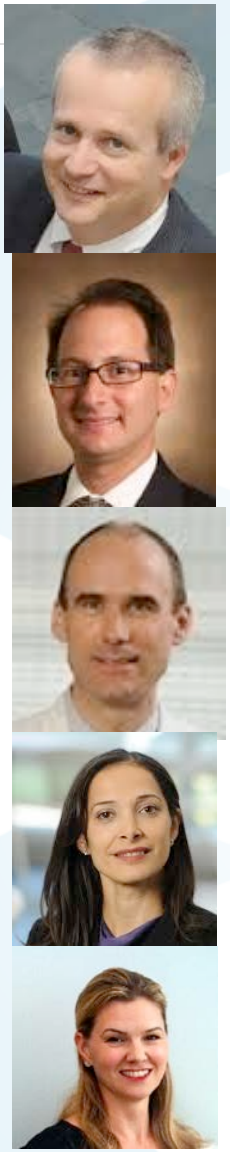
ADAPTABLE Leadership

- 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



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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/PPRNs (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 cerebro-vascular disease and/or peripheral artery disease,
- known ejection fraction <50%
- current smoker

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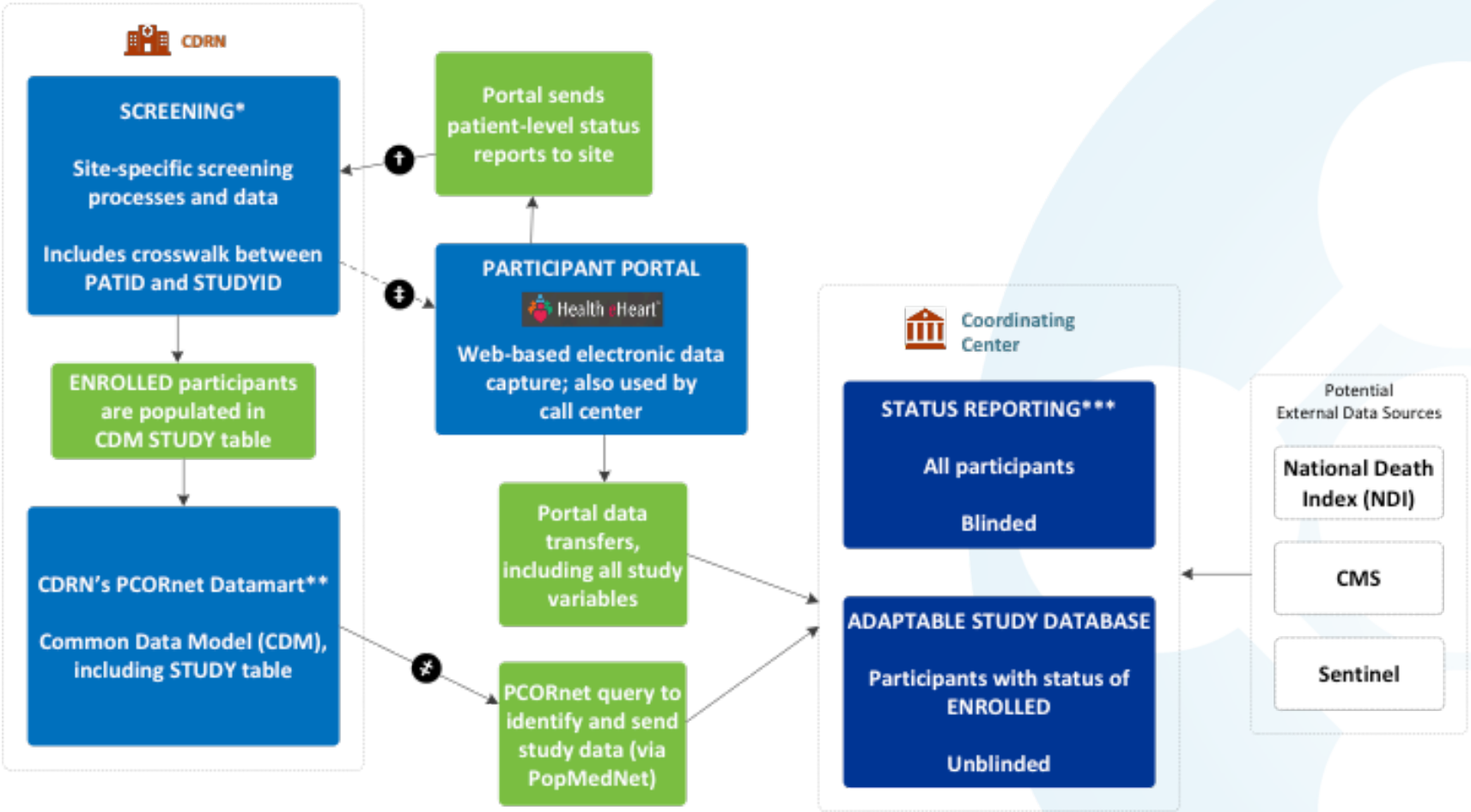
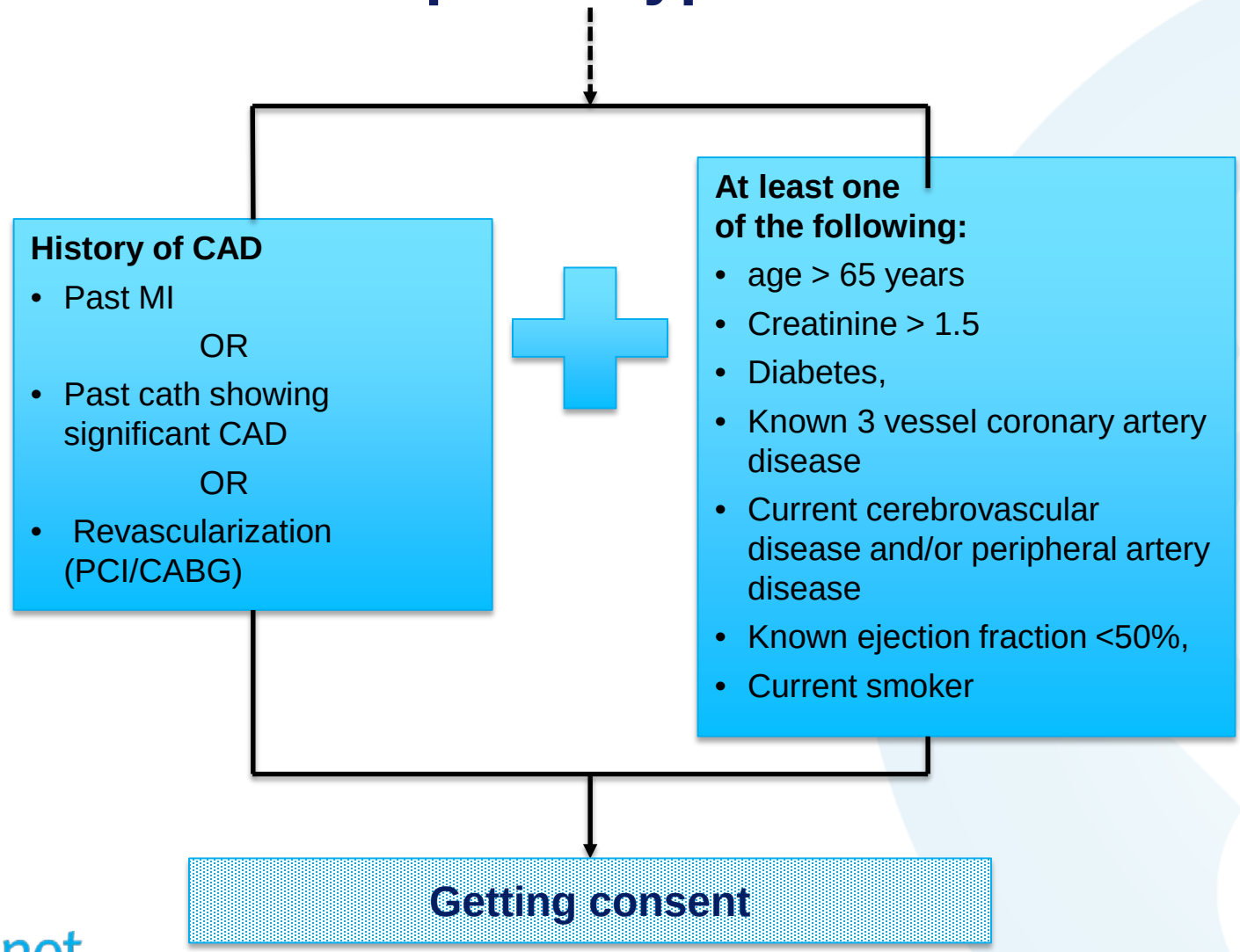
Trial Logistics: Leveraging PCORnet Infrastructure

Screening, Enrollment & Data Flow



Computable phenotype



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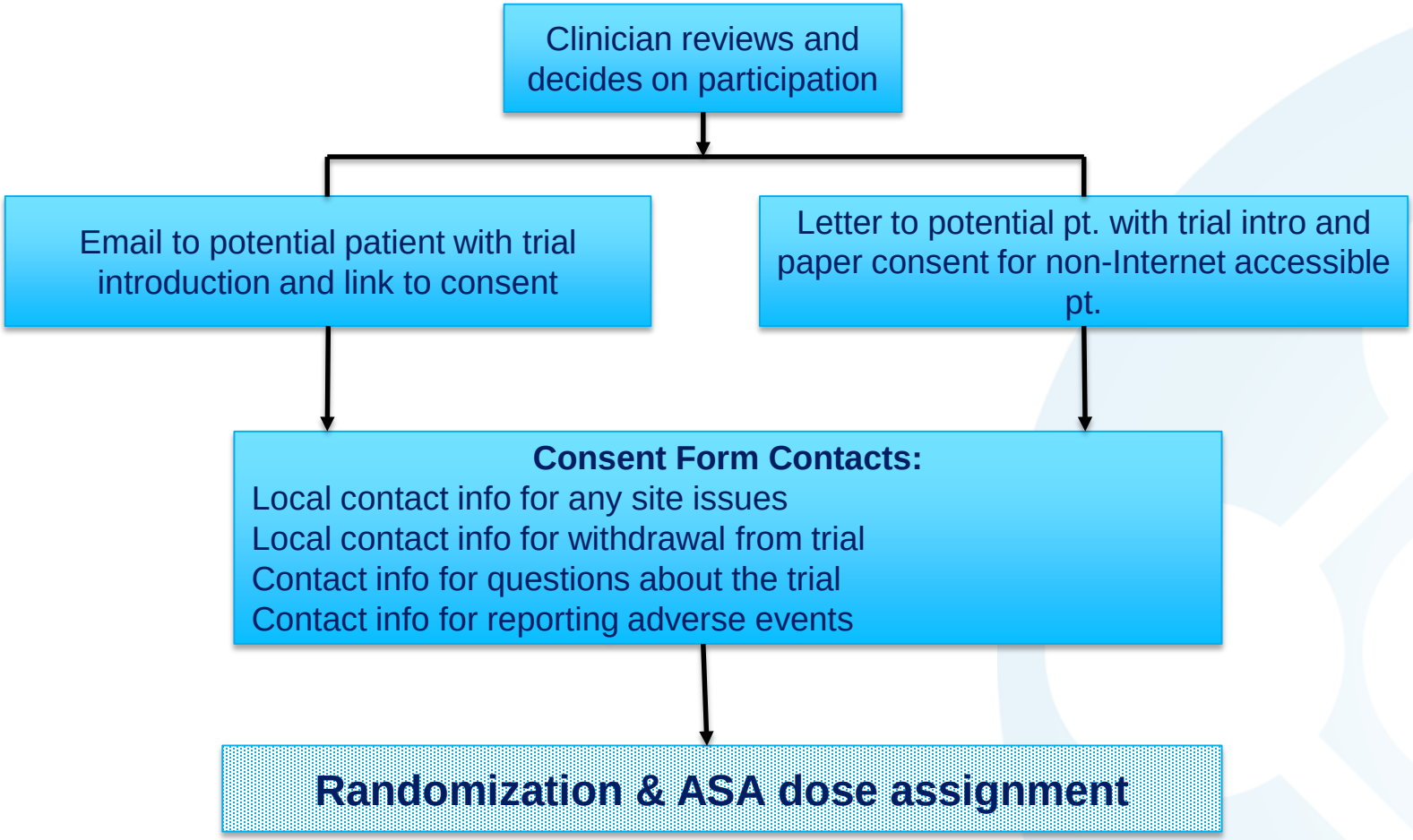
Getting Informed Consent



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Centralized follow-up

ADAPTABLE Enrollee

Baseline Data

OR

Health eHeart

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

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

4 8 12 16 20--- 30

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

CMS Virtual Data Warehouse FOLLOW-UP
- *Longitudinal health outcomes*

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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

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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

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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

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Questions?

Breakout Sessions

1. Registry-Related Research (Columbia A & B)
   - Call-in: Stay on this line
2. Diagnostics (Columbia C)
   - Call-in: 1 (866) 640-4044 – Enter 109712# when prompted

Break – visit www.pcornet.org

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Reports from Breakout Sessions: Opportunities, Areas for Further Exploration

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Open Discussion

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Observations and Next Steps

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Closing Remarks and Adjournment

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