

# PCORnet Phase I Status Update: April 2015

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**pcornet**

The National Patient-Centered Clinical Research Network

# Overview

- PCORnet Vision and Hallmarks of Success
- Key areas of progress
- PCORnet's Emerging Operational Model
- Challenges



# 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”**

# 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. Over 100 conditions represented.



## Coordinating Center

Provides technical and logistical assistance for CDRNs and PPRNs

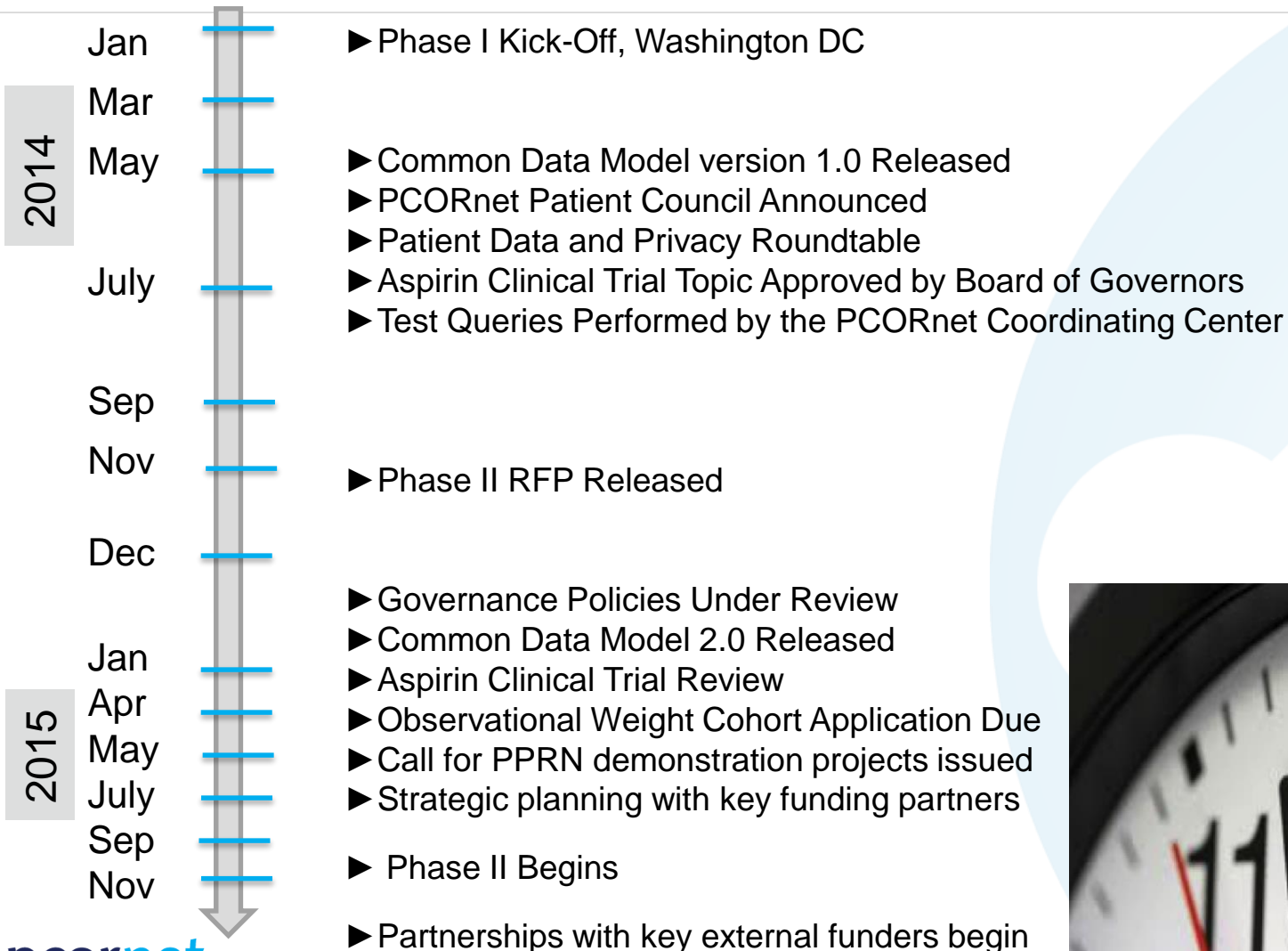
# Spring 2015: Coming Into View



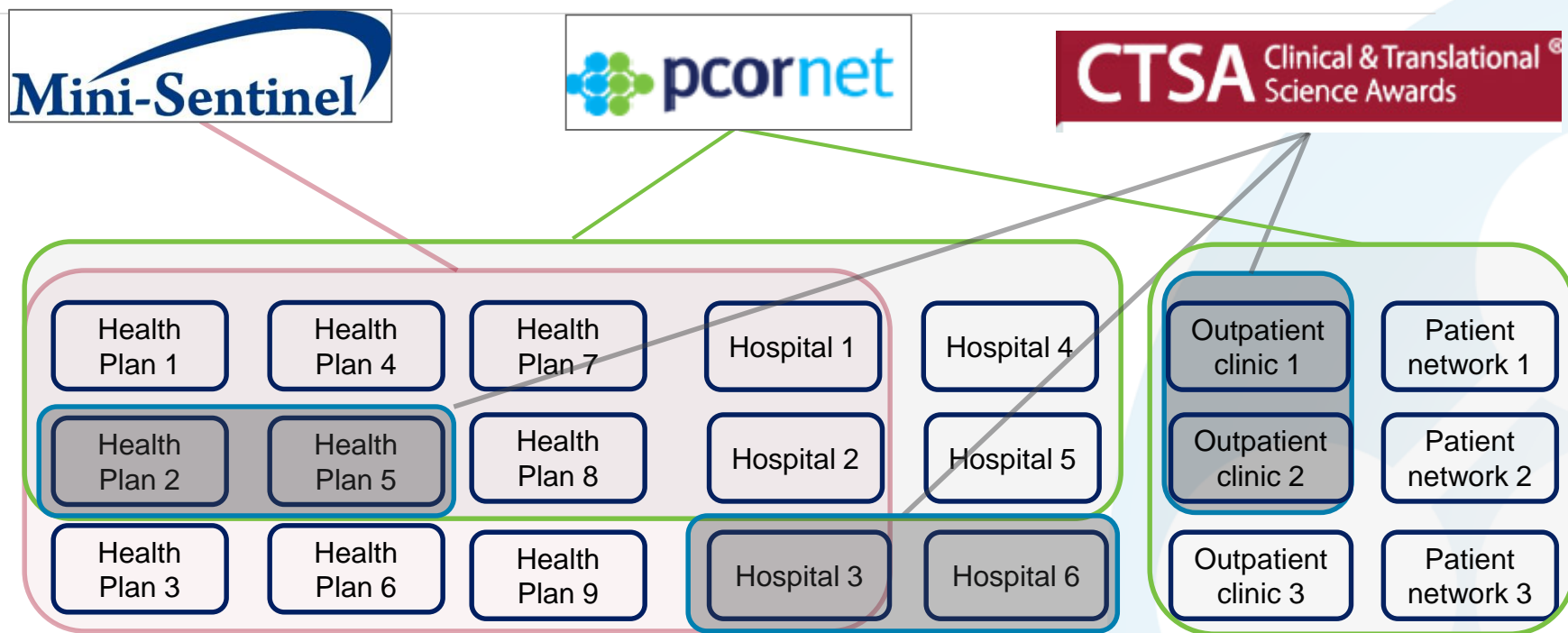
## PCORnet's infrastructure built to:

- 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

# PCORnet Phase I: 2014 – 2015



# Critical Partners in a National Infrastructure



- Each organization can participate in multiple networks
- Each network controls its governance and coordination
- Networks share infrastructure, data curation, analytics, lessons, security, software development
- Other potential partners: disease or treatment-specific networks; health communities

# 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)
- Pilot with the CC, **CMS** and 2 CDRNs about to launch to link with **Medicare** data
- 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 (March 2015)

- ❖ 17 of 18 actively enrolling patients, 3 have achieved target **enrollment**
- ❖ 18 of 18 have completed **governance** documents
- ❖ 17 of 18 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 18 have the ability to engage their community in **trial participation**, and are co-creating and prioritizing research questions
- ❖ **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
- ❖ Very strong **collaboration** across the PPRNs in sharing and leveraging knowledge and expertise



# 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

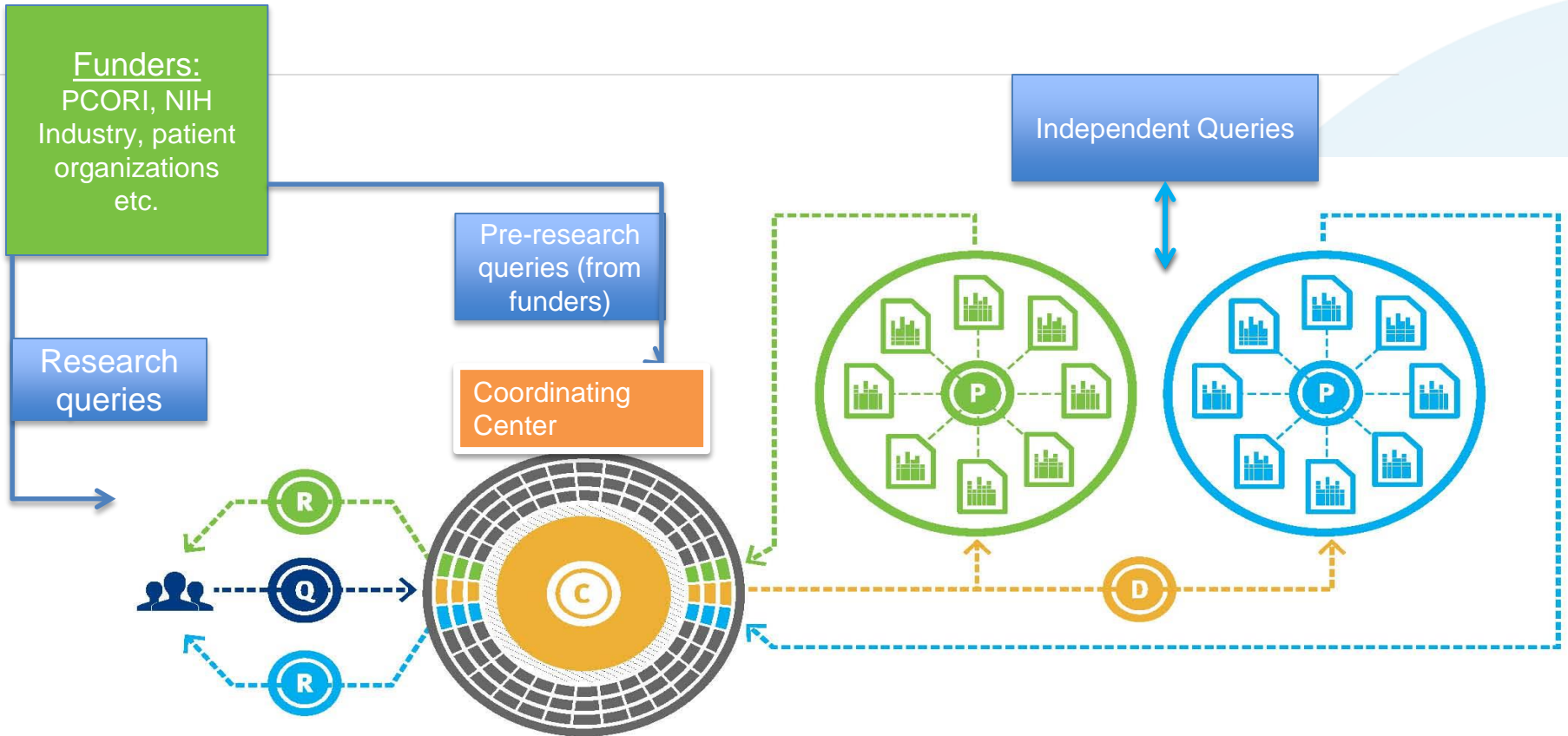
- Compare bariatric surgery procedures on weight loss, regain, and other outcomes
- Comparative effect of different antibiotics in children under 2 years on BMI, patterns of growth, and rates of obesity by ages 3-5 years


## PPRN Demonstration Projects

- PCORI will fund CER projects generated by patient communities of the PPRNs



# PCORnet uses a privacy protecting distributed data network



- |   |                       |   |                    |  |                             |   |                              |
|---|-----------------------|---|--------------------|--|-----------------------------|---|------------------------------|
|  | PCORnet investigators |  | Question submitted |  | Question converted to query |  | Query distributed to network |
|  | PPRN                  |  | Query Processed    |  | Response                    |  | Secure Portal                |
|  | CDRN                  |   |                    |  |                             |  | DataMart                     |
|  | Coordinating Center   |   |                    |  |                             |   |                              |



# 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

# CTSA – PCORnet Collaboration

## IRB Dyad

- Jill Pulley (Vanderbilt) & Alan Green (Dartmouth)

## Contracts Dyad

- Jerry Krishnan (Illinois) & Karl Kiebertz (Rochester)

## Informatics Dyad

- Lesley Curtis (Duke) / Mike Becich (Pittsburgh) & Nick Anderson (UC Davis) / Doug McFadden (Harvard)



# Parts of PCORnet are still under construction





# Policy and Scientific Challenges

- ⊕ Balancing the **individual network incentives** with the charge to build a national network
- ⊕ Ensuring the **patient voice** is weaved into all aspects of PCORnet
- ⊕ Protecting **patient privacy**
- ⊕ Establishing **governance** that develops a national resource while:
  - Incentivizing participation from member networks
  - Attracting a range of research funders including
- ⊕ Leveraging the **power of EHR** while seeking to obtain complete longitudinal data on patients
- ⊕ Achieving **research ready data** with varying data collection standards
- ⊕ Some promising areas, but not quite ready for widespread use in PCORnet: Blue Button, mobile health data