Clinical and Translational Science Award (CTSA) Program

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National Center for Advancing Translational Sciences

APRIL 29, 2016
Clinical and Translational Science Awards (CTSA) Program Sites

- Work together to improve the way clinical and translational research is conducted nationwide
- Provide training for clinical and translational researchers
Getting from Discovery to Health Benefits Faster

- Training and cultivating the translational science workforce
- Including patients and communities as active partners
- Improving tools and methods
- Focusing on understudied populations
- Harnessing the power of cutting-edge informatics

Promoting synergy among stakeholders
CTSA Program is Streamlining Multisite Clinical Studies

• The problem: Current fragmented system is inefficient, costly and often ineffective
  ➢ Duplicative IRB reviews among sites
  ➢ Subcontracting harmonization among institutions delays start-up
  ➢ Duplicative investigator/site qualification

• Solutions in progress
  ➢ Centralized IRB review (reliance agreements, IT solutions)
  ➢ Streamlined contracting (pre-negotiated master agreements)
  ➢ GCP training across CTSA sites
PCORnet and CTSA Network – Synergizing National Initiatives

*PCORnet Overview:*
*The National Patient-Centered Clinical Research Network*

Rachael Fleurence, PhD

*PCORnet Program Director, Research Infrastructure, PCORI*

April 29, 2016
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”
PCORnet embodies a “community of research” by uniting people, clinicians & systems

21 Patient-Powered Research Networks (PPRNs) + 13 Clinical Data Research Networks (CDRNs) = PCORnet
A national infrastructure for people-centered clinical research
PCORnet is Growing

130 health systems across the country
Over 60 data marts
Data on over 110 million patients
Research Demonstration Projects

1 Clinical Trial: ADAPTABLE

2 Observational Studies:
   - Antibiotic Use and Excess Weight Gain in Children
   - Bariatric Surgery: Benefits and risks of three main surgical treatment options

6 PPRN demonstration projects
Administrative Simplicity: Streamlining Research Processes

- **IRB**
  - Scalability
  - IRBrely and pilot

- **Data Sharing Agreement (DSA)**
  - Potential for use in demonstration projects

- **Master Contract**
PCORnet/CTSA Dyad Initiative

- Bringing together PCORI and NCATS leadership to leverage work being done within PCORnet and CTSAs
- Exploring pathways for collaborative national clinical research infrastructures
- Particular focus on advancing:
  - Contracting
  - IRB
  - Informatics
Implementing the PCORnet Data Strategy

Keith Marsolo and Lesley Curtis
PCORnet Coordinating Center
PCORnet Data Strategy

- Standardize data into a common data model
  - Attention to data quality
- Build a secure querying infrastructure
- Build re-usable tools to query the data
- Send questions to the data and only return required information
- Learn by doing and repeat
Standardize to a common data model

**Fundamental basis**

**DEMOGRAPHIC**
Records direct attributes of individual patients.

**Associations with PCORnet clinical trials**

**PCORNET TRIAL**
Patients with are enrolled in PCORnet clinical trials.

**Process-related data**

**HARVEST**
Attributes associated with specific PCORnet datamart implementations.

**Data captured from processes associated with healthcare delivery**

**ENROLLMENT**
Concept that defines a period of time during which all medically-attended events are expected to be observed.

**DISPENSING**
Outpatient pharmacy dispensing, such as prescriptions filled through a neighborhood pharmacy with a claims paid by an insurer. Not commonly captured within healthcare systems.

**Data captured within multiple contexts: healthcare delivery, registry activities, or directly from patients**

**VITAL**
Vital signs directly measure an individual's current state of attributes.

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

**PRO CM**
Patient-Reported Outcome (PRO) Common Measures (CM) are standardized measures that are defined the same way across all PCORnet networks. Each measure is recorded at the individual item level.

**Data captured from healthcare delivery, direct encounter basis**

**ENCOUNTER**
Interactions between patients and providers within context of healthcare delivery.

**DIAGNOSIS**
Diagnosis codes indicate results of diagnostic processes and medical coding.

**PROCEDURES**
Procedure codes indicate discrete medical interventions or diagnostic testing.

**PRESCRIBING**
Provider orders for medication dispensing or administration.

**LAB RESULT CM**
Specific types of quantitative and qualitative measurements from blood and body specimens, standardized across all networks.

PCORnet Common Data Model v3.0
Attention to data quality

Step 1: Diagnostic Query (Partner)

Step 2: Data Characterization (Partner)

Step 3: Review of results (CC)

Mitigation plan (Partner & CC)

Data Refresh (Partner)

Generation of Empirical Data Characterization Report (CC)

No issues

Research
Attention to data quality

Step 1
Diagnostic Query (Partner)

Step 2
Data Characterization (Partner)

Step 3
Review of results (CC)

Mitigation plan (Partner & CC)

Data Refresh (Partner)

Generation of Empirical Data Characterization Report (CC)

64 DataMarts characterized!

Research

No issues
Here’s how PCORnet’s distributed research network works:

The Researcher sends a question to the PCORnet Coordinating Center through the Front Door.

The Coordinating Center converts the question into a query with an underlying executable code, and sends it to PCORnet partners.

PCORnet partners review the query and provide a response, which is sent back through the Front Door to the Researcher.
Build reusable tools to query the data
Build reusable tools to query the data

Study Design:

Identify patients <AGE RANGE> with a <NEW / REFILL> dispensing of a <DRUG CLASS>. To be eligible, patients must have met the following criteria in the <LOOKBACK PERIOD> days before the index dispensing: (1) continuous enrollment in <TYPE(S) OF INSURANCE> benefits, (2) no prescription for <DRUG CLASS> or <DRUG CLASS>, and (3) no diagnosis of <DISEASE / CONDITION> in <INPATIENT / OUTPATIENT / ED> care setting.

The primary outcome of interest is <EVENT> identified with <DIAGNOSIS CODE> in <PRIMARY / SECONDARY / ANY> position during an <INPATIENT / OUTPATIENT / ED> encounter.
Build reusable tools to query the data

Study Design:

Identify patients with a dispensing of a <DRUG CLASS>. To be eligible, patients must have met the following criteria in the <LOOKBACK PERIOD> days before the index dispensing: (1) continuous enrollment in <TYPE(S) OF INSURANCE> benefits, (2) no prescription for <DRUG CLASS> or <DRUG CLASS>, and (3) no diagnosis of <DISEASE / CONDITION> in <INPATIENT / OUTPATIENT / ED> care setting.

The primary outcome of interest is <EVENT> identified with <DIAGNOSIS CODE> in <PRIMARY / SECONDARY / ANY> position during an <INPATIENT / OUTPATIENT / ED> encounter.
Resulting in a national evidence system with unparalleled research readiness

People’s data available in PCORnet to date:

~110 Million
Resulting in a national evidence system with unparalleled research readiness

<table>
<thead>
<tr>
<th>Gender</th>
<th>Female</th>
<th>Male</th>
</tr>
</thead>
<tbody>
<tr>
<td>Race</td>
<td>White</td>
<td>Non-White</td>
</tr>
<tr>
<td>Age</td>
<td>0–4</td>
<td>5–14</td>
</tr>
<tr>
<td>Pool of patients</td>
<td>For clinical trials</td>
<td>~ 33 Million</td>
</tr>
<tr>
<td></td>
<td>For observational studies</td>
<td>~ 68 Million</td>
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</tbody>
</table>
Trial Innovation Network

Mission

- Create a national laboratory to study, understand, and improve multi-center research, (clinical trials, observational studies, etc.)
- Leverage, the talent, expertise, & resources of the CTSA Program to transform clinical trials
  - Collaborative national network
  - Accelerate planning & implementation of high quality multi-center trials
  - Provide more treatments to more patients
  - Learning health system
Trial Innovation Network

Network Accelerates the Translation of Best Practices and Novel Interventions to Evidence Based Treatments

Develop - Science/Create
- Not enough to create another network

Demonstrate - Measure
- Evidence that Changes Practice

Disseminate - Care
- Tools/Ideas that have an impact
Trial Innovation Network

Cooperative Network with a Unified Mission
- 64 CTSA Programs
- RICs Recruitment Innovations Centers
- TICs Trial Innovation Centers
- NCATS/DCI
Trial Innovation Network

Accrual for Clinical Trials (ACT) Accomplishments

• Developed policies and procedures that govern identification of study participant cohort across multiple sites.

• Pilot project(s) that demonstrate that EHR-driven cohort exploration for multi-site research is enabled across the federated network.

• Steps toward making i2b2/SHRINE platform interoperable with PopMedNet, including the mapping of i2b2 to Common Data Model - SCILHS

• Effort, cost and time estimates for making two sites not using i2b2 interoperable with the ACT network.

ACT Team: Firestein, M.D, Toto, M.D., Reis, M.D., Nadler MD
Trial Innovation Network

Clinical Trials Bioinformatics Development Framework

- Bioinformatics Innovation - Learning Health System for CQI

Development Framework

The National Center for Advancing Translational Sciences (NCATS) maintains a software development framework. The framework consists of two environments: a development environment and a production environment. Each environment includes a set of software development tools (Source Control, Bug tracking, and ticketing systems). The development framework is a shared resource where individuals and institutions can collaboratively develop innovative tools, which can be disseminated to the community at large.

Software developed at NCATS will be freely available for the community, however, in an effort to encourage entrepreneurship, derivative versions of the program for commercialization will be encouraged. The governance of the Development framework will be a shared effort between CTSA members and NCATS.
Learning Health System

- Evidenced Based Performance - Use Data to maximum value
- Help Clinicians to ‘Work Smarter not Harder’
Trial Innovation Network

PCORNet / NCATS: Trial Innovation Network

Areas of **Potential Collaboration**

- Patients Centered Involvement
- Single IRB
- Governance in areas like Data Sharing
- Trial Design
- Common Data Elements
- Dissemination of Evidence: Best Practices, FDA
- PCORNet informatics Experience
Questions