Trial Innovation Network & PCORnet

Collaborations & Synergies

Monica Shah, Gordon Bernard, and Danny Benjamin
Trial Innovation Network

Adrian Hernandez
PCORnet
Agenda

• Trial Innovation Network
• PCORNet
• Common Goals
  • Creating a Durable Trial Infrastructure
  • Streamlining Trial Administration
  • Optimizing Protocols
  • Enhancing Stakeholder Engagement
  • Optimizing Data Use
• Collaboration and Opportunities
Trial Innovation Network
The Vision

CTS Clinical and Translational Science

Early Vision for the CTSA Program Trial Innovation Network: A Perspective from the National Center for Advancing Translational Sciences (NCATS)

Monica R. Shah, Michelle A. Culp, Kenneth R. Gersing, Patricia L. Jones, Mary E. Purucker, Tiina Urv, Todd M. Wilson, Petra Kaufmann

Accepted manuscript online: 8 March 2017  Full publication history

National Platform for Clinical Trials that Focuses on Operational Innovation, Operational Excellence, and Collaboration

Resource for NIH, Industry, and Other Partners
CTSA PROGRAM HUBS: Leading excellence and innovation locally

Boston University, Case Western Reserve University, Children’s Research Institute, Columbia University, Cornell University, Dartmouth College, Duke University, Einstein-Montefiore, Emory University, Georgetown-Howard Universities, Harvard University, Icahn School of Medicine at Mount Sinai, Indiana University, Johns Hopkins University, Mayo Clinic, Medical College of Wisconsin, Medical University of South Carolina, New York University, Northwestern University, Ohio State University, Oregon Health & Science University, Pennsylvania State University, Rockefeller University, Scripps Research Institute, Stanford University, Tufts University, University at Buffalo, State University of New York, University of Alabama at Birmingham, University of California - Davis, University of California - Irvine, University of California - Los Angeles, University of California - San Diego, University of California - San Francisco, University of Chicago, University of Cincinnati, University of Colorado - Denver, University of Florida, University of Illinois at Chicago, University of Iowa, University of Kansas, University of Kentucky, University of Massachusetts, University of Miami, University of Michigan, University of Minnesota, University of New Mexico, University of North Carolina, University of Pennsylvania, University of Pittsburgh, University of Rochester, University of Southern California, University of Texas HSC at Houston, University of Texas HSC at San Antonio, University of Texas Medical Branch at Galveston, University of Texas Southwestern, University of Utah, University of Washington, University of Wisconsin - Madison, Vanderbilt University Medical Center, Virginia Commonwealth University, Wake Forest University, Washington University in St. Louis, Yale University

Collaborating regionally and nationally

Domain Task Forces
- Methods Processes
- Collaboration Engagement
- Understudied Populations
- Informatics
- Workforce Development

Consortium-wide programs
- Collaborative Innovation Awards
- Trial Innovation Network
- CTSA Program Data Harmonization
- Future Innovations & Partnerships

CTSA Clinical & Translational Science Awards
Trial Innovation Network

CTSA Program Hubs

NIH Institutes
Industry Foundations

Partners
Participants
Providers
Public

Trial Innovation Centers (TICs)

Recruitment Innovation Centers (RIC)

Trial Innovation Network

Hub Liaison Teams

CTSA Clinical & Translational Science Awards

Tufts Medical Center

University of Utah Health Care

Vanderbilt University Medical Center

Johns Hopkins Medicine

Duke Clinical Research Institute
Trial Innovation Network
Operational Excellence

**Trial Planning**
- Protocol Design
- Study and Budget Feasibility
- Statistical Analysis Plan
- Risk Assessment
- Engagement and Recruitment Plans
- Patient Engagement Studio
- Cohort Discovery Leveraging EHR
- Recruitment Training
- Access to unique populations – Rare Diseases
- Key Opinion Leader/Clinical Expertise

**Trial Execution**
- 3 Academic Central IRBs
- Standard Agreements Used Across Network *(FDP-CTSA)*
- CTSA Program Recruitment Sites with Trial Innovation Network Hub Liaison Teams
- Regulatory Support
- Project Management
- Consent Forms, CRFs
- Site Selection, Initiation, Training
- Enrollment Metrics and Performance Accountability
- Recruitment Plans and Tools
- Data Management
- DSMB
- Study Close Out, Statistical Analysis
- Publications
What Makes the Trial Innovation Network Different?

**Operational Innovation**

- A living laboratory to study and innovate key elements of clinical trials
- Goal isn’t just to complete a trial – but to improve the clinical trials process
Trial Innovation Network

Innovating and Harmonizing to Clear Roadblocks

- Delays in IRB Review
- Delays in Contracting
- Complex Protocols
- Recruitment Challenges
- Data not Fully Utilized
- Fragmented Site Based Research
Harmonized Site Based Research System
Harmonized Data Standards
Harmonized Recruitment System
Harmonized Protocol System
Harmonized Contracting System
Harmonized CIRB System
Complex Protocols
Recruitment Challenges
Data not Fully Utilized
Fragmented Site Based Research

Trial Innovation Network
Innovating and Harmonizing to Clear Roadblocks
Trial Innovation Network
Innovating and Harmonizing to Clear Roadblocks

Harmonized CIRB System
Harmonized Contracting System
Harmonized Protocol System

Recruitment Challenges
Data not Fully Utilized
Fragmented Site Based Research
Trial Innovation Network

Innovating and Harmonizing to Clear Roadblocks

- Harmonized CIRB System
- Harmonized Contracting System
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CTSA Clinical & Translational Science Awards
Trial Innovation Network
Innovating and Harmonizing to Clear Roadblocks

- Harmonized CIRB System
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Trial Innovation Network
Innovating and Harmonizing to Clear Roadblocks

Harmonized CIRB System
Harmonized Contracting System
Harmonized Protocol System
Harmonized Recruitment System
Harmonized Data Standards
Harmonized Site Based Research System
Trial Innovation Network
Central IRB System

- Duke/Vanderbilt TIC
  - Vanderbilt IRB
- Johns Hopkins/Tufts TIC
  - Johns Hopkins IRB
- Utah TIC
  - Utah IRB

- **SMART IRB** Master Common Reciprocal Institutional Review Board Authorization Agreement
  - A national, master reliance agreement supporting single IRB review
- **CIRB Letter of Indemnification**
  - A separate agreement concerning indemnification and related terms that is required by Vanderbilt University Medical Center
- **SMART IRB Exchange** Portal Access Form and web-based support system
  - A web-based platform to support IRB reliance initiation, documentation, tracking, and between participating IRBs, Hub Liaison Teams, and study teams
SMART IRBexchange Website Tracks Site Sign-on and Status

<table>
<thead>
<tr>
<th>Site</th>
<th>SMART IRB</th>
<th>SMART IRB Exchange</th>
<th>SSRP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Louisiana State University Health Science Center New Orleans</td>
<td></td>
<td>✓</td>
<td>Not registered</td>
</tr>
<tr>
<td>Oregon Health &amp; Science University</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>University of Chicago - University of Chicago Medicine - Comer Children's Hospital</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Case Western Reserve University</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Children's National Medical Center</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Columbia University</td>
<td>✓</td>
<td>✓</td>
<td>Complete</td>
</tr>
<tr>
<td>Duke University</td>
<td>✓</td>
<td>✓</td>
<td>Pending acceptance</td>
</tr>
<tr>
<td>Emory University</td>
<td>✓</td>
<td>✓</td>
<td>Complete</td>
</tr>
<tr>
<td>Harvard University</td>
<td>✓</td>
<td>✓</td>
<td>Complete</td>
</tr>
<tr>
<td>University of California, San Francisco - UCSF Benioff Children's Hospital</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vanderbilt University Medical Center - Monroe Carell Jr. Children's Hospital</td>
<td></td>
<td></td>
<td>Complete</td>
</tr>
<tr>
<td>Yale University</td>
<td></td>
<td></td>
<td>Complete</td>
</tr>
</tbody>
</table>

Sign-on status incomplete

Coming Soon: Capturing local context completion

Registration Stage
SMART IRBexchange

Document Management System for Relying Sites with Version Control
Dear All,

Boston University Medical Center has shared IRB approval for your institution, Columbia University, for the following study:

**A Phase 2 Multicenter, Randomized, Double-blind, placebo-controlled study to Assess the Safety and Efficacy of Ilotroba in Patients with Diffuse Cutaneous Systemic Sclerosis or Systemic Sclerosis-associated Pulmonary Arterial Hypertension**

This was an Initial Study. Full Board approval by the Reviewing IRB. The expiration date is 03/21/2017.

Principal Investigators & Study Contacts:
Your approval documents are attached. Please refer to the submission instructions sent previously regarding how to handle future submissions and reporting of events.

Access the study at: [https://victrextest.irbchoice.org/environ/irbchoice/primary/project/viewprote?broj=337](https://victrextest.irbchoice.org/environ/irbchoice/primary/project/viewprote?broj=337)

Thank you,
The SMART IRB Exchange Team
**Trial Innovation Network**

Federal Demonstration Project Clinical Trials Subaward (FDP-CTSA) Agreement

- Developing the FDP-CTSA Agreement
  - Start with NIH (funding agency)
  - Start with Fixed Price
  - Domestic enrolling sites only
  - Comply with all federal regulations
  - Adhere to ACTA terms whenever possible
  - Allow study specific terms to be added
  - Create budget guidance document

- Product
  - FDP Fixed Price Clinical Trials Subaward Agreement Template – NIH
Trial Innovation Network
Standard Agreement System

• 3 TICs will use FDP-CTSA Agreement with Trial Innovation Network-specific Attachment 2B

• 50 of 64 CTSA Hubs have officially registered to use the FDP-CTSA Trial Innovation Network Standard Agreement

• **GOAL:** 90% of CTSA Hubs registered by June 1st
Trial Innovation Network

Innovating and Harmonizing – Protocols

Roadblock

Suboptimal Protocols

Exclusive Focus on Science

Execution

Limited Secondary Use of Data

Reactive Recruitment Planning

Analytics
Trial Innovation Network

Innovating and Harmonizing – Protocols

**Trial Design**
- Novel Study Designs
- Quality by Design
  - Compelling Scientific Endpoints
  - Feasibility
- Limit Complexity
- Optimize Data Collection
- Metrics/Milestones
- Develop Realistic Budgets

**Recruitment Planning**
- Engage Stakeholders
- Tailored Messages and Recruitment Material
  - Pre-specified Recruitment Budgets
  - Monitor Recruitment Process, Metrics

**Data Driven Approaches**
- EHR Based Cohort Discovery and Site Selection
- Recruitment modeling to minimize amendments

**Strategically Designed Protocols**

**Analytics**

**Execution**

**TIC and RIC Collaboration**
Trial Innovation Network
Proposal Process

- Trial Innovation Network offers services and consultations
- Services – Ala Carte Services
  - CIRB
  - Standard Agreements
  - Recruitment Services
  - Community Engagement Studio
  - Cohort Discovery
- Consultations
  - Study design, budget, feasibility, timelines
  - Potential to implement study in Trial Innovation Network with TIC/RIC as coordinating center and CTSA Program Hubs as sites

Trial Innovation Network Website

Trial Innovation Network Proposal Process

The Trial Innovation Network is a rapidly developing and evolving collaborative initiative of the CTSA Program that leverages the expertise, skills, and knowledge of the entire CTSA Consortium. The Trial Innovation Network is composed of three key organizational partners – the Trial Innovation Centers (TICs), the Recruitment Innovation Center (RIC), and the CTSA Program Hubs. Each partner plays a unique and essential role.

The Trial Innovation Network is a resource for investigators to request consultations and services for multi-center clinical trials and studies. The goal of the Trial Innovation Network is to provide a disruptive new model for clinical trials and a flexible resource that allows investigators to choose from a menu of consultations and services. Some consultations may be selected for further development into clinical protocols that may be implemented in the Trial Innovation Network.

Review Services We Offer

The Trial Innovation Network offers study investigators the ability to request an initial consultation on specific services depending on the funding status of the proposal. A comprehensive consultation cannot be selected by an investigator. Refer to your toolbox on the right to see definitions for all services and consultations.

Connect with Local Experts

Prior to submitting a Trial Innovation Network Project Proposal, study investigators must discuss the proposal with their CTSA Program Hub Principal Investigator and the Trial Innovation Network Hub Liaison Team. Refer to your toolbox on the right to access proposal submission guidelines and checklists for both Investigators and Hub Liaison.

Learn About the Proposal Process and Get Started

Once a study investigator submits a proposal to the Trial Innovation Network, the proposal undergoes a series of reviews to ensure completion and assess alignment with the mission of the Network. Refer to your toolbox on the right to see guidelines and instructions for submitting proposals. Investigators are invited to submit proposals to the...
Trial Innovation Network
Proposal Process

Investigator develops proposals

Investigator works with CTSA Hub Liaison Team to leverage local resources
CTSA PI must approve proposal submission

Investigator works with NIH Program Officer
Ensures proposal to ensure ideas would be of interest to NIH Institute

TIC/RIC Assigned
Decision Letter sent to investigator

Proposal reviewed by Trial Innovation Network Proposal Assessment Team

Investigator submits proposal to Trial Innovation Network
## Proposal Metrics

<table>
<thead>
<tr>
<th>Proposal Metrics</th>
<th>Nov 2016 – May 2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proposals Submitted (Total)</td>
<td>44</td>
</tr>
<tr>
<td>Proposals Approved (Total)*</td>
<td>27</td>
</tr>
<tr>
<td>Consultations Approved</td>
<td>19</td>
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<tr>
<td>Services Approved</td>
<td></td>
</tr>
<tr>
<td>• CIRB</td>
<td>9</td>
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<tr>
<td>• Standard Agreements</td>
<td>3</td>
</tr>
<tr>
<td>• Recruitment</td>
<td>1</td>
</tr>
<tr>
<td>• Recruitment</td>
<td>5</td>
</tr>
<tr>
<td>Demonstration and Pilot Projects**</td>
<td>6</td>
</tr>
</tbody>
</table>

*One proposal requested 2 services

**Demonstration Projects – Services initiated in an expedited fashion as a use case

Pilot Project – Trial initiated in an expedited fashion as a use case
# Trial Innovation Network

## Approved Proposals by Therapeutic Area

<table>
<thead>
<tr>
<th>Types of Proposals</th>
<th>Nov 2016-May 2017</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Therapeutic Area</strong></td>
<td></td>
</tr>
<tr>
<td>Cardiology</td>
<td>5</td>
</tr>
<tr>
<td>Endocrinology</td>
<td>3</td>
</tr>
<tr>
<td>Internal Medicine</td>
<td>1</td>
</tr>
<tr>
<td>Neurology/Psychiatry</td>
<td>3</td>
</tr>
<tr>
<td>Obstetrics/Gynecology</td>
<td>1</td>
</tr>
<tr>
<td>Oncology</td>
<td>1</td>
</tr>
<tr>
<td>Ophthalmology</td>
<td>1</td>
</tr>
<tr>
<td>Pediatrics</td>
<td>5</td>
</tr>
<tr>
<td>Rheumatology</td>
<td>1</td>
</tr>
<tr>
<td>Renal</td>
<td>1</td>
</tr>
</tbody>
</table>
Trial Innovation Network
Pilot Project

The Society of Thoracic Surgeons
Congenital Heart Surgery Database

Steroids to Reduce Systemic Inflammation after Neonatal Heart Surgery
STRESS Trial

Challenge

• Neonatal cardiac surgery associated with high morbidity and mortality
• Steroids used but not tested in trials – rare disease, costs too high

Innovation

• Randomized registry trial using STS CHD database – minimize data collection and reduce costs
• n=1500 neonates at up to 15 CTSA Hubs
• Data pull from EHR for specified labs
• 11 CRF pages in total
• Vanguard for Trial Innovation Network

CIRB, standard agreements, data standards and harmonization efforts

Perspective
The Randomized Registry Trial — The Next Disruptive Technology in Clinical Research?

Michael S. Lauer, M.D., and Ralph B. D’Agostino, Sr., Ph.D.
TRIAL INNOVATION NETWORK
Operational innovation, excellence, and collaboration.

The Trial Innovation Network has received more than 40 proposal submissions! We continue to accept new proposals. Click the submit button to get started.

WELCOME!
The Trial Innovation Network is a collaborative national network that focuses on operational innovation, excellence and collaboration and will leverage the expertise and resources of the CTSA Program.

www.trialinnovationnetwork.org
PCORnet® & National Evidence System

The National Patient-Centered Clinical Research Network
A System: Engagement, Research, Evidence

Key areas & questions

Electronic Health Data

Health Systems & Communities

Engagement| Enrollment

EHR extraction

PRO

Common Data Model

Study data

Analysis/Results

Evaluation & Feedback/Dissemination

Notifications and Messaging

Devices, surveys, wearables, etc.

Personalized Health Initiatives

Web-based | Mobile (iOS & Android) | Function phones

Hernandez, A.F. and Cruz H Circulation. 2017;135:1478-1480
A community of research that unites data from patients, clinicians, and systems
A community of research that unites data from patients, clinicians, and systems
A community of research that unites data from patients, clinicians, and systems.
DATA

PATIENT DATA
- Demographics
- Enrollment
- Administrative Claims

MEDICAL RECORDS
- Condition
- Diagnosis
- Procedures

GENOMICS
- Medications
- Labs
- Vital Status

HEALTH PLANS
- Encounters

DEATH INDEX

pcornet
Fundamental basis

Data captured from processes associated with healthcare delivery

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

Data captured from healthcare delivery, direct encounter basis

Associations with PCORnet clinical trials

PCORNET TRIAL

Process-related data

HARVEST

ENCOUNTER

DIAGNOSIS

PROCEDURES

PRESCRIBING

LABORATORY RESULTS (COMMON MEASURES)

DEMOGRAPHIC

ENROLLMENT

DISPENSING

DEATH

DEATH CAUSE

VITAL

CONDITION

PATIENT-REPORTED OUTCOMES (COMMON MEASURES)

Standardize to a Common Data Model
Learn by doing

Data Curation

Research & Analytic Tools

CDM Development
Resulting in a national evidence system with research readiness
Resulting in a national evidence system with research readiness

<table>
<thead>
<tr>
<th>Race</th>
<th>Sex</th>
<th>Age</th>
<th>Pool of patients</th>
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</thead>
<tbody>
<tr>
<td>White</td>
<td>Female</td>
<td>0–4</td>
<td>For clinical trials 42,545,341</td>
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<tr>
<td></td>
<td></td>
<td>5–14</td>
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<td></td>
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<td>15–21</td>
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</tr>
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<td></td>
<td></td>
<td>22–64</td>
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<tr>
<td>Non-White</td>
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<td>65+</td>
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</tr>
<tr>
<td>Missing</td>
<td>Male</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Missing</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Non-White

Female

Male

For observational studies 83,131,450
Resulting in a national evidence system with research readiness

PCORnet represents:

~ Millions of people

who have had a medical encounter in the past 5 years

*some individuals may have visited more than one Network Partner and would be counted more than once
## Conditions

<table>
<thead>
<tr>
<th>Condition</th>
<th>PCORnet</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respiratory conditions</td>
<td>2,837,803</td>
</tr>
<tr>
<td>Selected malignancies</td>
<td>1,294,158</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>354,929</td>
</tr>
<tr>
<td>Stroke</td>
<td>420,802</td>
</tr>
<tr>
<td>Rheumatoid arthritis</td>
<td>254,803</td>
</tr>
<tr>
<td>Ulcerative colitis</td>
<td>88,029</td>
</tr>
<tr>
<td>Hypertension</td>
<td>5,902,641</td>
</tr>
<tr>
<td>Renal disease</td>
<td>1,018,729</td>
</tr>
<tr>
<td>Influenza/pneumonia</td>
<td>869,306</td>
</tr>
</tbody>
</table>
# Lab Results

<table>
<thead>
<tr>
<th>Lab</th>
<th>Records</th>
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</thead>
<tbody>
<tr>
<td>Total</td>
<td>2.3 billion</td>
</tr>
<tr>
<td>A1C</td>
<td>72 million</td>
</tr>
<tr>
<td>CK</td>
<td>17 million</td>
</tr>
<tr>
<td>CK_MB</td>
<td>8 million</td>
</tr>
<tr>
<td>CK_MBI</td>
<td>3 million</td>
</tr>
<tr>
<td>Creatinine</td>
<td>288 million</td>
</tr>
<tr>
<td>HGB</td>
<td>298 million</td>
</tr>
<tr>
<td>INR</td>
<td>78 million</td>
</tr>
<tr>
<td>LDL</td>
<td>89 million</td>
</tr>
<tr>
<td>TROP_I</td>
<td>21 million</td>
</tr>
<tr>
<td>TROP_T(QL)</td>
<td>273K</td>
</tr>
<tr>
<td>TROP_T(QN)</td>
<td>4 million</td>
</tr>
<tr>
<td>Other</td>
<td>1.4 billion (~12 DataMarts)</td>
</tr>
</tbody>
</table>
Case Example: ADAPTABLE

Pragmatic Design
- eScreening, eEnrollment, and eFollowup

Pragmatic Results
- Enrolling between 12 – 52 patients/month at <$1K per pt

Engagement: Partnership with Patient ‘Adaptors’

<table>
<thead>
<tr>
<th>CDRN</th>
<th>First Site Activated</th>
<th>Started Enrollment</th>
<th>Total Enrolled</th>
<th>Enrollment Rate/Month</th>
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</thead>
<tbody>
<tr>
<td>PaTH</td>
<td>7/18/2016</td>
<td>August</td>
<td>423</td>
<td>52.9</td>
</tr>
<tr>
<td>MidSouth</td>
<td>4/18/2016</td>
<td>April</td>
<td>630</td>
<td>52.5</td>
</tr>
<tr>
<td>GPC</td>
<td>7/18/2016</td>
<td>August</td>
<td>297</td>
<td>37.1</td>
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<tr>
<td>NYC</td>
<td>11/1/2016</td>
<td>November</td>
<td>156</td>
<td>31.2</td>
</tr>
<tr>
<td>OneFlorida</td>
<td>11/1/2016</td>
<td>November</td>
<td>138</td>
<td>27.6</td>
</tr>
<tr>
<td>REACHnet</td>
<td>4/18/2016</td>
<td>April</td>
<td>237</td>
<td>19.8</td>
</tr>
<tr>
<td>CAPriCORN</td>
<td>8/30/2016</td>
<td>September</td>
<td>97</td>
<td>13.9</td>
</tr>
<tr>
<td>pScanner</td>
<td>11/7/2016</td>
<td>November</td>
<td>61</td>
<td>12.2</td>
</tr>
</tbody>
</table>

CV trial average 1-2
Case Example: IRB & INVESTED

Synergy

- 203 institutions have signed, including all 100% (n=64) of CTSA Hubs

- SMART IRB evaluation in PCORnet’s INVESTED trial:
  - Faster
  - Reasonable cost (~$24K) for multi-center trial

<table>
<thead>
<tr>
<th></th>
<th>SMART IRB</th>
<th>Standard *</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time to approval</td>
<td>83.0</td>
<td>103</td>
</tr>
<tr>
<td>Time to first enrollment</td>
<td>120.0</td>
<td>169</td>
</tr>
</tbody>
</table>

People-Centered Research Foundation

Opening Soon
So what are the synergies of these two networks?

Collaborative Framework:

• Very large overlap in academic medical centers in CTSA/TIN and PCORnet
• Large problems in need of common solutions
• Common funders
• Case Examples:
  SMART-IRB
  Clinical trial development
  Clinical trial execution
  Dissemination/implementation
The Opportunity

• To fully leverage two mission-aligned networks to promote internal and research efficiency

• To capitalize on strengths of each, and accommodate any weaknesses

• How can we ensure alignment? Are there particular challenges people see?
For More Information

Trial Innovation Network CIRB:  
https://trialinnovationnetwork.org/elements/central-irb/

SMART IRB Exchange:  https://trialinnovationnetwork.org/smart-irb-exchange/?key-element=1603

FDP-CTSA Standard Agreement:  

PCORnet:  http://pcornet.org/

PCRF:  http://pcrfoundation.org/