Recruiting research participants - Innovations in the CTSA Program

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NIH COLLABORATORY/PCORI GRAND ROUNDS
MAY 15, 2015
Background
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• Most research studies experience delays in participant recruitment
• Clinical research costs are high
• Patients, clinicians and the public are affected by delays in generating much needed medical evidence
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Improving participant recruitment could accelerate translation
Improving Participant Recruitment

- Ongoing demonstration project in the CTSA network (ACT)
- “Recruitment Innovation Centers” planned

Planning phase

- Data-driven site selection
- Feasibility analysis

Implementation phase

- Privacy and IRB compliant recruitment plan
- Funded expert staff to help implement

Notice of Intent to Publish a Funding Opportunity Announcement for Recruitment Innovation Centers (RICs) for the Clinical and Translational Science Award Network (U01)

Notice Number:
NOT-TR-15-003

Key Dates
- Release Date: December 19, 2014
- Estimated Publication Date of Announcement: February 2015
- First Estimated Application Due Date: June 2015
- Earliest Estimated Award Date: February 2016
- Earliest Estimated Start Date: February 2016

Related Announcements
RFA-TR-14-009

Issued by
National Center for Advancing Translational Sciences (NCATS)

Purpose
Multi-site clinical trials are a critical scientific step in bringing new interventions to patients. However, they frequently experience challenges in recruiting participants, leading to additional cost and delays. The National Center for Advancing Translational Sciences (NCATS) intends to promote innovation and efficiency in participant recruitment into multi-site studies through a multi-disciplinary, multidimensional approach to research.
NIH Collaboratory

CTSA

T1-T4

- Embedded in NIH mission “...to seek fundamental knowledge ...and the application of that knowledge to enhance health...”
- And NCATS mission “...to catalyze the generation of innovative methods that will enhance the development., testing and implementation of diagnostics and therapeutics...”

PCORI

CER

- PCORI “helps people make informed healthcare decisions, and improves healthcare delivery and outcomes, by producing and promoting high integrity, evidence-based information that comes from research guided by patients, caregivers and the broader healthcare community.”

- Patient engagement
- Health care community/stakeholder engagement
- Innovative IT methods to integrate EMR and research
- IRB
- Contracting
Opportunities to coordinate
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Thank you!

….on to the ACT investigators
GOAL

NCATS Charge:
Increase Accrual to High Priority
NIH Clinical Trials
The Vision

**Stage 1 – De-identified counts**

**Stage 2 – Engaging the patient**

**Stage 3 – Patient engaging the researcher**
ACT and PCORNNet

ACT
- Accrual to NIH Clinical Trials
- Common informatics platform
- Investigator-driven queries
- Patient/community engagement through CTSA program
- Sustainable funding source
- Interoperable ontology

PCORNNet
- Clinical Effectiveness (may include trials)
- Different informatics platforms linked centrally
- Central queries
- Interoperable ontology
Building on Existing Networks

• i2b2/SHRINE Cohort Identification
  – Feasibility demonstrated:
    o UC BRAID- 5 UC sites
    o Harvard- HMS-affiliated hospitals

• ACT is an implementation project
“I Want to Recruit Patients with Rheumatoid Arthritis…”

UC BRAID and the UC Research Exchange
“…who were seen between 1/1/10 and 7/7/14…”

UC BRAID
and the UC Research Exchange
“...and are women between 35 and 54 years old”
“Where are they located?”

Female rheumatoid arthritis patients since 2010 between age 35-54

UC BRAID and the UC Research Exchange
“What about an uncommon disease?”

Low grade myelodysplasia patients since 2012

UC BRAID and the UC Research Exchange
ACT Project Plan

Stage 1: Cohort Exploration (i2b2/SHRINE)

Wave 1 Wave 2 Wave 3 Wave 4 … Wave n

Stage 2: Identify/Contact/Enroll Patients

Plan Build/Test Implement

Stage 3: Patients/Practitioners Identify Trials

Plan Implement
ACT Site Distribution

Legend
Red: Wave 1
Blue: Wave 2
ACT Governance Structure

PI Group
(Steven Reis, Lee Nadler, Robert Toto, Gary Firestein)

Executive Committee
(Lead from each work group, PI group, NCATS rep)

Budget and Contracting
Harold Pincus
Evaluation

Central PM
(Vince D’Ittri-Aspen Advisors)

Work Groups

Governance
Dipti Ranganathan
Robert Toto

Regulatory
Karen Allen

Technology
Doug McFadden
Nick Anderson

Data Harmonization
Shyam Visweswaran

Project Management Support
# ACT Work Group Membership: Wave 1

<table>
<thead>
<tr>
<th>Name</th>
<th>Institution</th>
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<tr>
<td>Kahn, Michael</td>
<td>Colorado</td>
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<td>Lockie, Tim</td>
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<td>Schulte, Gregory</td>
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<td>Sengupta, Soumitra</td>
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<td>Alema-Mensah, Ernest</td>
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<td>Klement, Brenda</td>
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<td>Conlon, Mike</td>
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<td>Reeder, Phillip</td>
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<td>Toto, Bob</td>
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Technology Work Group

Stage 1 Objectives

• Create a network of CTSA hubs
• Cohort exploration in EHRs
• Create foundation for:
  – Additional waves of CTSA hubs
  – Stage 2: Identify, Contact and Enroll Patients in Trials
Technology Work Group

Stage 1 Deliverables (High Level)

• Local Software Install
• Connect Sites to Network Infrastructure
• Activate Production Network
Stage 1 Objectives

- Semantic interoperability
  - Common data elements document
  - ACT ontology file in i2b2 format
  - Coordinate with PCORNet
- Oversee data quality
Data Harmonization Work Group

ACT Ontology

- Demographics
- Diagnoses
- Procedures
- Visit Details
- Medications
  - RxNorm +NDF-RT
- Laboratory Test Results
  - LOINC
Regulatory Work Group

Stage 1 Objectives

• Identify common regulatory approach
  – Compliant access of EHRs across network
• Facilitate IRB approval (Stage 1)
  – Stage 1: Cohort Exploration (de-identified patient counts)
• Stage 2: Regulatory approaches for contacting identified patients
Regulatory Work Group

Stage 1 Deliverables

- Development of Regulatory Guidance Summary
  - Roadmap of Phase 1 Regulatory issues/concerns
- White Paper for local i2b2 Clinical Data Warehouse
- White Paper for Cohort Exploration - Non-Human Subjects Research Activity
Governance Work Group

Stage 1 Objectives

• ACT Governance Document
  – Communications
  – Site Participation
  – Query Access - Terms-of-Data-Access Agreement
  – Standard Operating Procedures
Project Management: Aspen Advisors

- Single point of contact for information
- Manage communications and reporting
- Deploy a consistent set of tools and processes for site implementations
- Encourage collaboration, best practices, information sharing
- Maintain a state of low overhead, simple processes
Progress and Milestones
Timeline

• September
  – 9/1/14: Project initiated
  – Technology implementations begin

• October
  – 10/7: Face-to-Face Meeting
  – Ontology and initial Use Cases
  – IRB submissions

• November
  – Selection of Wave 2 Sites
  – Begin Stage 2 Planning
Timeline

• January: NCATS 4 Month Milestone
  – IRB Approval for At Least 7 Sites
    ○ 21 sites have approved
  – Identify 8 Wave 2 Sites
    ▪ Children’s National Medical Center
    ▪ Duke University
    ▪ Indiana
    ▪ Northwestern University
    ▪ Oregon Health & Science University
    ▪ Stanford University
    ▪ University of Cincinnati – Cincinnati Children’s Hospital
    ▪ Medical University of South Carolina
Timeline

• January: NCATS 4 Month Milestone
  – Identify At Least 2 Non-i2b2 Sites
    o Virginia Commonwealth University
    o NYU Langone/NYC Health & Hospitals Corp
    o Washington University in St Louis
    o University of Michigan
Timeline

• April
  – 4/30: Network Agreement Signed by 4 Lead Sites

• May
  – 5/31: Joinder Agreements to be signed

• June
  – 6/1: NCATS 9 Month Milestone
    o First pilot query implemented
      ▪ Rheumatoid Arthritis, Hepatitis
    o SOPs: installation, data harmonization, queries

• August
  – 8/31: All project work products due to NCATS
Special Considerations
ACT and PCORNet: Ongoing Collaboration

• Acknowledgment of synergistic missions
• Many overlapping institutions
• Some overlapping informatics platforms
• Same ontologies
• Ongoing communications
  – NCATS/PCORI “Dyads”