

The CTSA Program: Collaborative Innovation for Translational Research

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NCATS ADVISORY COUNCIL MEETING
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NCATS

Updates on the CTSA Program

- Innovating multi-site clinical research
- Integrating electronic health records and research data
- Collaborative Innovations Awards
- Tracking outcomes for collaborative strategic management

Innovation for Multi-site Studies: Streamlining and Harmonizing Processes

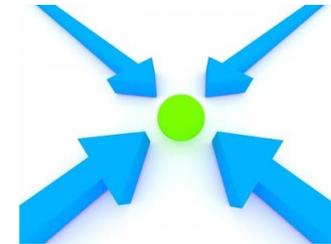
Research training standards

- Good Clinical Practice
- Translational Competencies

Streamlined budgeting and contracting

Single IRB

IRBrely



Innovation for Multi-site Studies: Streamlined Contracting

Accelerated Confidential
Disclosure Agreement
ACDA

Accelerated Clinical Trial
Agreement
ACTA

Accelerated Subcontracting

<https://www.ara4us.org/>

Khosla, Bernard, Edwards et al,
and CTSA teams

IRBrely

One IRB per multi-site study

Accomplishments:

- ✓ IRB Reliance Agreement
- ✓ Workflow
- ✓ IT Solutions
- ✓ Pilot test underway
 - CARRA: Childhood Arthritis & Rheumatology Research Alliance (Laura Schanberg (Duke University))
 - Feedback and testing to revise and enhance processes.

Team:

- Lead Investigator: Alan Green, Dartmouth
- Senior Reliance Advisor: Barbara Bierer, Harvard
- Regulatory Leads: Sabune Winkler, Harvard; and Nichelle Cobb, MC Wisconsin
- Informatics Lead: Amarendra Das, Dartmouth
- Critical contributions and support: CTSA investigators and their teams

Coordinating with: PCORnet, CTTI, RDCRN and others

RFA-TR-15-002: CTSA Network - Trial Innovation Centers (TICs)

- Centers of excellence that facilitate and innovate the implementation of multi-site clinical studies by the CTSA Network
- Activity code: U24
- Key dates:
 - Released: June 5, 2015
 - Application Due: September 15, 2015
 - Scientific Merit Review: February 2016
 - Advisory Council Review: May 2016
 - Earliest Start Date: June 2016
- Award
 - Up to \$4M (total cost per center) to fund 3 awards in 2016
 - Up to 7 years
- Partner: National Institute of Aging (NIA)

Innovation for Multi-site Studies: Participant Recruitment

Study planning phase



Study implementation phase

Data-driven site selection

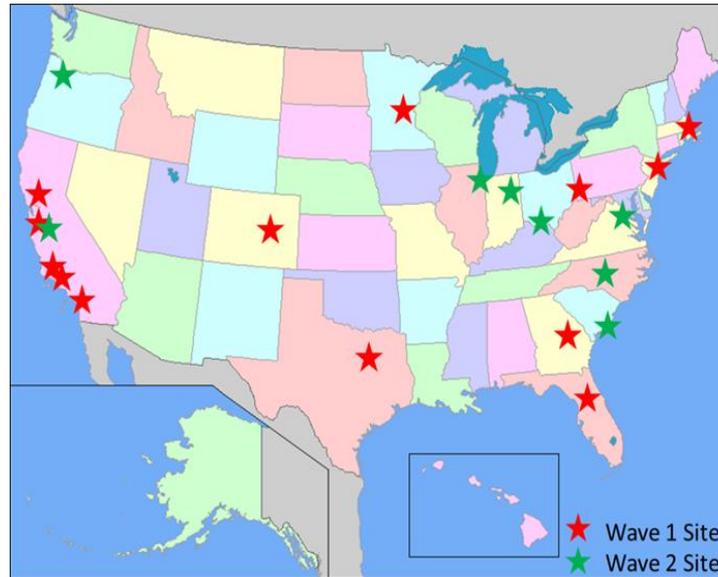
Privacy and IRB compliant
recruitment plan

Feasibility analysis

Funded expert staff to help
with implementation

Ongoing initiative:
Accrual to Trials (ACT)

Initiative: Accrual to Clinical Trials



- I2b2/SHRINE platforms to build federated network
- IRB approval obtained
- Waves 1 and 2 sites recruited
- Infrastructure and SOP's for governance, technology and regulatory issues
- Pilot query with rheumatoid arthritis study as use case
 - 22 sites participated in 6 sets of queries
- Additional query pilots underway
- Harmonization with PCORI in progress

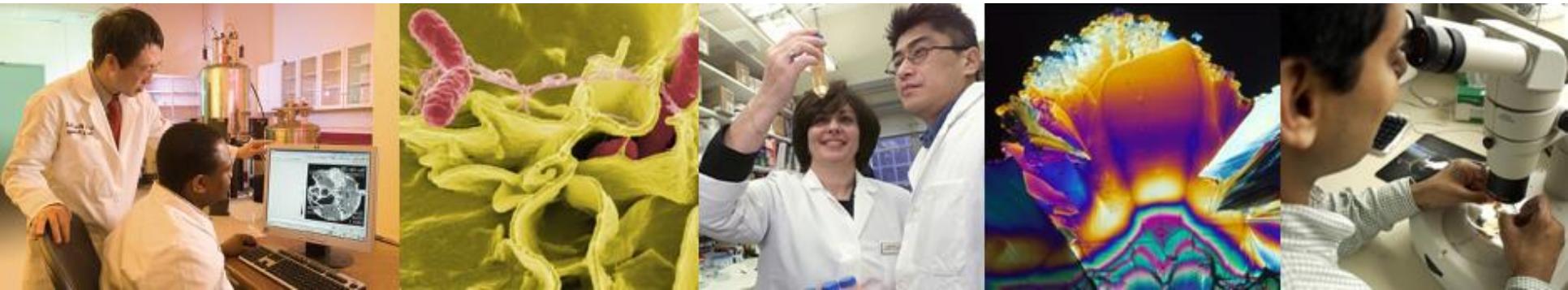
RFA-TR-15-042 - CTSA Network Recruitment Innovation Centers (RICs)

- Activity code: U24
- Key Milestones:
 - Applications received: July 22, 2015
 - Scientific Merit Review: November 2015
 - Advisory Council Review: January 2016
 - Earliest Start Date: February 2016
- Award
 - Up to \$3M (total cost per center and year) to fund 2 awards in 2016
 - Up to 5 years
- Partner: National Library of Medicine (NLM)

Funding Opportunity: CTSA Collaborative Innovation Awards (CCIA) PAR-15-173 (X02) and PAR-15-172 (U01)

**Encourage collaborations between investigators
from at least 3 CTSA Program hubs**

- First X02 applications received, June 2015
- X02 Review, Sept 21, 2015
- Next X02 deadline, Nov 10, 2015
- U01 notifications will be sent out November 2015
- First U01 deadline: February 2016



Common Metrics

Transforming how we measure impact
and manage strategically

CTSA Program
Principal investigators

4 groups

CTSA Program
Evaluators

Steering Committee
and NCATS

Common Metrics PI Working Groups

Consortium 2.0

Richard J. Barohn, MD
Lars Berglund, MD, PhD
Bruce Blazar, MD
Judith S. Hochman, MD
Anantha Shekhar, MD, PhD



Workforce Development at CTSA Program Hubs

James E. Heubi, MD
Rebecca Jackson, MD
Sundeep Khosla, MD
Katherine Luzuriaga, MD
Reza Shaker, MD



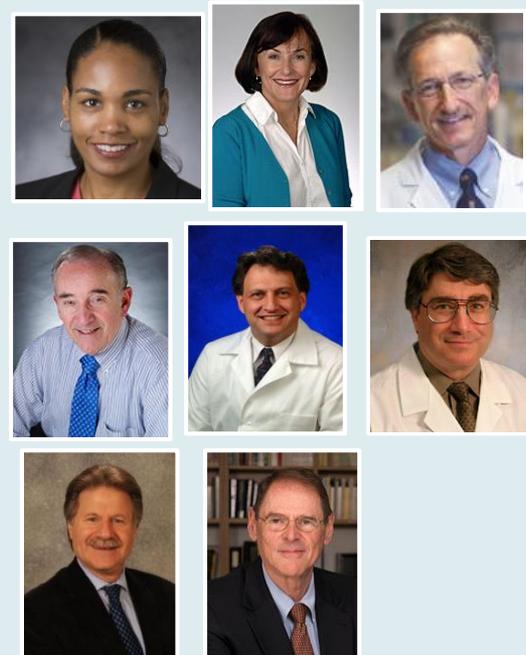
Collective Impact of CTSA Program Hubs

Karl D. Kiebertz, MD, MPH
Harry Selker, MD, MSPH
Tom Shanley, MD
Paula Shireman, MD, MS
Robert (Bob) Toto, MD



Resources and Services at CTSA Program Hubs

Leigh Ebony Boulware, MD
Kathleen Brady, MD
Gary Firestein, MD
Henry Ginsberg, MD
Lawrence Sinoway, MD
Julian Solway, MD
Ron Sokol, MD
Jose Szapocznik, PhD



Take-Home Message

The CTSA program is innovating and accelerating the process from discovery to health benefit through:

- **Strengthening Network Capacity** – enabling multi-site studies
- **Collaborations** – innovative projects across the translational spectrum
- **Common Metrics** – for collaborative strategic management



DISCUSSION