

Trial Innovation Network Hub Liaison Team Meeting

May 2, 2017

CTSA Clinical & Translational[®]
Science Awards

TRIAL INNOVATION NETWORK



Trial Innovation Network

Hub Liaison Team Meeting Agenda

May 2, 2017
3:00 – 4:30PM ET

Meeting Co-Chairs: Dr. Daniel Ford, Johns Hopkins University and Dr. Monica Shah, NCATS

<i>Time</i>	<i>Topic</i>	<i>Purpose</i>	<i>Speakers</i>
3:00 PM (10 min)	Welcome / Update on Trial Innovation Network	Review Meeting Goals / Overall Progress Update	Dan Ford Monica Shah
3:10 PM (5 min)	Trial Innovation Network Website Update	Progress Update	Paul Harris (PI, VU RIC)
3:15 PM (5 min)	PAT Charter – Executive Summary	Progress Update	Lori Poole (Duke/VU TIC)
3:20 PM (15 min)	Hub Liaison Team <ul style="list-style-type: none">Medical University of South Carolina	Share Information	Signe Denmark (Hub Liaison Team Member, MUSC)
3:35 PM (15 min)	Hub Liaison Team <ul style="list-style-type: none">University of Rochester	Share Information	Eric Rubinstein (Hub Administrator, U of Rochester)
3:50 PM (15 min)	Hub Liaison Team <ul style="list-style-type: none">Duke University	Share Information	Jamie Roberts (Hub Liaison Team Project Manager, Duke)
4:05 PM (20 min)	Chat Box Discussion	Chat Box Q&A	Dan Ford Monica Shah Hub Liaison Teams
4:25 PM (5 min)	Closing Remarks	Summary	Dan Ford
4:30 PM	Next Meeting: June 6, 2017, 3-4:30pm ET Recurring Meetings: First Tuesday Each Month	Adjourn	Dan Ford

Trial Innovation Network

Focus on Hub Liaison Teams

Monica R. Shah, MD

Director, Trial Innovation Network

CTSA Clinical & Translational[®]
Science Awards

TRIAL INNOVATION NETWORK




Trial Innovation Network

The Vision


- Long Term Goal
 - Build national platform for clinical trials focused on operational innovation, operational excellence, and collaboration
- Year One Goal
 - Build harmonized key elements of Trial Innovation Network

CTS Clinical and Translational Science
Open Access
[Explore this journal >](#)

 Open Access


COMMENTARY

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](#)

Accepted Articles



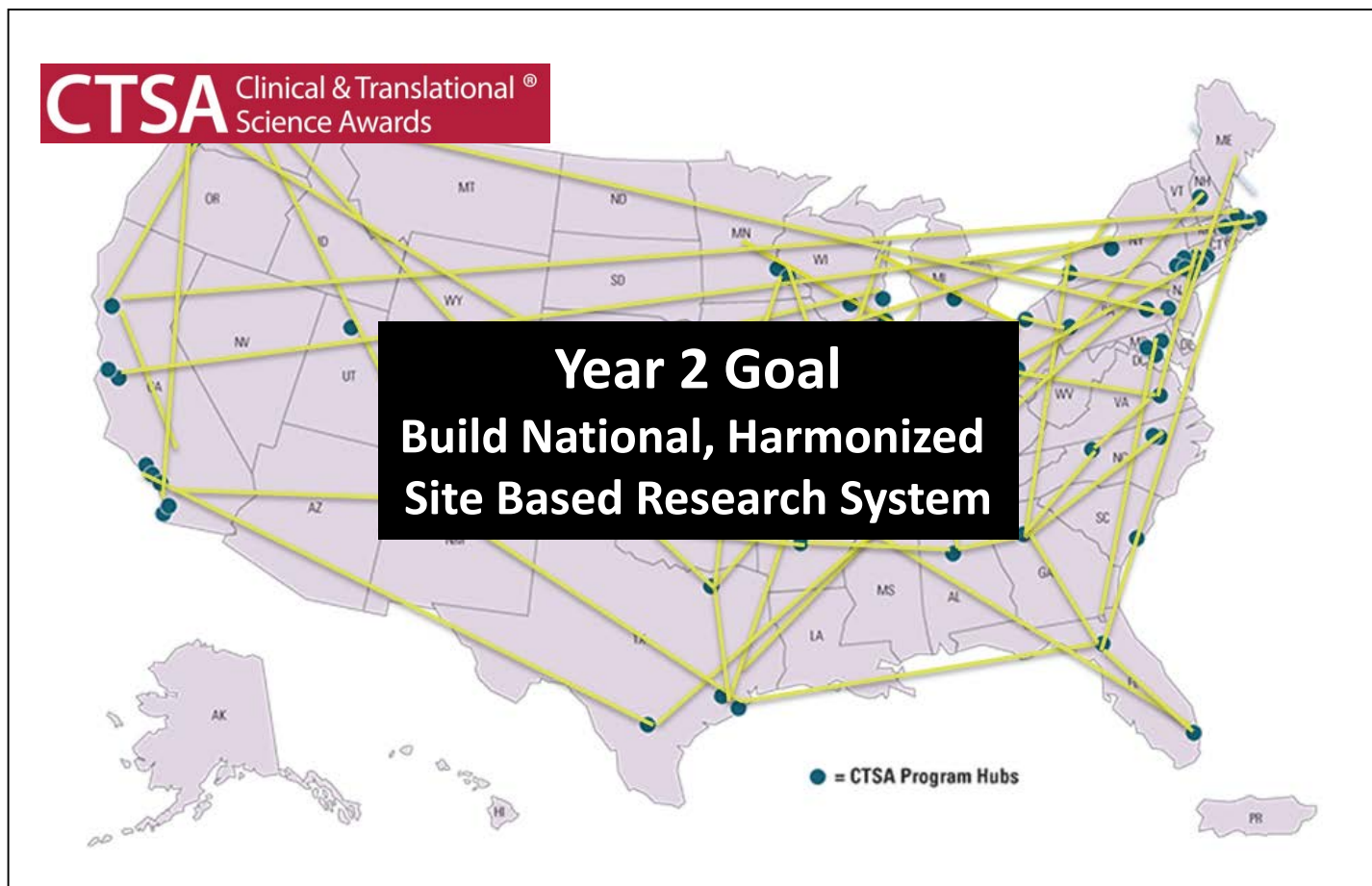
[Browse Accepted Articles](#)

Accepted, unedited articles published online and citable. The final edited and typeset version of record will appear in future.



Trial Innovation Network

The Vision



Trial Innovation Network

Site Based Research

JAMA[®]

The Journal of the American Medical Association

Robert M. Califf, MD

Clinical Research Sites— The Underappreciated Component of the Clinical Research System

PROJECT:

Investigator Community



Workload balance

- ▶ Long work hours
- ▶ Finding time to devote to activities fostering academic promotion
- ▶ Finding time to devote to other work activities (non-clinical)
- ▶ Finding time to devote to other work activities (clinical)
- ▶ Unpredictable work hours

Time requirements

- ▶ Amount of time required by investigator to support trial and site staff
- ▶ Amount of time required to implement the trial
- ▶ Amount of time required to prepare for trial start-up
- ▶ Amount of time required by staff to support the trial

Data and safety reporting

- ▶ Amount
- ▶ Method
- ▶ Frequency

Finance-related issues

- ▶ Sponsor/site budget negotiations
- ▶ Sponsor/site contract negotiations
- ▶ Final site budget

REASONS
"ONE-AND-DONE"
INVESTIGATORS
NO LONGER CONDUCT
FDA-REGULATED
DRUG TRIALS



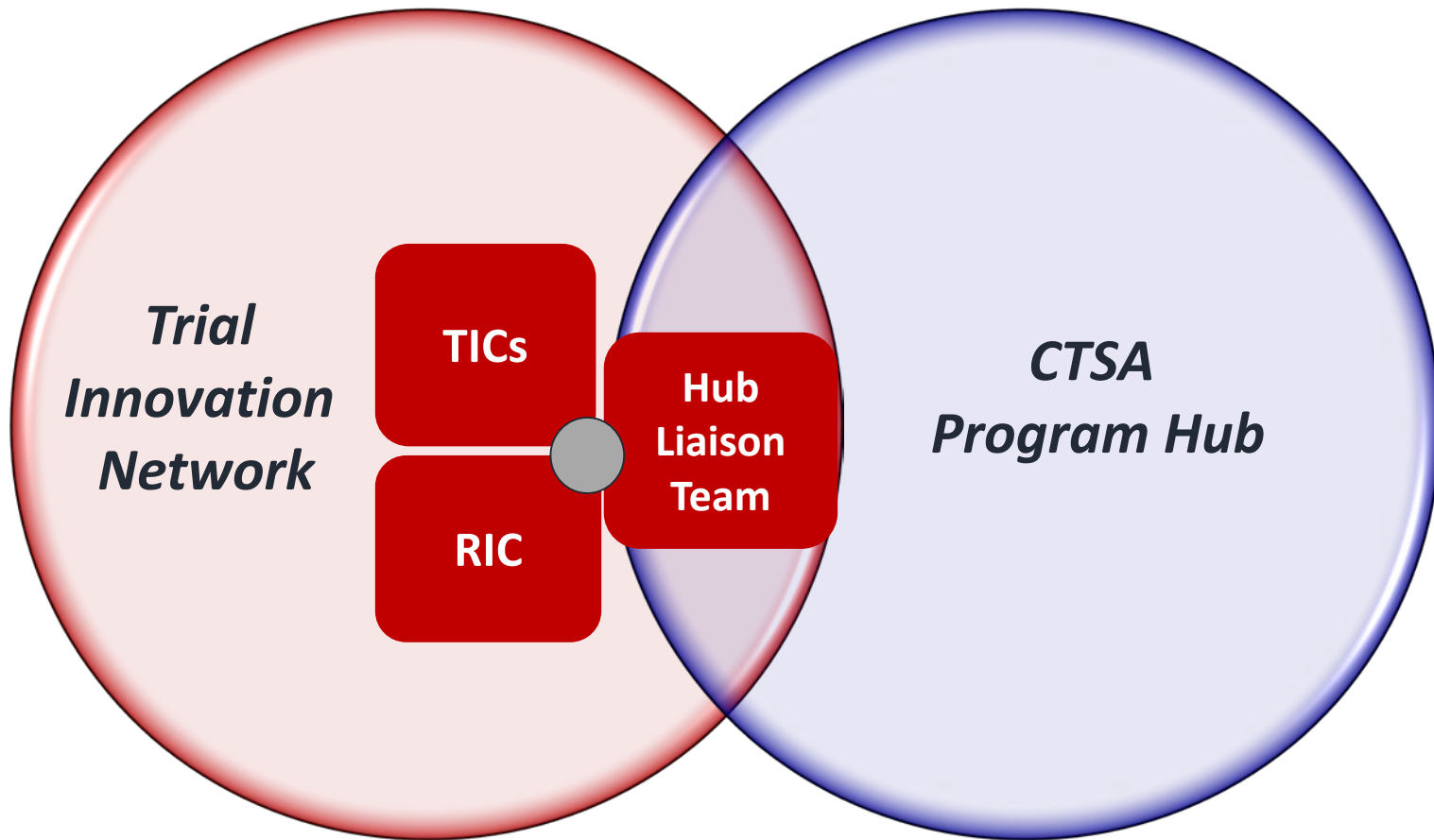
Roadblock

- Workload, time, research a “secondary job”
- Complex institutional systems
- Regulatory and bureaucratic burdens
- Lack of harmonization of processes
- Variability in training and expertise of local study teams



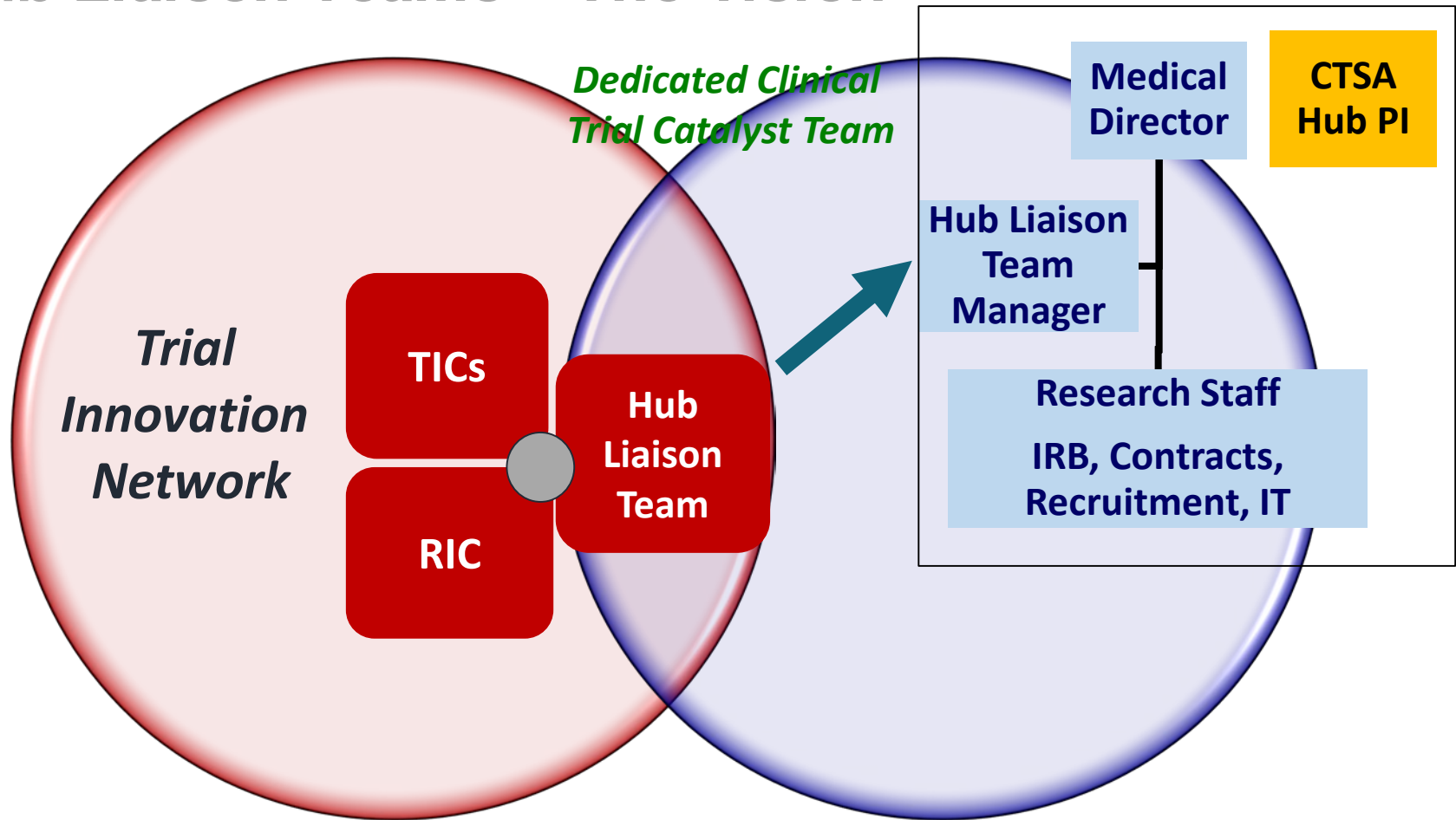
Trial Innovation Network

Hub Liaison Teams – The Vision



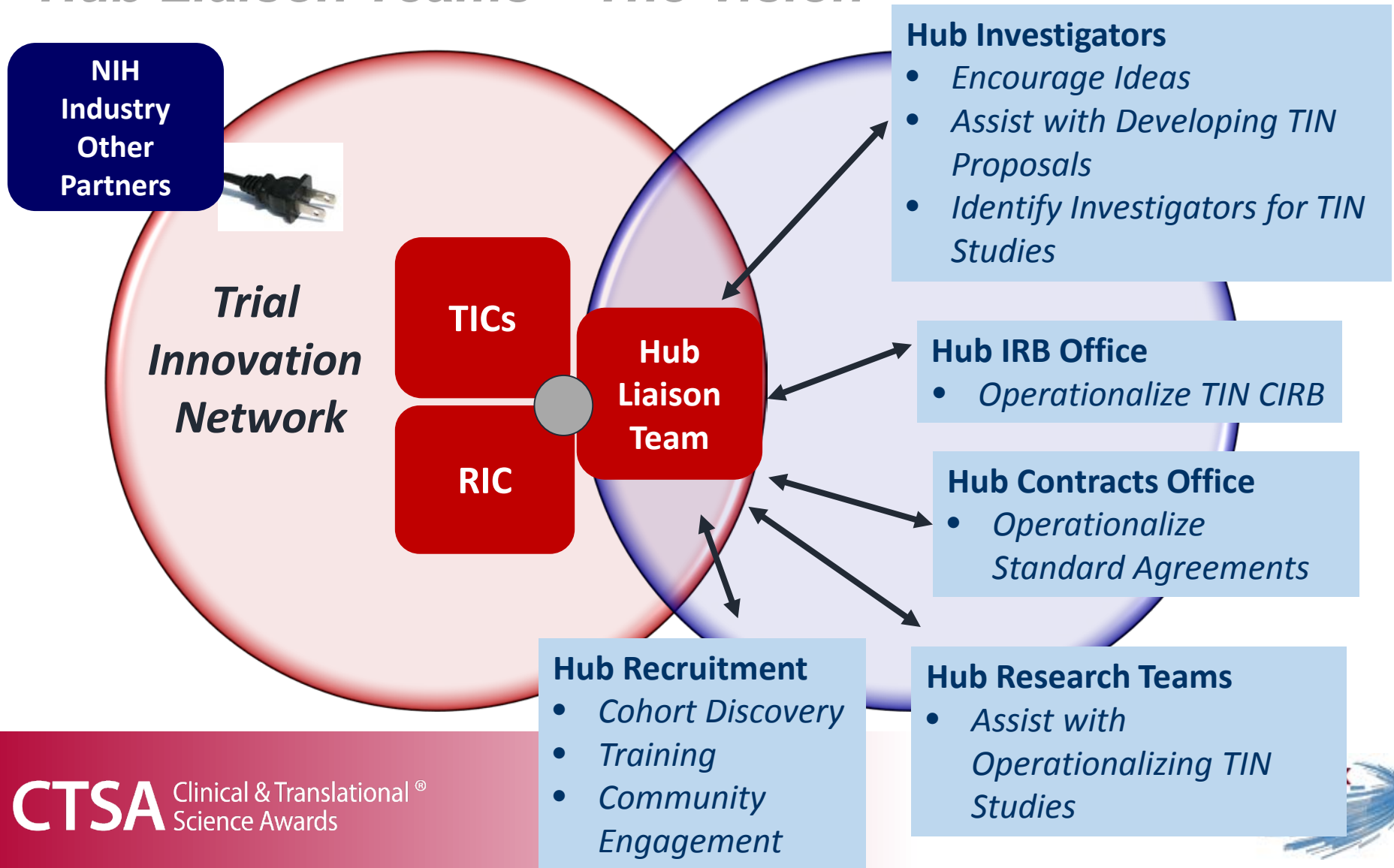
Trial Innovation Network

Hub Liaison Teams – The Vision

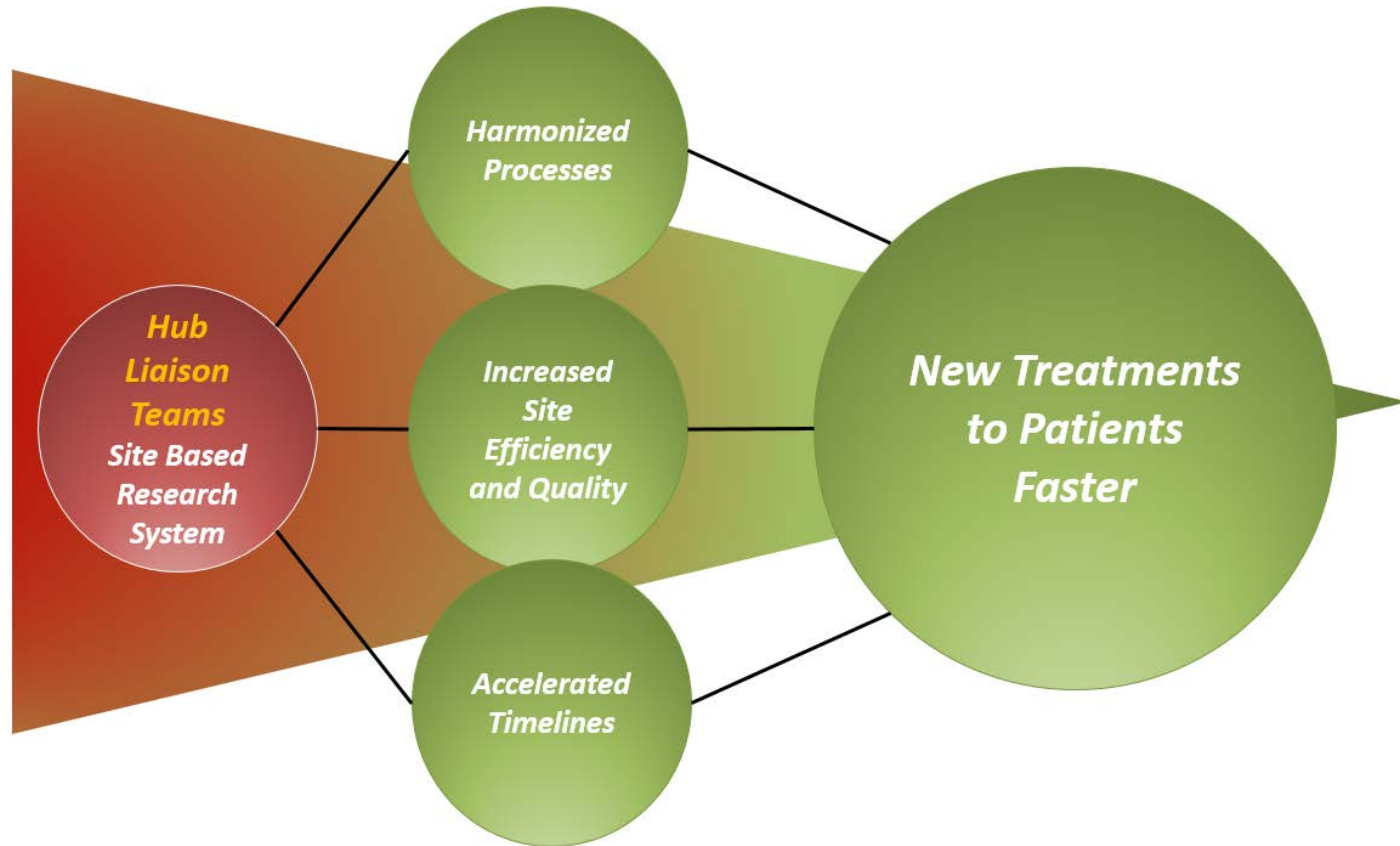


Trial Innovation Network

Hub Liaison Teams – The Vision



Trial Innovation Network



Trial Innovation Network

Website Update

Paul Harris
PI, VU RIC

CTSA Clinical & Translational[®]
Science Awards

TRIAL INNOVATION NETWORK

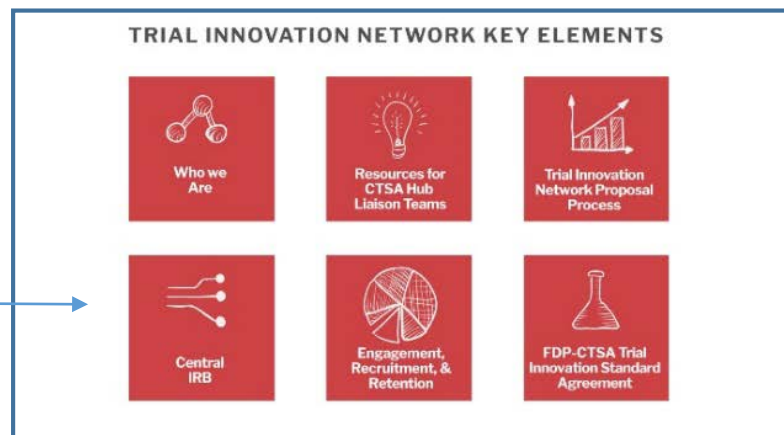


Redesign – Launches May 8

What To Expect – Navigation
from “Command Central”



Command Central
on homepage



Trial Innovation Network

Key Elements Navigation

Who We Are

- Vision
- TICs
- RIC
- Working Groups

Resources for Hub Teams

- Meeting Materials
- FAQs
- Talking Points

Proposal Process

- Access To Submit Proposal
- Guides and Resources

Trial Innovation Network

Key Elements Navigation

Central IRB

- Tools & Materials
- SMART IRB Exchange

Engagement, Recruitment, & Retention

- Charge
- Goals
- Guiding Principles

Standard Agreement

- Registered sites
- Agreement



Trial Innovation Network

Key Elements Navigation

Collaboration Webinars

- Upcoming webinars
- Archive of past webinars w/ recording & materials


Toolkit


- Recruitment and Retention Toolkit – tools, resources, best practices

NEW – Proposal Submission

Launching with new website on May 8

- Updated proposal submission process

TRIAL INNOVATION NETWORK 

Resize font:  [Returning?](#)

Trial Innovation Network Proposal Intake Form

We will take you through a few quick questions to set up your Trial Innovation Network Project Proposal. You can save your submission and return at any time to complete. For any questions, please contact us at info@trialinnovationnetwork.org. Thank you!

Page 1 of 8

PROPOSAL TITLE

What is the title of the Trial Innovation Network Project Proposal?
* must provide value

Expand

What is the short title for the Trial Innovation Network Project Proposal?
* must provide value

[Next Page >>](#)

[Save & Return Later](#)

REDCap 7.3.5 - © 2017 Vanderbilt University

Trial Innovation Network

PAT Charter – Executive Summary

Lori Poole

Duke/VU TIC

CTSA Clinical & Translational[®]
Science Awards

TRIAL INNOVATION NETWORK



Trial Innovation Network

PAT Charter Network Updates

- Executive Summary Posted to Website
 - Summarizes Proposal Assessment Team processes
 - Addresses policies on conflict and confidentiality
 - Outlines the Proposal Review Process
- Target Rollout for IT Platform is May 8, 2017
 - Includes Proposal Intake process
 - Supports Proposal Assessment Team review process
 - Supports metrics collection and reporting

Medical University of South Carolina

South Carolina Clinical & Translational Research Institute

Signe Denmark

Hub Liaison Team Member, MUSC

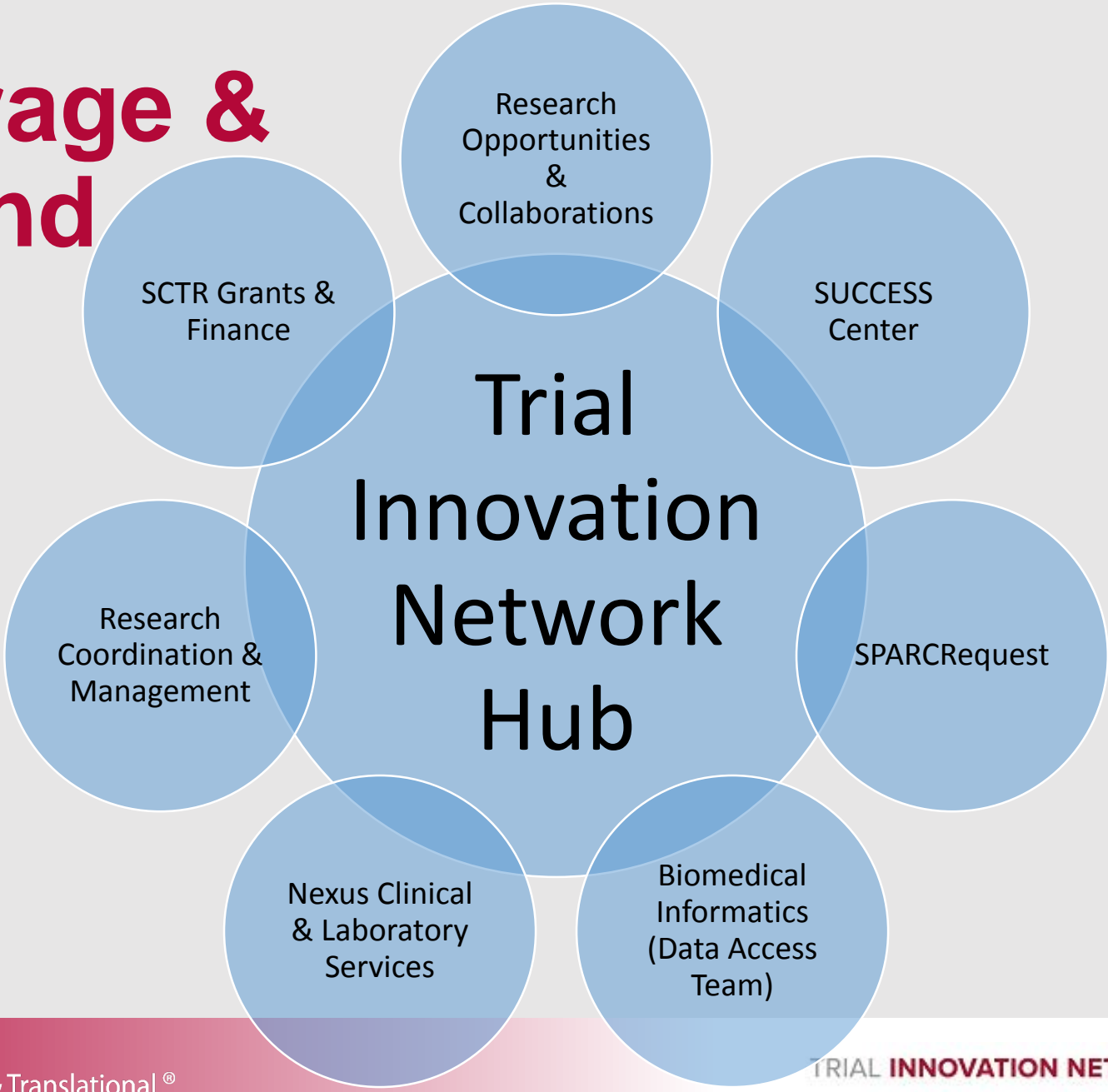


CTSA Clinical & Translational[®]
Science Awards

TRIAL INNOVATION NETWORK



Leverage & Expand



Leverage & Expand



Leverage & Expand



Biomedical Informatics (BMIC)

- SPARCRequest© research service management & metric tracking
- Data Access: Epic Research, Clinical Data Warehouse, CDRNs, TriNetX

SCTR Research Nexus

- Clinical research infrastructure, specialized research nursing
- Clinical research laboratory staff & services

SCTR Research Coordination & Management

- Clinical research coordinator service center
- Clinical research staff training & workforce development program



SCTR TIN Hub Liaison Team



Marc Chimowitz, M.B.,Ch.B.
Medical Director



Amanda Cameron, CCRP, CPH
Program Manager, Metrics & Evaluation

Royce Sampson, MSN, RN, CRA
Program Administrator



Toni Mauney, BA, CCRP
Single IRB Facilitation



Signe Denmark, MS, CCRP
Opportunity Manager



Ryan Mulligan, MRA, MS, CCRP
Master Contract Facilitation

SCTR TIN Hub Liaison Team Collaborators



Karen Packard, MSN, RN, AOCN, CCRP
Clinical Nursing & Laboratory Services



Clare Tyson, MA, CCRA
Research Coordination & Management



Stephanie Gentilin, MA, CCRA
SUCCESS Center Director

SCTR TIN Hub Liaison Team Collaborators



UR-CTSI Network Capacity Core

A Hub within the NCATS Trial Innovation Network

Eric Rubinstein

Hub Administrator, University of Rochester



CTSA Clinical & Translational[®]
Science Awards

TRIAL INNOVATION NETWORK



University of Rochester

Network Hub Liaison Team



Robert Holloway, MD, MPH
Medical Director



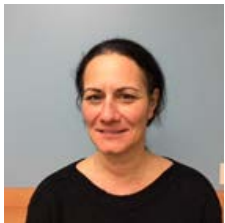
Kelley O'Donoghue, MPH, CIP
***Associate Vice President for
Human Subject Protection***



Carrie Dykes, PhD
***Research Engagement
Specialist***



Tiffany Gommel, MS, CIM, CIP
***Director, Research Subjects
Review Board***



Karen Rabinowitz, JD
***Director, Trial
Innovation Unit***



Eric P. Rubinstein, JD, MPH
***Hub Liaison Team
Administrator***

Aim 1: To Establish a Local *Trial Innovation Unit*

1. Implement a database to track relevant trial milestones
2. Maintain a Clinical Research Review Process Improvement Team
3. Actively seek complementary CTSA Consortium projects
4. Distribute our developing capabilities and technologies

Aim 2: To Expand Our *Recruitment Unit*

1. Provide consultations to investigator and research teams
2. Identify and deploy novel and established best practices
3. Enable patient engagement in research
4. Implement policy changes and enhance routine recruitment practices

Accomplishments to Date

- CTSI Spring Semester Grand Rounds: "*Research Networks: Benefits, Challenges, and Leveraging Resources.*"
- Executed Smart IRB Authorization Agreement
- Approved use of the Trial Innovation Network (TIN) Standard Trial Agreement
- Engaging Investigators to submit proposals
- Carrie Dykes (manager of the CTSI Recruitment and Retention Unit) hosts the CTSA Recruitment and Retention Working group web meeting with the Recruitment Innovation Center (RIC)
- Modified TIN checklists to manage Hub TIN-related activities
- Co-Sponsoring Technology and Rare Neurological Diseases Symposium (TRNDS) May 12th (event information on CTSACentral.org)

Duke Hub Liaison Team

*A Resource for the Duke Clinical Research Network
Community*

Jamie Roberts, MPH, MA

Senior Staff Director, Duke Clinical Research Networks Community

Duke CTSA Hub Liaison Team Manager

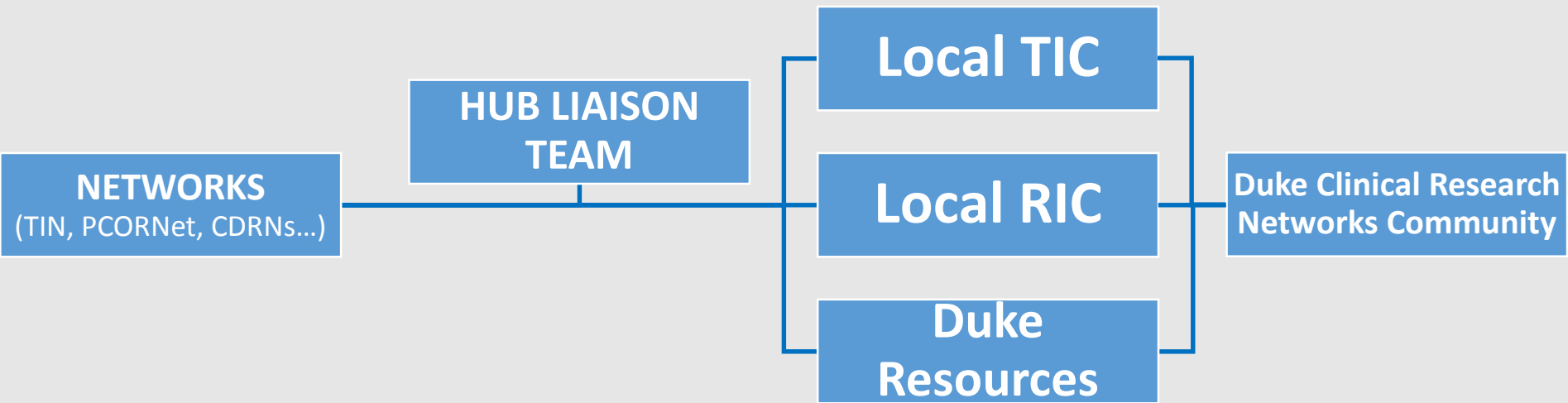
CTSA Clinical & Translational[®]
Science Awards

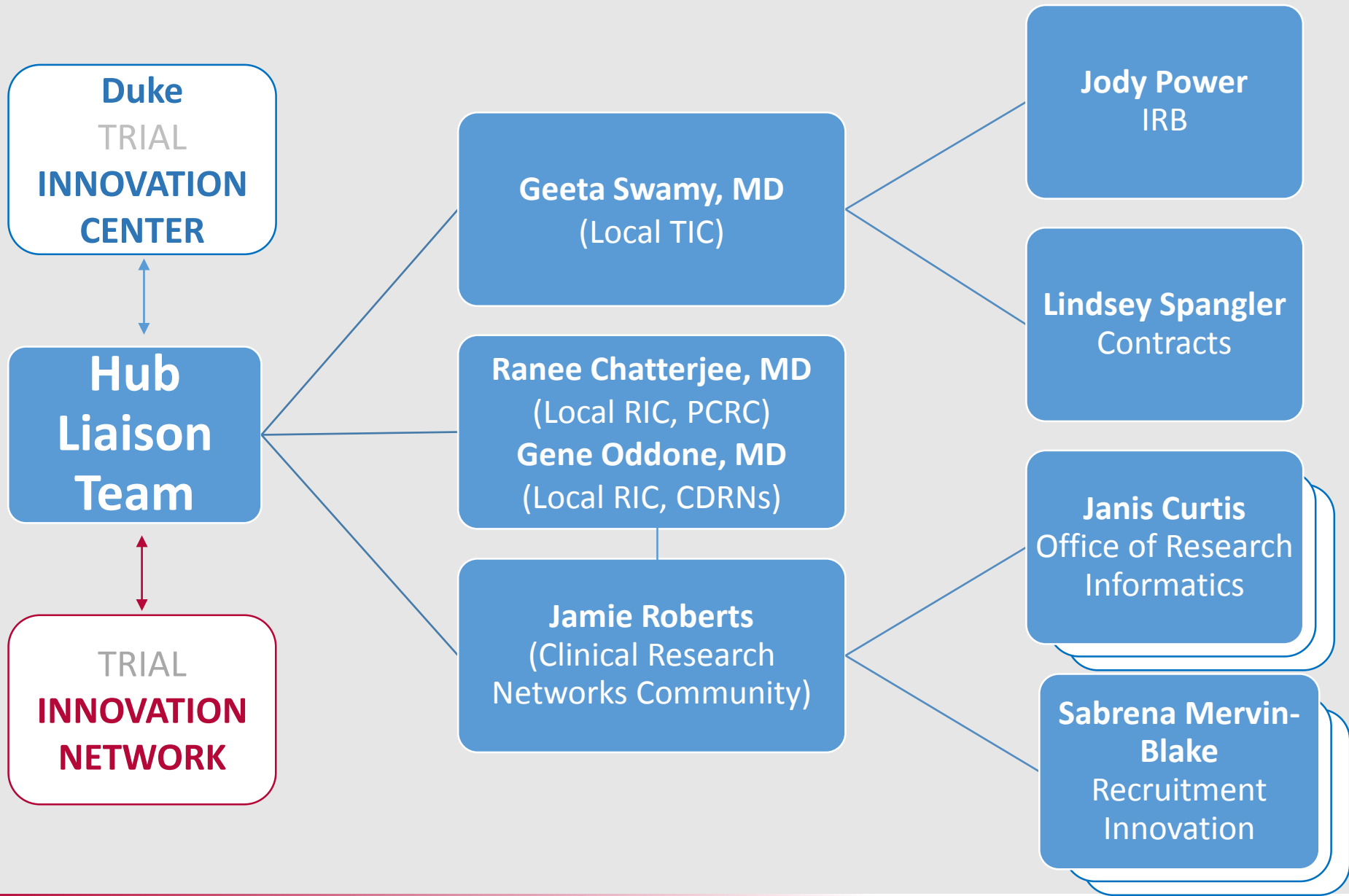
TRIAL INNOVATION NETWORK



Leverageable Efforts, Opportunities & Synergies

- Duke leads a number of networks and network efforts, including TIC, PCORNet, ECHO, and the PTN
 - DCRI is the coordinating center for 14 NIH/PCORI funded networks
 - Duke is an enrolling site in 31 NIH/PCORI networks
- The Duke HLT serves as one component of the bi-directional gateway for Duke staff to ALL networks
 - Central Hub of the Duke Clinical Research Network Community





Trial Innovation Network

Chat Box Discussion – Q&A

CTSA Clinical & Translational[®]
Science Awards

TRIAL INNOVATION NETWORK



Trial Innovation Network

Next Meeting: June 6, 2017, 3-4:30PM ET