

Trial Innovation Network

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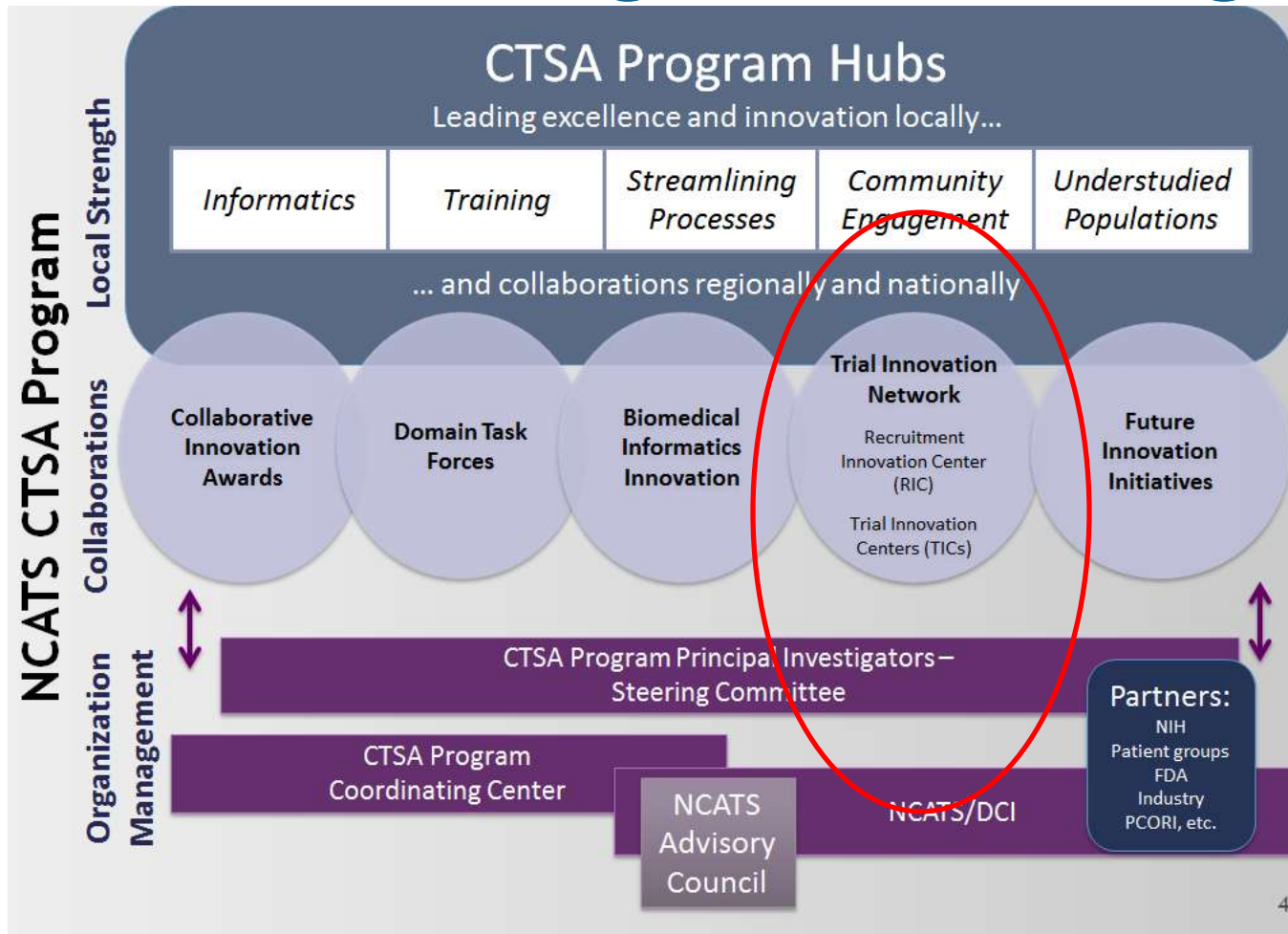


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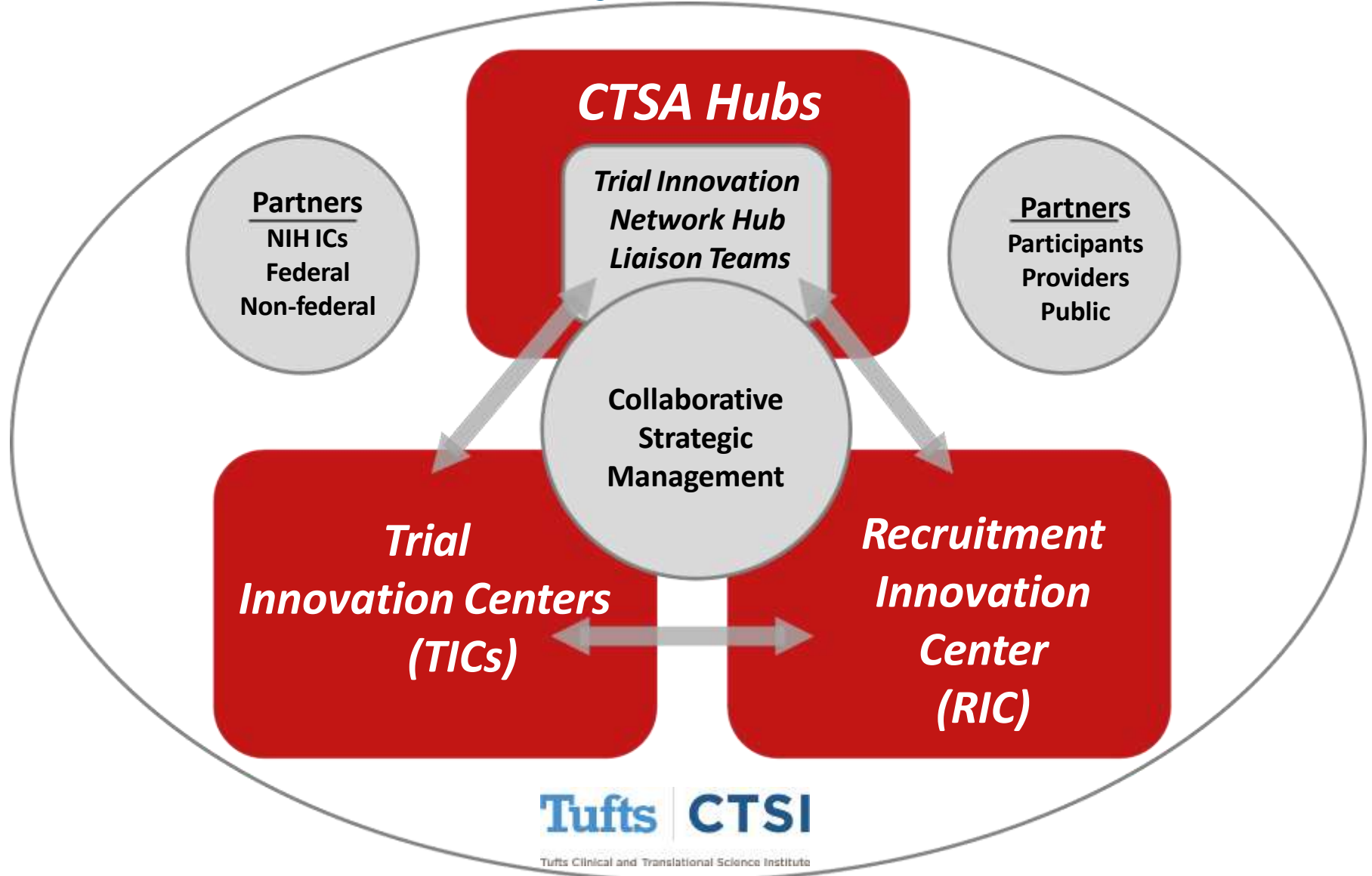
Trial Innovation Network

A Part of the Larger CTSA Program



Trial Innovation Network

Key Partners



Trial Innovation Network

Glossary

- Trial Innovation Network
 - Composed of the TICs, RIC, and CTSA Hubs
 - All are Key Partners and make unique & essential contributions
- Trial Innovation Centers (TICs)
 - Coordinating centers focused on innovation & quality by design
 - Responsible for support & implementation of trials/studies
- Recruitment Innovation Center (RIC)
 - Coordinating center focused on patient engagement & evidence-based recruitment approaches
 - Consult service for focused support of trials/studies

Who Are We?

Dedicated core team at each TIC/RIC:

Biostatisticians, data managers, clinical trialists, cIRB

JHU-Tufts TIC Expert Pool:

Expertise in clinical domain/trial design/project management

Key People:

Edward Kuczynski and Jonathan Davis: Hub Liaison Team

Harry Selker: CTSI PI

Sheeona Gorman: TIC Project Director

Leveraging the Network: Key Questions

- How to leverage the Trial Innovation Network?
 - Submit a Network Project proposal through the website
 - www.trialinnovationnetwork.org
 - Proposal process is in a pilot phase
- Who can submit Network Project proposals?
 - CTSA Hub and Affiliate Faculty
- How to prepare a Network Project proposal?
 - **Investigators should contact Hub Liaison Team (Jon and Ed) to discuss proposals before submitting**

What can the TIC do for you?

Level 1 Network Projects

- Basic Services and Consultations

Key Points

- Investigators can select from an array of services/consultations
- Investigators can use their own coordinating centers
- **What does it cost?**
No cost-Covered by TIC budget

	<i>Basic Services and Consultations</i>
Level 1 Network Projects	<ul style="list-style-type: none">A. Operationalize Master AgreementsB. Operationalize Single IRBC. Study Design ConsultationD. Study Budget ConsultationE. Site Identification ConsultationF. Recruitment Planning ConsultationG. Recruitment Feasibility AssessmentH. Recruitment Materials (Standard Tools)I. Patient Engagement StudioJ. Other Consultation/Service, specify _____

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Level 1 Network Project – Key Steps

Step 1

Tufts Investigator contacts Jon/Ed to discuss potential application to Trial Innovation Center.

Step 2

Investigator submits Level 1 Network Project proposal to Trial Innovation Network

Step 3

Proposal reviewed by Proposal Assessment Team

Step 4

If approved, proposal assigned to TIC or RIC

Step 5

TIC/RIC provides service

What can the TIC do for you?

Level 2 Network Projects

- Comprehensive Consultation
- Investigators work with TICs/RIC to develop a proposal into a protocol

Key Points

- Investigators have access to operational and recruitment experts
- Protocols vetted with potential CTSA Hubs before funding decisions

- **What does it cost?**

In depth consultation: TIC budget will provide services up to a pre-specified amount (tbc).

DCC/CCC service for trial execution: IC pay for study specific/patient costs and TIC budget will support infrastructure up to a pre-specified amount (tbc)

Level 2 Network Projects	
Level 2 Network Project (Comprehensive Consultation)	A. Protocol Development and Potential Trial Implementation <ol style="list-style-type: none">1. Development of Protocol<ol style="list-style-type: none">a. Project Planningb. Development of Study and Site Budgetsc. Site Selection/Assessmentd. Data Safety and Monitoring Plane. Statistical Analysisf. Risk Based Monitoring Plang. Regulatory Support for FDA Submissionh. Development of Recruitment Plan/Feasibility Assessment/Informatics Tool Consultation/Recruitment Training2. Trial Implementation<ol style="list-style-type: none">a. If study funded, potential implementation of clinical trial

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Level 2 Network Project – Key Steps

Step 1

Tufts Investigator contacts Jon/Ed to discuss potential application to Trial Innovation Center *

Step 2

Investigator submits Level 2 Network Project proposal to Trial Innovation Network

Step 3

Proposal reviewed by Protocol Assessment Team and assigned to TIC/RIC

Step 4

Investigator and TIC/RIC develop proposal into protocol.
CTSA Hubs vet protocol/budget

Step 5

Investigator submits application to IC.
If funded, study can be implemented within Trial Innovation Network

How to submit a request for consultation



WHO WE ARE SUBMIT A NETWORK PROPOSAL OPEN INNOVATION TOOLS/RESOURCES FOR TRIALS

Deadline 12/7

Proposals received after this date will be included in the next round of reviews



Our Vision

The Trial Innovation Network is a new collaborative initiative within the CTSA Program and is composed of three key organizational partners – the CTSA Program Hubs, the Trial Innovation Centers (TICs), and the Recruitment Innovation Center (RIC).

The vision for the Trial Innovation Network is to innovatively address critical roadblocks in clinical trials and accelerate the translation of novel interventions into life-saving therapies. The Trial Innovation Network is a collaborative national network that focuses on *operational innovation*, *operational excellence* and *collaboration* and will leverage the expertise and resources of the CTSA Program. The Trial Innovation Network will feature a single IRB system, master contracting agreements, quality by design approaches, and a focus on evidence-based strategies to recruitment and patient engagement.

The goal of the Trial Innovation Network is to not only execute trials better, faster, and more cost-efficiently but, importantly, to be a national laboratory to study, understand and innovate the process of conducting clinical trials.

The investigators are currently building the key elements of the Trial Innovation Network. The goal is to start early projects as soon as possible and collaborate with other NIH Institutes and partners to launch clinical trials in 2017.



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TRIAL INNOVATION NETWORK

Proposal Submission Questions



PROPOSAL TITLE

What is the title of the Trial Innovation Network proposal? _____

What is the short title for the Trial Innovation Network proposal? _____

SITES AND SUBJECTS

Estimated number of subjects? _____

Estimated number of sites? _____

INVESTIGATOR

Are you the Principal Investigator (PI)? Yes No

[If No] Please provide PI contact info: _____

First Name: _____

Last Name: _____

Organization: _____

REVIEWS

By what date do you need a decision? _____

Has this proposal been discussed with the CTSA Yes No

Hub Site PI and/or the Hub Trial Innovation
Network Liaison Team?

CTSA Hub site: _____

Has/will this study/project undergone
scientific peer review? Yes, by NIH
 Yes, by other group
 Planned prior to implementation

CONSULTATIONS AND SERVICES

Are you submitting a Level 1 or a Level 2 Network Project Proposal?

Select either Level 1 or Level 2, then select the boxes to select specific services/consultations.

LEVEL 1 Network Project (Basic Consultation or Service)

The Trial Innovation Network provides specific consultations or services (up to a pre-specified threshold) but the Trial Innovation Network is not responsible for recruiting patients or managing data.

- Operationalize Master Agreements
- Operationalize Central IRB
- Protocol Design Consultation (Basic)
- Study Budget Consultation (Basic)
- Site Identification Consultation (Basic)
- Recruitment Plan Consultation (Basic)
- Recruitment Feasibility Assessment
- Recruitment Materials
- Patient Engagement Studio
- Other Limited Service: _____

Level 2 Network Project (Comprehensive Consultation and Potential Implementation)

- Comprehensive Consultation to Develop a Proposal into a Protocol

STUDY SYNOPSIS (Each: Limit: 500 words)

Primary Objective/Hypothesis:

Brief Scientific Rationale/Public Health Impact

Specific Aims:

Proposed Study Design

Study Population

Entry Criteria

Intervention

Primary Endpoint

Disclosure/Conflicts

Statistical Plan (Optional)

Enrollment Plan (Optional)

Attachments (Optional)

Trial Innovation Network Website

TRIAL INNOVATION NETWORK

WHO WE ARE SUBMIT A NETWORK PROPOSAL OPEN INNOVATION TOOLS/RESOURCES FOR TRIALS

Call for Trial Innovation Network Project Proposals Open for Submissions on November 16, 2016

INVESTIGATORS!
SUBMIT A NETWORK PROPOSAL

Submit

www.trialinnovationnetwork.org

Questions? E-mail us at

info@trialinnovationnetwork.org



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