

Trial Innovation Network How to Leverage the Network

NCATS

Trial Innovation Network

How to Leverage the Network

- Two different levels of Trial Innovation Network services and consultations were developed to provide investigators with flexibility and options
- Two ways to leverage the Trial Innovation Network
 - Level 1 Network Projects
 - Level 2 Network Projects

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How to Leverage the Network

- 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
- NCATS will provide service/consults up to a pre-specified threshold

	<i>Basic Services and Consultations</i>
<i>Level 1</i> Network Projects	A. Operationalize Master Agreements B. Operationalize Single IRB C. Study Design Consultation D. Study Budget Consultation E. Site Identification Consultation F. Recruitment Planning Consultation G. Recruitment Feasibility Assessment H. Recruitment Materials (Standard Tools) I. Patient Engagement Studio J. Other Consultation/Service, specify _____

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Level 1 Network Project - Key Steps

Level 1 Network Project

Step 1

Investigator submits
Level 1 Network
Project proposal to
Trial Innovation
Network

Step 2

Proposal reviewed
by Proposal
Assessment Team

Step 3

If approved,
proposal assigned to
TIC or RIC

Step 4

Service/Consultation
Provided

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How to Leverage the Network

- **Level 2 Network Projects**
 - Comprehensive Consultation
 - Investigators work with TICs/RIC to develop a proposal into a Trial Innovation Network protocol
- **Key Points**
 - Investigators have access to operational and recruitment experts
 - Protocols vetted with potential CTSA Hubs before funding decisions
 - If TICs/RIC used as Coordinating Centers, NCATS will provide infrastructure/resources up to a pre-specified threshold

	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 Projects - Key Steps

Level 2 Network Project



Trial Innovation Network Website



The screenshot shows the homepage of the Trial Innovation Network website. At the top left is the logo for the Trial Innovation Network, which includes the text "TRIAL INNOVATION NETWORK" and a stylized blue graphic of a network or pathway. To the right of the logo is a navigation menu with four items: "WHO WE ARE", "SUBMIT A NETWORK PROPOSAL", "OPEN INNOVATION", and "TOOLS/RESOURCES FOR TRIALS". Below the navigation menu is a large banner area with a light background and faint text listing various academic institutions. Overlaid on this banner is a white circular call-to-action box with the text "INVESTIGATORS! SUBMIT A NETWORK PROPOSAL" and a red "Submit" button. A dark red horizontal bar at the bottom of the banner contains a calendar icon and the text "Trial Innovation Network Kickoff Meeting".

www.trialinnovationnetwork.org

Questions? E-mail us at
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