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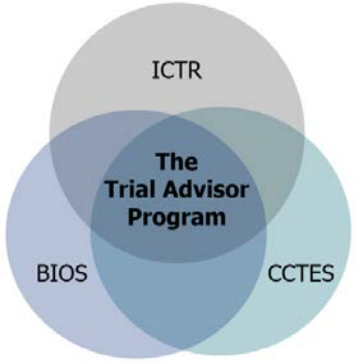
Trial Advisor Program (TAP)



The JHU ICTR Trial Advisor Program:

- Key organizational partners: the ICTR, BIOS CTCC, a JHU-based academic research organization, and the CCTES consulting service
- Expert consultative support to investigators with single- and multi-site translational clinical trials needing:
  - Strategic advice
  - Trial start-up, enrollment, data quality, GCP, IRB and sIRB processes, contracting, human subjects research
  - Leadership and management of research teams
  - Use of performance metrics
  - Comprehensive safety and risk management

TAP Leadership - Johns Hopkins University Senior Trialists

ICTR

- Daniel E. Ford, MD, MPH
  - *Director, Johns Hopkins Institute for Clinical and Translational Research (ICTR)*
  - *David M Levine Professor of Medicine*
- Charles Flexner, MD
  - *Chief Scientific Officer for Strategy and Integration*
- Liz Martinez, RN, BSN, CCRC
  - *Advocate Senior Clinical/Research Liaison*

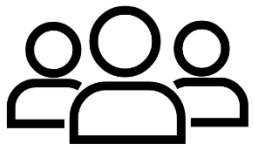
BIOS CTCC

- Daniel F. Hanley, MD
  - *Director, BIOS Clinical Trials Coordinating Center*
  - *ICTR Deputy Director for Support & Innovation in Multi Center Trials, Principal Investigator*
- Karen Lane, CMA, CCRP
  - *Deputy Director, BIOS Clinical Trials Coordinating Center*
  - *Trial Coordination*
- Nichol McBee, MPH, ACRP-CP
  - *Executive Director, BIOS Clinical Trials Coordinating Center*
  - *Data Coordination and Quality*
- Jessica Baird, PhD & Stephanie Swords
  - *Consult Navigators*

CCTES

- Douglas A. Jabs, MD, MBA
  - *Director, Center for Clinical Trials and Evidence Synthesis*
- Amy Zemanick
  - *Research Program Manager, CCTES*

Team Science Approach Connects Investigators to Trialists, Experts, & Services



Cohort discovery via PCORNet and TriNetX mechanisms

Site selection and readiness assessment within and beyond the Johns Hopkins Clinical Research Network

Single IRB (sIRB) review in collaboration with the regulatory knowledge and support core

Review method development to track study performance and outcomes at the local hub and affiliated sites

Organization and trial execution strategy consultation

Direction and strategy for grant preparation

TAP Strategies

- Develop a portal for local investigative teams to access trial development resources available within the CTSA
- Organize strategic trial planning by integrating team's study development with the BERD & appropriate CTSA cores and CRUs
- Provide learning and mentoring opportunities for young investigators (K and T awardees)
- Integrate trial planning with University of Maryland, Kaiser Permanente, and Morgan State University to expand statewide research opportunities
- Collect TAP metrics to gauge program success

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Requests/Resources

Requests

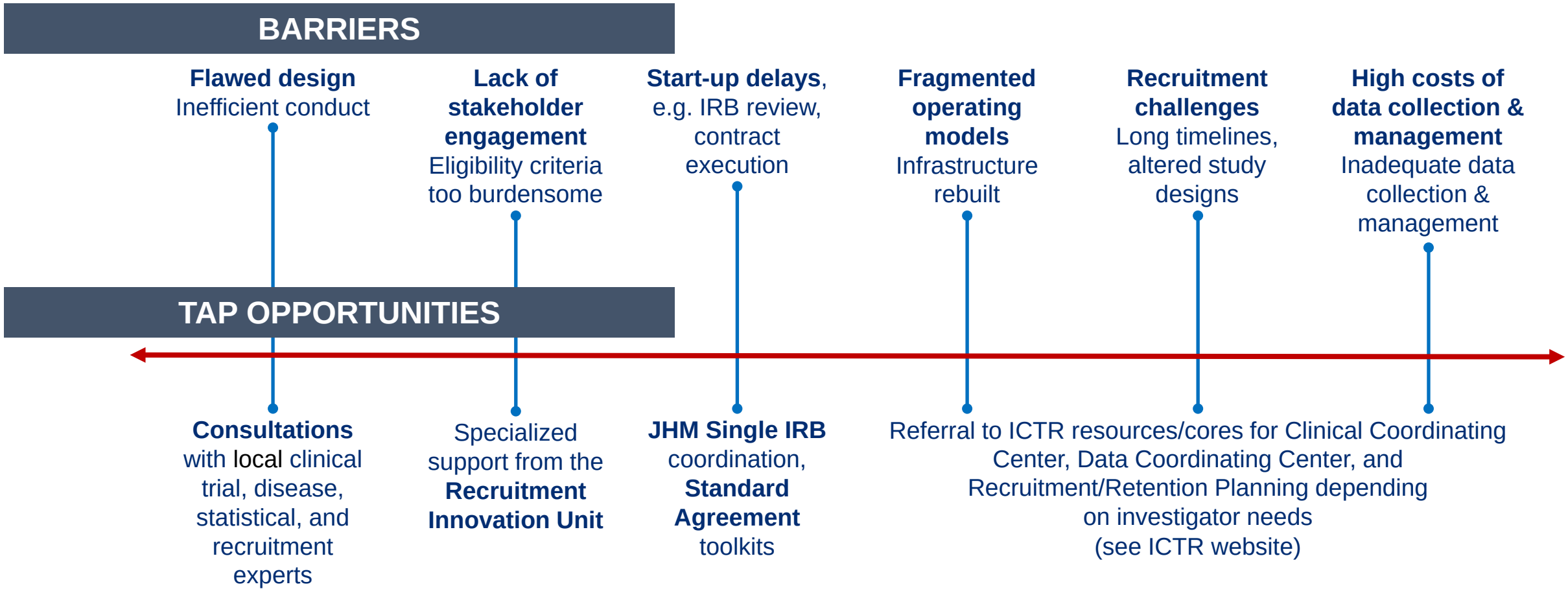
- Study Design*
- Study Budget
- Projected Timelines
- Recruitment Feasibility Assessment
- Study Feasibility
- Comparative Effectiveness

Resources

- Single IRB
- Standard Agreements
- Recruitment and Retention Plan
- Community Engagement Studio
- EHR-Based Cohort Assessment
  - — PCORNet, TriNetX

**Collaboration with ICTR Biostatistics Consultation Service integrates statistical support during the TAP consultation*

Addressing Barriers to Clinical Research within the Trial Advisor Program



TAP Triage for JHU Investigators

Request a TAP consult via the ICTR website

↓

5 business days to schedule an initial consult

↓

Initial consult is a 1- to 2-hour meeting with content appropriate experts;
Follow-up meetings may occur; Consultation will be completed within 30-60 days

↓

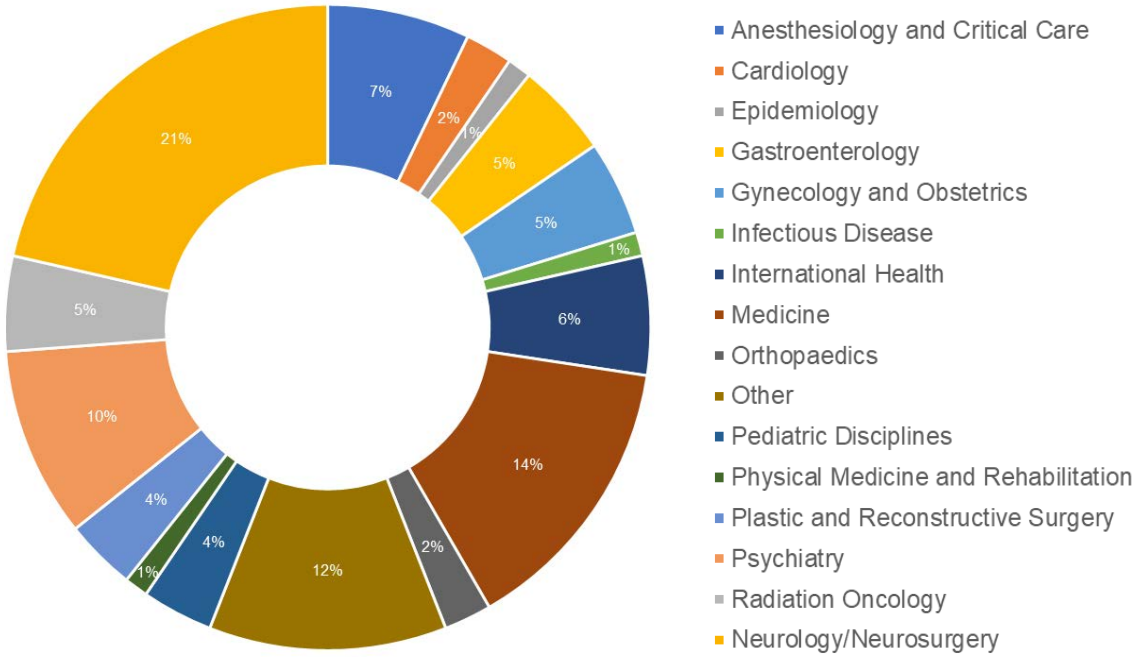
Monthly TAP review for final recommendations, which may include referral to:

- BIOS or CCTES for comprehensive consultation
- ICTR Studio
- Specific ICTR cores
- TIN for consultation
- No further support needed

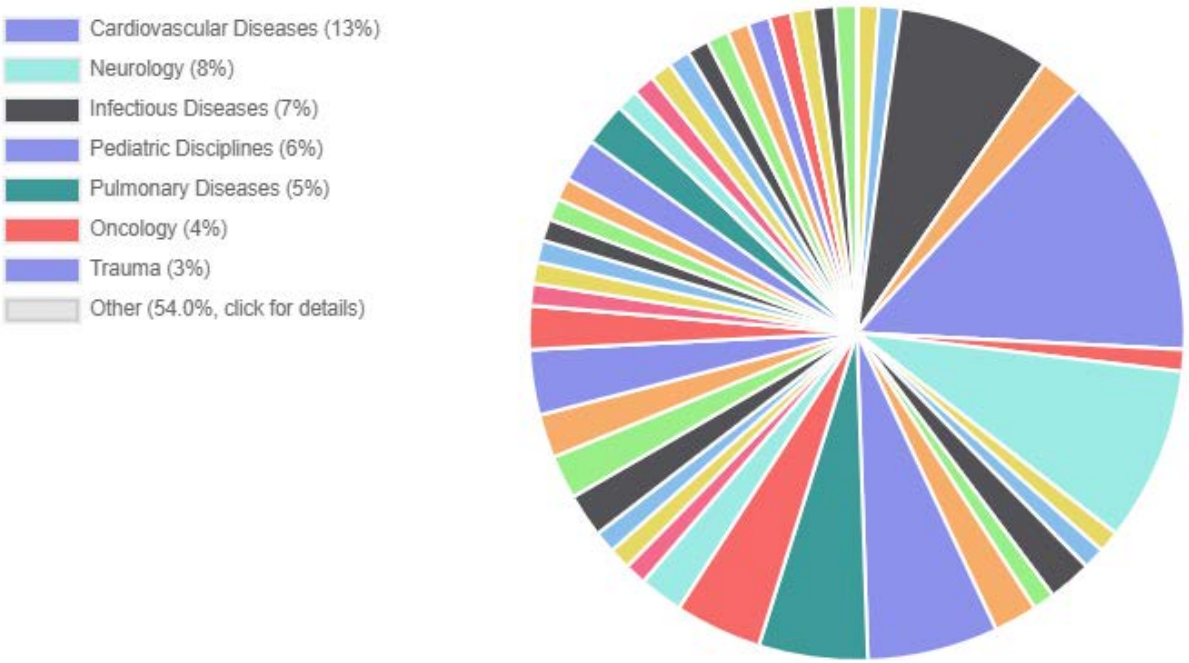
Johns Hopkins
Institute for Clinical & Translational Research

TIN & TAP Consultations for Trial Design

JHU TAP Consultation Clinical Domains



TIN Consultation Clinical Domains



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TAP Satisfaction Survey Results

Sept. 2021 – Nov. 2024*

Q1: How would you rank the consultation process, including submitting an intake form, scheduling meetings, timeline of the consultation?

Responses	Frequency	Percentage
Neutral (7)	2	7.14%
Positive (8-10)	26	92.86%
Total	**28**	**100.00%**

Q2: How satisfied are you with the clinical trial understanding and expertise of the TAP consultation team in assessing your needs?

Responses	Frequency	Percentage
Neutral (7)	1	3.57%
Positive (8-10)	27	96.43%
Total	**28**	**100.00%**

Current Response Rate: **60%**

***TAP/TIU** Satisfaction Survey Collection began with CTCCS consults in Sept 2021

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TAP Consultation 0038: Reorientation for Delirium prevention: The ReDi Trial Proposal

Frederick E. Sieber, M.D.
Professor
Department of Anesthesiology and Critical Care Medicine
Director of Anesthesiology
Johns Hopkins Bayview Medical Center

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The Clinical Problem: Postoperative Delirium

- The most common complication after major elective surgery in older patients
- Associated with impairment of functional and cognitive recovery leading to prolonged length of stay, increased rates of both institutional discharge and 30-day readmission.
- Medicare costs attributable to postoperative delirium following elective surgery are estimated to total over $44,000 per patient over one year after a new delirium event.
- Prevention of postoperative delirium will impact long term patient function, family wellbeing, and health system costs.

Current State: Postoperative Delirium Prevention

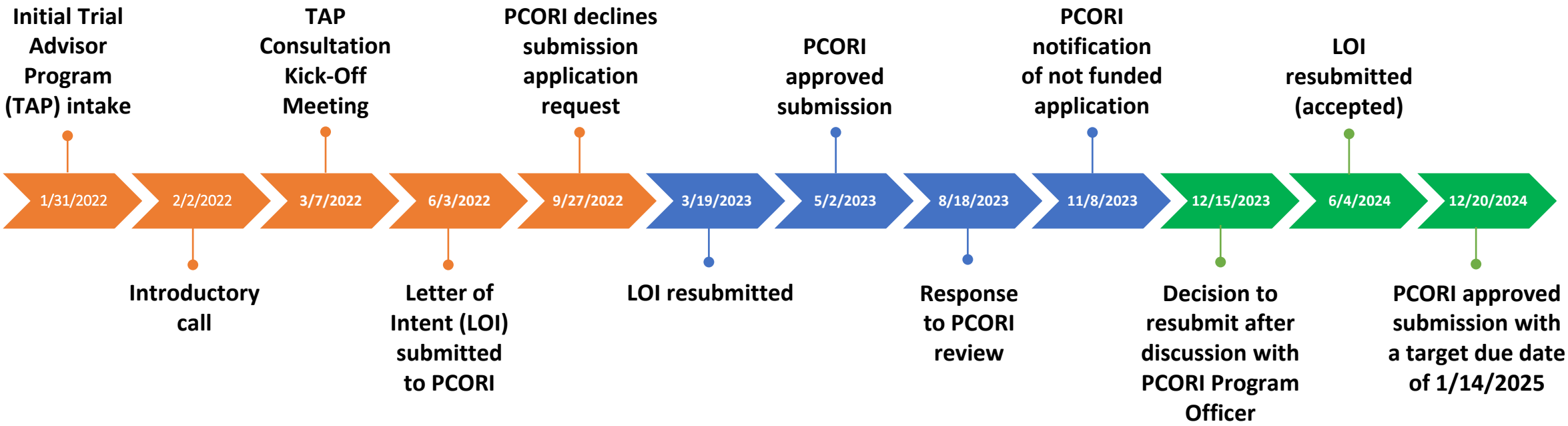
- No definitive pharmacologic approach
- Multicomponent interventions are effective in reducing delirium rates
- Widespread adoption of multicomponent interventions has been hindered by resource constraints and implementation challenges.
- These limitations have been addressed by focusing on the most effective individual components of multicomponent interventions.
- Network meta-analysis suggests that reorientation is most beneficial in delirium prevention.

Research Question

What is the comparative effectiveness for postoperative delirium prevention of a nurse guided vs standardizing the frequency of PACU reorientation in frail, older surgical patients?

TAP 0038: The ReDi Trial

Consultation Timeline



PCORI Submission 1
5 month Consultation

PCORI Submission 2
5 month Consultation

PCORI Submission 3
12 month Consultation

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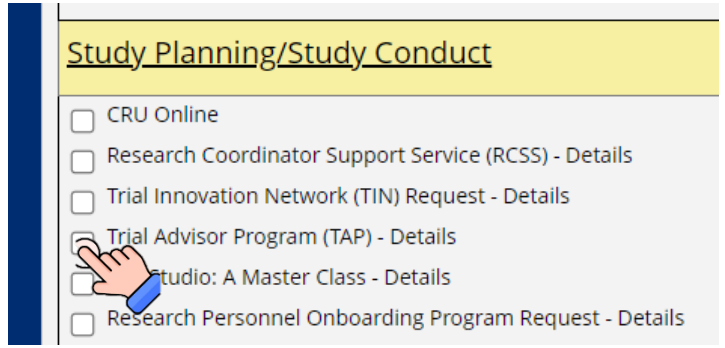
Consultation Impact

	Design	Intervention	Consortium	Study Duration	Sample Size	Stakeholders
Pre Consultation	Stepped Wedge	Low intensity reorientation (R)/cognitive stimulation (CS) PACU protocol vs high intensity R/CS PACU protocol	5 sites	60 months	5,000	Focus Groups
Post Consultation	Stepped Wedge	Nurse guided vs standardized frequency PACU reorientation	20 sites	48 months	4,800	Focus Groups, CTSA, PCORNet, PATH

How to Access the TAP

https://ictr.johnshopkins.edu/service/study-planning/trial-advisor-program-tap/



Contact us: TAPTeam@jhu.edu

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Trial Innovation Network (TIN)

Acronyms

Trial Innovation Network (TIN)
- Clinical & Translational Science Awards (CTSA) program
- Focuses on operational innovation
- Goal: Execute trials better, faster, and more cost-efficiently

Trial Innovation Centers (TICs)
- Johns Hopkins University
- Vanderbilt University

Recruitment Innovation Center (RIC)
- Vanderbilt University

Trial Advisor Program (TAP) – Johns Hopkins University
- ICTR – Institute for Clinical & Translational Research
- BIOS CTCC – BIOS Clinical Trials Coordinating Center
- CCTES – Center for Clinical Trials and Evidence Synthesis

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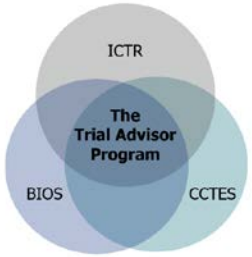
Trial Innovation Network Structure



JH ICTR

TIN Liaison Team (Liz Martinez: POC)
Trial Advisor Program (TAP)
Recruitment Innovation Unit (RIU)

NCATS

CTSA Clinical & Translational Science Awards Program

TRIAL INNOVATION NETWORK

CTSA Hubs (60+)

Innovation Centers

TICs

RIC

Vanderbilt University Medical Center

Johns Hopkins University

Vanderbilt University Medical Center

YOU ARE HERE

BIOS Clinical Trials Coordinating Center

TRIAL INNOVATION NETWORK

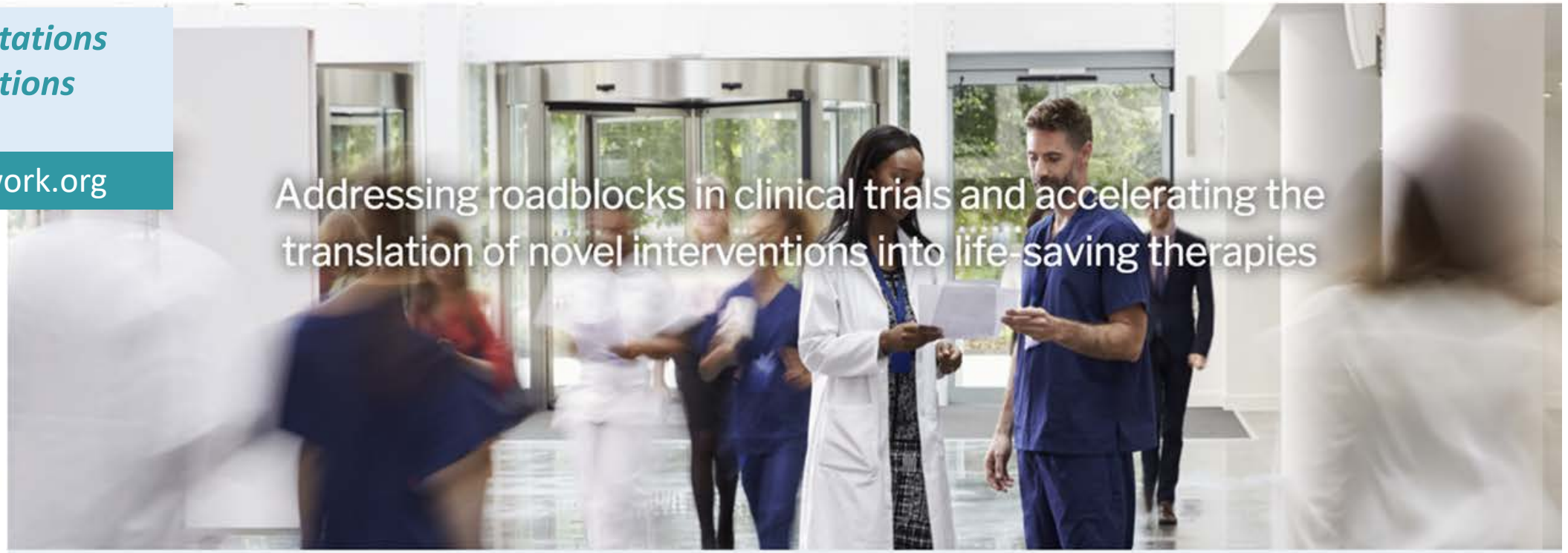
CTSA Clinical & Translational Science Awards Program

TRIAL INNOVATION NETWORK

Support for the development and conduct of multi center clinical trials

No cost for Consultations and Recommendations report

trialinnovationnetwork.org



Operational innovation, excellence, and collaborati

The Trial Innovation Network continues to accept new proposals!

CLICK HERE TO REQUEST A CONSULT FROM THE TIN

TIN Support Starts Here

463 TOTAL PROPOSALS SUBMITTED

NETWORK PROPOSALS	STANDARD AGREEMENTS	SIRB METRICS
100 INSTITUTIONS WITH 76 THERAPEUTIC AREAS	73 SITES WITH 9 STUDIES	288 SITES WITH 80 STUDIES

JHU U24TR004440 / VUMC U24TR004437 / VUMC U24TR004432

Types of TIN Support

TRIAL INNOVATION NETWORK

Investigators can request consultations and resources for multi-center clinical trials and studies across disciplines and disease areas.

Initial Consultation

All proposals accepted into the TIN portal are provided with an initial consultation

Resources

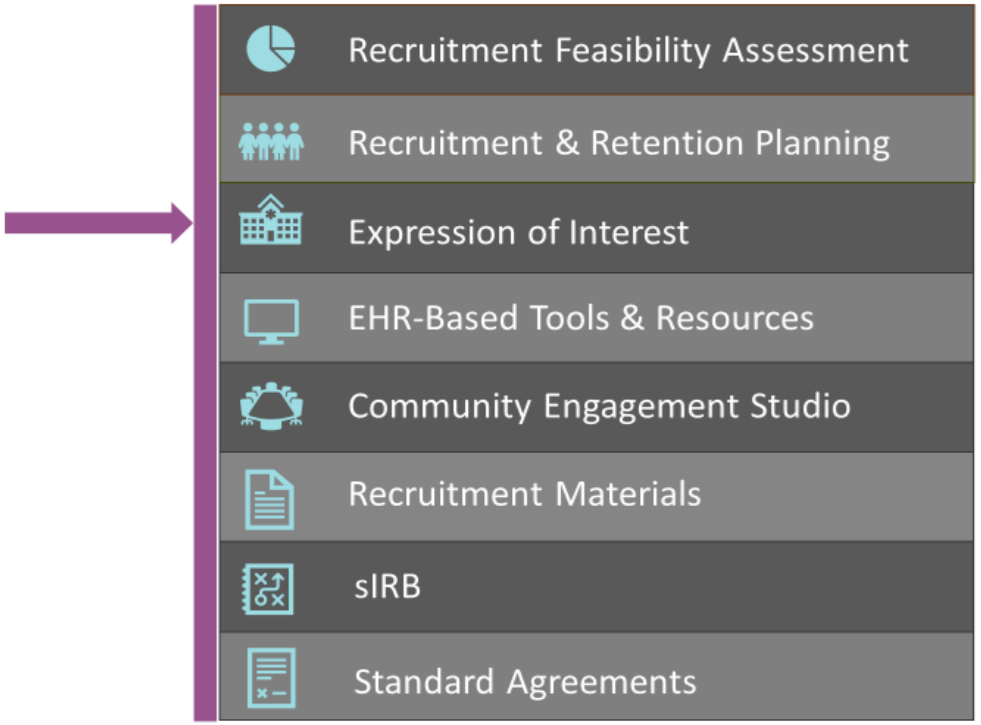
Requests for additional resources are put forward for internal approval

Comprehensive Consultation

The investigator and TIN work together to develop and submit a proposal

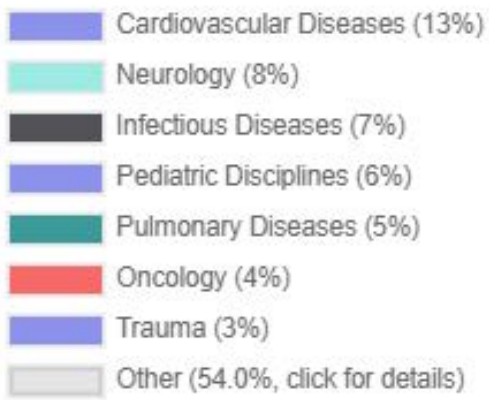
Trial Implementation

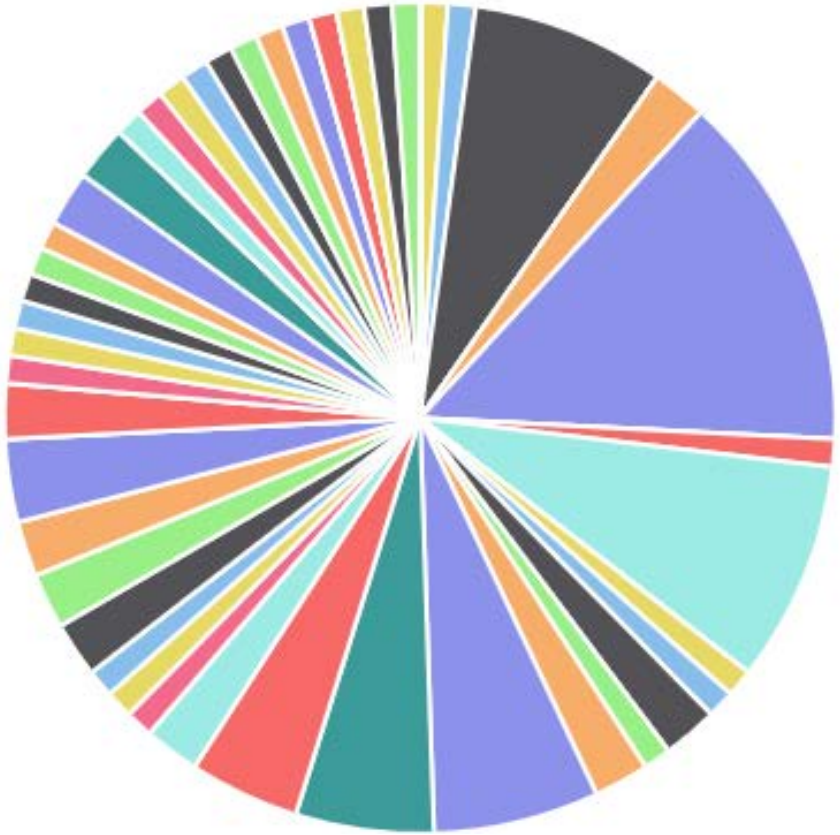
The TIN serves as the trial data or clinical coordinating center



Network Proposals

% of Therapeutic Areas Represented





483
REQUESTED NETWORK SUPPORT

21
NIH I/Cs ENGAGED

77
THERAPEUTIC AREAS REPRESENTED

96%
% OF CTSA SUBMITTED PROPOSALS

TRIAL **INNOVATION** NETWORK

CTSA Clinical & Translational Science Awards Program

Thank you!

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