Leading Efforts to Tackle Roadblocks & Leverage Efficiencies

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It takes a really long time...
The Vision for a Big, Bold, Hairy, Audacious Idea
Trial Innovation Network

Vision

Accelerate Translation
Trial Innovation Network

CTSA Program
Hubs (n=64)

Research Network Liaison Teams

Partners
Participants
Providers
Public

NIH
Institutes
Industry
Foundations

Trial Innovation Centers
(TICs) (n=3)

Recruitment Innovation Center
(RIC) (n=1)
Trial Innovation Network
Operational Excellence

**Trial Planning**
- Protocol Design
- Study and Budget Feasibility
- Statistical Analysis Plan
- Risk Assessment
- Engagement and Recruitment Plans
- Patient Engagement Studio
- Cohort Discovery Leveraging EHR
- Recruitment Training
- Access to unique populations – Rare Diseases
- Key Opinion Leader/Clinical Expertise

**Trial Execution**
- 3 Academic Central IRBs
- Standard Agreements Used Across Network (*FDP-CTSA*)
- CTSA Program Recruitment Sites with Trial Innovation Network Liaison Teams
- Regulatory Support
- Project Management
- Consent Forms, CRFs
- Site Selection, Initiation, Training
- Performance Metrics
- Recruitment Plans and Tools
- Data Management
- DSMB
- Study Close Out, Statistical Analysis
- Publications
What Makes the Trial Innovation Network Different?

Operational Innovation

A living laboratory to study and innovate key elements of clinical trials

Goal isn’t just to complete a trial – but to improve the clinical trials process
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Innovating and Harmonizing – IRB Review

Harmonization

- 3 Harmonized Central IRBs
- All use same reliance agreement, standard procedures, and IT platform
- Metrics – time, cost, quality

Johns Hopkins

Harmonized CIRB Processes

SMART IRB Agreement

Vanderbilt

Utah
Trial Innovation Network

Innovating and Harmonizing – IRB Review

**Trial Innovation Network**

*Operational Innovation*

Does a harmonized IRB system increase the quality and efficiency of IRB review?

Does a harmonized IRB system decrease burden on research staff?
Innovation and Harmonization

Roadblock

- Contract negotiations are top reason for study delay

Innovation and Harmonization

- FDP-CTSA Master Contract
  - Addresses Indemnification, Confidentiality, Publication, Intellectual Property
- Harmonized Contracting System
- Metrics

Kiriakis, Clin & Transl Science, 2013; www.ara4us.org
Does a master contracting system decrease start up times for a clinical trial?
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Innovating and Harmonizing – Protocols

Exclusive Focus on Science
Limited Secondary Use of Data
Reactive Recruitment Planning
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Innovating and Harmonizing – Protocols

**Trial Design**
- Novel Study Designs
- Quality by Design
  - Compelling Scientific Endpoints
  - Feasibility
  - Limit Complexity
- Optimize Data Collection
- Metrics/Milestones
- Develop Realistic Budgets

**Recruitment Planning**
- Engage Stakeholders
- Tailored Messages and Recruitment Material
  - Pre-specified Recruitment Budgets
  - Monitor Recruitment Process, Metrics

**Data Driven Approaches**
- EHR Based Cohort Discovery and Site Selection
- Recruitment modeling to minimize amendments

**TIC and RIC Collaboration**
Poor recruitment is a top reason for trial delays

Recruitment often addressed after problems occur

Recruitment approaches often disorganized

Research staff often not trained to implement interventions

Adapted from a slide by R. Kost, Rockefeller Univ.
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Innovating and Harmonizing – Recruitment

Optimized Recruitment and Retention → Accelerated Trials

- Recruitment training
  - Training for specific populations
- Entry Criteria
  - Minimize Barriers
    - Stringency of Entry Criteria
      - Time/Risks
    - Adverse Events
      - Pain/Invasiveness
      - Procedures
      - Lost Wages
      - Language Barriers
- EHR to identify participants and sites
- Recruitment models
- Target audience, patient pathways, messaging, recruitment approaches
- Engagement studios, focus groups

- Assessment experience of participation
- Return of results
- Workflows
  - Metrics
- Participant Experience
- Protocol Design
- Proactive Systematic Recruitment
- Data Driven Cohort Discovery and Site Selection
- Engagement/Recruitment Plans
  - Outreach
  - Advertising & Social Media
- Recruitment Workflows
- Research Team
Duke Trial and Recruitment Innovation Center*

*Name tbd – Ideas Welcome!
Our Goals: Supporting Efficient, Engaged Health Research @ Duke

- Providing Duke’s clinical research community with the **resources and tools** necessary to support
  - Rapid study start-up (master contracts, cIRBs, etc.)
  - Efficient and effective study enrollment

- Providing the local community with **opportunities to engage with and information about** ongoing Health Research @ Duke
  - Bidirectional dialog
  - Health Research Navigation and Concierge services
  - Community events and consultations
    - Community Engagement Advisory Panels
TIC
• Master CTAs
• cIRBs

RIC
• Plan, design, facilitate
• Data-driven innovation

CDRNs
• Data access
• Study design
• Prep to research
• Embedding PCPs in the process

PCRC
• Embedding PCPs in the process

Your Dedicated Clinical Trial Catalyst Team

Duke Research Community

Trials Innovation Network

D-TRIC
Unleashing The Power of Clinical Data

• Weaving people, researchers, the health system and clinicians into the fabric of the clinical research process

• Leveraging the use of existing medical data to improve study design, care delivery and outcomes
  • Faster, more generalizable information
  • More efficient and cost effective study design and delivery
  • Allows for the development of questions and studies that resonate with patients and their providers and are based on real needs

• Using clinical data to drive
  • Hypotheses generation
  • Cohort discovery
  • Site selection and
  • Longitudinal follow-up (reducing participatory burden and costs)
Next Step for PCORnet

www.pcrfoundation.org
RIC Suite of Services

Consultations
- Pre-Planning
- NIH Recruitment and Retention Plan Support and Guidance
- Study Execution
- Rescue/Contingency

Connections
- Data Resources
- Community Resources
- Networks
- Mobile App Gateway
- BASE Lab

Communications
- Study Postings (Oncore)
- Social Media/digital engagement
- Concierge Service
- Marketing

Tools
- Resource List (Coming soon)
- NIH R&R Planning Guide
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