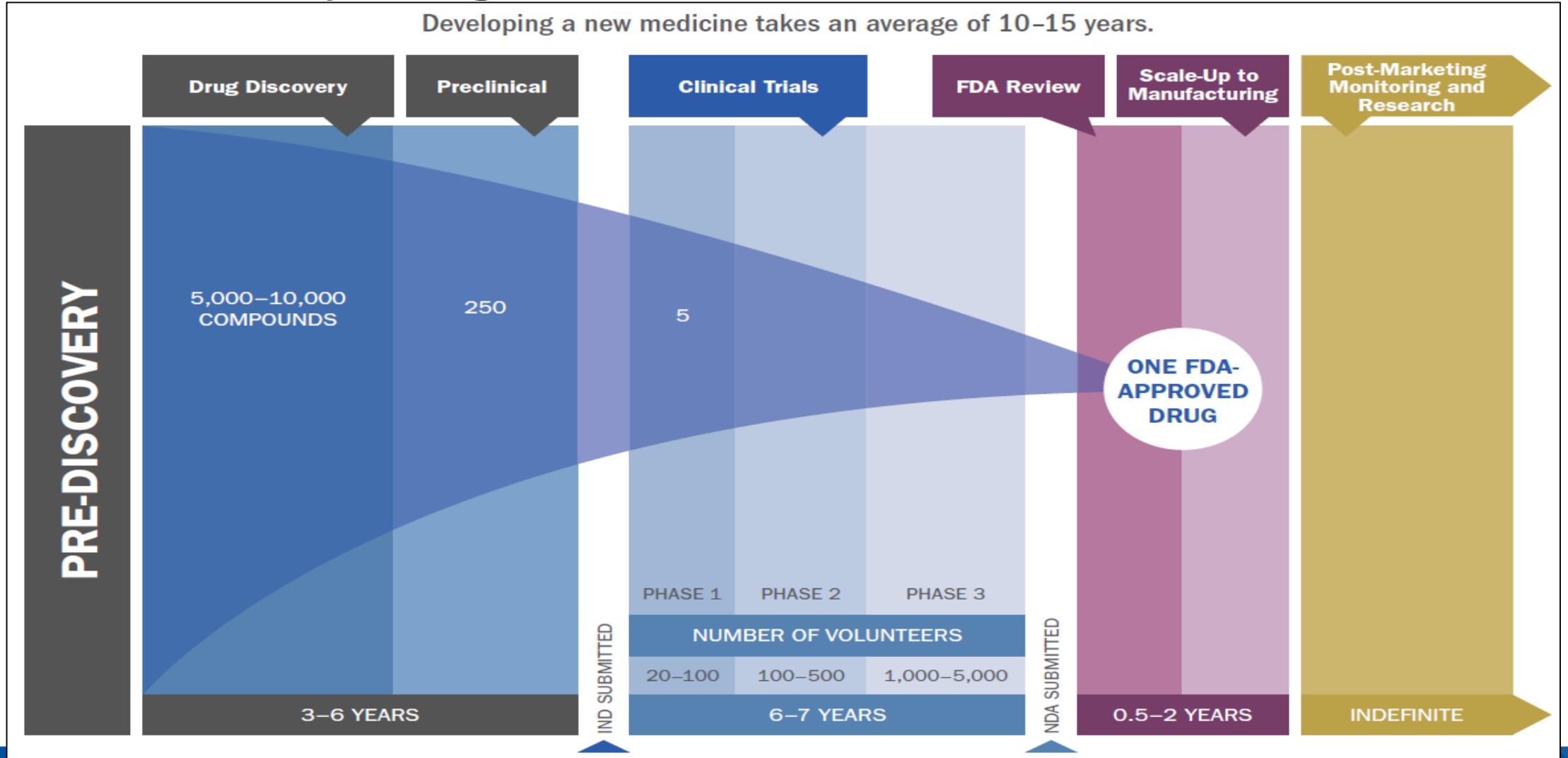


Leading Efforts to Tackle Roadblocks & Leverage Efficiencies

Jamie Roberts, MPH, MA, CCRP
Director, Research Networks
Duke CTSI



It takes a really long time...



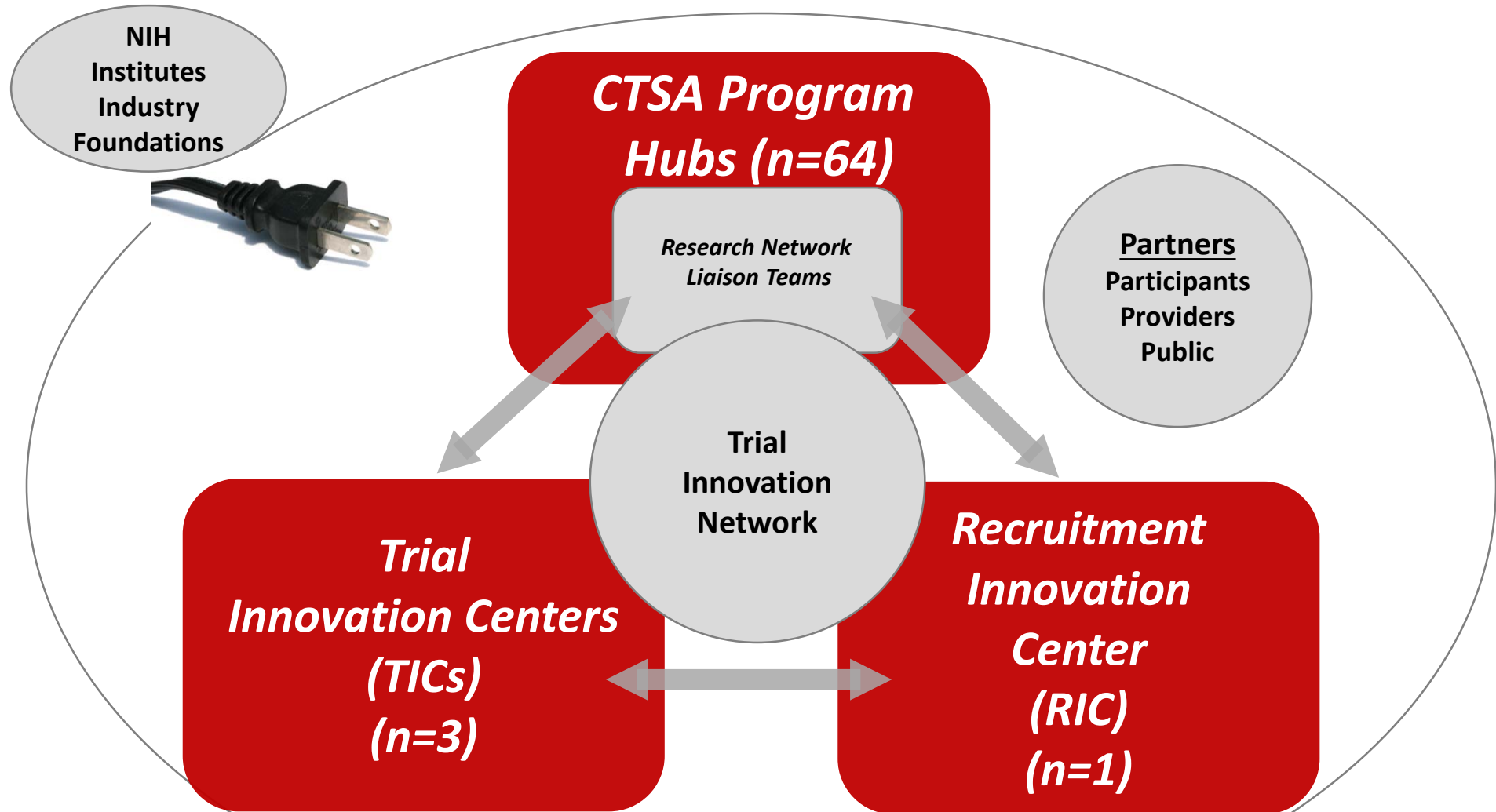


The Vision for a Big, Bold, Hairy, Audacious Idea

Trial Innovation Network *Vision*



Trial Innovation Network





Trial Innovation Network

Operational Excellence

TRIAL INNOVATION NETWORK

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 INNOVATION NETWORK

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

Trial Innovation Network

Operational Innovation

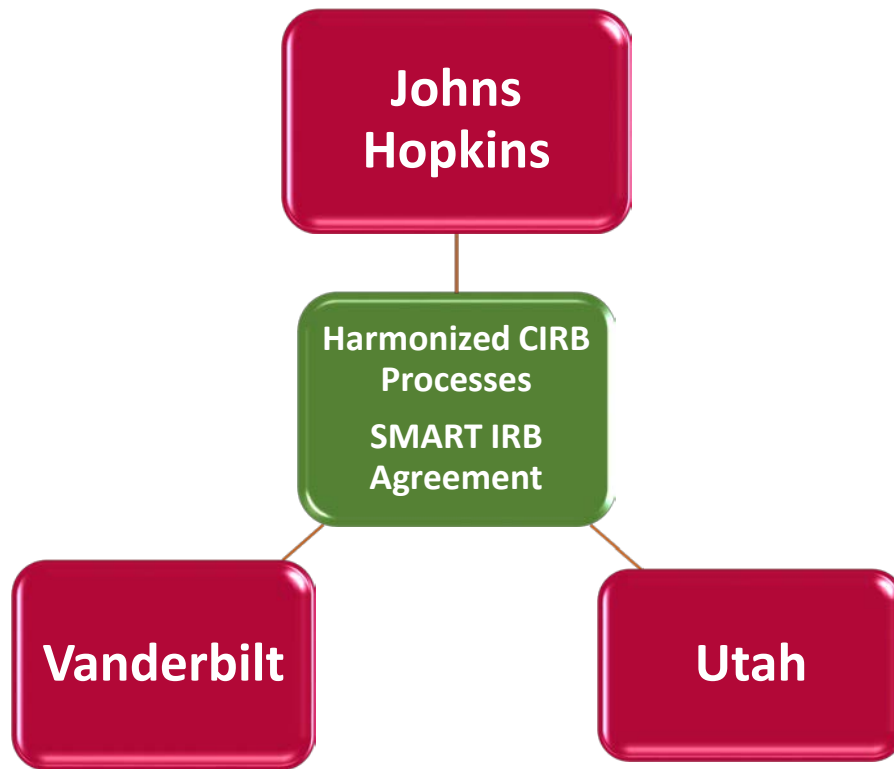
What Makes the Trial Innovation Network Different? *Operational Innovation*

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

Trial Innovation Network

Innovating and Harmonizing – IRB Review



Harmonization

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

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Innovating and Harmonizing – IRB Review

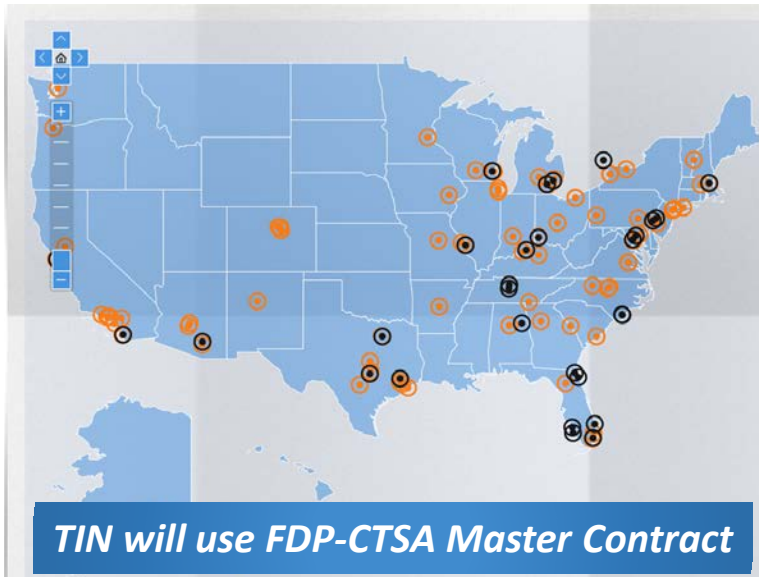
Trial Innovation Network ***Operational Innovation***

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

**Does a harmonized IRB system decrease
burden on research staff?**

Trial Innovation Network

Innovating and Harmonizing – Contracts



Kiriakis, Clin & Transl Science, 2013; www.ara4us.org

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

Trial Innovation Network

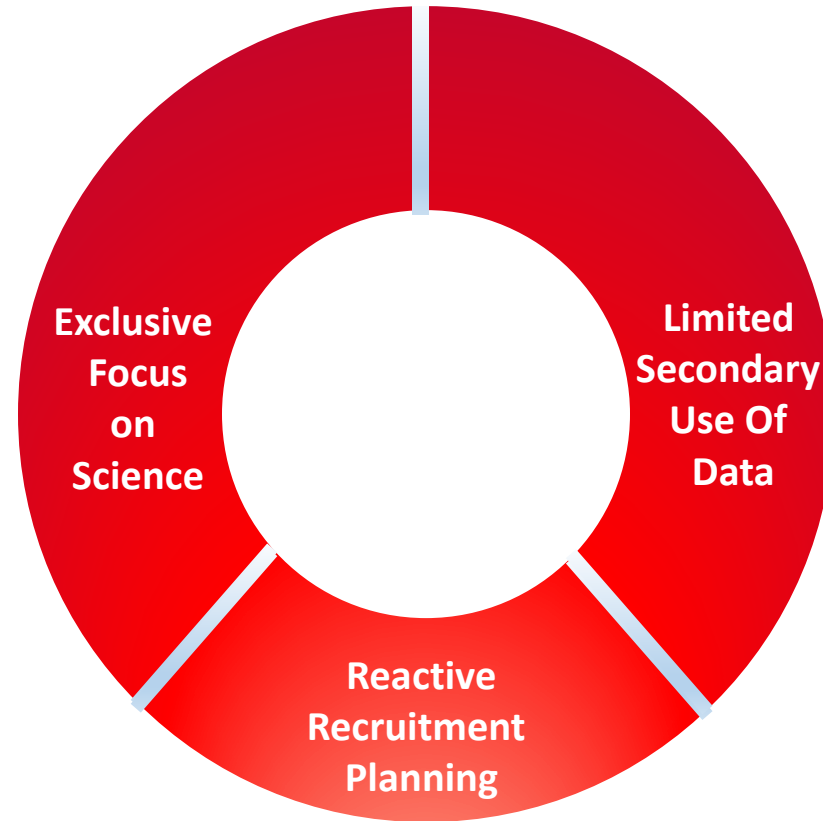
Innovating and Harmonizing – Contracts

Trial Innovation Network
Operational Innovation

**Does a master contracting system decrease start up times
for a clinical trial?**

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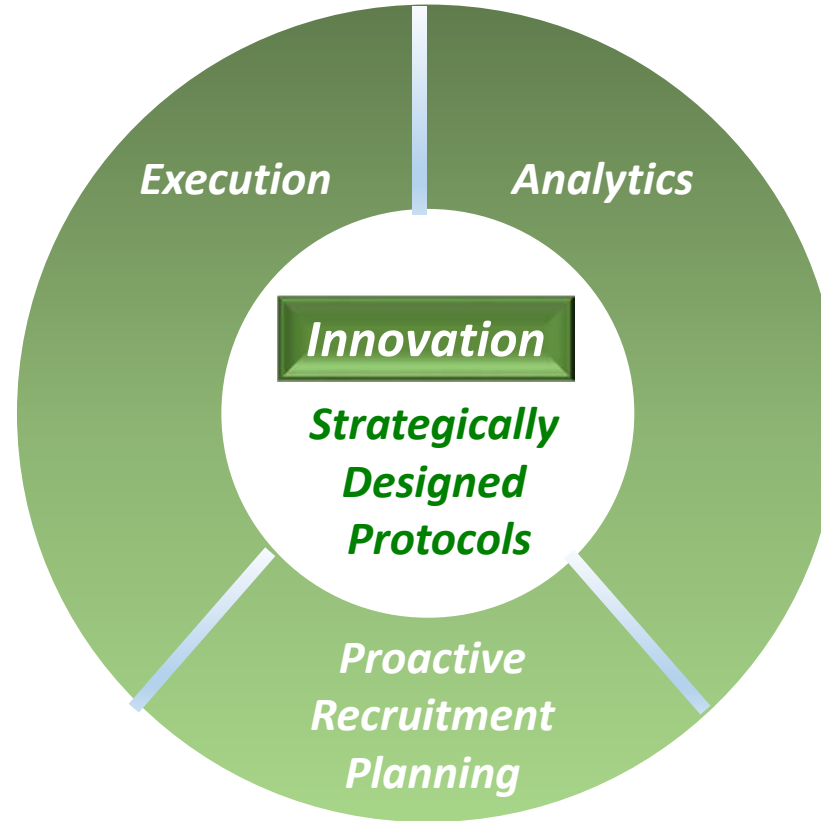
Innovating and Harmonizing – Protocols



Trial Innovation Network

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



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

TIC and RIC Collaboration

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

Trial Innovation Network

Innovating and Harmonizing - Recruitment

Roadblock

**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

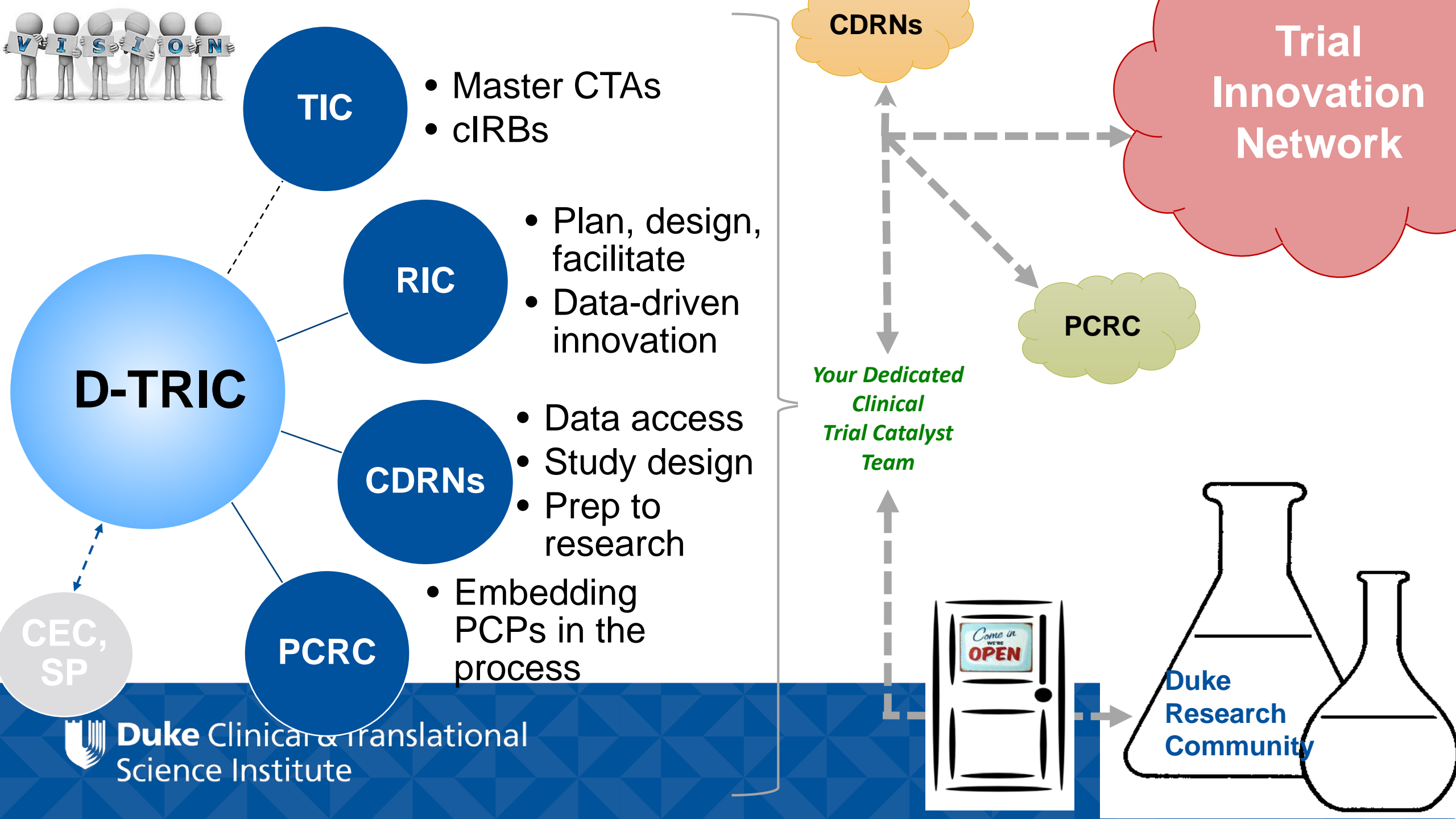


Duke Trial and Recruitment Innovation Center*

*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



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)



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Research Networks

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