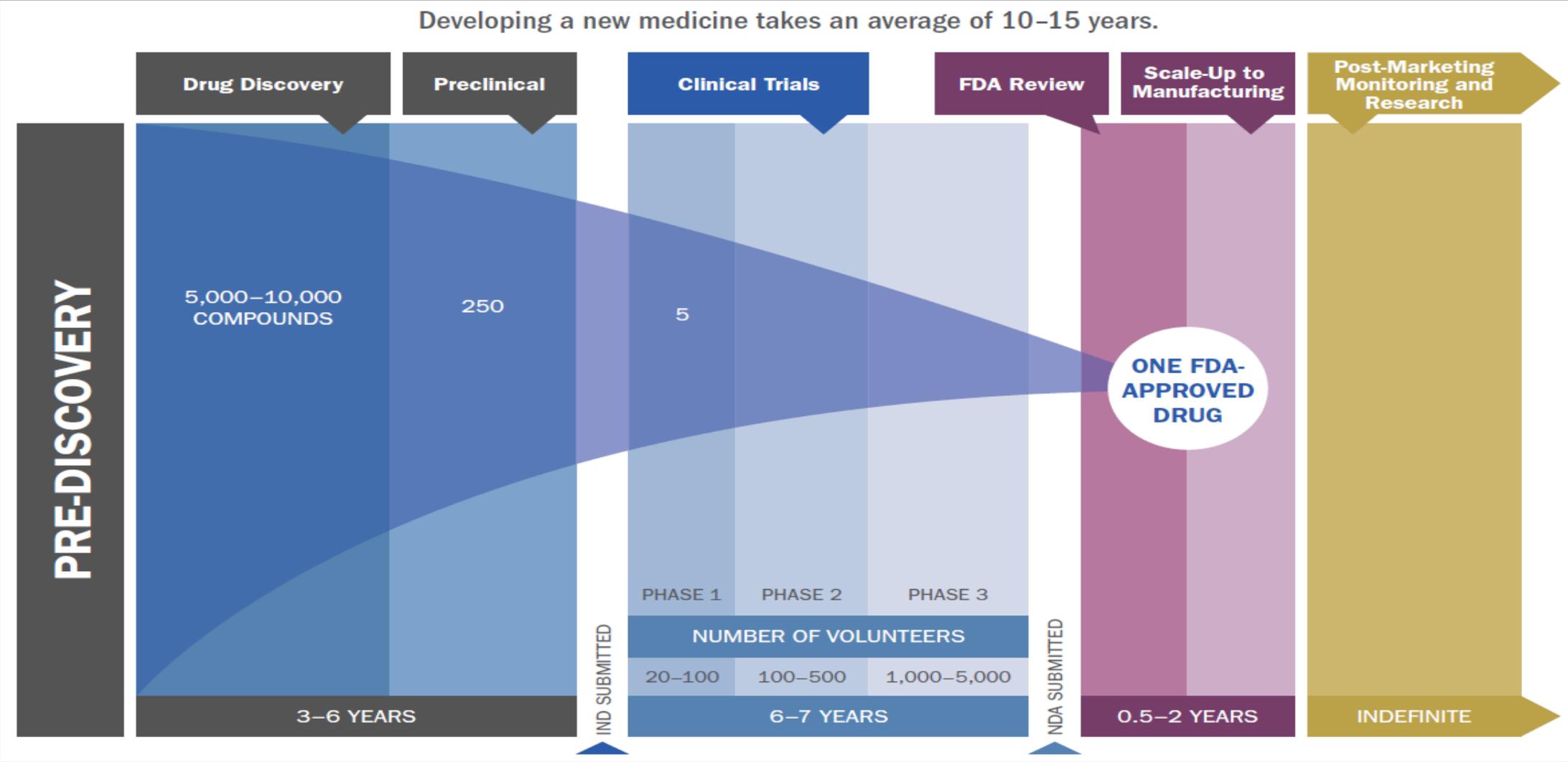


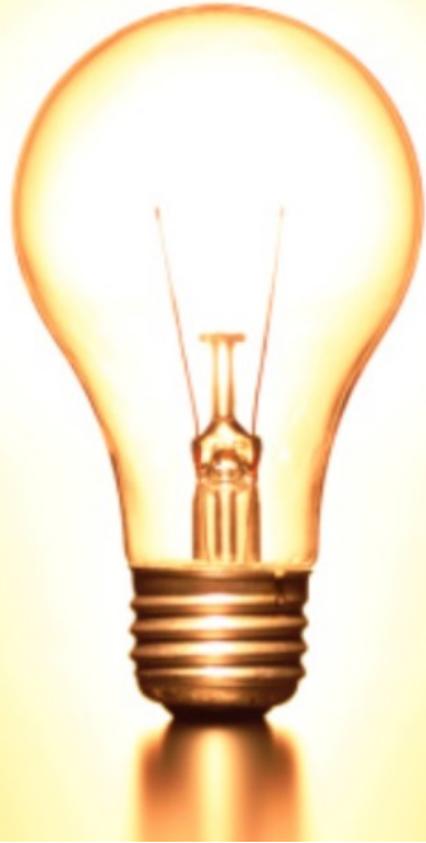
Leading Efforts to Tackle Roadblocks & Leverage Efficiencies

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



It takes a really long time...





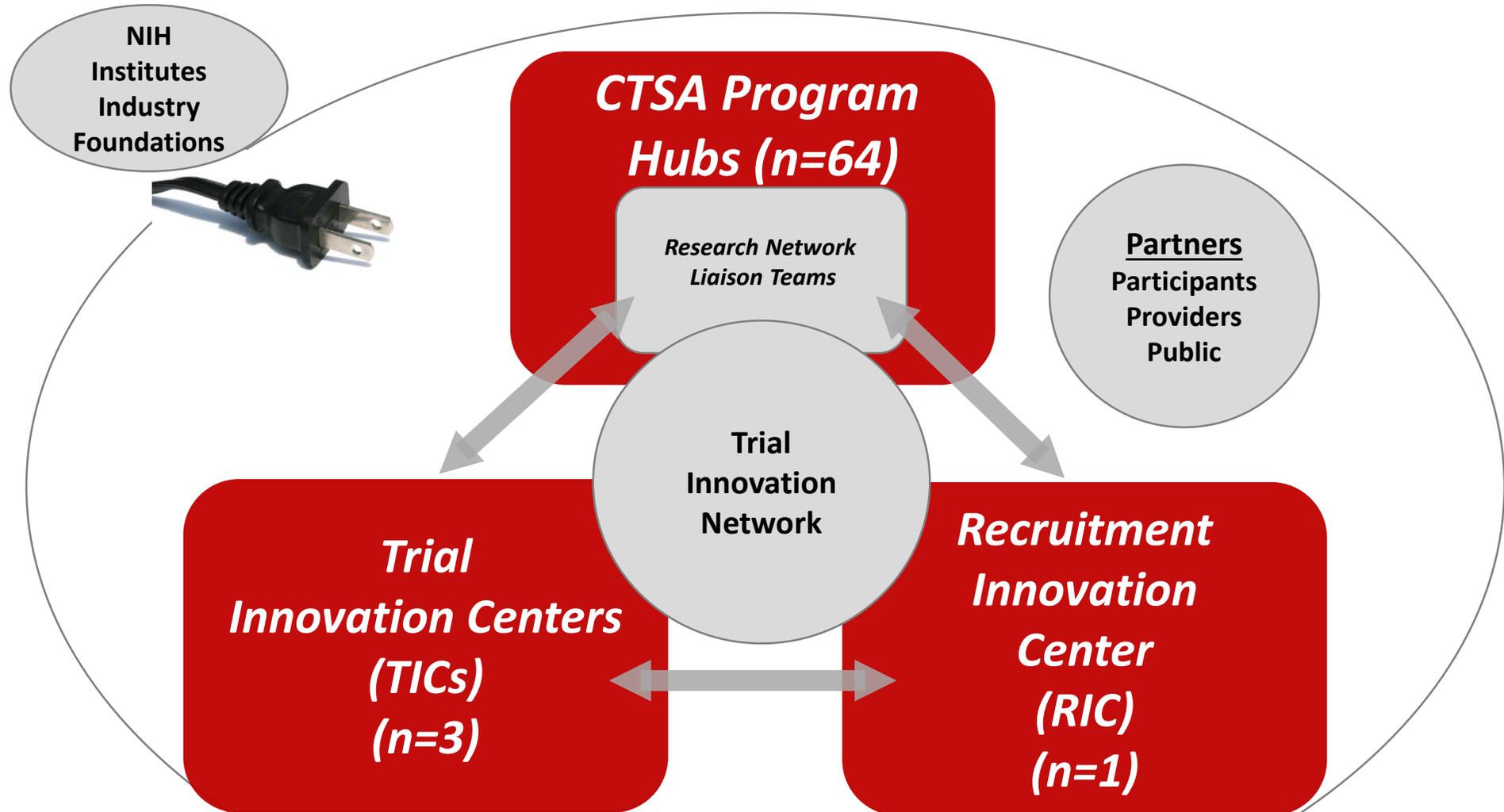
The Vision for a Big, Bold, Hairy, Audacious Idea



Trial Innovation Network *Vision*



Trial Innovation Network



Duke Clinical Research Institute

UNIVERSITY OF UTAH HEALTH CARE

Ford

VANDERBILT UNIVERSITY MEDICAL CENTER

Benjamin

Dean

JOHNS HOPKINS MEDICINE

Bernard

CTSA Clinical & Translational[®] Science Awards

Hanley

Tufts Medical Center

Selker

Wilkins

NIH National Institute on Aging

NIH NLM

Harris

VANDERBILT UNIVERSITY MEDICAL CENTER

MEHARRY MEDICAL COLLEGE

NIH National Center for Advancing Translational Sciences

NIH

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*

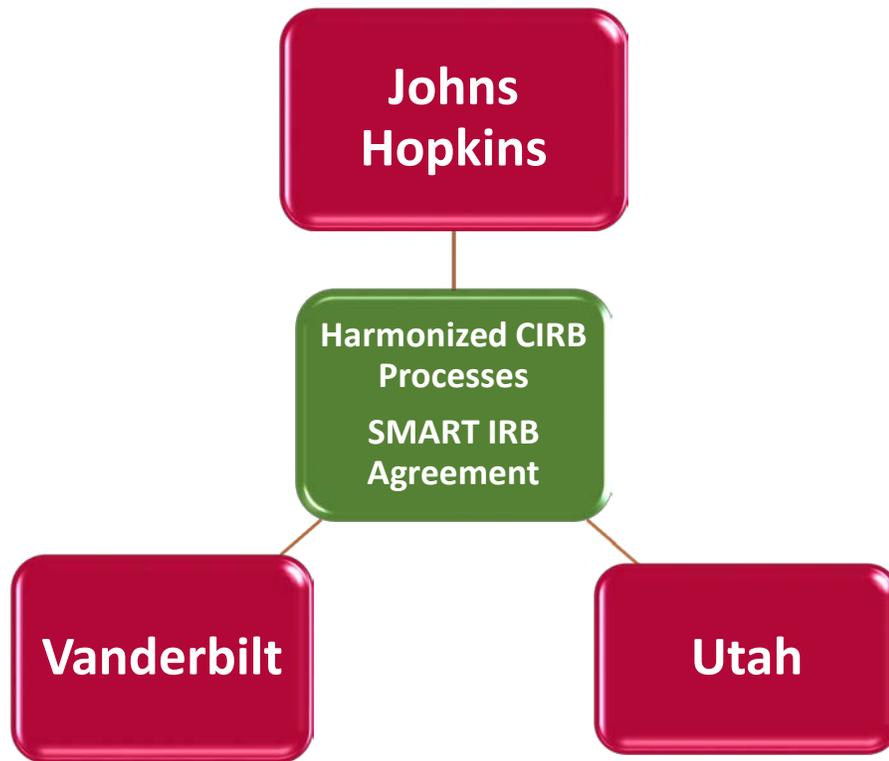
A living laboratory to study and innovate key elements of clinical trials

Goal isn't just to complete a trial – but to improve the clinical trials process



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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



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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?**

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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

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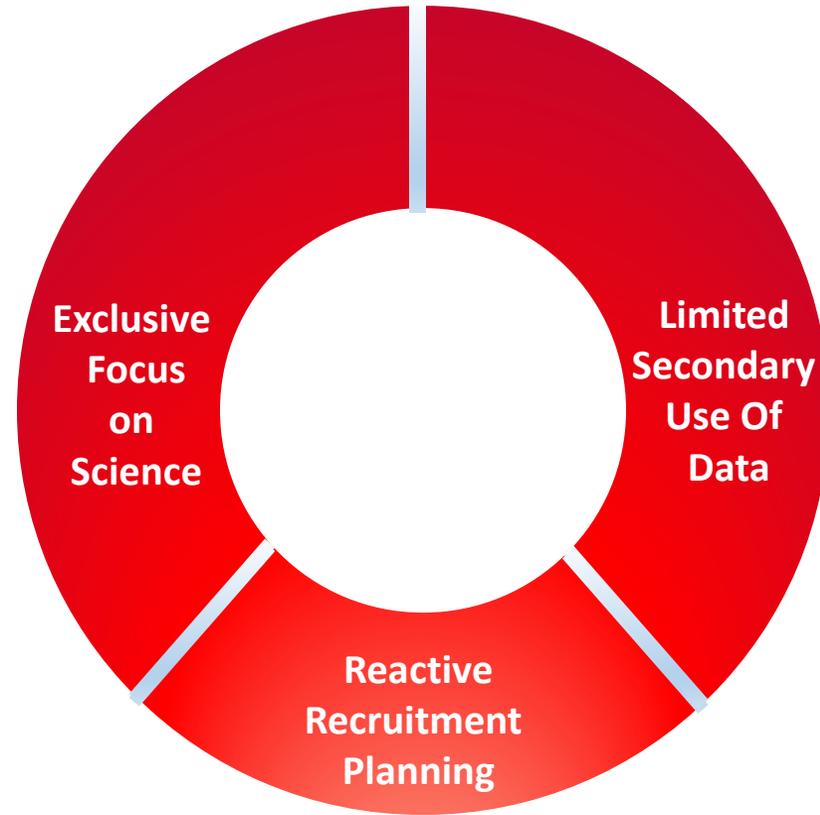
Innovating and Harmonizing – Contracts

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Operational Innovation

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

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Innovating and Harmonizing – Protocols



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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



- 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

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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

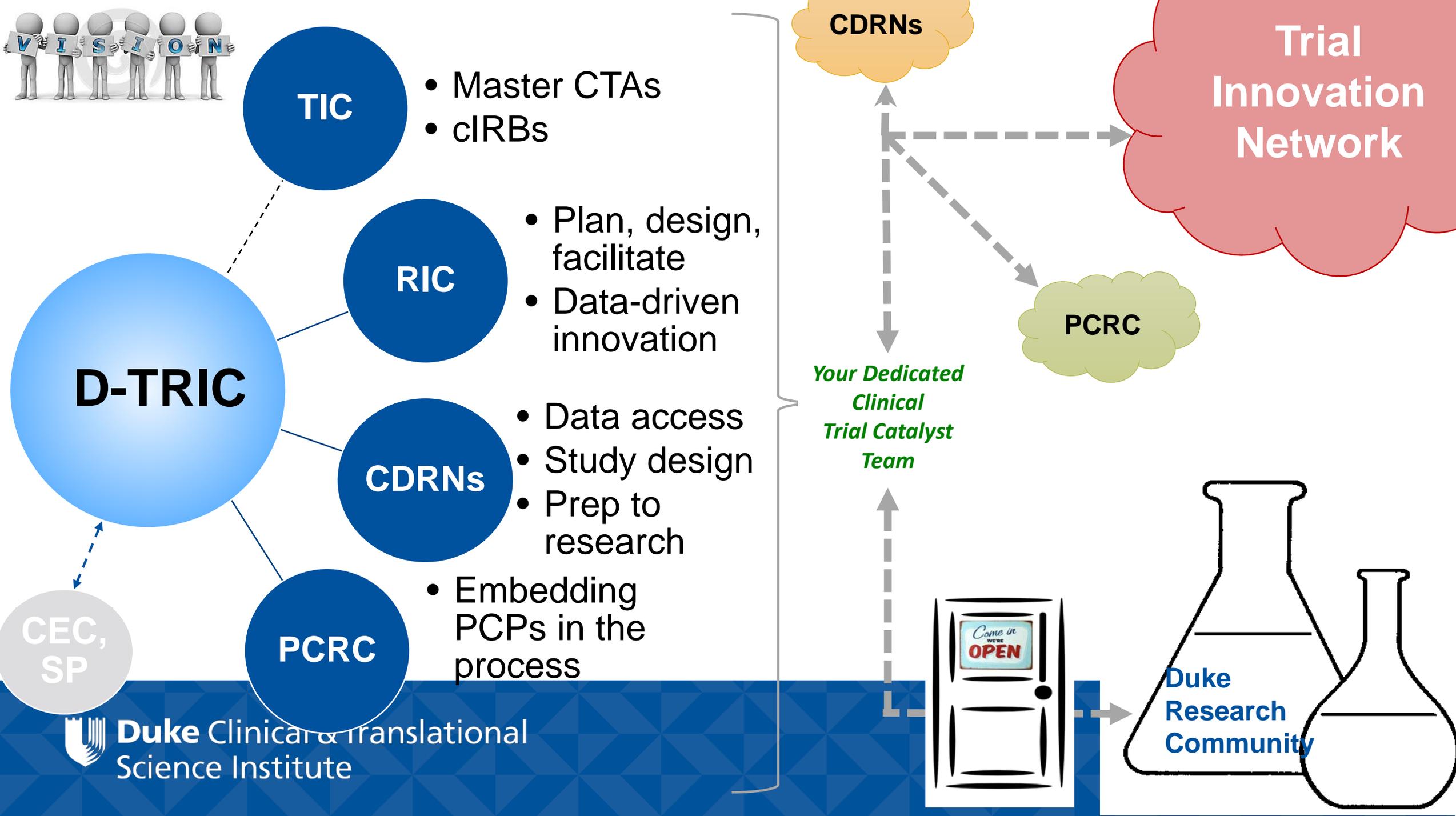


Duke Trial and Recruitment Innovation Center*

*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



CEC, SP

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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www.pcrfoundation.org

RIC Suite of Services





Duke Clinical & Translational Science Institute

Research Networks

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Duke Clinical & Translational
Science Institute