NCATS Improving Health Through Smarter Science

CTSA Program PI Webinar

Wednesday, February 28, 2018

2:00 – 3:00 ET

National Center for Advancing Translational Sciences

Agenda

Time	Topic	Presenter
2:00	Welcome	Michael G. Kurilla
2:05 – 2:20	NCATS and CTSA Program Updates	
2:20 – 2:30	Center for Leading Innovation and Collaboration (CLIC) Updates	Martin Zand and Deborah Ossip
2:30 – 3:00	Trial Innovation Network: The Trial Innovation Network at 18 months	Jane Atkinson (NCATS) Gordon Bernard (Vanderbilt) Dan Ford (JHU)

NCATS and CTSA Program Updates

Michael G. Kurilla

Bipartisan Budget Act of 2018 – 2/9/18

- Provided overall spending caps (Defense and Non-Defense) for FYs 2018 and 2019

- Extended the Continuing Resolution (CR) through March 23
  - NCATS and NIH operating at slightly below FY 2017 levels
    - In-line with NIH policy, NCATS currently funding awards at reduced amounts
      - Non-competing – 90% of committed (restoration pending determination of full-year budget by Congress)
      - Competing – will be commensurate with available funding

President's FY 2019 Budget Request
Released Feb 12th

- Printed before Bipartisan Budget Act (BBA) passed; therefore OMB included an addendum to account for the BBA:
  - NIH shows a slight increase compared to FY 2017, however…
  - NCATS like many other components of NIH shows a 2.7% decrease
    - Funding for some priorities placed in the OD, NIH
  - HHS Budget-in-Brief: https://www.hhs.gov/sites/default/files/fy-2019-budget-in-brief.pdf
    - NIH described on pages 40-46

Additional information may be released in the coming weeks

Success Stories – We want to hear from you!

- Success Story Form on:
  - CTSA Program Consortium website:
    - https://ctsa.ncats.nih.gov/policies?type=guidelines&date=2018-02-28&title=success-story-form
  - CLIC website:
    - https://clic-ctsa.org/news

Upcoming Events

Rare Disease Day 2018
February 28, 2018
https://www.rarediseaseday.org/

Rare Disease Day at NIH
Masur Auditorium, NIH Campus
March 1, 2018
https://events-support.com/events/NIH_Rare_Disease_Day

CTSA Clinical & Translational Science Awards Program

CTSA Program Steering Committee Meeting
Marriott Wardman Park, Washington, DC
April 18, 8:00 am – 12:00 pm

CTSA Clinical & Translational Science Awards Program

CTSA Program Meeting
Marriott Wardman Park, Washington, DC
April 18, 1:00 pm – 5:00 pm
https://clic-ctsa.org/events/spring-ctsa-program-meeting

Upcoming Events

CTSA Clinical & Translational Science Awards Program

DTF, KL2 and TL1 Meetings on April 19, 2018

8:00 am – 10:00 am KL2 Meeting
8:30 am – 11:30 am Methods & Processes DTF Meeting
10:00 am – 2:00 pm Workforce Development DTF Meeting
12:30 pm – 4:30 pm Collaboration/ Engagement DTF Meeting
2:00 pm – 4:00 pm TL1 Meeting

ACTS ASSOCIATION FOR CLINICAL AND TRANSLATIONAL SCIENCE

Association for Clinical and Translational Science Conference
Marriott Wardman Park, Washington, DC
April 19 - 21, 2018
http://www.actscience.org/

CTSA Clinical & Translational Science Awards Program

Informatics DTF Meeting
Parc 55 San Francisco Hotel, in San Francisco
Friday, March 16, 2018 from 7:30AM-12:30PM
In conjunction with the AMIA 2018 Informatics Summit
Register here: REGISTRATION FORM

CTSA Clinical & Translational Science Awards Program

Lifespan DTF Meeting
Metro Toronto Convention Center, Toronto, Canada
Saturday, May 5, 2018
In conjunction with the Pediatric Academic Societies Meeting

NIH National Center for Advancing Translational Sciences

CTSA Clinical & Translational Science Awards Program

Spring 2018 CTSA Program Meeting

Marriott Wardman Park Hotel Washington, DC
Wednesday, April 18, 2018

12:00 - 1:00 pm	**Registration**
1:00 - 1:30 pm	**Welcome, NCATS and CTSA Program Updates** Christopher P. Austin, M.D. and Michael G. Kurilla, M.D., Ph.D.
1:30 - 2:00 pm	**CTSA Program Steering Committee Updates** Kathleen Brady, M.D., Ph.D. and Christopher P. Austin., M.D.
2:00 - 2:45 pm	**CLIC Updates: Communications, Common Metrics and Collaborations** CTSA Program Coordinating Center for Leading Innovation and Collaboration (CLIC) Martin Zand, M.D., Ph.D. and Deborah Ossip, Ph.D.
2:45 - 3:15 pm	**Networking Break**
3:15 - 4:00 pm	**Clinical Trials Registration and Reporting** Valery Gordon, Ph.D., M.P.H., Sarah White, M.P.H., C.I.P., and Anthony Keyes, M.B.A., P.M.P.
4:00 - 5:00 pm	**Collaborative Innovation Awards** • Assessing the fitness of clinical data for research within a multi-institutional network: First steps toward a centralized data warehouse, Douglas S. Bell, M.D. • Early Check: A Collaborative Innovation to Facilitate Pre-Symptomatic Clinical Trials in Newborns, Lisa Gehtland M.D. • Trial Finder, Jennifer Grandis, M.D. and Harold Collard • TBD
5:00 - 5:15 pm	**Closing Remarks** Christopher P. Austin, M.D. and Michael G. Kurilla, M.D., Ph.D.

Register here: https://clic-ctsa.org/events/spring-ctsa-program-meeting

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Collaborative Innovation Award

- Collaborative Innovation Award – U01 Notice released Jan 16, 2018:
  - Purpose: To expand the list of high priority translational research opportunities to conduct novel clinical research studies intended to ***develop and test models of care for Opioid Use Disorders within medical settings including primary care, emergency departments, and neo-natal units***.
- Receipt dates: March 8, 2018 and July 11, 2018
- https://grants.nih.gov/grants/guide/pa-files/PAR-18-244.html
- Contact: PJ Brooks pjbrooks@mail.nih.gov

NIH Somatic Cell Genome Editing Program

- **Program Snapshot:** Many common and rare diseases are caused by changes to the genetic code. Genome editing technologies present an exciting prospect for treatments and possibly even cures for these diseases. The NIH Common Fund's Somatic Cell Genome Editing program aims to **develop quality tools to perform effective and safe genome editing in human patients**. These research tools will be made widely available to the research community to reduce the time and cost required to develop new therapies.
- More information: https://commonfund.nih.gov/editing
- Letter of Intent Due: March 3rd
- Receipt Date: April 3rd
- **Questions?** Contact PJ Brooks

Small Business Innovation Research and Technology Transfer Opportunities

- Applicants to NCATS may address a range of its research priorities relevant to any stage of translational science, from target validation through pre-clinical and clinical evaluation, to intervention implementation and dissemination, including:
  - Drug Discovery and Development
  - Biomedical, Clinical and Health Research Informatics
  - Clinical, Dissemination and Implementation Research
- SBIR: PA-18-574 (R43/R44)
- STTR: PA-18-575 (R41/R42)
- Standard Dates: April 12 / August 12 / December 12
- Questions? NCATS encourages applicants to email NCATS-SBIRSTTR@mail.nih.gov to discuss potential project ideas and related questions.

SBIR · STTR
America's Seed Fund

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National Research Mentoring Network

Recent FOAs:

- National Research Mentoring Network: The Science of Mentoring, Networking, and Navigating Career Transition Points (RFA-RM-18-004)
- National Research Mentoring Network (NRMN) Coordination Center (RFA-RM-18-003)
- National Research Mentoring Network (NRMN) Resource Center (RFA-RM-18-002)
    - Research Strategy: The NRMN Resource Center should describe how it will accomplish the following in collaboration with the other NRMN components: ***Serving as a platform for other NIH-supported mentoring activities (e.g., Clinical and Translational Science Awardees)**
- Receipt Date: June 11, 2018

Training Data Tables – KL2 and TL1s

- **Reminder:** KL2 and TL1 awards are required to report Program Outcomes in the RPPR using the following required tables:

KL2	TL1 (depending on the program)
Table 8C: Program Outcomes: Postdoctoral	Table 8A: Program Outcomes: Pre-doctoral
	Table 8B: Program Outcomes: Short-Term
	Table 8C: Program Outcomes: Postdoctoral

- **NOT-OD-18-133 Advance Notice of Transition to the xTRACT System for Preparing Research Training Data Tables**
  - Beginning with RPPRs due on or after October 1, 2019 and applications submitted for due dates on or after January 25, 2020, NIH anticipates that it will mandate that required training data tables submitted with T32, TL1, T90/R90, and T15 applications and progress reports be created via the xTRACT system. Learn more about xTRACT.

NCATS/ Eli Lilly Externship Program Update

- On February 13, 2018, **Josephine Taverna, MD** from the University of Texas Health Sciences Center, San Antonio, gave a presentation at NCATS on Mechanistic Modeling of the Tau Pathway in Alzheimer's Disease (scholar from 2nd cohort)
- **2018 'Call' for Applications:**
  - Expect to announce by early March 2018
  - Application deadline: April 16th, 2018
  - Start date: ~July 9th, 2018
- https://ncats.nih.gov/ctsa/training/resources/lilly-externship
- Share with your scholars, KL2 PIs, TL1 trainees and CTSA investigators

Featured above: Christopher P. Austin, M.D., Director, NCATS; Joan Nagel, M.D., M.P.H., Medical Officer, Division of Clinical Innovation, NCATS; Danise Subramaniam, Ph.D., Senior Director, Global Regulatory Affairs-NA Eli Lilly and Company; Josephine Taverna, M.D., NCATS Eli Lilly Scholar; Michael Kurilla, M.D., Ph.D., Director, Division of Clinical Innovation, NCATS

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Center for Leading Innovation & Collaboration

Update:
Center for Leading Innovation and Collaboration

PI Call

February 28, 2018

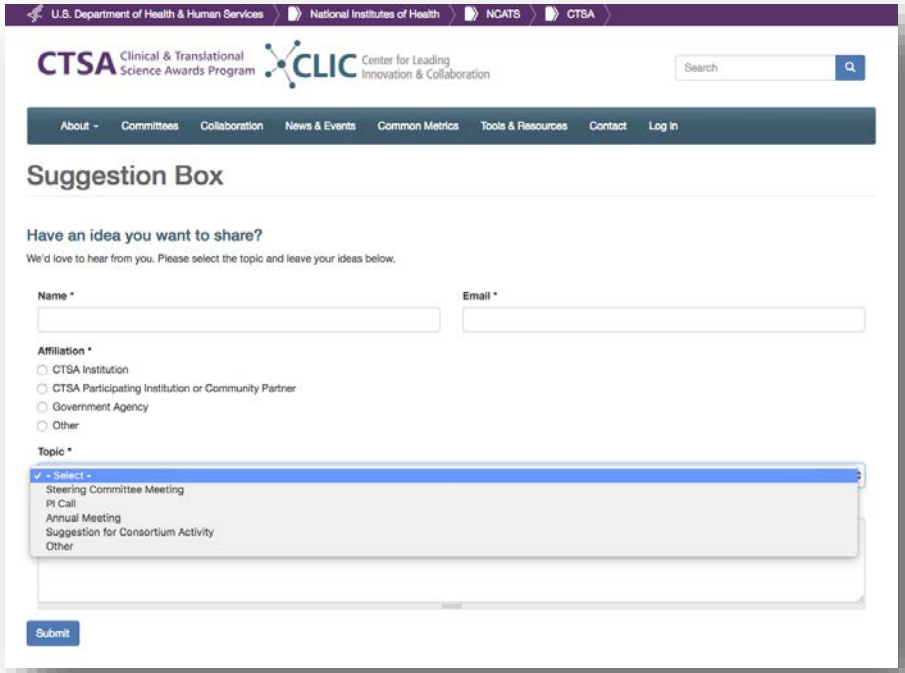
Deborah J. Ossip PhD

Martin S. Zand MD PhD

NIH
National Center for Advancing Translational Sciences

I. Communications: Suggestion Box

- Suggestion Box
  - Bidirectional
  - Asynchronous
  - Democratizes Communication
- Goals include
  - Track individual communications and themes
  - Regular review by NCATS, CTSA Steering Committee
  - “Close the loop” feedback



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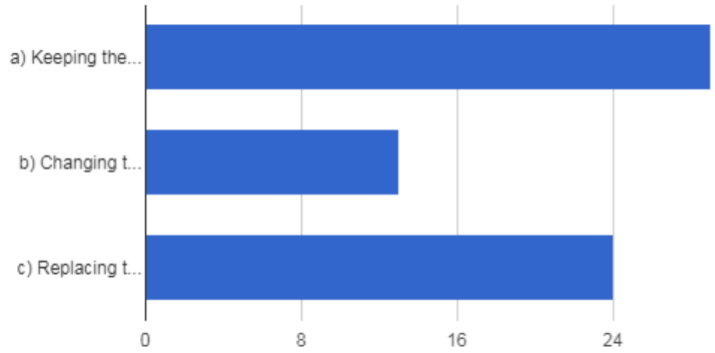
I. Communications: Moderated Forum

- Coming in Fall 2018
- Forum will facilitate *asynchronous conversations*
- Moderated
- Topics could include
  - Meeting session ideas
  - Ask the community for help
  - Guidance on policies

I. Communications: Surveys Posted

- Pod Survey now available
- “Close the loop” feedback
- Surveys to be posted regularly



“Do you recommend:”

a) Keeping the pod structure "as is" (29, 43.9%)

b) Changing the frequency to "as needed" (13, 19.7%)

c) Replacing the pod mechanism with an alternative communication mechanism(s) (24, 36.4%)

https://clic-ctsa.org/sites/default/files/20180219_CTSA_Program_Pod_Feedback_Report.pdf

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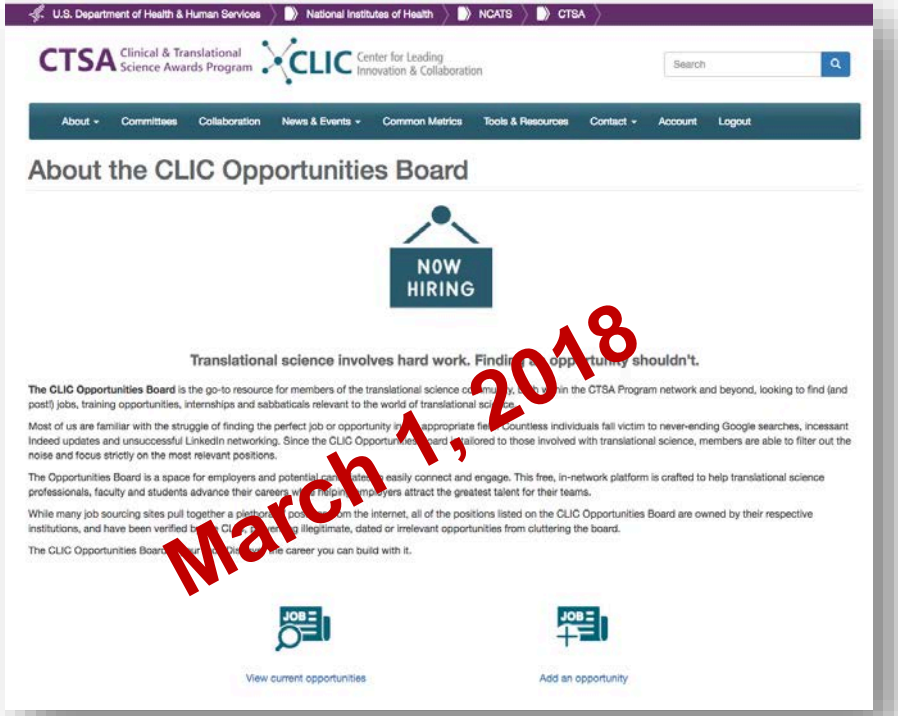
II. CLIC Opportunities Board

A workforce development resource for members of the translational science community.

- Purpose
  - Allows individuals and employers to find and post jobs, internships, sabbaticals and training opportunities related to translational science
- Differentiation
  - Targeted and tailored to the translational science community
  - Postings originate from their respective institutions
- Audience
  - Available to members of the CTSA Program network and beyond



March 1, 2018

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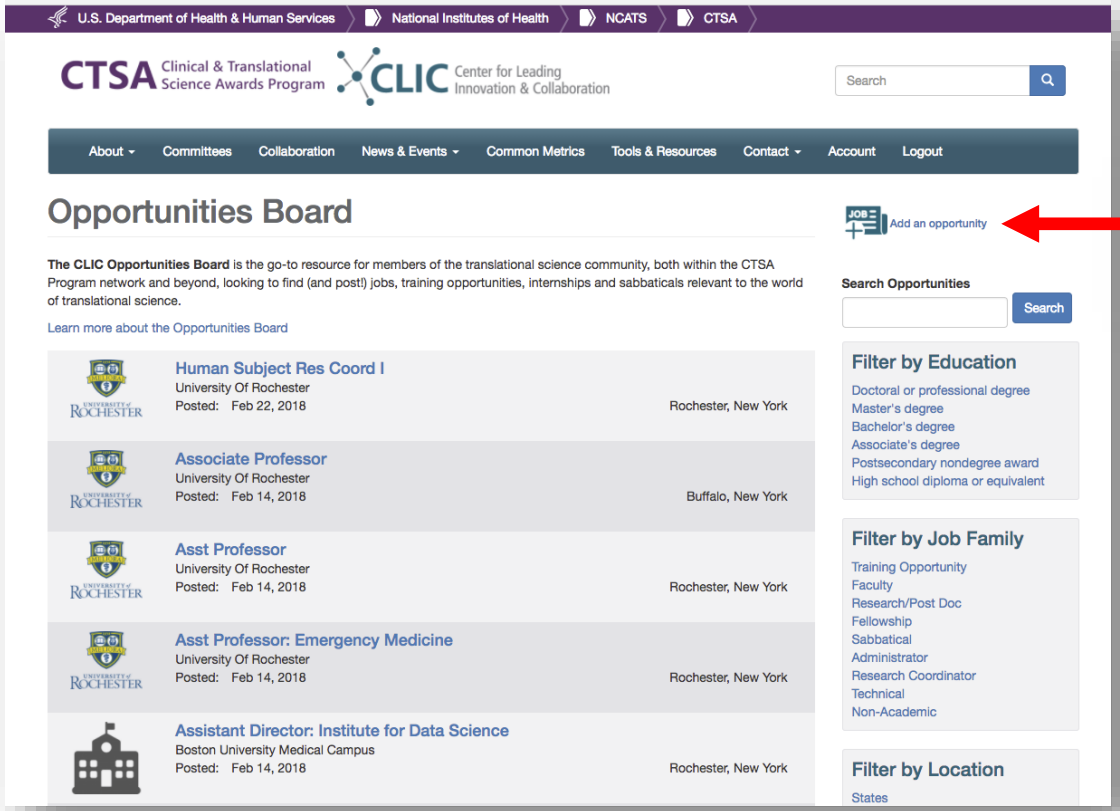
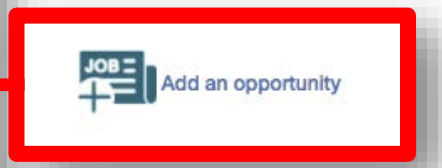
II. CLIC Opportunities Board

A workforce development resource for members of the translational science community.





CLIC Center for Leading Innovation & Collaboration

National Center for Advancing Translational Sciences

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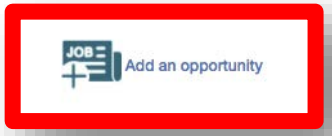
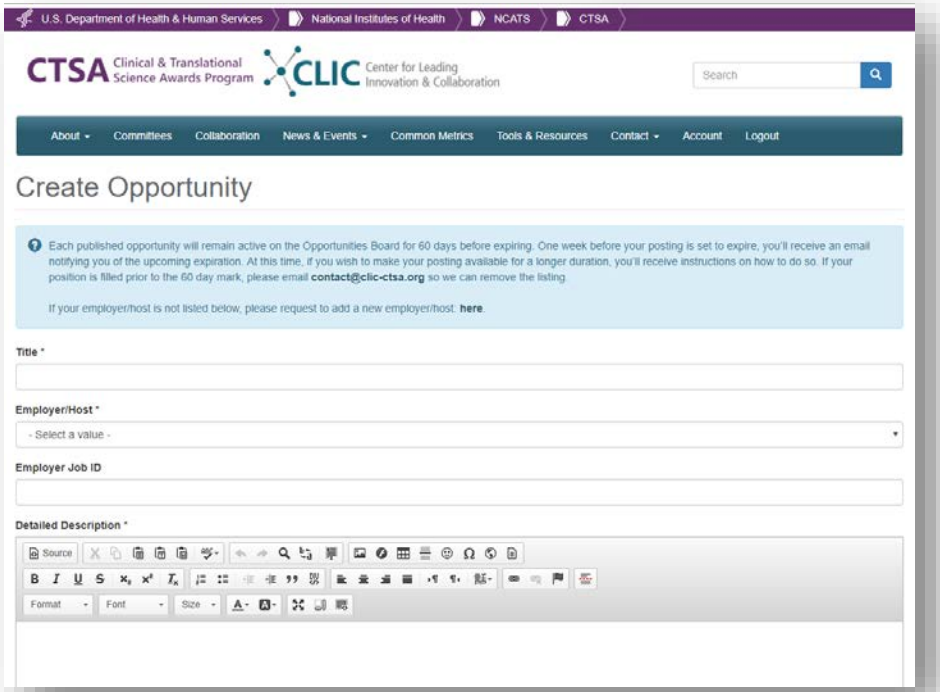


Posting an Opportunity

- Opportunities are reviewed for completeness and relevance to the CTSA Program.
- Opportunities remain active on the site for 60 days before expiring
- If you wish to make your posting available for a longer duration, you'll receive instructions on how to do so



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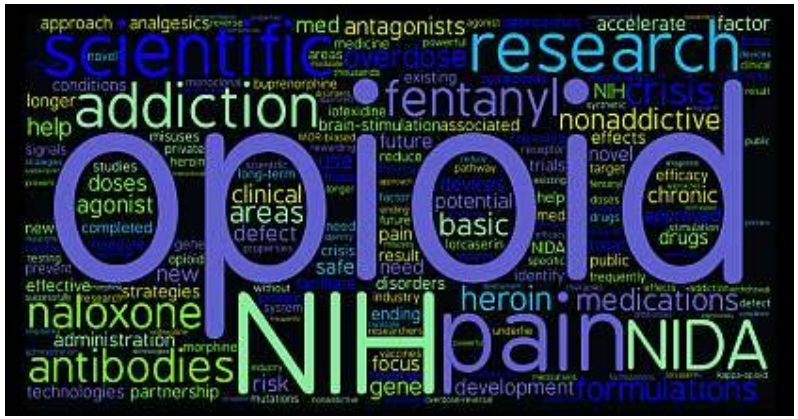
III. CLIC Un-Meeting: The Opioid Crisis

- June 2, 2018 @University of Rochester
  - NCATS response to Opioid Crisis
  - One day meeting
  - 75 -100 attendee spots
- “All the hallway conversations… none of the talking heads”



National Center for Advancing Translational Sciences

National Institute on Drug Abuse
Advancing Addiction Science

National Center for Advancing Translational Sciences

IV. 2017 Common Metrics Reminder

- Deadline for Common Metrics Reporting: ***August 30, 2018.***
- **Update Common Metric values through 2017**
- **Modify Turn-the-Curve (TTC) plans** for the first three metrics: Careers in Clinical and Translational Research, IRB Duration, and Pilot Funding and Publications.
- **Update TTC plans:** Describe any changes to underlying factors, the progress you have made by implementing selected strategies, and the results of any additional measures you are using to track progress with these strategies.
- As in the past, work with your teams (evaluator, content expert(s), data support person, others as warranted).

Assistance is available from our Common Metrics team at common_metrics@clic-ctsa.org.

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IV. Scorecard License Change

- On **May 1, 2018**, the management of the Clear Impact Scorecard Licenses for hubs will transition from Tufts University to CLIC.
- ***CLIC will purchase two Scorecard Licenses per hub***.
- Hubs may purchase more licenses: $240/user/year.
- Over the next month, Clear Impact will reach out and inform you of the transitioning licensing process.
- Questions about this upcoming process?
- Contact Lauren Chambers, (lauren@clearimpact.com) Impact Consultant at Clear Impact.

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See you in April !

NIH
National Center for Advancing Translational Sciences

Trial Innovation Network:

The Trial Innovation Network at 18 months

Jane Atkinson, Gordon Bernard and Dan Ford

Trial Innovation Network at 18 months

Jane Atkinson - NCATS

Gordon Bernard – Duke University/Vanderbilt University Trial Innovation Center

Daniel Ford – Johns Hopkins University/Tufts University Trial Innovation Center

CTSA Clinical & Translational Science Awards®

TRIAL INNOVATION NETWORK

Question to address

- **Topic #3:** The TIN has been a challenge to participate in. We have sent projects in that have either been rejected or referred elsewhere (eg SMART IRB). It would be helpful if we could learn about successful TIN examples - even if hypothetical - and discuss ways to engage everyone (not just a select few) in the TIN process

The TIN at 18 months

- Who we are.
- What we are doing.
- How we are doing it.
- Who is working with us.

Jul 2016- Jun 2017

Iteratively built Key Elements of Network

Built TIC, RIC Teams

Feb 2017

Launched Network Projects

2017

Investigators submitted applications to NIH Institutes

Pilot studies

Focused on Hub Liaison Teams

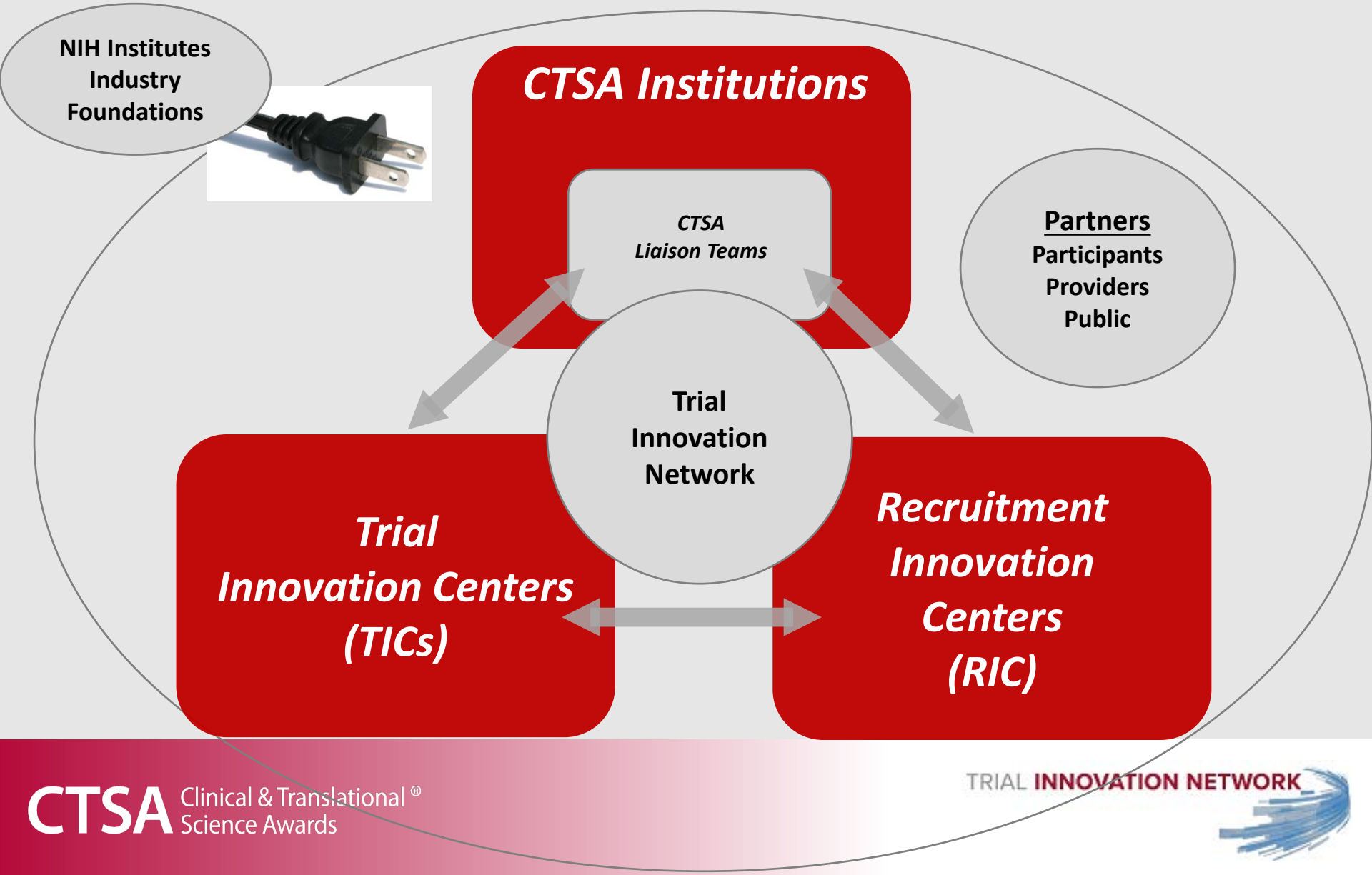
2017-2018

Built Harmonized National Site Based Research System

The Trial Innovation Network

- The Trial Innovation Network is a new collaborative initiative within NCATS' CTSA Program composed of three key organizational partners:
  - Trial Innovation Centers (TICs)
  - Recruitment Innovation Center (RIC)
  - CTSA Institutions
- NCATS' vision for the Trial Innovation Network is to address critical roadblocks in clinical trials and to accelerate the translation of novel interventions into life-saving therapies.
- The goal is not only to execute trials better, faster and more cost-efficiently, but also to be a national laboratory to study, understand and innovate the process of conducting clinical trials.

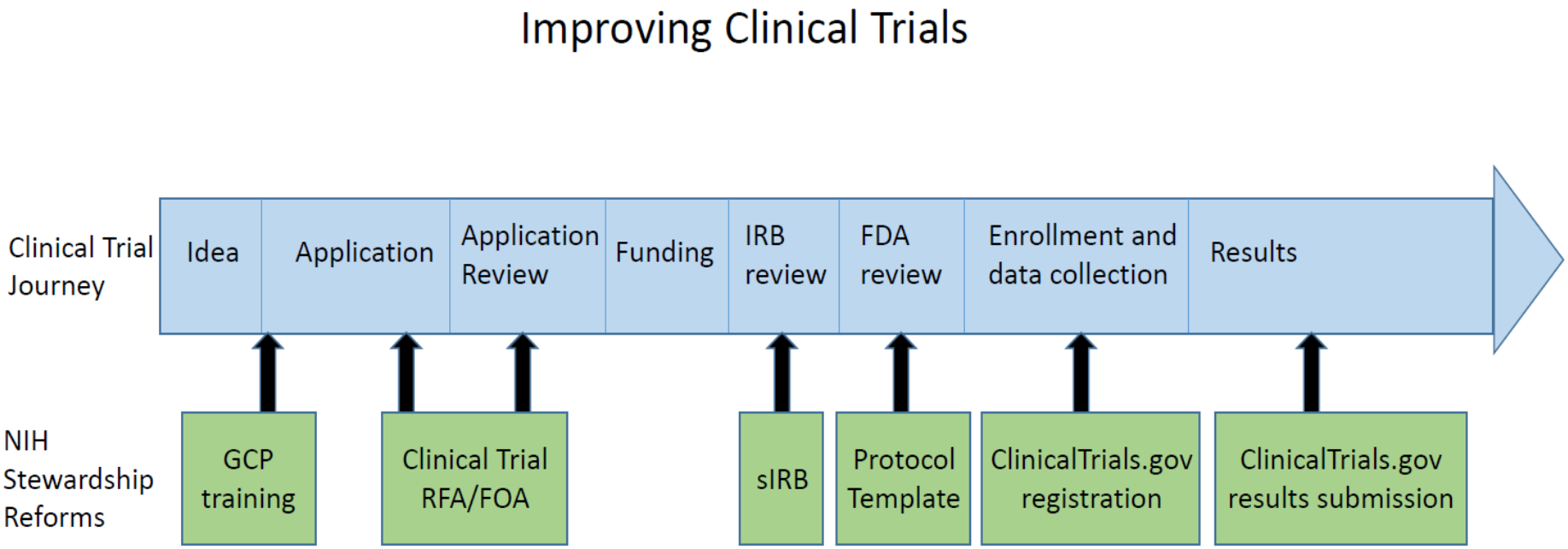
Trial Innovation Network



Trial Innovation Network

Trial Innovation Network

A framework to improve Clinical Trials

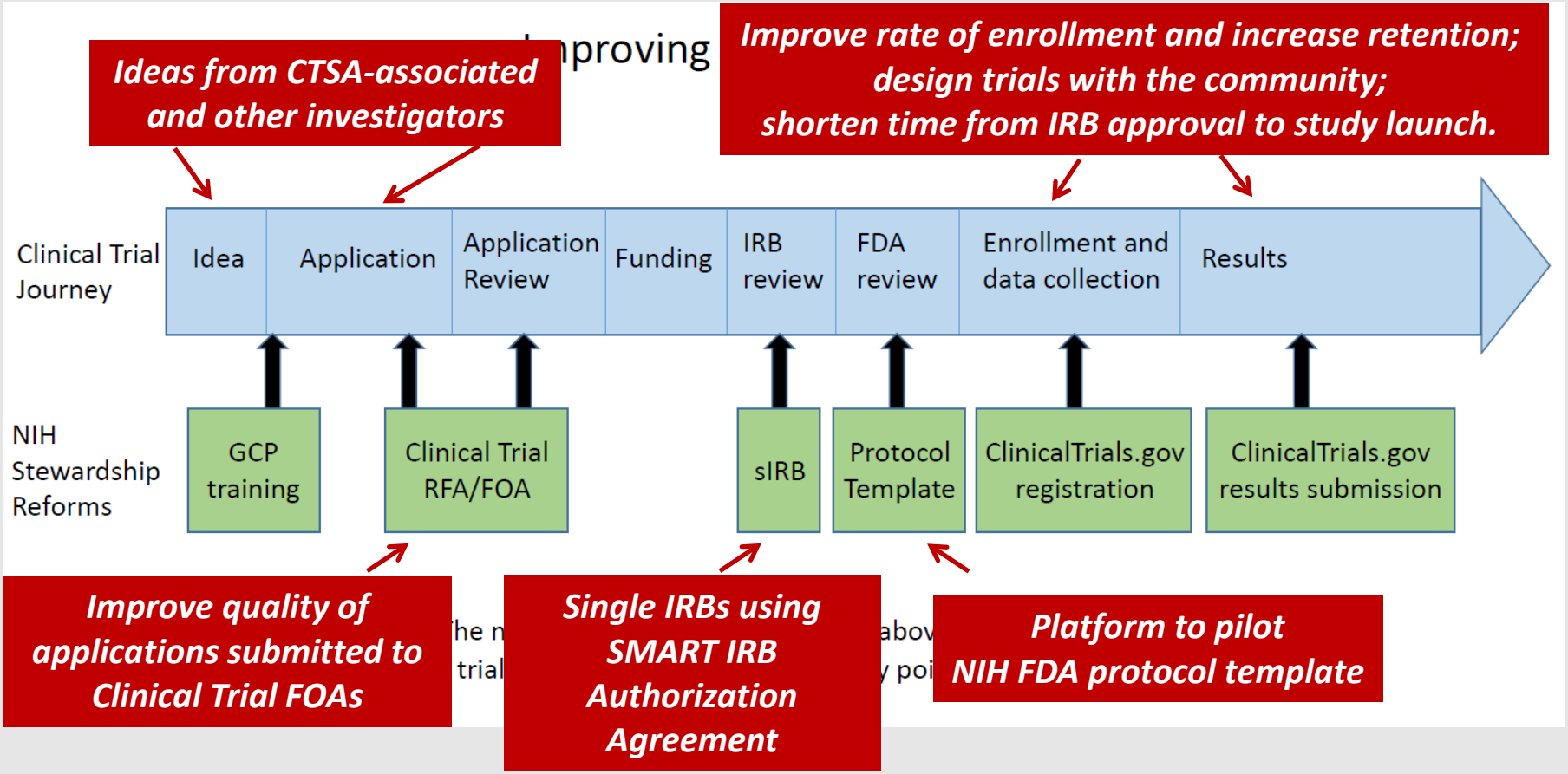


eFigure. Improving Clinical Trials. The new, multifaceted effort shown above will enhance the quality and efficiency of NIH-supported clinical trials by focusing on a variety of key points along the "lifespan" of a clinical trial.

Hudson KL, Lauer MS, Collins FS. JAMA 2016.

Trial Innovation Network

A framework to improve Clinical Trials



Hudson KL, Lauer MS, Collins FS. JAMA 2016.

Trial Innovation Network Liaison Teams

Daniel Ford, Johns Hopkins/Tufts TIC

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TRIAL INNOVATION NETWORK

Trial Innovation Network
Hub Liaison Teams – The Vision

- Hub Liaison Teams as clinical trial "catalysts"
  - Work with local study teams to expedite clinical trials
  - Develop harmonized processes
  - Increase quality and efficiency
- Responsibilities
  - Support TIN CIRBs, master contracts, recruitment, study operations
- Standardized training and competencies for Hub Liaison Teams

TRIAL INNOVATION NETWORK

CTSA Clinical & Translational ® Science Awards

metrics

NETWORK PROPOSAL SUBMISSIONS		CIRB		STANDARD AGREEMENT (in FDP-CTSA)	
# of institutions	# of therapeutic areas	# of sites	# of studies	# of sites	# of studies
43	35	208	29	73	6

Search

INVESTIGATORS

submit your proposal

Hear from us within 5 business days.

TRIAL INNOVATION NETWORK

Operational innovation, excellence, and collaboration.

The Trial Innovation Network continues to accept new proposals!
Click the button below to get started.

Get Started now!

94 total proposals submitted

WELCOME!

The Trial Innovation Network is a collaborative national network that focuses on operational **innovation, excellence and collaboration** and will leverage the expertise and resources of the CTSA Program.

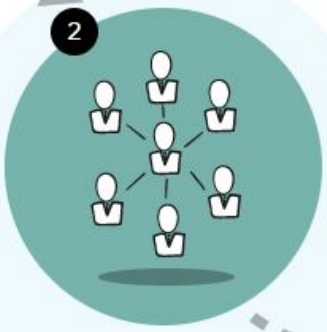
NETWORK LOGIN

Review Services We Offer

The Trial Innovation Network offers study investigators the ability to request an initial consultation or specific services depending on the funding status of the proposal. Refer to your toolbox on the right to see definitions for all services and consultations.

Click on the funding status of your proposal in order to view what level of...

Learn more!



Connect with Local Experts

Prior to submitting a Trial Innovation Network Project Proposal, study investigators must discuss the proposal with his/her CTSA Program Hub Principal Investigator and the Trial Innovation Network Liaison Team. Refer to your toolbox on the right to access proposal submission guidelines and checklists for both investigators and Liaison Teams.

...

Learn more!

Learn About the Proposal Process and Get Started

Once a study investigator submits a proposal to the Trial Innovation Network, the proposal undergoes a series of reviews to ensure completion and assess alignment with the mission of the Network. Refer to your toolbox on the right to see guidelines and instructions for submitting proposals.

Investigators are invited to submit proposals to the...

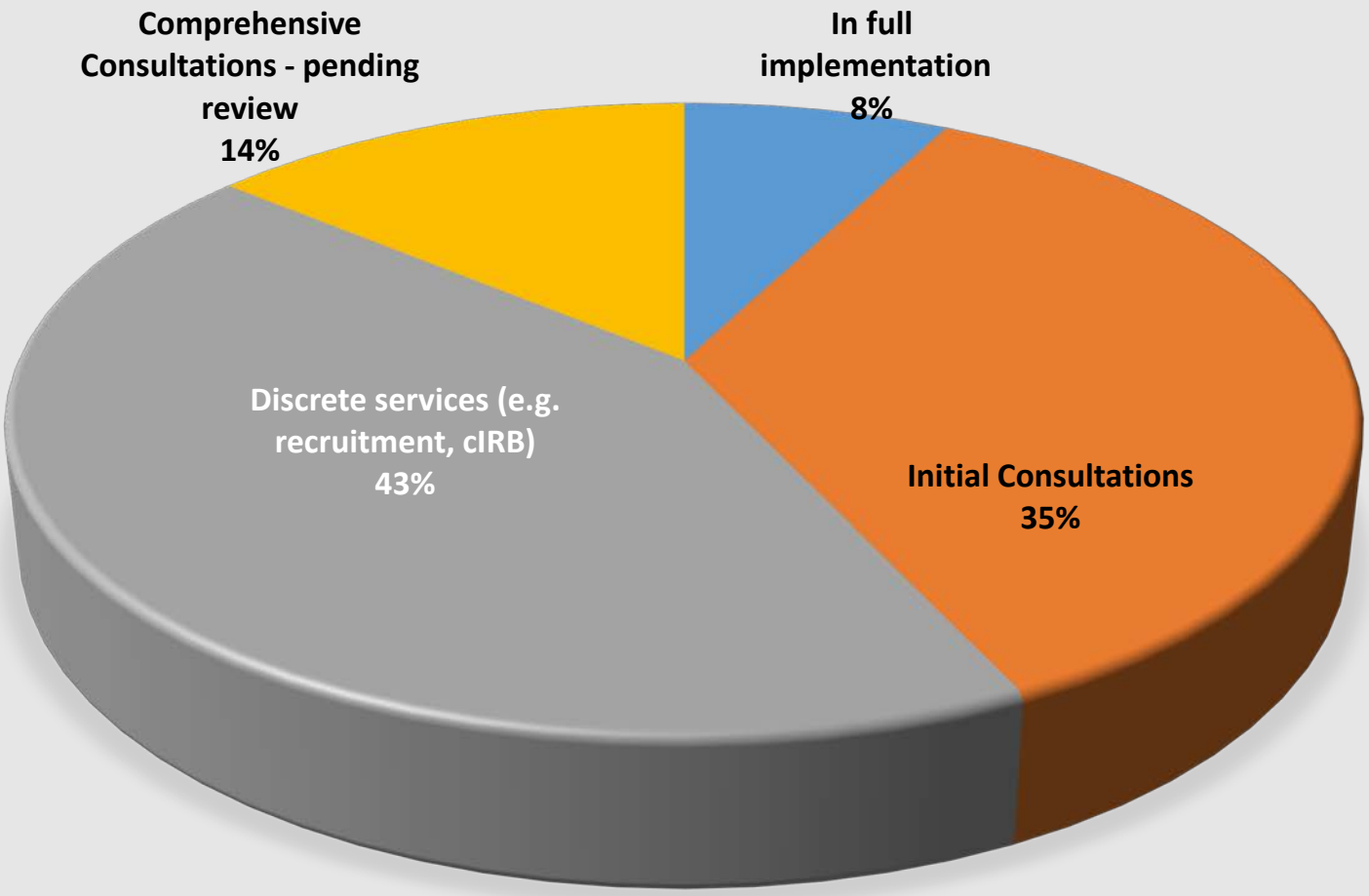
Learn more!

SUBMIT A PROPOSAL

Trial Innovation Network Proposal Process Toolbox

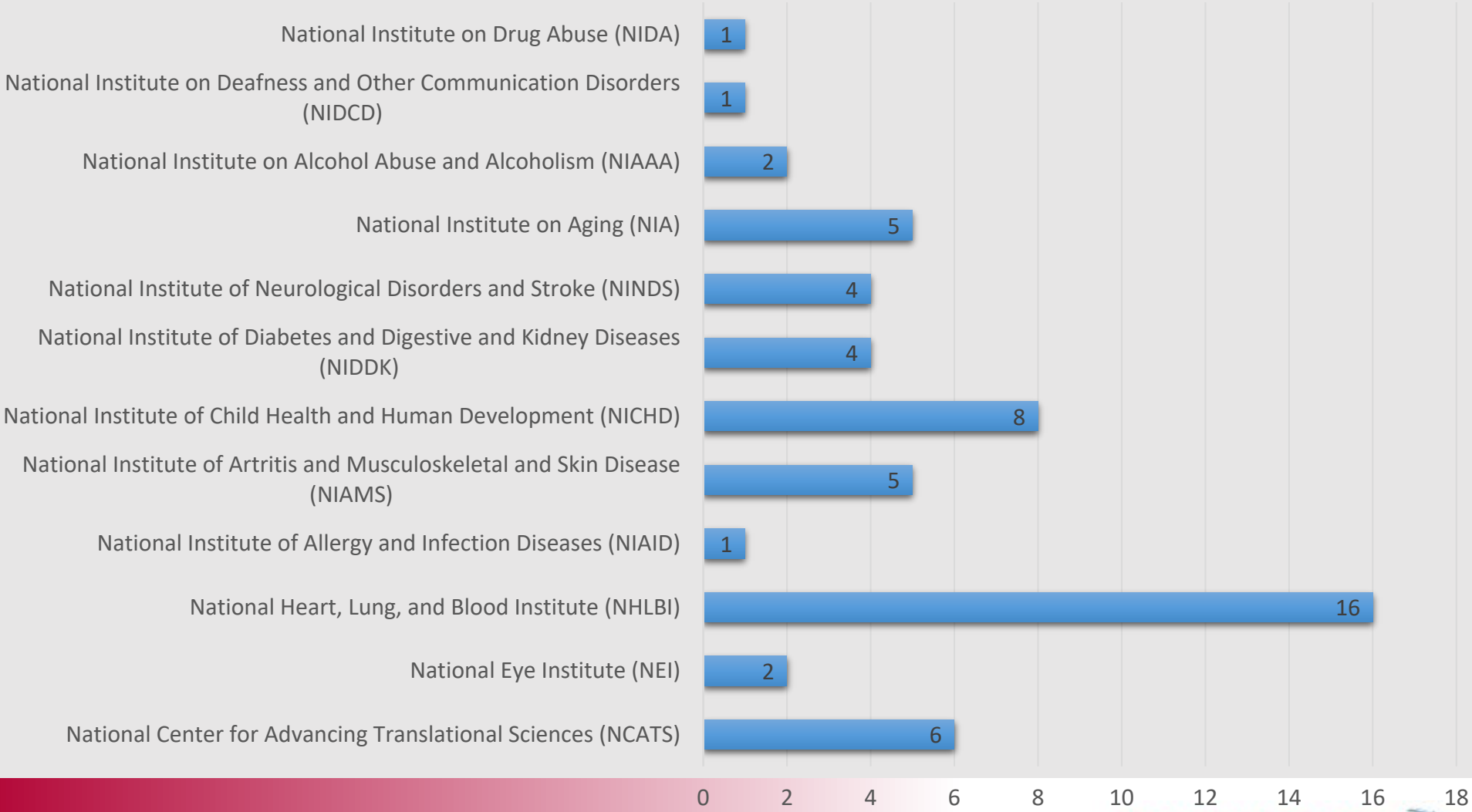
- Investigator Proposal Submission Instructions
- Submission Platform General Instructions
- Definition of Services and Initial Consults
- E2E Consultations: Efficacy to Effectiveness Trial Design
- Tips for Talking with Your NIH Program Officer
- Partnering with Potential Funding Partners on Proposals
- Proposal Submission Guidelines and Checklist for Liaison Teams
- Confidentiality and Non-Disclosure Policy

Snapshot of 79 of 94 proposals receiving Network support

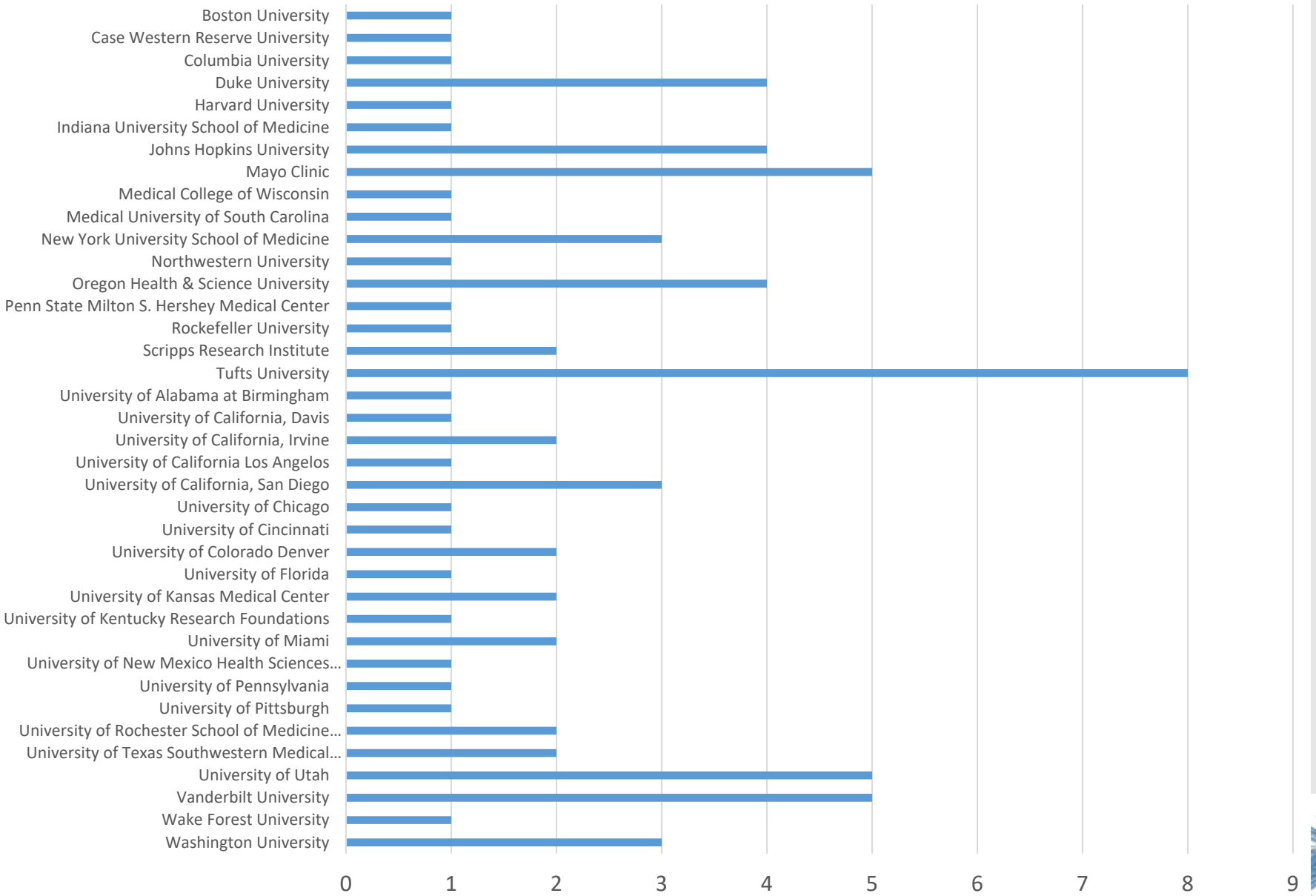


NIH involvement with the TIN

Projects Associated with NIH ICs



CTSAs submitting to the TIN (38)



Harmonizing the Network

Gordon Bernard - Duke/VUMC TIC

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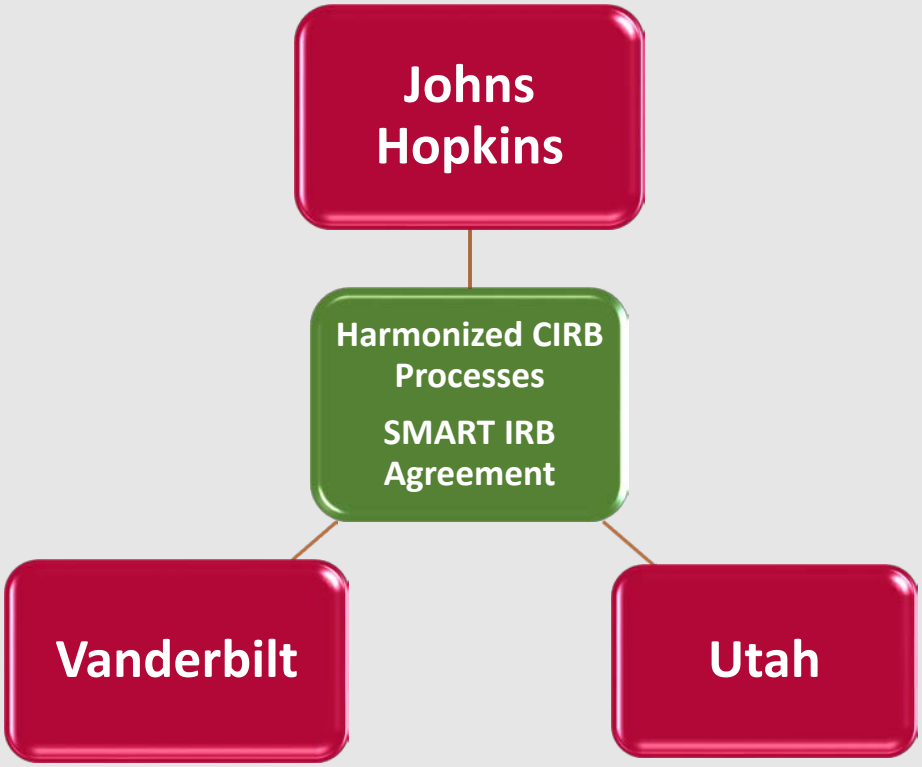
TRIAL INNOVATION NETWORK

Trial Innovation Network

Innovating and Harmonizing – IRB Review



Roadblock

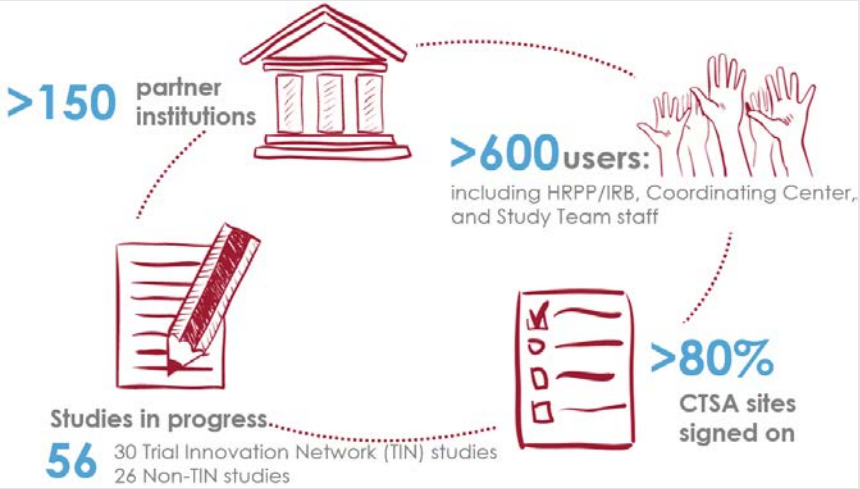
Duplicative IRB reviews are time Consuming and unnecessary.

Harmonization

- 3 Harmonized Central IRBs.
- All use same reliance agreement, standard procedures, and IT platform.
- Collecting metrics – time, cost, quality and analyzing outcomes.
- Will disseminate best practices.

TIN CIRB Services: Year 1 Overview

- **37 studies actively under CIRB review**
  - ~20 additional studies approved for CIRB services pending NIH funding
- **224 sites undergoing CIRB review**
  - 3-67 sites per study with an average of 15.5 sites/study
  - 5 studies with >40 sites
- **147 sites with CIRB approval**
- **IRB Exchange Statistics**
  - ✓ Document reliance arrangements
  - ✓ Capture local context from participating sites
  - ✓ Track site progress towards initial approval
  - ✓ Capture CIRB approvals for life of study
  - ✓ Automate communications from CIRB to participating sites



Central IRB support: Lessons Learned

- Studies not a good fit for CIRB services (e.g., foreign and VA sites.
- Steep learning curve for study teams is steep.
- All institutional HRPPs are still establishing or revising their local processes.
- CIRB-related instructions should be disseminated by the coordinating/lead center.

Trial Innovation Network

Innovating and Harmonizing – Contracts

ARA4US.ORG
ACCELERATED RESEARCH AGREEMENTS

TIN will use FDP-CTSA Master Contract

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
- Collecting metrics and analyzing outcomes.

Standard Agreements Updates

Agreement	CTSAs Signed	Affiliates Signed
FDP-CTSA TIN Standard Agreement*	63	10
Network Umbrella CDA	55	19

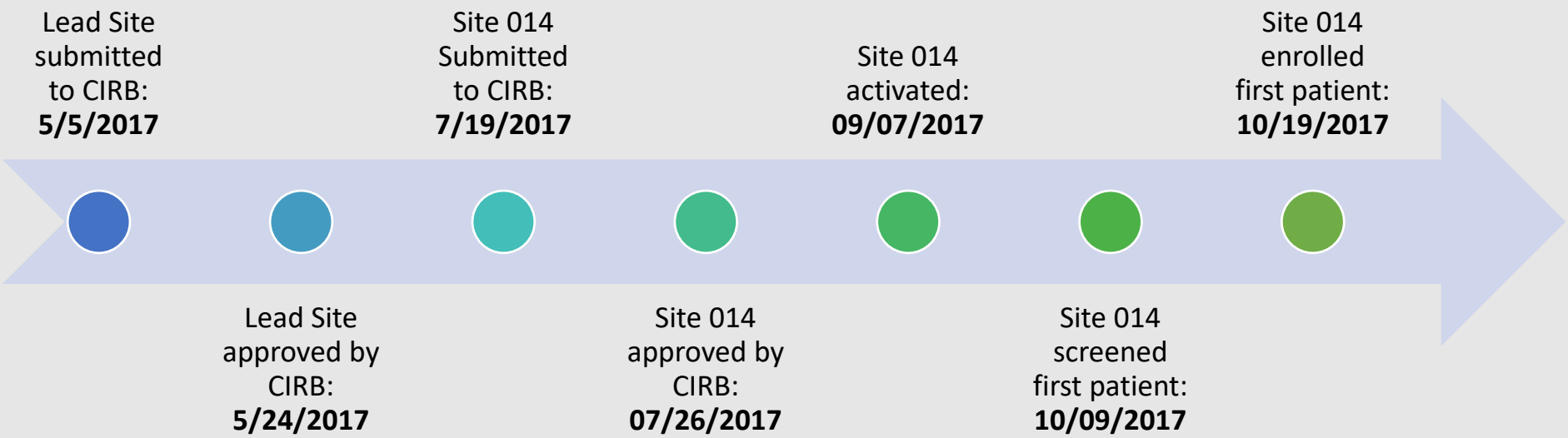
Network Umbrella CDA

Purpose: Allows sharing of Network protocols across participating sites without confidentiality agreement negotiation delays

The Umbrella: Rather than have a separate sign-off for each study, the Network Umbrella CDA allows a one-time approval of terms and fosters the ability to share information throughout the Network.

*FDP –CTSA = Federal Demonstration Partnership Clinical Trials Sub-award Agreement

ZEDS



# Sites	RELIANCE-RELATED AGREEMENTS			# IRB approved
	# Signed SMART	# Signed LOI	# Signed Exchange	
56	52	53	54	**40**

Sites must complete all agreements and submit their local context before the CIRB can review and approve their site

FAQs

- When is the best time to submit to the TIN?
- When should CTSAs and affiliates be expected to provide input?
- Will a CTSA be penalized if they say “no” to participating in a TIN project?

Thank you!

Next Call: March 28, 2018

Topic: Delayed Onset Prior Approvals (DOPA)

2:00 – 3:00 ET

Upcoming Meetings

Date	Institution/Organization	Event Name
March 1-2, 2018	Scripps Institution of Oceanography	Future of Genomic Medicine
March 8–10 2018	University of Florida	Precision Medicine Conference
March 16, 2018	Informatics DTF	Informatics DTF Face-to-Face Spring Meeting
March – April 2018	University of Michigan	FFMI fastPACE Train-the-Trainer Course
April 13, 2018	University of Kentucky	OPIOIDS: Addressing the Public Health Crisis through Translational Science
April 18, 2018	Tufts and Children's National	Challenges & Opportunities in Pediatric Clinical Trials
April 18, 2018	NCATS	Spring CTSA Program Meeting
April 19-21, 2018	Association for Clinical and Translational Science	Association for Clinical and Translational Science Annual Meeting
April 30, 2018	Harvard Medical School	Reimagining the Frontier of Public Health Approaches to Eating Disorders Prevention
May 1, 2018	Harvard Medical School	Informed Consent: Content, Communications and Emerging Technologies
May 3, 2018	Boston University	Addiction Medicine 2018: Translational Science at the Cutting Edge
May 14-18, 2018	University of Pennsylvania	Workshop on human iPSC Derivation, Maintenance, Differentiation, and CRISPR/Cas9 Gene Editing in iPSCs
May 21-24, 2018	University of Texas Medical Branch in Galveston	Science of Team Science (SciTS) 2018 Conference

Add your events on the CLIC website here: https://clic-ctsa.org/event-list (login required)