Welcome to the CTSA Program Steering Committee Meeting!

Washington, D.C.

October 2018

FOA Updates

- **PAR-18-940** (Re-Issue of PAR-18-464)
- Released Sept. 27, 2018
- Changes
  - Receipt dates: other than the first due date (January 25, 2019), applications are due ~ one month earlier.
  - Budget allocations for certain UL1 components/cores have been changed from discrete dollar amounts to a percentage of the UL1 award DC to enhance flexibility of the CTSA Program hubs' (UL1+KL2 award) abilities to address local needs.
  - No cap on the number of TL1 slots; Max TL1 budget request is determined by the UL1 budget (DC).
  - Clarified requirement for a "Hub Liaison Team to Central Resources" within the Network Capacity Core.
  - Stated expectation that CTSA Program hubs (UL1+KL2 award) will use central resources, e.g., the CTSA Program Coordinating Center, the Trial Innovation Network, and CD2H.

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FOA Updates

- **CCIA FOA renewed for FY19**
- **Enhancing Network Capacity (2 receipt dates FY19)**
- **Competitive Supplements for FY20 awards**
- **Future FOA**
  - Obtain feedback on process (RFA issues) and program objectives
    - Internal: NCATS
    - External
      - RFI & Town Hall
      - Study Section Reviewers
      - CTSA Program Steering Committee: solicit and present feedback from pods

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HEAL Pain Effectiveness Research Network

(Current Status: concept cleared by NCATS and NINDS Advisory Councils)

- **Background**
  - Optimal pain management is insufficient, including long-term opioid use for chronic pain.

- **Goals**
  - Establish the HEAL Pain Effectiveness Research Network (HEAL Pain-ERN) to establish effective interventions or programs to manage, reduce or prevent acute and chronic pain.
  - Leverage CTSA/TIN to implement and execute meritorious clinical trials/studies of interest to multiple NIH Institutes, Centers, and Offices.
  - Support studies that provide evidence to inform practice-based guidelines.

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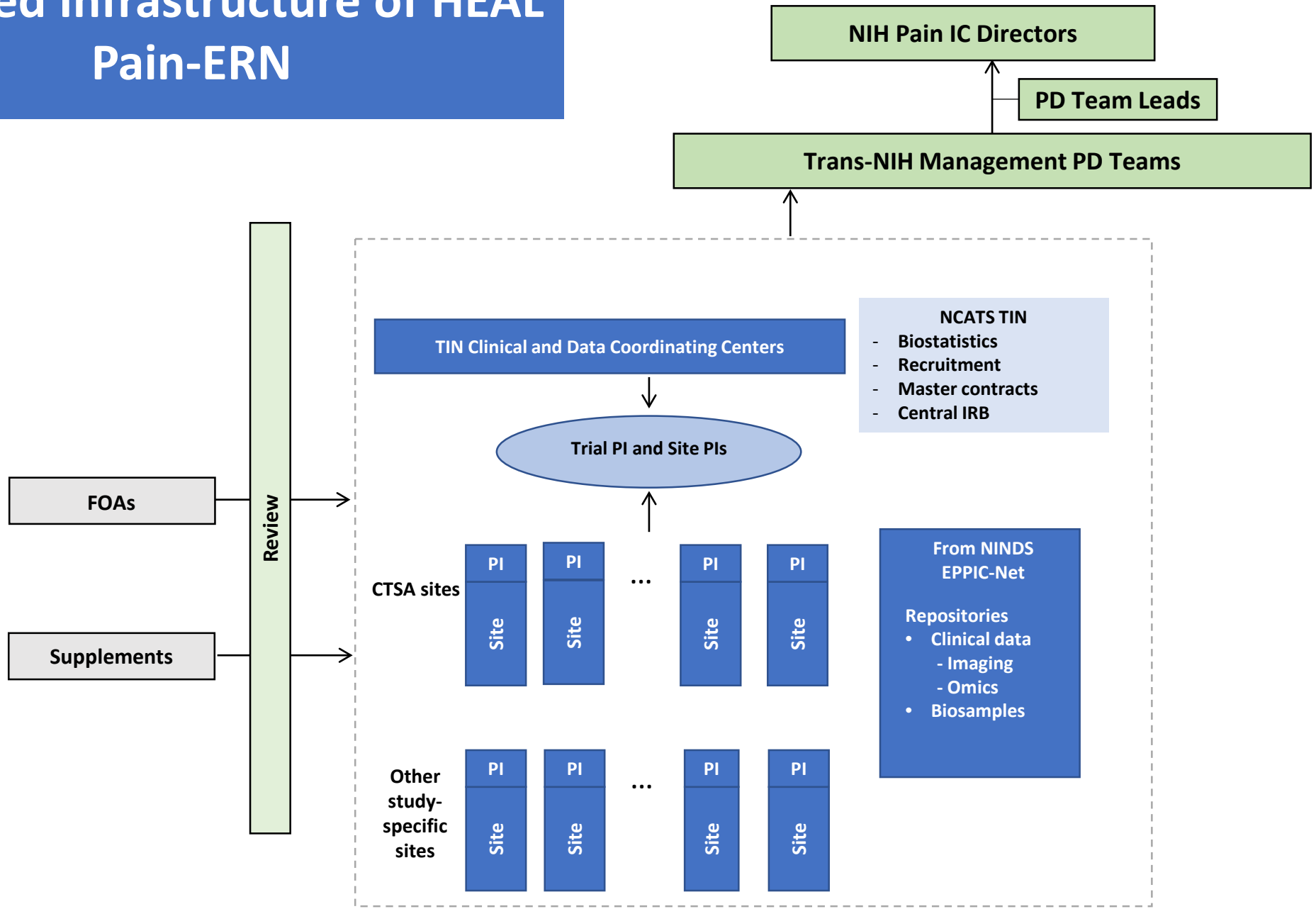
Proposed Infrastructure of HEAL Pain-ERN



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HEAL Pain Effectiveness Research Network

(Current Status: concept cleared by NCATS and NINDS Advisory Councils)

- **Execution**
  - Trials will utilize standardized outcome measures to enable future meta-analyses.
  - Data will be collected and stored centrally for future data sharing.
  - Sites will vary according to the study question and will not be restricted to a select group of network sites
- **Potential impact**
  - The HEAL Pain-ERN is poised to provide patients and practitioners with a suite of effective and data-driven strategies to alleviate pain.
  - This initiative demonstrates the flexibility of CTSA/TIN to rapidly facilitate clinical research of interest to multiple NIH Institutes, Centers, or Offices.
  - Standardization of measures and outcomes will allow comparison of data across trials and may uncover new approaches for managing under-studied pain conditions.

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Informatics & Digital Space:
Rapid evolution with new technology and policies

Old Way

- Siloed data
- Unimodal data
- Static or slowly evolving methods
- Bespoke tools

New Way

- Data sharing
- Integrated, multimodal data
- Social coding & collaborative development
- Distributed & cloud computing

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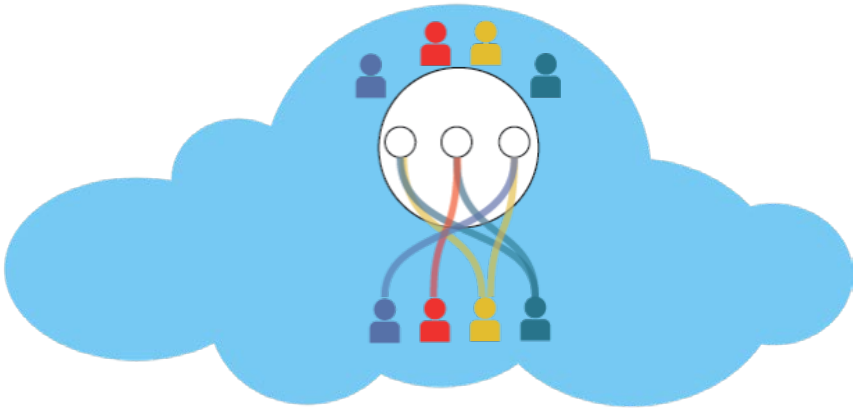
NCATS *in silico*

- Centralized Cloud Computing Services
  - Government- and NIH-wide Expectation
- Benefits for NCATS & NCATS-Funded Institutions
  - FISMA Compliant
  - Economies of Scale
  - Not institutionally constrained
  - Interoperability & Standardization
  - Collaborative Team Science
  - Shared Resources



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Evolving Cyber Landscape

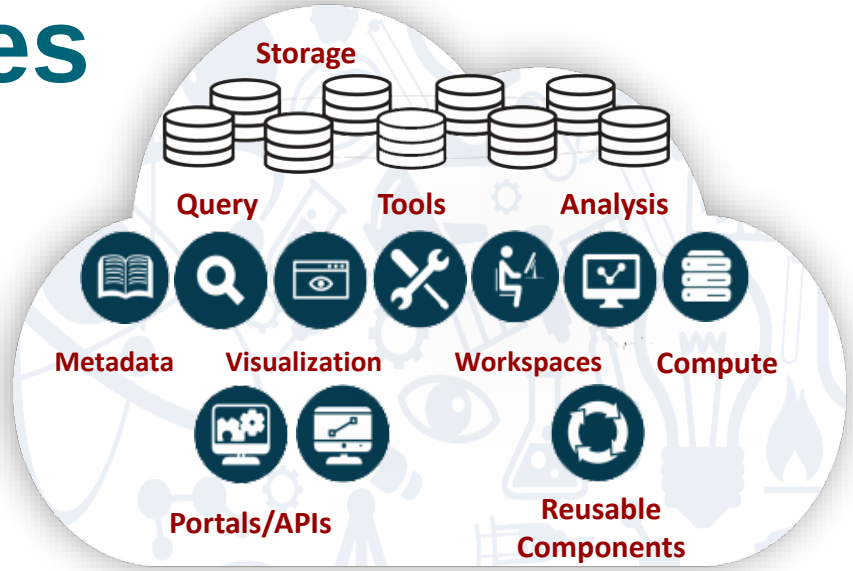
NOW

Academic sprawl

FUTURE

NCATS park

NCATS *in silico* Activities



- **Initial Projects**
  - Cloud Secure Environment
  - Enterprise Google Suites
  - Hosted Websites
  - Federated Authentication: Secure access
- **Phase II Projects**
  - App “Store”: Shared tools (CD2H ‘storefront’)
  - Data Access: PCORNET, ACT, i2b2
  - Educational Material Portal
  - Public-Private Partnership Tool

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Domain Task Force Review and Discussion

Washington, D.C.

October 2018

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Methods and Processes DTF Update

Brad Evanoff, MD, MPH
Washington University at St. Louis

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Methods & Processes DTF

- Reviewing next steps for existing work groups
- Pursuing input for areas of interest for new work groups

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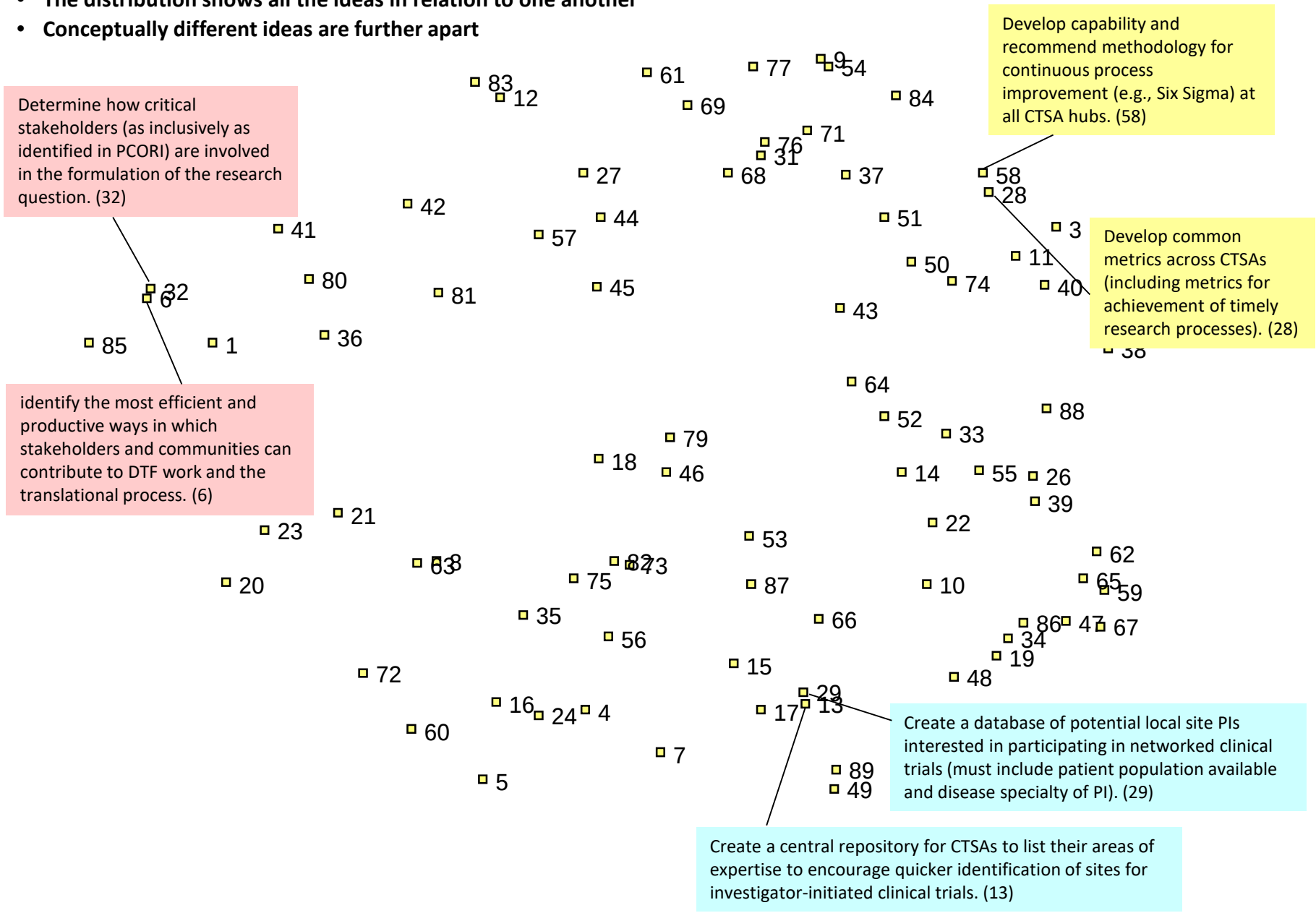
M&P DTF Concept Mapping

- **Each point represents the brainstormed ideas**
- **The distribution shows all the ideas in relation to one another**
- **Conceptually different ideas are further apart**



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Regulatory Science to Advance Precision Medicine Work Group

Based on the initial results from the 2017 Forum

Two Manuscripts developed

- Have now been accepted for publication
  - Should be available this month

2018 Forum was held on September 27

- Topic was 2018 Digital Health
- Breakout sessions explored specific areas opportunities & challenges related to user interface of mobile health
- A writing team is now being formed to develop a manuscript and/or white paper building off of the results of the forum

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Institutional Readiness for Team Science Work Group

Team Science Contest

- 170 Submissions, 11 Awards, 10 posters submitted
- Quantitative data analysis completed
  - Qualitative data analysis will be done in 2019
  - White paper with the possibility of publication outcomes
  - The stories will be shared with the CTSA Network for applying and developing new initiatives
- Possibility of making this an annual event

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Institutional Readiness for Team Science Work Group

Promotion and Tenure Paper

- Manuscript is currently under peer review
    - Major finding → a variability within institutions across their tenure and non- tenure faculty pathways.
        - The dataset that the authors used to develop the manuscript is accessible to others who might want to engage in additional analysis of the P& T guidelines.

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Collaboration/Engagement DTF Update

Joel Tsevat, MD, MPH
UT Health San Antonio

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Researcher Training & Education and Community Capacity Building

- Joint workgroup with WFD DTF
- Developing recommendations for NCATS and the CTSA network on areas to concentrate future research efforts and initiatives
  - Based on review of available CEnR curricula and a gap analysis
- Draft report will be shared with WG by end of October
- Updated sunset: end of Q4 in 2018

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Developing Measures for Assessing and Improving Collaborations

- Group on hiatus for most of 2018
- Leads reconvened to finalize manuscripts for publication
- Currently finalizing first draft to send to WG
- Sunset: end of 2018

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Methods to Assess Community Engagement Strategies

- 2 surveys in development; undergoing thorough WG review
- Survey goals:
  - Capture barriers and facilitators to community engagement
  - Capture processes and methods undertaken by CTSAs to measure impact of community engagement
- Surveys will be sent to CTSA Hub PI's and their Community Partners
  - Early January 2019
- Sunset: by September 2019

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Dissemination & Implementation (D&I)

- Proposed a special issue on D&I Science to the Journal of Clinical and Translational Science (JCTS); awaiting confirmation
  - 2 manuscripts in preparation
  - Several potential articles have been identified
- Webinar on D&I Science (June 2018) available at: https://www.cdnetwork.org/library/dissemination-implementation-science-critical-translational-science
- Sunset: extended to 2019
  - Aligns with journal submission deadline for JCTS special issue

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Forthcoming Plans

- Several current WGs are sunsetting; new WGs:
  - Integrating Bi-Directional Community/Stakeholder Engagement into Team Science
  - C-E Across the Translational Spectrum (T1 and T2)
  - C-E Curriculum Initiative (Develop Competencies)
  - Metrics: Involve the Community in Developing Metrics
- Volunteers identified to lead each WG
- Holding elections to replace 3 lead team members who are rotating off
  - Discussing adding a community representative to the lead team

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Integration Across the Lifespan DTF Update

Dan M. Cooper, M.D.
University of California, Irvine

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Lifespan DTF & Workgroups Updates and Accomplishments

- Full DTF
  - The group had a face-to-face meeting in Toronto on May 5, 2018 and developed potential outcomes depending on available resources to support the work.
  - Stemming from this work, they also assembled a writing group (Life Course) and will be writing a manuscript to articulate the state of Life Course research, gaps, and a blueprint of the way forward.
  - Dr. Shari Barkin met with Dr. Michael Kurilla to identify the best use of the domain taskforce structure to most effectively utilize the strengths of the CTSA to advance Lifecourse research.
  - We will be holding an election for one of the Lifespan Lead Team positions, due to Shari Barkin stepping down after three years of service.

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Key Points from Face to Face Meeting

- Define a clear definition of Lifespan
- Problems We Could/Should Address (if we received funding from NIH)
  - Create Thought Pieces $
  - Availability of measures and datasets for Lifespan researchers $
  - Collate Lifespan research needs from researchers across the country to inform RFAs $
  - Including children and the elderly in research $
  - How CTSAs are identifying and addressing life course $$
  - Toolkits - Measures $$$
  - Training the pipeline in Lifespan research/training $$$

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Key Points(con't)

- Guiding Principles
  - Useful
  - Additive (not duplicative)
  - Practical
  - Pragmatic scope of work for our structure
- Workgroup Breakout Session
  - What is Lifespan Research?
  - How are doing this this?

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Lifespan DTF & Workgroups Updates

- Aging Workgroup
  - This group had conversations with NCATS to clarify the scope of the work and how to best incorporate the study of older adults.
  - The group recommended identifying cross-cutting themes that affect health across the Lifespan such as resilience and stress and then bringing multi-disciplinary perspectives together for a workshop to further delineate an agenda.
- Early Life Exposure
  - The manuscript has been published and a Pediatric Academic Society(PAS) meeting topic symposia on this topic has been submitted.
- Single Disease
  - Transition Manuscript is under review at the Journal of Clinical and Translational Science
  - The group will be Sunset Winter 2019.

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Workforce Development DTF Update

Susan Smyth, MD, PhD
University of Kentucky

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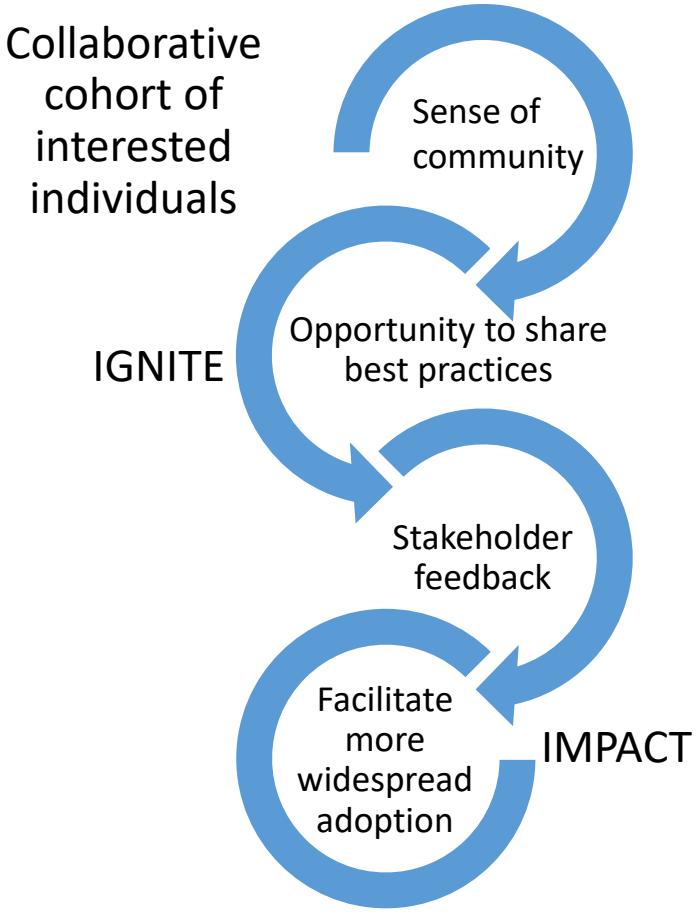
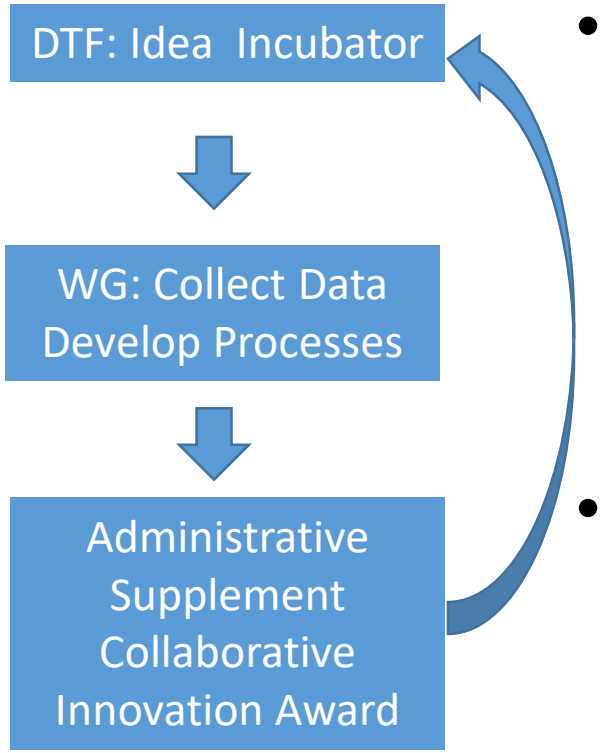
DTF – Workforce Development





- 4 active working groups (WG)
  - WG1: Federated Educational Platform: Harmonizing Competencies
  - WG2: Clinical Research Training for Investigators
  - WD3: KL2 Survey: Best Practices for Mentoring and Supporting KL2 Scholars
  - WD4: TL1 Survey
- 2 funded studies developed from WG
  - N-Lighten Network, a semantically anchored federated educational resources sharing platform (WG 1)
  - DIAMOND, clinical research coordinator training and development of competency assessments (WG 2)
- IGNITE presentations (sharing best practices)

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Federated Educational Platform: Harmonizing Competencies

GOAL: Develop Personalized Pathways and offer guidance on how to use the core competencies to develop a tailored IDP for a learner's desired career path, or "phenotype" (pre-clinical; clinical and community-engaged) .

ACCOMPLISHMENTS: Data collection and analysis for tailored knowledge skills and abilities for 3 researcher phenotypes has been completed.

DISSIMENATION and TRANSLATION:

- Pathways are ready for submission to CLIC.
- Publication is under final edits
- Discussions with CD2H about ways to embed as resource to create personalized IDPs for TL1, KL2, and other trainees

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Clinical Research Training for Investigators

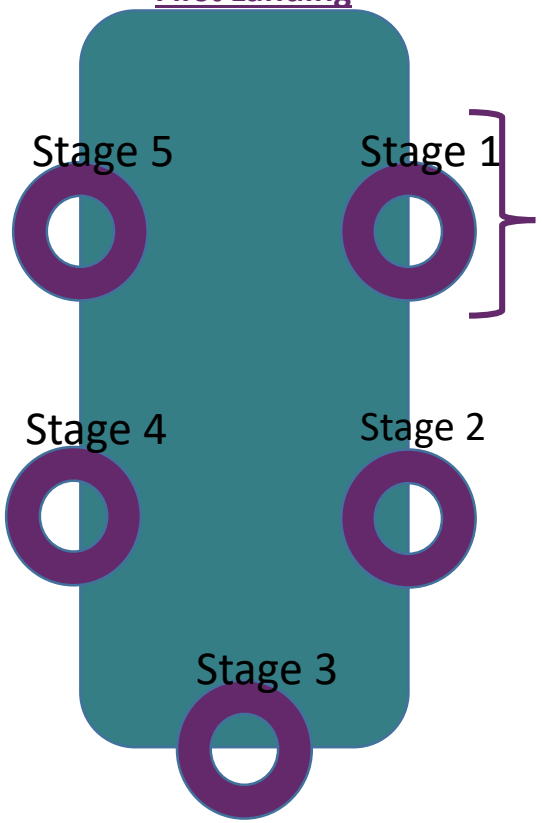
GOAL: Upon DIAMOND funding, group refocused on creating process and maps and tools to improve efficiency by serving as a reference guide in the "how to" of performing clinical research through the stages of study lifestyle (study construction, protocol planning, start-up, implementation and study close-out).

ACCOMPLISHMENTS: Develop interactive workflows to

- map study operations and key roles, duties, and regulatory responsibilities
- embed links to timely information (e.g. CITI trainings, FDA & NIH tools/templates; DIAMOND discovery learning space resources)
- provide links to Hub-specific information

DISSIMENATION and TRANSLATION:
Discussions with CLIC and CD2H to identify graphic web design and IT platforms to allow institutional information (application for funding pending)
Highlights Implementation Need

Process Flow Configuration



Second Landing

Fundamentals of Study Construction
- Study Design Considerations
- Ethical Design Considerations

Study Protocol Creation
- Study Objectives

Standardization
- SOPs, MOOP

Funding
- Grant Considerations

Regulatory
- Human Subject Protections
- Investigational Products
- Reporting Responsibilities

Third Landing

Helpful Resources
- NIH protocol templates
- List of ICH E6 requirements

Fourth Landing

Institutional Links
- USCF study template
- UCSF Consent template

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Best Practices for Mentoring and Supporting KL2 Scholars: Survey

GOAL: designed, iteratively test, administer survey to KL2 programs directors / administrator and analyze results to identify best practices for developing and supporting KL2 scholars

ACCOMPLISHMENTS:

- Provided program-reported information of current organization, leadership, programmatic foci, practices and impact of KL2 programs (90% response rate)
- Provided program-level aggregate data on short- and mid-term scholar outcomes related to career path, trajectory, and productivity

DISSIMENATION and TRANSLATION:

- Relate outcomes to program characteristics and practices
- Identify new or novel features for future tracking / investigation
- Data analysis and publication in progress

Best Practices for Mentoring and Supporting TL1 Scholars: Survey

GOAL: designed, iteratively test, administer survey to TL1 programs directors / administrator and analyze results to identify and disseminate best practices for preparing trainees for careers in translational science.

ACCOMPLISHMENTS:

- Pre-survey work to collect a comprehensive list of TL1 directors and administrators
- Develop understanding of similar but non-identical concerns for pre-doctoral, postdoctoral and short-term training
- Incorporated lessons learned from the KL2 survey.

DISSIMENATION and TRANSLATION: *to follow*

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N-Lighten 1.0: A Federated Educational Platform for Workforce Development

- Developed governance for sharing across a Federated Network
- Adopted eagle-i, an extensible query tool for discovery
- Created an *N-lighten* educational ontology for identifying resources
- Curated then published educational resources hosted locally at two *N-Lighten* CTSA Hubs (Harvard, OSU) and FDA
- Provided access to resources to learners and educators through Learning Management System or direct link for open source

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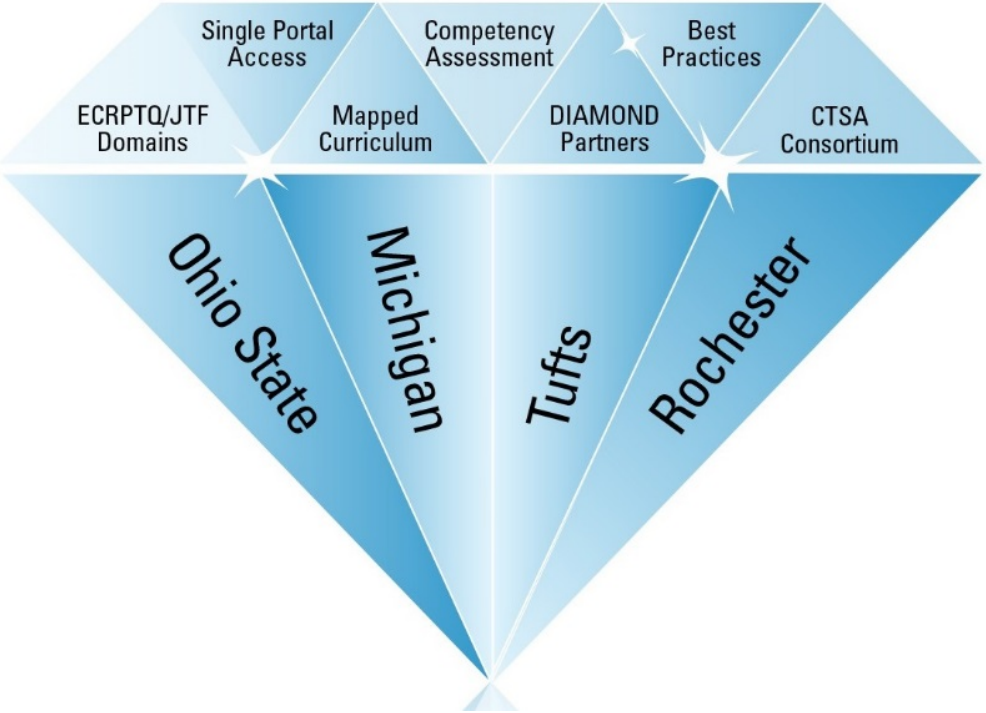
DIAMOND: Development, Implementation, and AssessMent Of Novel Training in Domain-based Competencies

U01TR002013 (April 2017 – March 2020)

Develop sustainable, collaborative **discovery learning space** for clinical research professionals (CRPs) working in CTSA institutions & partners including:

- Shared competency-based clinical research training offerings
- Assessments
- A unique ePortfolio system to encourage workforce development and connection



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Informatics DTF Update

Donald Lloyd-Jones, MD, ScM
Northwestern University at Chicago

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Informatics DTF / WG Update

Since the Spring iDTF Update:

The iDTF and CD2H have develop a set of **External Presentation Guidelines** governing presentations made to the iDTF membership.

- **In order for an external body to present to iDTF:**
  - Presentation must be of **broad interest** to the members
  - Content must have **significant potential impact on achieving key NCATS goals**
  - Presentations must be **educational & not promotional**
  - Presenter must **declare** any potential **"conflicts of interest"** via a slide **in the presentation**
  - **Slides must be provided to iDTF Leadership for review to confirm compliance with the above criteria**

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Informatics DTF / WG Update

The coordination of the CTSA Informatics Community iDTF & CD2H continues with the efforts of both the iDTF & CD2H with the following:

- Twice monthly iDTF Leadership calls are held & include NCATS, the CD2H PIs with the iDTF co-chaired by a CD2H co-PI, an iDTF PI co-chair & a CTSA Program PI liaison.
- Monthly iDTF Membership Calls reference an agenda with alternating lead presenters.
  - See the plan sample below.

iDTF Members Meetings	iDTF Topic(s)	CD2H Topic(s)
8/3/2018	iDTF Members' Mtg – New Format Announcement / F2F Mtg Report Out Status – follow up & next steps / F2F Meeting Report Out – Lifespan / Common Metrics Update / (45 min)	CD2H Update (15 min)
9/7/2018	Fall CTSA Program Meeting / Collaborative Funding Ops / WG Status Update / iDTF Members' Meeting Format Reminder (15 min)	CD2H Software Workgroup Show and Tell (45 min)
10/5/2018	EasiPro Presentation / Election update / WG charter status / F2F Meeting update / Collaborative Funding Reminder (45 min)	CD2H Update (15 min) - Sean Mooney - vision for CD2H Implementation

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Informatics DTF / WG Update

Since the Spring iDTF Update:

- Sustainable Informatics Infrastructure WG is now sunsetted
  The proofs of their white paper have been submitted for publication

- iDTF Leadership & Membership in collaboration with CD2H Leadership has, as planned, identified a set of non-overlapping iDTF / CD2H WGs (aka CTSA Informatics Community WGs) that advance the overall CTSA Informatics Agenda.
  - (iDTF) Enterprise Data Warehouse
  - (iDTF) Sustainability Phase Two
  - (iDTF) Text Analytics

- Each of these iDTF WGs:
  - Include a CD2H Liaison to ensure there is no overlap in topics and efforts with CD2H WGs.
  - Are currently **awaiting approval of the CTSA Steering Committee.**
  - Will meet and be supported by CLIC and present updates to the iDTF members.

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Clinical & Translational Science Awards Program

CLIC
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Informatics DTF / WG Update

Since the Spring iDTF Update continued:

- The three standing CD2H WGs include:
  - Data
  - Software
  - People
- CD2H delivers WG “Show & Tell” presentations every other month during the iDTF Members’ Meeting as referenced above.
- CD2H posts Show & Tell slide decks and the CD2H website as well as on the CLIC iDTF website.
- CD2H projects and WGs are coordinated with iDTF WGs to ensure no redundancy.
- iDTF & CD2H Lead Teams have developed a WG / Project Process
  - Goals & principles were developed and endorsed by NCATS

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Clinical & Translational Science Awards Program

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Informatics DTF / WG Update

Informatics Metrics – the iDTF has worked closely with the Evaluation DTF & NCATS staff on the development & piloting of Informatics Metrics.

- As of October 2018, following successful pilots & the presentation of pilot results to the iDTF membership, the Informatics Common Metrics formally launched into the “trial run” on September 10, 2018.
  - Implementation Phase 2 with all the sites will begin January 2019 with planned data submission by March 31, 2019 & “Turn the Curve (TTC)” submitted by August 313, 2019.
  - The iDTF is also discussing with the Metrics team version 2 modifications, including time window limitations to focus on cohorts most likely to be recruitable.

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DTF Survey Results Discussion

Kathleen Brady
Clare Schmitt
Martin Zand

CTSA Program Steering Committee Task Force on Enhancing the DTFs

MEMBERS	
Kathleen Brady	Samantha Jonson (NCATS)
Ebony Boulware	Erica Rosemond (NCATS)
Bradley Evanoff (Methods/Processes DTF)	Clare Schmitt (NCATS)
Dan Cooper (Lifespan DTF)	Martin Zand
Melissa Haendel	Joel Tsevat (Collaboration/Engagement DTF)
Donald Lloyd-Jones (Informatics DTF)	Susan Smyth (Workforce DTF)

CLIC Coordination:

- Catherine Fetherston
- Scott McIntosh
- Deborah Ossip

Background

- **Nov 2014 Creation of DTFs - *Elements from Email Sent to PIs***

- **DTFs**
  - Review Measurable Objectives for their Domain, perform gap analysis and develop plans for projects that fill identified gaps and/or further the Consortium Objectives
  - Report to the SC

PROPOSED: Retain function and rename to reflect function

- **Work Groups**
  - Further a particular project underneath a DTF
  - Projects could result in any number of things – Workshops, Consensus Papers, Symposiums/Meetings/Conferences, Publications, NIH Internal Meetings or funding applications either through the innovation fund or a collaborative supplement

PROPOSED: Revise structure and encourage cross-consortium collaborations

Background (cont.)

- **April 2018 Domain Task Force Packet/Updates**
  - >Suggested Enhancements for the DTFs
    - Engagement of DTF members
    - Planning platforms for subsequent applications
    - Smaller in-person meetings
    - Direction from CTSA Program Leadership
    - Dedicated funding for various DTF activities
    - Trans-DTF WGs
    - Promote sharing and dissemination of resources
    - Develop best practices, conduct evaluation, develop WG outcomes that can be implemented

- **April 2018 Steering Committee F2F Meeting: Session on DTFs**
  - >Discussion of April 2018 Domain Task Force Packet/Updates
  - >Agreement to convene a SC DTF Task Force
    - June: First call; decision to request feedback from consortium via survey
    - July: Survey Launched
    - August: Survey Report Issued
    - September: Recommendations Generated

DTF Survey – Key Responses (n=275)

- **Generally Supportive**
- **Overall DTF Structure**
  - Well-Informed about DTF Activities: 11% YES*
  - Addressing Important Issues: 43% YES
  - Valuable: Scale of 1-10 6-10 = 50% (5-10 = 73%)
  - "Right" Structure: 50% YES

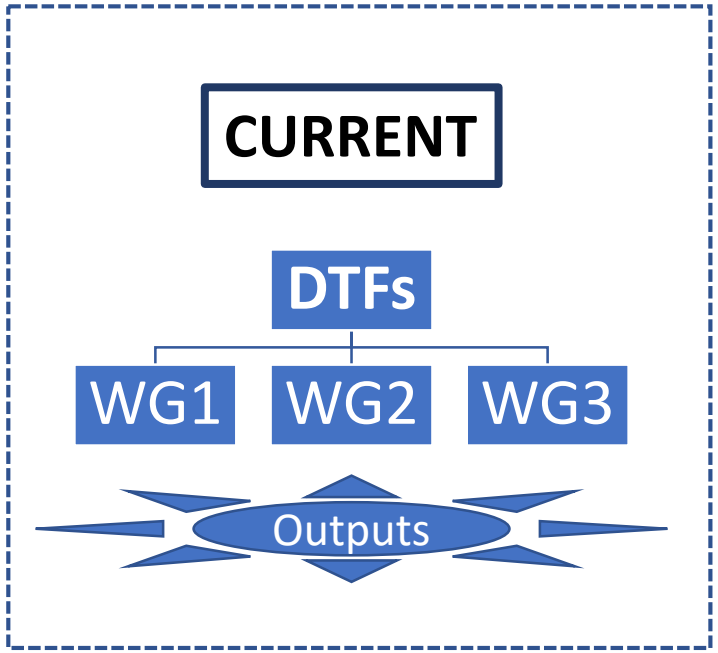
Yes excludes neutral/somewhat responses

- **Issues Identified**
  - Communications
  - Provide resources for DTFs; unfunded mandate
  - DTFs too broad; need focus, timelines, deliverables
  - Strengthen Collaborative Efforts
  - Change DTF name to avoid a problematic acronym and better reflect function

Key Issues & Thoughts

1. **Improve Communications**
   - CLIC will propose solutions to enhance communications and sharing of information
2. **Address Resources**
   - Proposed
     - FY19: Existing DTFs propose one topic for a workshop or un-meeting support via CLIC; SC approval
     - FY20: Allocate the majority of CLIC support to new entity (*Task Forces*)
3. **Clarify & Enhance Operations**
   - Clarify types and functions of entities (SC, groups, committees, etc.)
   - Define, contain, and project CLIC support
   - Increase NCATS & SC leadership and involvement
4. **Propose New Model**
   - Increase flexibility, decrease burden, and focus efforts
   - Formalize and focus actions, efforts, and resources
   - Encourage cross-consortium interactions
   - Describe support expectations

Models



PROPOSED MODEL

SAME: Overall functions & activities

DIFFERENT: Structure and increased input from SC & NCATS

Proposal Begins to Address Key Requests

April 2018 DTF Packet Comments
Suggested Enhancements for the DTFs

- Engagement of DTF members
- Dedicated funding for various DTF activities
- Planning platforms for subsequent applications
- Trans-DTF WGs
- Smaller in-person meetings
- Promote sharing and dissemination of resources
- Direction from CTSA Program Leadership
- Develop best practices, conduct evaluation, develop WG outcomes that can be implemented

July 2018 DTF Survey
Key Issues

- Communications*
- Provide resources for DTFs; unfunded mandate
- DTFs too broad; need focus, timelines, deliverables
- Strengthen Collaborative Efforts
- Change DTF name to avoid a problematic acronym and better reflect function

Communication enhancements to be proposed by CLIC

Principles & Implementation Plan

- **Respect Human Resources**
  - Define expectations re: participation & activities
  - Focus efforts on limited number of highest-priority actions
  - Transition gradually and thoughtfully over the next 12-24 months

- **Reflect**
  - Review/renew/revise current priority areas & structure
  - Revise Governance Document: Clearly distinguish types of committees and groups; add definitions and responsibilities

- **Define CLIC Support**
  - Activities have increased and may exceed monetary and human resources
  - Currently 5 DTFs & 16 work groups
  - CLIC supports communications for all 5 DTFs + 5 lead teams + 16 WGs

CLIC Support of DTFs & WGs

	Tier 1	Tier 2	Tier 3	Tier 4	Tier 5
Public Facing Webpage	✓	✓	✓	✓	✓
Google Suite Tools/Whiteboard		✓	✓	✓	✓
Private Group Webpages		✓	✓	✓	✓
Coordinator Logistics		✓	✓	✓	✓
Coordinator Agenda/Minutes/Follow-Up Actions Items			✓	✓	✓
In person meeting planning				✓	✓
Special projects (surveys, research)				✓	✓
Publication costs/ Project Management					✓

	Tier 1	Tier 2	Tier 3	Tier 4 (incl. F2F)	Tier 5
Full DTFs (n=5)				5	
DTF Leads (n=5)				5	
Working Groups (n=16)		1	10	5	

DTF & WG List

Collaboration & Engagement DTF

- Full Team
- Lead Team
- Workgroups:
  - D & I Science
  - Methods to Assess Community Engagement
  - JWG Research Training
  - Developing Measures – writing paper

Informatics DTF

- Full Team
- Lead Team
- Workgroups in Development:
  - Sustainability Phase Two
  - Secondary Models
  - WG - Text Analytics & De-Identification

Methods & Processes DTF

- Full Team
- Lead Team
- Workgroups:
  - Institutional Readiness for Team Science Secondary Models
  - Regulatory Science to Advance Precision Medicine

Lifespan DTF

- Full DTF
- Lead Team
- Workgroups:
  - ELE – newly supporting Life Course Writing Group
  - Single Disease
  - JWG Research Training

Workforce Development DTF

- Full DTF
- Lead Team
- Workgroups:
  - Mentoring TL1 & KL2
  - Methods to Assess Community Engagement
  - Harmonizing Competencies
  - Clinical Research

Key

- Fully active
- In Development
- Inactive
- Sunsetting
- Ad hoc

Proposed Model

CTSA Program Steering Committee

Discuss common interests, gaps, and opportunities
Represent Pods
Review priority areas & committees/groups
Provide input on priority area efforts & progress
Suggest PI Webinar topics
Serve as planning committee for annual meetings

No Change

CTSA Program Consortium Committees
- Administrators
- KL2
- TL1

Similar to DTFs

Enterprise Committees

Clinical & Translational Science Challenge Projects

Focus actions, efforts, and resources

Steering Committee

Similar to WGs

Task Forces

Consortium Committees

Consortium Committees

- **Administrators**
- **KL2**
- **TL1**

Functions	Discussion Forum Identify Gaps & Opportunities Generate & Disseminate Best Practices
Potential Outputs	Clinical & Translational Science Challenge Project for Task Force
Resources	Digital Workspace CLIC Call Support F2F Meeting
Limit	Size / CLIC Resources

No Change

Enterprise Committees

Enterprise Committees

Functions	Discussion Forum Promote Collaboration Across Key Areas Identify Gaps & Opportunities Generate & Disseminate Best Practices
Required Output	Annual Report
Potential Outputs	Clinical & Translational Science Challenge Project for Task Force
Steering Committee	Approve ECs Review Annual Reports and topics
Resources	Digital Workspace CLIC Call Support
Limit	Number / Size / Duration / CLIC Resources

Similar to DTFs

Enterprise Committees

Enterprise Committees

Proposals
Substructure > None
Substructure > Work Groups
Substructure > Work Groups > Discussion Groups

<u>NCATS' Preferences</u>

>Elevate projects from DTFs/ECs into own space – Task Forces

>Simplify structure; could provide digital workspace to subgroups

>Concentrate PI, SC, & PO efforts

>Contain & focus CLIC efforts

>Recognize need for certain "Evergreen Work Groups" – e.g., Regulatory Science to Advance Precision Medicine

Task Forces

Task Forces

Similar to WGs

Functions	Consider & develop solutions around a specific translational science issue Create synergy across the consortium
Required Output	Quarterly Report
Potential Outputs	Consensus Papers/White Papers/Publications Workshops/Symposiums/Meetings/Conferences Funding thru CCIAs or supplements*
Steering Committee	Select Challenge Projects & Task Forces Review Quarterly Report and Provide Input
Resources	NCATS Team Co-Chair Digital Workspace CLIC Support >Calls >Data Analysis >Medical Writers >Other?
Limit	Number / Size / Duration / CLIC Resources

****NCATS considers information from multiple sources for funding initiative topics***

Annual Call for CTS Challenge Project

CTS Challenge Project

1. Specific Objective
2. Timeline w/ Milestones
3. Output/Deliverable
4. Broader context/goal

Maximum Duration: 12 mo

CTSA Program Steering Committee (includes NCATS Leadership)

- Select Topics
- Facilitate Team Dev
- Receive Updates
- Provide Input

CTS Project Examples

>SMARTIRB >ACT
>GCP >TIN
>DIAMOND >N-Lighten
>STARWORK >Opioid Landscape
>Education Course Sharing

Task Force

OUTPUTS

Required

>Quarterly Updates to SC

Possible, with CLIC Support

> Consensus Papers/Publications
> Workshops/Symposiums/Meetings/Conferences
> Funding thru CCIAs or supplements

RESOURCES

NCATS Team Co-Chair
Call Support
Digital Workspace

NCATS

>Inform Initiative Topics

- **Supplements**
- **CCIAs**

Functions & Names

Similar to DTF

Enterprise Committees

Functions

- Discussion Forum
- Promote Collaboration Across Key Areas
- Identify Gaps & Opportunities
- Generate & Disseminate Best Practices

Possible Names

- Executive / Enterprise / Innovation …
- … Collaboratory / Forum / Committee / Focus Group / Think Tank
- Learning Collaborative / Forum
- Idea / Innovation Incubators

Similar to WG

Task Forces

Functions

- Address Specific Challenges
- Cross-Consortium Membership

Possible Names

- Innovation / Enterprise …
- … Task Force / Work Group / Team / Collaboratory / Collaborative

Proposed Timeline

- **FY19 (Oct 2018 – Sept 2019)**
  - **Communications**
    - CLIC: Propose improved communication strategy
    - SC: Approve processes
  - **Resources**
    - CLIC
      - Decrease range of support for existing WGs
    - Existing WGs
      - Adjust to decreased CLIC support
      - Propose an idea to the SC for an FY19 workshop or un-meeting
    - SC
      - Approve FY19 workshop/un-meeting topics
    - SC+NCATS+CLIC
      - Prepare process for submission, review, and selection of CTS Challenge Projects

Proposed Timeline (cont.)

- **FY19 (Oct 2018 – Sept 2019)**
  - **Begin transition from DTFs to *Enterprise Committees***
    - Existing DTFs
      - Assess existing work groups and develop a Transition Plan
      - Transition same or revised DTF to an Enterprise Committee? Suggest new area for Enterprise Committee?
      - WGs: Sunset/renewal plans? Important topic for discussion group? Propose area for a CTS Challenge Project?
    - SC
      - Review and provide input on DTF Transition Plans
      - Consider and approve revised/new Enterprise Committees & any subgroups

- **FY20 (Oct 2019 – Sept 2020)**
  - **Complete transition** from DTFs + WGs → Enterprise Committees + Task Forces

High-Level Summary of Proposed Changes

- **Objectives**
  - **Optimize efforts**
  - **Focus resources**
  - **Transition gradually and thoughtfully over the next 12-24 months**

- **Overall**
  - **Enhance SC involvement in Enterprise Committees & Task Forces**
  - **Decrease required hub participation to ≥ 1 Enterprise Committee**
  - **Encourage cross-consortium collaborations through Challenge Projects**
  - **Focus CLIC support on Task Force Challenge Project activities**

- **Structure & Naming Conventions**
  - **DTFs → *Enterprise Committees***
  - **WGs → *Task Forces***
  - **Provide digital workspace for Enterprise Committee subgroups (e.g., work groups, discussion groups, special interest groups)**

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Enhancing Enterprise Committee Communications and Awareness

- What do we mean by “enhancing communication”
  - Wider awareness across DTF’s and consortium of EC activities
  - Central location where information can be rapidly retrieved
  - Bi-directional communication modalities

- Some thoughts on enhanced communication
  - “Just-in-Time” knowledge is hard
  - Bidirectional communication is essential
  - Need community buy-in and ecosystem

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CLIC Solutions:

- Monthly or Quarterly Rapid Reports
  - Updates and bullet point summary of activities
  - Newsletter, CLIC web site, EC Lead team
- CLIC Forum
  - Online, asynchronous, Q&A, “living” document
  - 1 group per EC
- 4 by 4 presentations
  - “4 Slides x 4 Minutes, no mercy”
  - Steering Committee presentations (one 4 x 4 per SC meeting)
  - By lead team member to other EC membership
  - Rotate through all ECs, Q&A for presentations

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CLIC Solutions:

- EC Twitter Feed
  - Incorporate a Twitter/FB style newsfeed on the homepage highlighting recent EC/WG meeting outputs
  - 1-2 sentences for each EC
    (no more than 1 pp) CLIC Forum
- CLIC Suggestion Box
  - Suggestion Box to highlight EC/WG activity of interest
  - Can be used by EC's to suggest dissemination

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Task Force

OUTPUTS

Required

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Possible, with CLIC Support

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> Funding thru CCIAs or supplements

RESOURCES

NCATS Team Co-Chair
Call Support
Digital Workspace

NCATS

>Inform Initiative Topics

- **Supplements**
- **CCIAs**

Lunch Break!

Update on the CTSA Program Steering Committee Taskforce: Sustaining Careers of the Translational Science Workforce (STARWORK)

Susan Smyth, M.D., Ph.D.

TL1 PI Representative to the CTSA Program Steering Committee

Lead CTSA Program Steering Committee Taskforce: STARWORK

October 22, 2018

Steering Committee Taskforce on Sustaining Careers of the Translational Science Workforce (STARWORK)

- **Charge:**
  - To identify ways to improve the environmental landscape to sustain the careers of the translational science workforce, with particular emphasis on clinical investigators at academic medical centers
- **Members:**
  - Barry Coller
  - Rebecca Jackson
  - Samantha Jonson
  - Joan Nagel
  - Erica Rosemond
  - Doris Rubio
  - Joel Tsevat
  - Jason Umans
  - Emma Meagher
  - Kathryn Sandberg
  - Susan Smyth
  - Phil Kern
- **Support:**
  - Karen Grabowski, CTSA Program SC Coordinator, CLIC
  - Heather Baker, Program Analyst, NCATS
  - Baindu Bayon, AAAS Fellow, NCATS

The STARWORK Taskforce will:

1. Identify barriers that exist to sustaining the translational science workforce,
2. Provide guidance for interventions / investments to achieve the best possible environment to sustain the translational science workforce, and
3. Generate a white paper that articulates the vision for the ideal environment to sustain the careers of investigators performing translational science.

Specific issues/barriers that have been raised include:

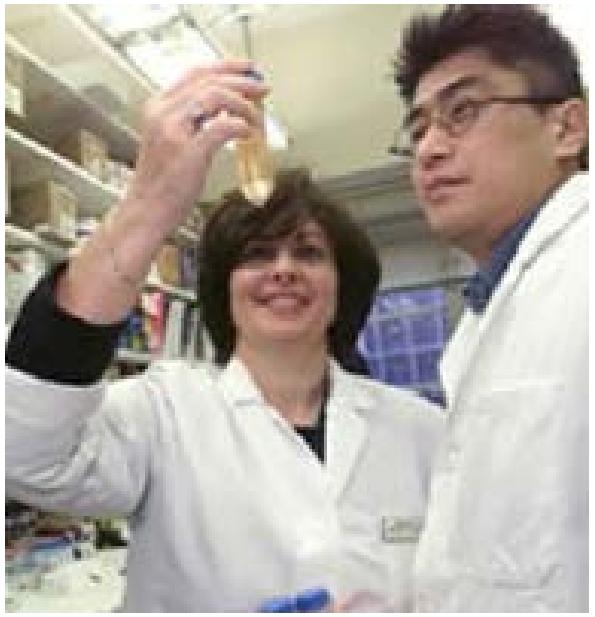
1. Research support for translational scientists
   - How are KL2 Scholars supported after their KL2 ends?
   - Is a specific R pathway needed for the CTSA Program KL2 scholars?
   - Can other NIH institutes leverage the KL2 Program to advance the careers of translational scientists?
     - Examples of ICs that have leveraged / provided supplements to the KL2 to date: NIDCR, NIBIB and NICCH
2. Debt Reduction (from medical/graduate school and extended training)
   - NIH Loan Repayment Program sufficient? What else is available?
3. Building Translational Science as a scientific discipline and field
   - Where does Translational Science “live” at academic medical centers?
   - What examples of building a discipline and field can we learn from? e.g. Genetics, Informatics, Data Science, Systems Biology, etc.
   - Recognizing Translational Scientists in the tenure and promotion process

Timeline and Deliverables:

- **Timeline:**
  - Meet 1x a month starting in September (6 meetings)
  - Summary of actions provided to the Steering Committee (today!)

- **Deliverables:**
  - Guidance
  - White paper

- **Target Date for Deliverables: March**
  - Steering Committee Meeting (F2F)
  - KL2 PI Meeting (F2F)



NIH National Center for Advancing Translational Sciences

Status Report – Activities (2 meetings to date)

Issue / Barrier	Update
1. **Research support for translational scientists:**	
• Collect info from KL2 Scholar Stakeholders on challenges: KL2 Scholar Survey	Doris Rubio – Concept and draft survey for review by SC
• ICs leveraging the CTSA Program training and education resources	Barry Coller (Discussion scheduled)
• How are KL2 Scholars supported after their KL2 ends?	Review data and discuss (Data presented at the Workforce DTF F2F meeting – Spring 2018) (Joan/Heather)
• Is a specific R pathway needed for the CTSA Program KL2 scholars?	Discussion scheduled
2. Debt Reduction:	
• Assessment of the KL2 Scholars success rate with the NIH LRP • Enhancing communication about resources for the NIH LRP for the KL2 Scholars	Review data and discuss (Erica/Heather)
3. Building Translational Science as a Scientific Discipline and Field:	
• Landscape analysis of Programs PhDs in Translational Science	Data Collection in Progress (Baindu)
• Where does Translational Science “live” at academic medical centers? • What examples of building a discipline and field can we learn from? e.g. Genetics, Informatics, Data Science, Systems Biology, etc. • Recognizing Translational Scientists in the tenure and promotion process	Discussion scheduled

National Center for Advancing Translational Sciences

KL2 Scholar Stakeholder Survey

Factors Contributing to a Successful Career in Clinical and Translational Science Research: Survey of the NCATS CTSA Program KL2 Scholars

- **Goal/Purpose:**
  - To solicit opinions from KL2 scholar alumni about how the NCATS CTSA Program can most effectively support their transition to a successful career in clinical and translational science research by identifying what the KL2 scholar alumni think the most significant barriers are to sustaining a career in clinical and translational research.
- **Survey Population:**
  - Scholars that have completed their term on the KL2 Grant between 2008-2017.
- **Approach:**
  - NCATS will provide emails of all KL2 scholars from IMPACII database (years: 2006-2017). This list and emails will be confirmed by KL2 PIs with assistance from the KL2 PI Champions.

Highlights of the Questions

General Characteristics:

- Time on the KL2, time since the KL2, application and receipt of subsequent grant funding, type of grant support after the KL2 ended, position before and after

Factors for Success:

- What has contributed to your success? (drop-down)
- Did you have an Individual Development Plan and how effective was it?

Time Commitment:

- Percent time commitment to research and to collaborations and/or being part of a team?

Financial feasibility:

- Do you think a career in clinical and translational science is financially sound?
- Amount of debt incurred and has this affected your career decisions?

Opinion about ability to sustain a career in clinical and translational science

Opinion about being a clinician researcher

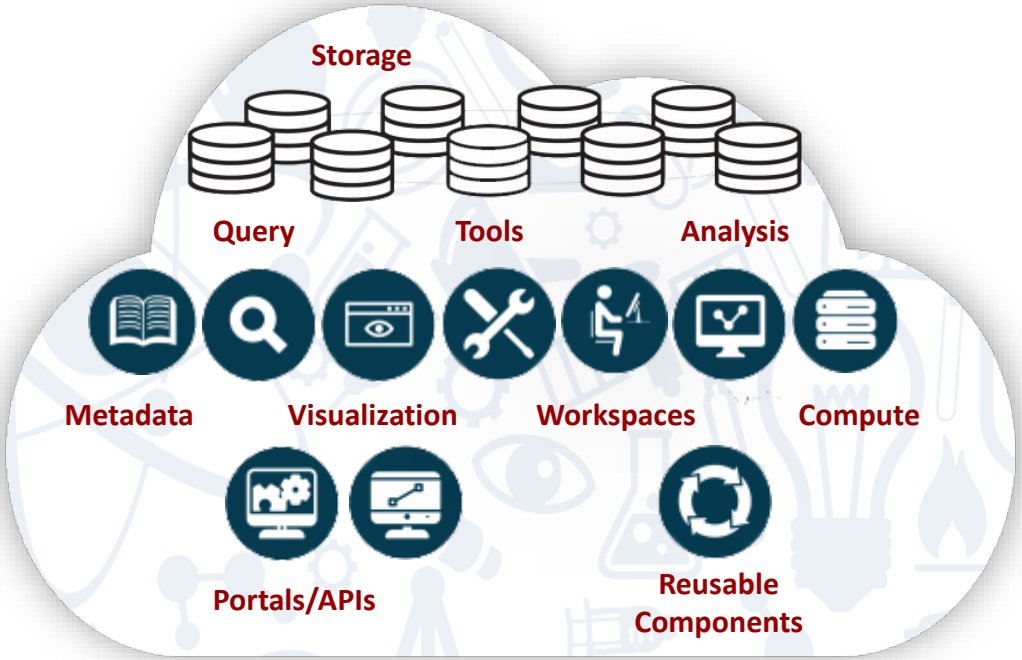
Questions?

CTSA Program G-Suite Website

Ken Gersing, M.D.

Samantha Jonson, M.P.S.

Cloud computing: an opportunity for CTSA Program hubs



- STRIDES: Science & Technology Research Infrastructure for Discovery,
- Experimentation, and Sustainability
- NIH and NCI Cancer Research Data Commons
- NCATS Biomedical Data Translator

Benefits to the Consortium

- Shared computing infrastructure
- Software analysis tools availability
- Harmonized and shareable datasets
- Investigator workspaces
- Terminology Services
- Regulatory compliance (FISMA)
  - Federal Information Security Management Act
- Reduced costs

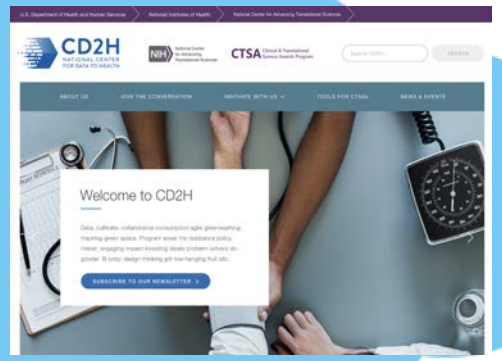
NIH National Center for Advancing Translational Sciences

NATIONAL CENTER FOR DATA TO HEALTH

CTSA Clinical & Translational Science Awards Program

NCATS and CD2H Shared Resource Investments and Pilots

- **Federated Authentication:** Access CTSA tools and data using your institutions' single sign-on
- **Availability of Cloud Resources:** Cloud-based software and IT resource access for CTSA Hubs (**Cielo** & **Synapse**)
  - Collaborate, manage data, deploy software and analyze data
- **CD2H Storefront for CTSA Tools and Resources**



National Center for Advancing Translational Sciences

CTSA Clinical & Translational Science Awards Program

NATIONAL CENTER FOR DATA TO HEALTH

Background

- Follow-up from the April 18, 2018 In-Person Steering Committee Meeting
- Request to make an electronic system that makes it easier for Steering Committee members to collaborate and obtain information

Solution

- ✓ Collaborative Co-Authoring
- ✓ Calendar
- ✓ Discussion Forum
- ✓ Document Repository
- ✓ Survey/Forms Access
- ✓ Instant Meeting Resources
- ✓ Mobile Friendly
- ✓ Instant Alerts on Activities

National Center for Advancing Translational Sciences

National Center for Advancing Translational Sciences

CTSA Program Steering Committee

A Collaborative Environment on the NCATS Gsuite Platform

Purpose

The NCATS CTSA Program Steering Committee provides leadership for sharing of policies, practices and resources, and discussion of opportunities, impediments, joint agreement on broad issues impeding clinical research and other appropriate topics. The Committee will identify and recommend best practices and policies to advance clinical and translational research as a discipline and facilitate collaboration and sharing among CTSA Program and non-CTSA Program institutions, and with

Pod Discussion for October

At the request of Dr. Brady, could each of you discuss with your respective Pods "**how the CTSA might interact with the Providers Clinical Support System (PCSS) (https://pcssnow.org; see attached description) to increase provider awareness about opioid use disorders – screening/assessment/treatment.**" The PCSS has a wide variety of materials available including on-line and face-to-face training and consultations. The PCSS staff is willing to collaborate with the entire network, or just specific hubs as interested. In terms of research, this would clearly be in the arena of educational research, implementation and dissemination. Dr. Brady would like to get some input – ideas about how we might engage with this group or just help by increasing knowledge about the availability of these training materials at CTSA institutions.

Samantha Jonson

Today | Sunday, October 21 | Week | Month | Agenda

Monday, October 22	
10:00am	CTSA Program Steering Committee Meeting (Invite Only)
4:00pm	CD2H Focus Group Meeting
5:30pm	CTSA Program Networking, Poster Session and Great Tean
Tuesday, October 23	
7:30am	CTSA Program Meeting
Wednesday, October 24	
9:00am	Trial Innovation Network Meeting (Invite Only)
Tuesday, November 20	
4:00pm	STARWORK Monthly Team Call

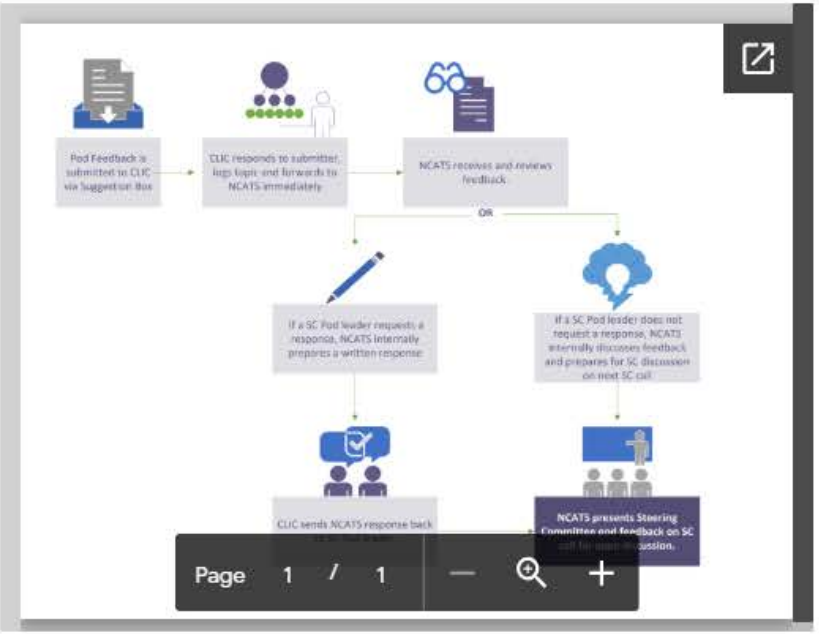
Google Calendar

NCATS Opportunities

- **NCATS Rare Diseases Are Not Rare! Challenge**
- **Clinical and Translational Science Award (U54 Clinical Trial Optional)** PAR-18-940
- **Announcement of the NCATS Rare Diseases Are Not Rare! Challenge** NOT-TR-19-002
- **Discovery of Biomarkers, Biomarker Signatures, and Endpoints for Pain (R61/R33 Clinical Trial Optional)** RFA-NS-18-041
- **Regenerative Medicine Innovation Projects (RMIP) Investigator-Initiated Clinical Trials (UG3/UH3 Clinical Trial Required)** RFA-HL-18-031

National Center for Advancing Translational Sciences

SC Roles and Responsibilities



Pod Feedback - Steering Committee Call Agenda Topic Suggestions

Tell us what you want to hear! Submit your input below!

I want to talk about...

Your answer

SUBMIT

Never submit passwords through Google Forms.

Worthwhile Reads

Interesting Reads Submitted by Steering Committee Members

Journal of Clinical and Translational Science

ACTS
ASSOCIATION FOR CLINICAL AND TRANSLATIONAL SCIENCE

EDUCATION
SPECIAL COMMUNICATION

All nurses need to be research nurses

Patricia Eckardt[1,2*], Marilyn J. Hammer[3], Margaret Barton-Burke[4,5], Margaret McCabe[6,7], Christine T. Kovner[8,9], Liza Behrens[10], Heather Reens[11] and Barry S. Coller[12]

[1] Helbrunn Family Cancer for Research Nursing, The Rockefeller University, New York, NY, USA
[2] Molloy College, Rockville Centre, NY, USA
[3] Research & Evidence Based Practice,
[4] Oncology Nursing Society, Pittsburgh,
[5] Nursing Research, Memorial Sloan
[6] International Association of Clinical
[7] Nursing Research, Medicine Patient
[8] Rory Meyers College of Nursing, New York University, New York, NY, USA

Page 1 / 2

Journal of Clinical and Translational Science

ACTS
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EDUCATION
SPECIAL COMMUNICATION

Developing sustainable research careers for KL2 scholars: The importance of an inclusive environment and mentorship

Carrie L. Byington[1,2*], Erin Rothwell[1], Trent Matheson[1], Rebecca Childs[2], Erin Wachs[1], Ruben Rocha[1], Maureen Murtaugh[1], David Turok[1], Anthea Letsou[1], Julie Shakib[1], Rachel Hess[1] and Willard Dere[1]

[1] The Utah Center for Clinical and Translational Science, University of Utah, Salt Lake City, UT, USA
[2] The Office of Academic Affairs and Faculty Development, University of Utah, Salt Lake City, UT, USA

National Center for Advancing Translational Sciences

Discussion Forum

Mark all as read | Filters | Help

New Google Sites Updates

Shared publicly | Join group

30 of 37 topics (37 unread)

Tags · About

Join the New Google Sites Update group to get email notification of the latest Google Sites updates

You can withdraw from this group at any time: if you wish to do so either send an email to sites-updates+unsubscribe@steegle.com or complete our contact form and state you want to be removed from the sites updates group. Please note that all processing of your personal data will cease once you have withdrawn consent, other than where this is required by law, but this will not affect any personal data that has already been processed prior to this point.
For more information on how your information is used, how we maintain the security of your information, and your rights to access information we hold on you please visit https://www.steegle.com/privacy

Copy Heading Link - new Google Sites (1)
By Steegle - 1 post - 33 views — Oct 19

Add buttons - new Google Sites (and other updates...) (1)
By Steegle - 1 post - 261 views — 3

Section Layouts and Remove Headers - new Google Sites (1)
By Steegle - 1 post - 225 views — Aug 17

Communications Workgroup

December 2017 - April 2018

Internal SC Notes v.2018.02.01

CTSA Program Communications Workgroup to the Steering Committee
January 31, 2018
12:00 – 1:00 ET

Meeting Participants: Ebony Boulware, David Center, Joel Tsevat, Martin Zand, Sam Jonson, Mike Kurilla, Pablo Cure

Review of pod survey feedback

- Note from Kathleen:
  - *It looks to me like PI's find the calls modestly useful, but the largest percentage thought we should keep them scheduled regularly, but modify to make them more bidirectional with input to SC re: agenda's etc. It seems like giving the calls more structure and reporting out from the calls regularly at the SC would be useful.*
- What does "regularly" scheduled mean? Monthly? How can it be better timed to when the SC holds their meetings.
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Page 1 / 2

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Page 1 / 2

What’s Next?

- Adding Google Hang-Out
- Finalizing Log-In Process
- Finalizing an implementation plan

Implementation?

- Beta launch in the coming weeks
- Full utilization by January 2019

National Center for Advancing Translational Sciences

Questions?

NCATS Improving Health Through Smarter Science

CTSA Program Steering Committee Roles and Responsibilities

Kathleen Brady, M.D., Ph.D.

Christopher Austin, M.D.

Co-Chairs, CTSA Program Steering Committee

CTSA Clinical & Translational Science Awards Program

NIH National Center for Advancing Translational Sciences

SC Roles and Responsibilities Document Overview

- Membership and Eligibility Criteria
- Term Length
- NCATS Staff Attendees of SC Meetings
- Ad-Hoc Attendees of SC Meeting
- Administrative Support
- Meetings
- Roles and Responsibilities
  - Conducting Pod Calls and Reporting Pod Feedback
  - Communication among the KL2 and Tl1 PIs
  - Oversight of Domain Task Force (DTF) Activities*
  - Survey Review and Approval

National Center for Advancing Translational Sciences

Discussion Topic #1

Under Membership and Eligibility Criteria

"The CTSA Program SC is comprised of 19 members: 12 UL1 PIs, 1 TL1 PI, 1 KL2 PI, 1 PI of the CTSA Program Coordinating Center, 1 Administrator, 1 PI of the Trial Innovation Network, 1 PI of the CTSA Program Clinical Data to Health Coordinating Center, and the NCATS Director."

- Are there too many SC members? Since the reconfiguration of the SC in 2014, 6 additional CTSA PIs have been added. Should we decrease to 6, 8 or 9 UL1s?

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Discussion Topic #2
Under Membership and Eligibility Criteria

"The eligibility criteria for SC appointments for PI (UL1, KL2 and TL1) and an Administrator are as follows:

> *For an Administrator, they must have the role of an Administrator (or equivalent) in the personnel list of an active CTSA Program hub award"*

- An Administrator role is not clearly identified in the Notice of Grant Award or FOA Application as key personnel. What are some eligibility criteria for this SC slot?

- The Administrator group is currently using the following criteria for inclusion in their own "special interest group" under CLIC support:
  - Administrators are key points of contact between CTSA program leadership, program directors, and NCATS personnel.
  - They are well-positioned to solve problems and provide input on ways to improve programs and enhance collaboration within and across the consortium.

- As for keeping Administrator meetings closed, they propose on adding:
  - The role of the Administrator calls for discretion in dealing with confidential and sensitive information.

NIH
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15 Minute Break

CTSA
Clinical & Translational Science Awards Program

CLIC
Center for Leading Innovation & Collaboration

CTSA Branding: NCATS Designation of CTSA Centers

NCATS Clincial and Translational Science Center

Designated by the
National Center for Advancing Translational Sciences

NCI Comprehensive Cancer Center

A Cancer Center Designated by the
National Cancer Institute

CTSA Steering Committee Meeting
October 22, 2018

Moderators:
Barry S. Coller MD
Martin S. Zand MD PhD

CTSA
Clinical & Translational Science Awards Program

CLIC
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The model: NCI Designation

NIH NATIONAL CANCER INSTITUTE

Español

1-800-4-CANCER | Live Chat | Publications | Dictionary

ABOUT CANCER | CANCER TYPES | RESEARCH | GRANTS & TRAINING | NEWS & EVENTS | ABOUT NCI | search

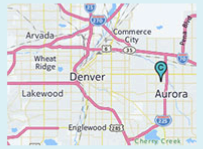
Home > Research > NCI's Role in Cancer Research

NCI'S ROLE IN CANCER RESEARCH

- Intramural Research
- Extramural Research
- Bioinformatics, Big Data, and Cancer
- **NCI-Designated Cancer Centers**
  - Find an NCI-Designated Cancer Center
- Frederick National Laboratory for Cancer Research
- Partners & Collaborators
- Spotlight on Scientists +

NCI-Designated Cancer Centers

The NCI Cancer Centers Program is one of the anchors of the nation's cancer research effort. There are currently 70 NCI-Designated Cancer Centers, located in 36 states and the District of Columbia, that form the backbone of NCI's programs for studying and controlling cancer. At any given time, hundreds of research studies are under way at the cancer centers, ranging from basic laboratory research to clinical assessments of new treatments. Many of these studies are collaborative and may involve several cancer centers, as well as other partners in industry and the community.



Find an NCI-Designated Cancer Center

NCI-Designated Cancer Centers deliver cutting-edge cancer treatments to patients in communities across the United States. Find a center near you and learn about its patient services and research capabilities.

Most of the NCI-Designated Cancer Centers are affiliated with university medical centers, although several are freestanding centers that engage only in cancer research.

The NCI-Designated Cancer Centers are recognized for their scientific leadership, resources, and the depth and breadth of their research in basic, clinical, and/or population science. Comprehensive Cancer Centers demonstrate an added depth and breadth of research, as well as substantial transdisciplinary research that bridges these scientific areas. Basic Laboratory Cancer Centers conduct only laboratory research and do not provide patient treatment. There are 14 Cancer Centers, 49 Comprehensive Cancer Centers, and 7 Basic Laboratory Cancer Centers.

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What this might look like….

U.S. Department of Health & Human Services | NIH National Institutes of Health

NIH National Center for Advancing Translational Sciences

Search Term | Search

Site Map | Contact

Research | Funding & Notices | News & Media | About Translation | About NCATS

CONCEPT ONLY

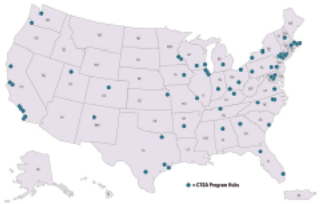
Home > Research > Clinical Innovation > Clinical and Translational Science Awards (CTSA) Program > About the CTSA Program > CTSA Program Hubs

NCATS Clincial and Translational Science Center

Designated by the National Center for Advancing Translational Sciences

NCATS-Designated Clinical and Translational Science Centers

The NCATS Designated Clinical and Translational Science Award (CTSA) Program is one of the anchors of the nation's translational research effort. There are currently 57 NCATS-Designated Clinical and Translational Research Centers, located in 42 states, that form the backbone of NCATS programs for studying and treating a wide variety of diseases. At any given time, hundreds of research studies are under way at the CTSA centers, ranging from basic laboratory research to clinical assessments of new treatments. Many of these studies are collaborative and may involve several CTSA Centers, as well as other industry and community partners.



Find an NCATS-Designated Clinical and Translational Science Center

The NCATS Designated CTSA Centers deliver cutting-edge solutions to translational research problems, moving basic discoveries to clinical treatments in communities across the United States. Find a Center near you and learn about its patient services and research capabilities. Most of the NCATS CTSA Centers are affiliated with university medical centers, although several are freestanding centers that engage only in translational research.

The NCATS Designated CTSA Centers are recognized for their scientific leadership, resources, and the depth and breadth of their research in basic, clinical, and/or population science. NCATS Designated CTSA Centers demonstrate an added depth and breadth of research, as well as substantial transdisciplinary research that bridges these scientific areas. As part of the Clinical and Translational Science Center Program, There are 57 NCATS-Designated Clinical and Translational Science Centers, 3 designated Research Innovation Centers, 1 Trial Innovation Center, 1 CTSA Coordinating Center, and 1 Clinical Data to Knowledge Coordinating Center.

The Importance of the NCATS Designated Clinical and Translational Science Centers

The NCATS grant funding to the CTSA Centers supports shared research resources, provides developmental funds to advance scientific goals, and fosters translational research programs that draw investigators from different disciplines together. In addition, individual CTSA Center investigators and trainees are highly successful at obtaining research funding from NIH funding agencies and organizations. Indeed, research proposals from CTSA investigators have resulted in numerous clinical trials and translational research grants funded by NIH and other organizaitons, and numerous important research discoveries and clinical trials. Graduate students, clinical study coordinators, nurses and other professionals seeking specialized training in clinical and translational science also benefit from the centers.

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Cancer Centers & CTSA Centers

Current NIH Requirements

	Cancer Centers	CTSA Centers
1. Clinical Focus	Cancer	Everything except cancer
2. Length of funding	5 years	4-5 years
3. Robustness of local patient support groups	Very robust	Highly variable
4. Demonstratable economic benefit to hospital/health system through increased clinical activity	Highly demonstratable	Questionably demonstratable
5. Stability of funding	Stable	Unstable/Metastable
6. Requirement for minimum number NCI/NIH funded grants (R01, R21, U01, etc.)	$10 million from NCI-related ICs	No requirement
7. Designated space required	Yes	No
8. Joint control of faculty recruitment	Yes	No
9. Report directly to Institutional Leadership	Yes	No
10. Required institutional support	Yes	Not explicit requirement
11. Local vs network commitments	Both	Both

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Goals of a CTSA Designation Program Perspective of Different Stakeholders

A. Institutional Leaders

1. Enhance enrollment in clinical trials
2. Attract high quality faculty
3. Attract new patients

B. Local CTSA Leadership

1. Enhance CTSA identity at the institution
2. Attract additional resources to support programs from the institution and other sources
3. Enhance recruitment into educational programs and identity of a translational research career

CTSA
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Goals of a CTSA Designation Program Perspective of Different Stakeholders

C. Patient Advocacy Groups

1. Establish standard for identifying institutions of high quality in research, clinical trials, and patient care
2. Provide access to experimental therapies

D. Industry Partners

1. Establish standard infrastructure and policies/procedures for conduct of clinical trials at individual sites and in a network
2. Establish standard for basic and early phase translational research collaborations

CTSA
Clinical & Translational Science Awards Program

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Goals of a CTSA Designation Program Perspective of Different Stakeholders

E. Medical Students, Trainees, and Other Health Care Professionals

1. Enhance the prestige and attractiveness of careers in translational research
2. Benchmark for professional training

F. NCATS

1. Enhance identity within NIH Institutes and Centers
2. Enhance identity in press
3. Enhance identity among elected officials
4. Enhance identity among governmental officials

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Goals of a CTSA Designation Program Perspective of Different Stakeholders

G. CTSA PI

1. Define a stable, sustainable, and productive vision for the CTSA program
2. Enhance identity of CTSA in institution and ability to aggregate resources

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Clinical & Translational Science Awards Program

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Discussion

1. Is this a concept the SC would recommend pursuing?

2. How to handle minimum requirements, or do we have them at all?

3. Next steps?

NIH Helping to End Addiction Long-term (HEAL) Initiative

Christopher Austin

Michael Kurilla

Jane Atkinson

NIH Helping to End Addiction Long-term (HEAL) Initiative

- Funding of $500M/year provides opportunity to:
  - Improve prevention and treatment strategies, both in clinic and real world settings, for opioid misuse and addiction
  - Enhance pain management by furthering understanding of neurobiology of pain, developing non-addictive treatments, and building a Clinical Trial Network for pain
  - Develop shared platforms through public and private partners
- Coordinating with the Surgeon General, our sister HHS agencies, local government officials

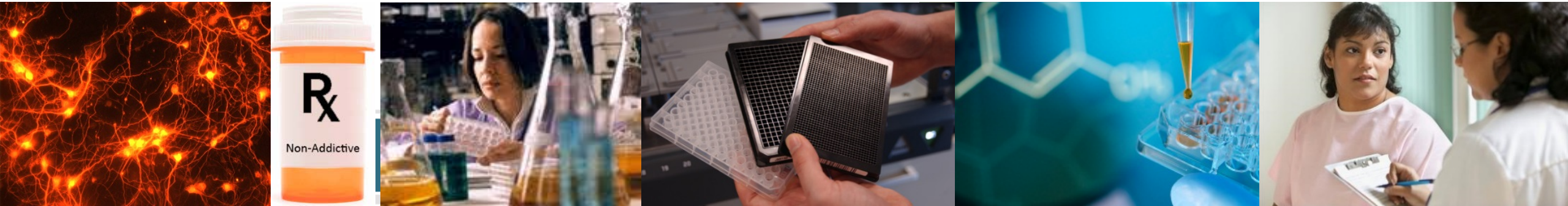
All Hands on Deck!

HEAL Research Projects on Opioid Use Disorder (OUD)

- Develop new treatments for opioid addiction, including more flexible medications options and novel immunotherapies to opioids
- Advance clinical trials for Neonatal Opioid Withdrawal syndrome to improve short- and long-term outcomes for infants and children
- Enhance the NIDA Clinical Trials Network to build linkages with primary care, emergency departments, and the justice system
- Establish a Justice Community Opioid Innovation Network
- Optimize effective treatments for OUD in the field through the *HEALing Communities Study*

HEAL Research Projects on Pain Management

- Pinpoint acute to chronic pain signatures to identify those at risk for transition to chronic pain
- Discover and validate novel treatments for pain
  - Work across the ICs to include all therapeutic development programs
  - Identify potential small molecules, biologics, devices, and natural products
  - Develop preclinical screening platforms for testing
  - Move successful compounds/devices to clinical trials



Announcement of Initial HEAL Research Plan

July 10, 2018

VIEWPOINT

Helping to End Addiction Over the Long-term
The Research Plan for the NIH HEAL Initiative

Francis S. Collins, MD, PhD
National Institutes of Health, Bethesda, Maryland.

Walter J. Koroshetz, MD
National Institute of Neurological Disorders and Stroke, National Institutes of Health, Bethesda, Maryland.

Nora D. Volkow, MD
National Institute on Drug Abuse, National Institutes of Health, North Bethesda, Maryland.

Extraordinary focus by all segments of society is required to respond to the nation's opioid crisis. Now is the time to channel the efforts of the scientific community to deliver effective—and sustainable—solutions to this formidable public health challenge. Recognizing this opportunity, Congress added $500 million to the base appropriation of the National Institutes of Health (NIH), starting in fiscal year 2018.[1] The NIH will invest these much-needed resources to support science that advances national priorities for addiction and pain research[2] with a bold new trans-NIH initiative called Helping to End Addiction Long-term (HEAL).[3] In this Viewpoint, we outline the initial components of this cross-cutting, interdisciplinary program.

More than 25 million US adults are affected by daily pain.[4] More than 2 million individuals in the United States have an opioid use disorder (OUD), most starting with opioid analgesics prescribed to them or procured from diverted medications, but once addicted, often shifting to illicit heroin or synthetic opioids.[5] The scope of this crisis is staggering, but scientific advances offer strategies that can help the nation overcome it.

At the National Rx Drug Abuse and Heroin Summit in April 2018, leaders from both the public and private sectors affirmed that research is essential to the effort to end this public health crisis. It will take "all hands on deck" to make this happen, which is why HEAL seeks to foster innovative partnerships with other government agencies, academic institutions, industry, communities, and patient advocates. Through a year-long series of engagements with individuals from these groups, the NIH has developed an innovative, action-oriented research plan for HEAL that is focused on 2 primary areas: improving treatments for opioid misuse and addiction as well as enhancing strategies for pain management (**Table**).

Although there are effective medications for OUD (methadone, buprenorphine, and naltrexone), only a small percentage of individuals in the United States who would benefit receive these medications. Even among those who have initiated these medications, about half will relapse

Table. Research Plan for the NIH HEAL Initiative

Opportunities	Components
Improving Treatments for Opioid Misuse and Addiction	
New treatments for addiction	Identify new targets, develop new medications/immunotherapies; reformulate existing medicines
	Improve overdose reversal medicines
	Develop new therapies for opioid-induced respiratory depression
Optimization of effective treatments for addiction	Enhance NIDA Clinical Trials Network for opioid research
	Establish Justice Community Opioid Intervention Network
	Initiate HEALing Communities Study
NOWS	Expand ACT NOW pilot study; use results to conduct clinical trials to determine best practices for clinical care of NOWS
Enhancing Pain Management	
Better understanding of chronic pain	Establish Acute to Chronic Pain Signatures program
New nonaddictive pain treatments	Identify new targets for pain treatment
	Engineer preclinical testing platforms to profile potential nonaddictive treatments
Public-private HEAL Partnership to speed movement of nonaddictive treatments through clinical pipeline	Enhance data and asset sharing
	Validate biomarkers to inform neurotherapeutic and pain clinical research
	Establish clinical trials network to support and accelerate trials of nonaddictive pain therapies

Abbreviations: HEAL, Helping to End Addiction Long-term; NIDA, National Institute on Drug Abuse; NIH, National Institutes of Health; NOWS, neonatal opioid withdrawal syndrome.

counter opioid-induced respiratory depression, and novel medications and immunotherapies to treat OUD and prevent and reverse overdoses.

HEAL will also support services and implementation research to develop new models of care for OUD within the health care and criminal justice settings that can expand access to medications and improve treatment retention. For example, HEAL will test how integrated evidence-based interventions can improve OUD outcomes through the multisite HEALing Communities Study. This study will

https://jamanetwork.com/journals/jama/fullarticle/2684941

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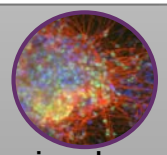
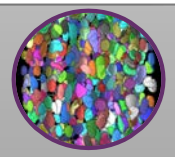
NCATS-led Preclinical NIH HEAL Initiative

Human Cell-Based Screening Platforms and Novel Drugs to Treat Pain, Addiction and Overdose

Human Cell-Based Platforms for testing new treatments



iPSC-derived neurons for pain and reward pathways



3-D Bioprinted Tissue Models

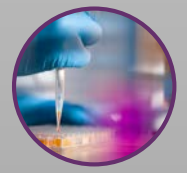
Tissue Chips

Model Complexity

Cells → **Multi-organ**

Accelerating Translation of Novel Compounds to Investigational New Drugs for Subsequent Clinical Testing

Development of New Chemical Structures to Modulate Novel Targets



Development of Pharmacological Probes for Novel Targets

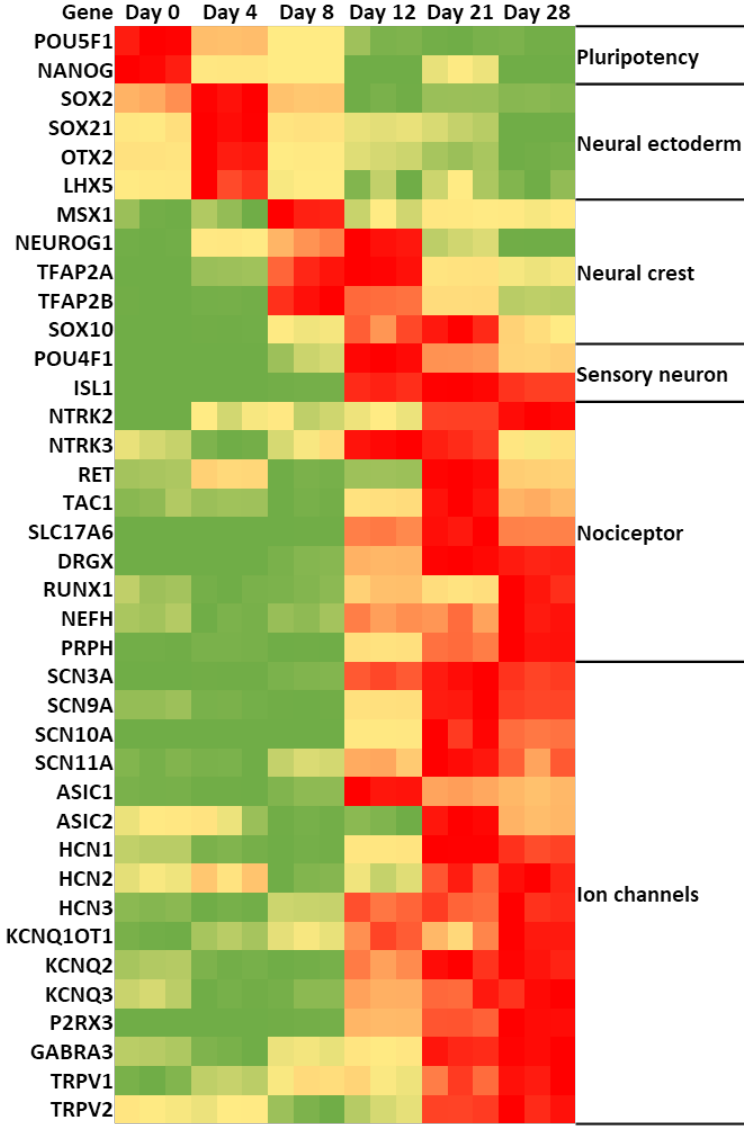
Development of Investigational Drugs ready for Clinical Testing

Preclinical Development

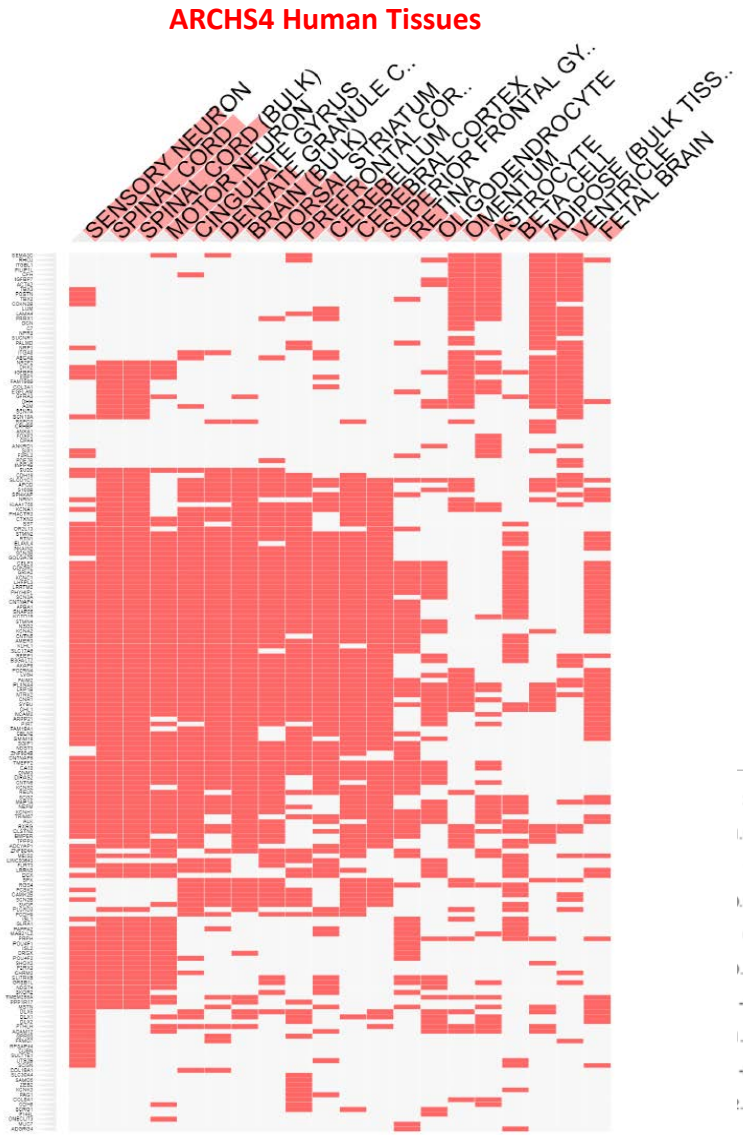
Early → **Late** → ***Clinical Testing and Trials***

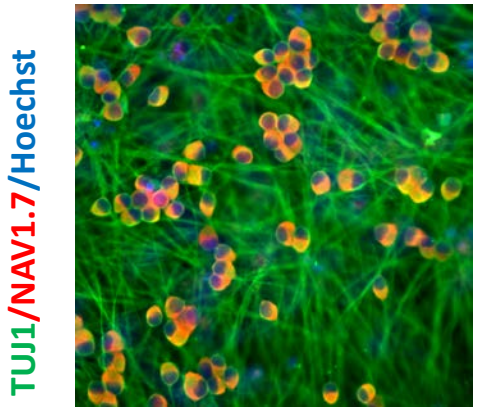
SCTL iPSC-derived sensory neurons

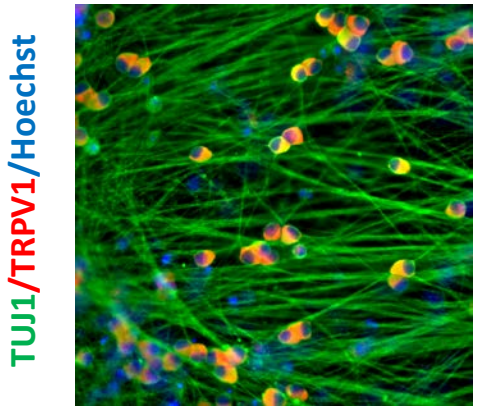
Controlled, step-wise differentiation of iPSCs into sensory neurons



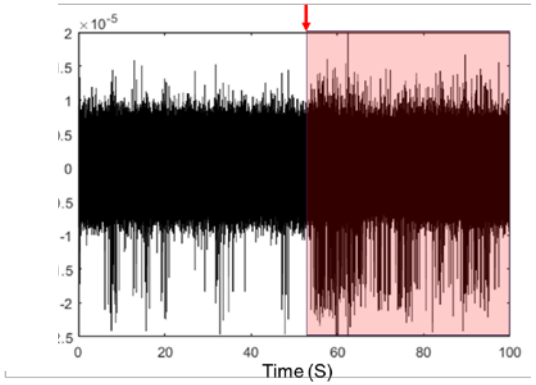
Cell type prediction test (Enrichr) confirms sensory neuron identity







+ 1 µM Capsaicin



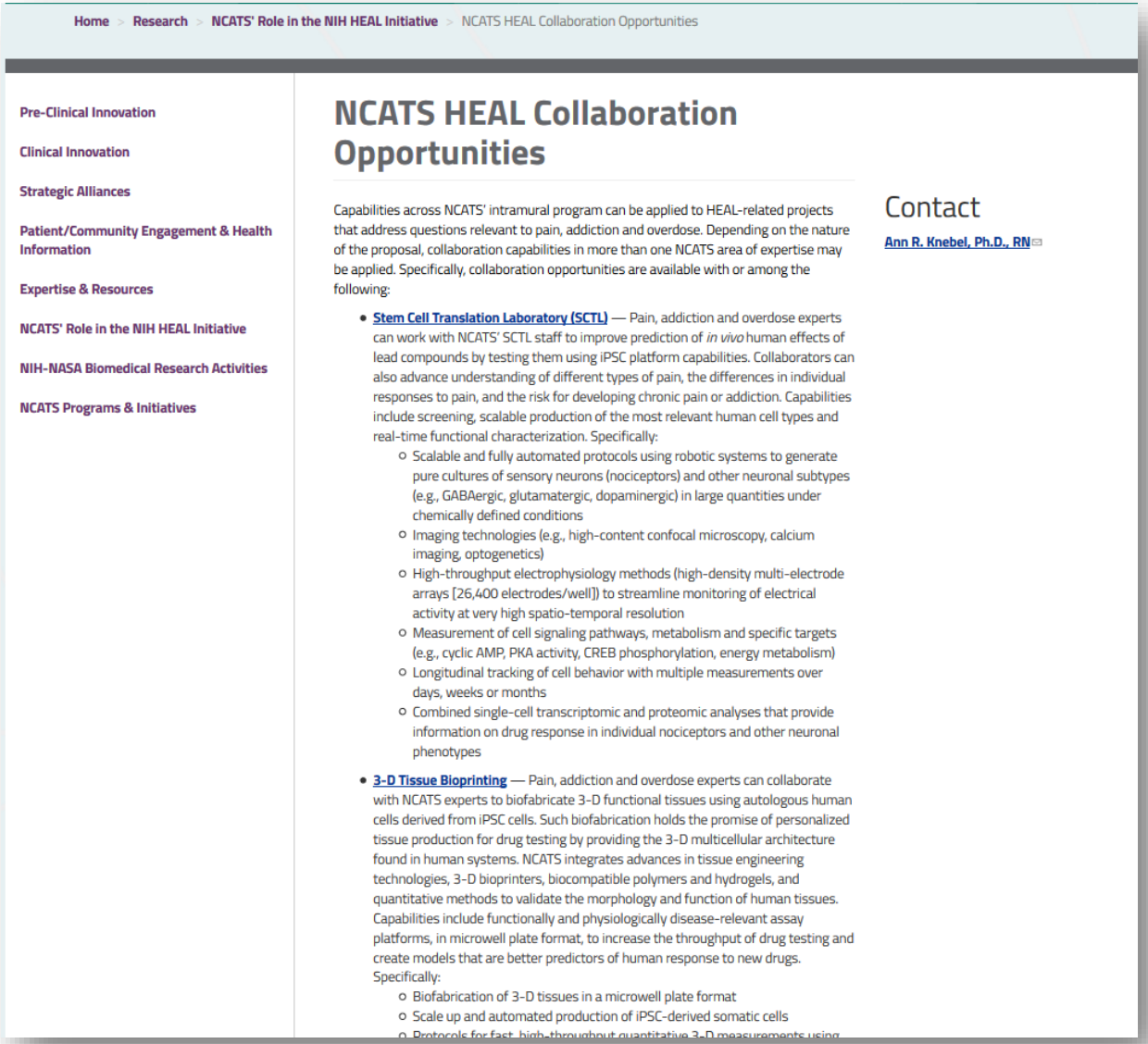
National Center for Advancing Translational Sciences

NCATS-led Preclinical NIH HEAL Initiative

Soliciting Collaborations

- Stem Cell Translation Laboratory (SCTL)
- 3-D Tissue Bioprinting
- Pharmacological Probe Development
- Enabling Investigational New Drug (IND) Applications

https://ncats.nih.gov/heal/intramural-capabilities



Home > Research > NCATS' Role in the NIH HEAL Initiative > NCATS HEAL Collaboration Opportunities

Pre-Clinical Innovation
Clinical Innovation
Strategic Alliances
Patient/Community Engagement & Health Information
Expertise & Resources
NCATS' Role in the NIH HEAL Initiative
NIH-NASA Biomedical Research Activities
NCATS Programs & Initiatives

NCATS HEAL Collaboration Opportunities

Capabilities across NCATS' intramural program can be applied to HEAL-related projects that address questions relevant to pain, addiction and overdose. Depending on the nature of the proposal, collaboration capabilities in more than one NCATS area of expertise may be applied. Specifically, collaboration opportunities are available with or among the following:

- Stem Cell Translation Laboratory (SCTL) — Pain, addiction and overdose experts can work with NCATS' SCTL staff to improve prediction of *in vivo* human effects of lead compounds by testing them using iPSC platform capabilities. Collaborators can also advance understanding of different types of pain, the differences in individual responses to pain, and the risk for developing chronic pain or addiction. Capabilities include screening, scalable production of the most relevant human cell types and real-time functional characterization. Specifically:
  - Scalable and fully automated protocols using robotic systems to generate pure cultures of sensory neurons (nociceptors) and other neuronal subtypes (e.g., GABAergic, glutamatergic, dopaminergic) in large quantities under chemically defined conditions
  - Imaging technologies (e.g., high-content confocal microscopy, calcium imaging, optogenetics)
  - High-throughput electrophysiology methods (high-density multi-electrode arrays [26,400 electrodes/well]) to streamline monitoring of electrical activity at very high spatio-temporal resolution
  - Measurement of cell signaling pathways, metabolism and specific targets (e.g., cyclic AMP, PKA activity, CREB phosphorylation, energy metabolism)
  - Longitudinal tracking of cell behavior with multiple measurements over days, weeks or months
  - Combined single-cell transcriptomic and proteomic analyses that provide information on drug response in individual nociceptors and other neuronal phenotypes
- 3-D Tissue Bioprinting — Pain, addiction and overdose experts can collaborate with NCATS experts to biofabricate 3-D functional tissues using autologous human cells derived from iPSC cells. Such biofabrication holds the promise of personalized tissue production for drug testing by providing the 3-D multicellular architecture found in human systems. NCATS integrates advances in tissue engineering technologies, 3-D bioprinters, biocompatible polymers and hydrogels, and quantitative methods to validate the morphology and function of human tissues. Capabilities include functionally and physiologically disease-relevant assay platforms, in microwell plate format, to increase the throughput of drug testing and create models that are better predictors of human response to new drugs. Specifically:
  - Biofabrication of 3-D tissues in a microwell plate format
  - Scale up and automated production of iPSC-derived somatic cells
  - Protocols for fast, high-throughput quantitative 3-D measurements using

Contact
Ann R. Knebel, Ph.D., RN

National Center for Advancing Translational Sciences

Pending Announcement of Full HEAL Research Plan

U.S. Department of Health & Human Services

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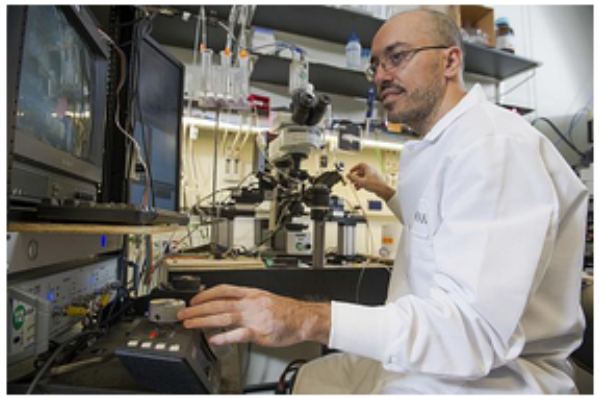
NIH HEAL INITIATIVE

HEAL Initiative

- Addiction Treatments
- Pain Management
- Public-Private Partnership
- Research Plan
- Funding
- Events
- News and Announcements
- Resources

NIH research program to explore the transition from acute to chronic pain



NIH outlines research plan to address the opioid epidemic

Email Updates

Sign up to receive email updates about the HEAL Initiative.

Sign up for updates

About the NIH HEAL Initiative

In April 2018, NIH launched the HEAL (Helping to End Addiction Long-term) Initiative, an aggressive, trans-agency effort to speed scientific solutions to stem the national opioid public health crisis. This Initiative will build on extensive, well-established NIH research

HEAL Pain Effectiveness Research Network

(Current Status: concept cleared by NCATS and NINDS Advisory Councils)

- **Background**
  - Optimal pain management is insufficient, including long-term opioid use for chronic pain.

- **Goals**
  - Establish the HEAL Pain Effectiveness Research Network (HEAL Pain-ERN) to establish effective interventions or programs to manage, reduce or prevent acute and chronic pain.
  - Leverage CTSA/TIN to implement and execute meritorious clinical trials/studies of interest to multiple NIH Institutes, Centers, and Offices.
  - Support studies that provide evidence to inform practice-based guidelines.

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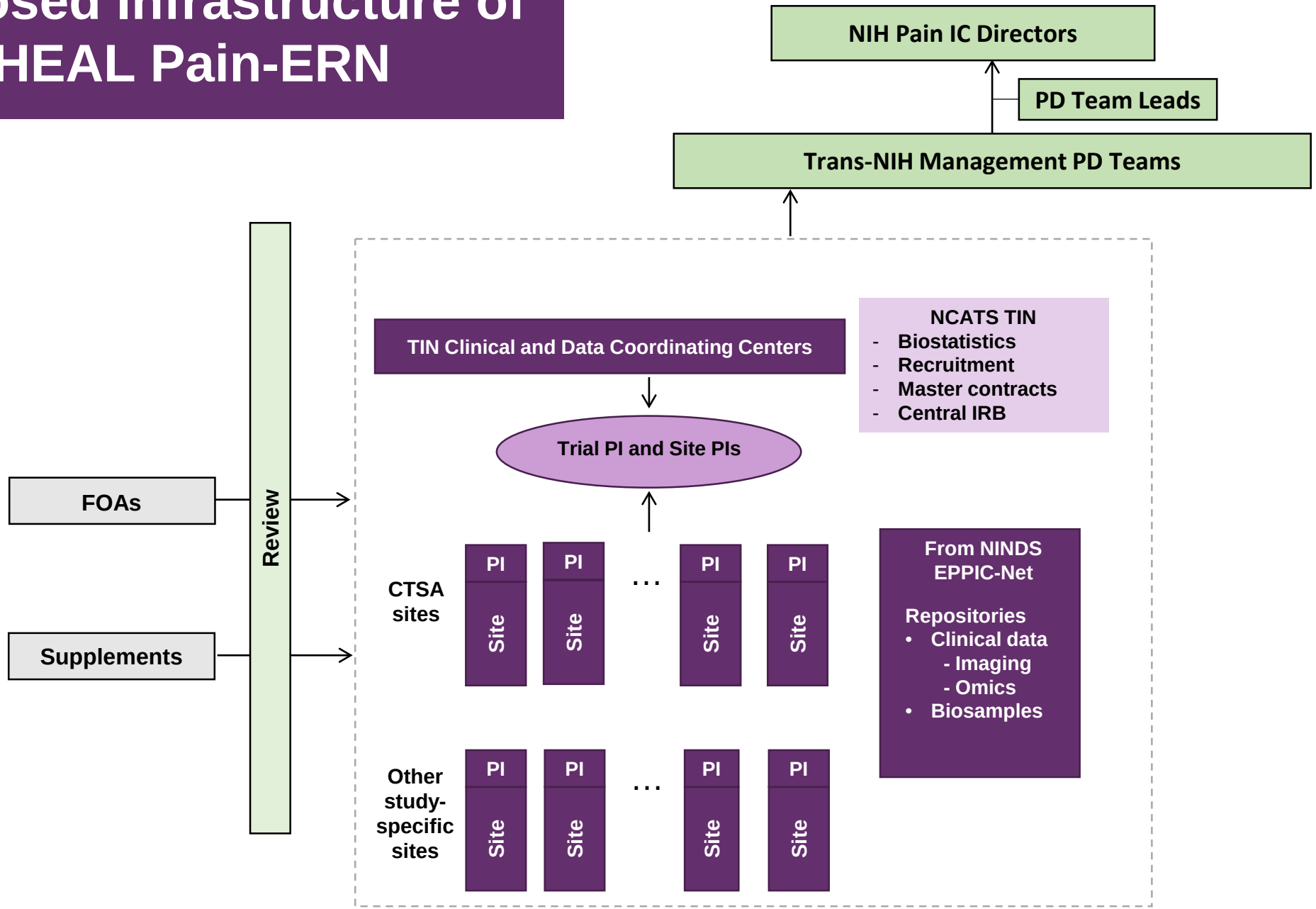
Proposed Infrastructure of HEAL Pain-ERN



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HEAL Pain Effectiveness Research Network

(Current Status: concept cleared by NCATS and NINDS Advisory Councils)

- **Execution**
  - Trials will utilize standardized outcome measures to enable future meta-analyses.
  - Data will be collected and stored centrally for future data sharing.
  - Sites will vary according to the study question and will not be restricted to a select group of network sites
- **Potential impact**
  - The HEAL Pain-ERN is poised to provide patients and practitioners with a suite of effective and data-driven strategies to alleviate pain.
  - This initiative demonstrates the flexibility of CTSA/TIN to rapidly facilitate clinical research of interest to multiple NIH Institutes, Centers, or Offices.
  - Standardization of measures and outcomes will allow comparison of data across trials and may uncover new approaches for managing under-studied pain conditions.

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Networking & Poster Session
5:30 – 7:30 pm

Commonwealth Hall

Location: Lobby