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.
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
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.
Proposed Infrastructure of HEAL Pain-ERN

- TIN Clinical and Data Coordinating Centers
  - Biostatistics
  - Recruitment
  - Master contracts
  - Central IRB

- From NINDS EPPIC-Net
  - Repositories
    - Clinical data
      - Imaging
      - Omics
    - Biosamples

- FOAs
- Review
- Supplements
- NIH Pain IC Directors
- PD Team Leads
- Trans-NIH Management PD Teams

Trial PI and Site PIs

CTSA sites

Other study-specific sites
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.
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
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
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
Domain Task Force Review and Discussion

Washington, D.C.
October 2018
Methods and Processes

DTF Update

Brad Evanoff, MD, MPH
Washington University at St. Louis
Methods & Processes DTF

• Reviewing next steps for existing work groups
• Pursuing input for areas of interest for new work groups
Develop capability and recommend methodology for continuous process improvement (e.g., Six Sigma) at all CTSA hubs. (58)

Develop common metrics across CTSAs (including metrics for achievement of timely research processes). (28)

Create a database of potential local site PIs interested in participating in networked clinical trials (must include patient population available and disease specialty of PI). (29)

Create a central repository for CTSAs to list their areas of expertise to encourage quicker identification of sites for investigator-initiated clinical trials. (13)

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

Determine how critical stakeholders (as inclusively as identified in PCORI) are involved in the formulation of the research question. (32)

Identify the most efficient and productive ways in which stakeholders and communities can contribute to DTF work and the translational process. (6)
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
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
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.
Collaboration/Engagement

DTF Update

Joel Tsevat, MD, MPH

UT Health San Antonio
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
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
Methods to Assess Community Engagement Strategies

• 2 surveys in development; undergoing thorough WG review

• Survey goals:
  o Capture barriers and facilitators to community engagement
  o 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
  o Early January 2019

• Sunset: by September 2019
Dissemination & Implementation (D&I)

• Proposed a special issue on D&I Science to the Journal of Clinical and Translational Science (JCTS); awaiting confirmation
  o 2 manuscripts in preparation
  o 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
  o Aligns with journal submission deadline for JCTS special issue
Forthcoming Plans

• Several current WGs are sunsetting; new WGs:
  o Integrating Bi-Directional Community/Stakeholder Engagement into Team Science
  o C-E Across the Translational Spectrum (T1 and T2)
  o C-E Curriculum Initiative (Develop Competencies)
  o 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
  o Discussing adding a community representative to the lead team
Integration Across the Lifespan DTF Update

Dan M. Cooper, M.D.
University of California, Irvine
Lifespan DTF & Workgroups
Updates and Accomplishments

• Full DTF
  o 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.
  o 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.
  o 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.
  o 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.
Key Points from Face to Face Meeting

• Define a clear definition of Lifespan

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

The University of Rochester Center for Leading Innovation and Collaboration (CLIC) is the coordinating center for the Clinical and Translational Science Awards (CTSA) Program, funded by the National Center for Advancing Translational Sciences (NCATS) at the National Institutes of Health (NIH), Grant U24TR002260.
Key Points (con’t)

• Guiding Principles
  o Useful
  o Additive (not duplicative)
  o Practical
  o Pragmatic scope of work for our structure

• Workgroup Breakout Session
  o What is Lifespan Research?
  o How are doing this this?
Lifespan DTF & Workgroups

Updates

• Aging Workgroup
  o This group had conversations with NCATS to clarify the scope of the work and how to best incorporate the study of older adults.
  o 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
  o The manuscript has been published and a Pediatric Academic Society (PAS) meeting topic symposia on this topic has been submitted.

• Single Disease
  o Transition Manuscript is under review at the Journal of Clinical and Translational Science
  o The group will be Sunset Winter 2019.
Workforce Development
DTF Update

Susan Smyth, MD, PhD
University of Kentucky
DTF – Workforce Development

- 4 active working groups (WG)
  - WG1: Federated Educational Platform: Harmonizing Competencies
  - WG2: Clinical Research Training for Investigators
  - 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)

The University of Rochester Center for Leading Innovation and Collaboration (CLIC) is the coordinating center for the Clinical and Translational Science Awards (CTSA) Program, funded by the National Center for Advancing Translational Sciences (NCATS) at the National Institutes of Health (NIH), Grant U24TR002260.
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
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

Stage 1
First Landing
Stage 5

Stage 2
Stage 4

Stage 3

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

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

Institutional Links
- USCF study template
- UCSF Consent template
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

DISSIPATION 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.

DISSIPATION and TRANSLATION: to follow
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
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
Informatics
DTF Update

Donald Lloyd-Jones, MD, ScM
Northwestern University at Chicago
Informatics DTF / WG Update

Since the Spring iDTF Update:

The iDTF and CD2H have developed 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
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.

<table>
<thead>
<tr>
<th>iDTF Members Meetings</th>
<th>iDTF Topic(s)</th>
<th>CD2H Topic(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>9/7/2018</td>
<td>Fall CTSA Program Meeting / Collaborative Funding Ops / WG Status Update / iDTF Members’ Meeting Format Reminder (15 min)</td>
<td>CD2H Software Workgroup Show and Tell (45 min)</td>
</tr>
<tr>
<td>10/5/2018</td>
<td>EasiPro Presentation / Election update / WG charter status / F2F Meeting update / Collaborative Funding Reminder (45 min)</td>
<td>CD2H Update (15 min) - Sean Mooney - vision for CD2H Implementation</td>
</tr>
</tbody>
</table>
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.
  o (iDTF) Enterprise Data Warehouse
  o (iDTF) Sustainability Phase Two
  o (iDTF) Text Analytics

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

Since the Spring iDTF Update continued:

• The three standing CD2H WGs include:
  o Data
  o Software
  o 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
  o Goals & principles were developed and endorsed by NCATS
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.

  o 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.

  o 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.
DTF Survey Results Discussion

Kathleen Brady
Clare Schmitt
Martin Zand
CTSA Program Steering Committee Task Force on Enhancing the DTFs

**CLIC Coordination:**
- Catherine Fetherston
- Scott McIntosh
- Deborah Ossip

**MEMBERS**

<table>
<thead>
<tr>
<th>Kathleen Brady</th>
<th>Samantha Jonson (NCATS)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ebony Boulware</td>
<td>Erica Rosemond (NCATS)</td>
</tr>
<tr>
<td>Bradley Evanoff (Methods/Processes DTF)</td>
<td>Clare Schmitt (NCATS)</td>
</tr>
<tr>
<td>Dan Cooper (Lifespan DTF)</td>
<td>Martin Zand</td>
</tr>
<tr>
<td>Melissa Haendel</td>
<td>Joel Tsevat (Collaboration/Engagement DTF)</td>
</tr>
<tr>
<td>Donald Lloyd-Jones (Informatics DTF)</td>
<td>Susan Smyth (Workforce DTF)</td>
</tr>
</tbody>
</table>
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
• 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
    • Develop best practices, conduct evaluation, develop WG outcomes that can be implemented
  • Dedicated funding for various DTF activities
  • Trans-DTF WGs
  • Promote sharing and dissemination of resources

• 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
     o FY19: Existing DTFs propose one topic for a workshop or un-meeting support via CLIC; SC approval
     o 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

Enterprise Committees
With or without Work Groups, Discussion Groups, Special Interest Groups

Clinical & Translational Science Challenge Projects

Task Forces

Outputs
Proposal Begins to Address Key Requests

<table>
<thead>
<tr>
<th>April 2018 DTF Packet Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Suggested Enhancements for the DTFs</strong></td>
</tr>
<tr>
<td>▪ Engagement of DTF members</td>
</tr>
<tr>
<td>▪ Dedicated funding for various DTF activities</td>
</tr>
<tr>
<td>▪ Planning platforms for subsequent applications</td>
</tr>
<tr>
<td>▪ Trans-DTF WGs</td>
</tr>
<tr>
<td>▪ Smaller in-person meetings</td>
</tr>
<tr>
<td>▪ Promote sharing and dissemination of resources</td>
</tr>
<tr>
<td>▪ Direction from CTSA Program Leadership</td>
</tr>
<tr>
<td>▪ Develop best practices, conduct evaluation, develop WG outcomes that can be implemented</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>July 2018 DTF Survey</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Key Issues</strong></td>
</tr>
<tr>
<td>▪ Communications*</td>
</tr>
<tr>
<td>▪ Provide resources for DTFs; unfunded mandate</td>
</tr>
<tr>
<td>▪ DTFs too broad; need focus, timelines, deliverables</td>
</tr>
<tr>
<td>▪ Strengthen Collaborative Efforts</td>
</tr>
<tr>
<td>▪ Change DTF name to avoid a problematic acronym and better reflect function</td>
</tr>
</tbody>
</table>

*Communication enhancements to be proposed by CLIC"
Principles & Implementation Plan

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

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

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

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

**Tier 1**
- Full DTFs (n=5)
- DTF Leads (n=5)
- Working Groups (n=16)

**Tier 4 (incl. F2F)**
- 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

### 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

**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

**Proposals**

<table>
<thead>
<tr>
<th>Substructure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Substructure &gt; None</td>
</tr>
<tr>
<td>Substructure &gt; Work Groups</td>
</tr>
<tr>
<td>Substructure &gt; Work Groups &gt; Discussion Groups</td>
</tr>
</tbody>
</table>

**NCATS’ Preferences**

- 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

| **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

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

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
Functions & Names

**Enterprise Committees**

**Similar to DTF**
- 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

**Task Forces**

**Similar to WG**
- Address Specific Challenges
- Cross-Consortium Membership

**Possible Names**
- Innovation / Enterprise ...
- ... Task Force / Work Group / Team / Collaboratory / Collaborative
Proposed Timeline

• FY19 (Oct 2018 – Sept 2019)
  o Communications
    ▪ CLIC: Propose improved communication strategy
    ▪ SC: Approve processes
  o 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)
  o **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)
  o **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
  - WG → Task Forces
  - Provide digital workspace for Enterprise Committee subgroups (e.g., work groups, discussion groups, special interest groups)
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

The University of Rochester Center for Leading Innovation and Collaboration (CLIC) is the coordinating center for the Clinical and Translational Science Awards (CTSA) Program, funded by the National Center for Advancing Translational Sciences (NCATS) at the National Institutes of Health (NIH), Grant U24TR002260.
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
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 Suggestion Box
  • Suggestion Box to highlight EC/WG activity of interest
  • Can be used by EC’s to suggest dissemination
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

- 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

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

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

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

---

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
New Google Sites Updates

30 of 37 topics (37 unread)

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

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

- **Section Layouts and Remove Headers - new Google Sites**
  By Steegle - 1 post - 233 views
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.
- SC Agendas should be circulated in advance of the SC call
- Pod feedback needs to be “plugged-in” to the SC meetings
CTSA Program Communications Workgroup to the Steering Committee
January 31, 2018
12:00 – 1:00 ET

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

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.
- SC Agendas should be circulated in advance of the SC call
- Pod feedback needs to be “plugged-in” to the SC meetings
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
Questions?
CTSA Program Steering Committee
Roles and Responsibilities

Kathleen Brady, M.D., Ph.D.
Christopher Austin, M.D.

Co-Chairs, CTSA Program Steering Committee
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
“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?
“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:
  o Administrators are key points of contact between CTSA program leadership, program directors, and NCATS personnel.
  o 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:
  o The role of the Administrator calls for discretion in dealing with confidential and sensitive information.
15 Minute Break
CTSA Branding: NCATS Designation of CTSA Centers

CTSA Steering Committee Meeting
October 22, 2018

Moderators:
Barry S. Coller MD
Martin S. Zand MD PhD
The model: NCI Designation

NCI Role in Cancer Research

Informed Research
Integrative Research
Translational 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.
What this might look like….

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 organizations, 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.
## Cancer Centers & CTSA Centers

### Current NIH Requirements

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

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

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 $1 billion to the base appropriation of the National Institutes of Health (NIH), starting in fiscal year 2018. The NIH will invest these much-needed resources to support science that advances national priorities for addiction and pain research.

More than 22 million US adults are affected by daily pain. More than 2.7 million individuals in the United States have an opioid use disorder (OUD), most starting with opioid analogues prescribed to them or procured from diverted medications, but once addicted, often shifting to both heroin or synthetic opioids. 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 focuses on 2 priority areas: improving treatments for opioid misuse and addiction as well as enhancing strategies for pain management.

Although there are effective medications for OUD (buprenorphine, naltrexone, and methadone), only small percentages of those who could benefit actually receive these medications. Even among those who have initiated these medications, about half will relapse due to opioid-induced respiratory depression, and novel medications and immunotherapies to treat Opioid-Induced Neuropathy and reverse overdose.

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

Table. Research Plan for the NIH HEAL Initiative

<table>
<thead>
<tr>
<th>Opportunities</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improving Treatments for Opioid Misuse and Addiction</td>
<td>Identify new targets, develop new medications/immunotherapies, reformulate existing medicines</td>
</tr>
<tr>
<td></td>
<td>Improve overdose reversal medicines</td>
</tr>
<tr>
<td></td>
<td>Develop new therapies for opioid-induced respiratory depression</td>
</tr>
<tr>
<td>Optimization of effective treatments for addiction</td>
<td>Enhance NIDA Clinical Trials Network for opioid research</td>
</tr>
<tr>
<td></td>
<td>Establish Justice Community Opioid Intervention Network</td>
</tr>
<tr>
<td></td>
<td>Initiate HEALing Communities Study</td>
</tr>
<tr>
<td>NOWS</td>
<td>Expand ACT NOW pilot study; use results to conduct clinical trials to determine best practices for clinical care of NOWS</td>
</tr>
<tr>
<td>Enhanced Pain Management</td>
<td>Establish Acute to Chronic Pain Signatures program</td>
</tr>
<tr>
<td>Better understanding of chronic pain</td>
<td>Identify new targets for pain treatment</td>
</tr>
<tr>
<td>Pain treatments</td>
<td>Engineer preclinical testing platforms to profile potential nonaddictive treatments</td>
</tr>
</tbody>
</table>

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

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

- 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

Model Complexity
- Cells
- Multi-organ

Preclinical Development
- Early
- Late

Clinical Testing and Trials
SCTL iPSC-derived sensory neurons

Controlled, step-wise differentiation of iPSCs into sensory neurons

TUJ1/NAV1.7/Hoechst
TUJ1/TRPV1/Hoechst
TUJ1/NAV1.7 + 1 µM Capsaicin

Cell type prediction test (Enrichr) confirms sensory neuron identity

ARCH54 Human Tissues

POU5F1
NANOG
SOX2
SOX21
OTX2
LHX5
MSX1
NEUROG1
TFAP2A
TFAP2B
SOX10
POU4F1
ISL1
NTRK2
NTRK3
RET
TAC1
SLC17A6
DRGK1
RUNX1
NEFH
PRPH
SCN3A
SCN9A
SCN10A
SCN11A
ASIC1
ASIC2
HCN1
HCN2
HCN3
KCNQ1OT1
KCNQ2
KCNQ3
P2RX3
GABRA3
TRPV1
TRPV2
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
Pending Announcement of Full HEAL Research Plan

NIH HEAL INITIATIVE

HEAL Initiative

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

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.
Proposed Infrastructure of HEAL Pain-ERN

- **TIN Clinical and Data Coordinating Centers**
  - Biostatistics
  - Recruitment
  - Master contracts
  - Central IRB

- **From NINDS EPPIC-Net**
  - Repositories
    - Clinical data
    - Imaging
    - Omics
    - Biosamples

- **NIH Pain IC Directors**
- **PD Team Leads**
- **Trans-NIH Management PD Teams**

**FOAs**

**Supplements**

**CTSA sites**
- PI Site
  - ... PI Site

**Other study-specific sites**
- PI Site
  - ... PI Site

**Review**

**Trial PI and Site PIs**

NIH Pain IC Directors and PD Team Leads are connected to the Trans-NIH Management PD Teams, which in turn connect to the TIN Clinical and Data Coordinating Centers. These centers handle various responsibilities such as biostatistics, recruitment, master contracts, and Central IRB. The FOAs and Supplements sections are linked to thereview process. The CTSA sites and other study-specific sites indicate the distribution of PI Site responsibilities across different sites.
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.
Networking & Poster Session
5:30 – 7:30 pm

Commonwealth Hall
Location: Lobby