

2018 Fall CTSA Program  
Steering Committee Meeting Summary

Hilton Crystal City at Washington Reagan National Airport

Arlington, VA

Virginia Ballroom

October 22, 2018

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## Agenda

Tuesday, October 23, 2018

<b>TIME</b>	<b>TOPIC</b>	<b>PRESENTERS</b>
10:00	Welcome Updates	Kathleen Brady Christopher P. Austin
10:00 – 10:10	CTSA Program Updates	Michael G. Kurilla
10:10 - 12:30	Domain Task Force Review and Discussion	Brad Evanoff Joel Tsevat Dan Cooper Susan Smyth Donald Lloyd-Jones Kathleen Brady, Clare Schmitt, Martin Zand
	10:10 – 10:20      Methods and Processes	
	10:20 – 10:30      Collaboration and Engagement	
	10:30 – 10:40      Integration Across the Lifespan	
	10:40 – 10:50      Workforce Development	
	10:50 – 11:00      Informatics	
	11:00 – 12:30      DTF Survey Results Discussion	
12:30 - 1:00	<i>Lunch Break</i>	
1:00 - 2:00	Update: Sustaining Careers of the Translational Science Workforce (STARWORK) Workgroup	Susan S. Smyth
2:00 - 2:15	CTSA Program Steering Committee G-Suite Website Demo	Ken Gersing Samantha Jonson
2:45 - 3:00	<i>Break</i>	
3:00 – 4:00	Discussion: CTSA Program Branding	Martin Zand Barry Coller
4:00 – 5:00	NIH Helping to End Addiction Long-term (HEAL) Initiative	Christopher Austin Michael Kurilla Jane Atkinson

## CTSA Program Updates

Michael G. Kurilla, MD, PhD

### FOA UPDATE

- **PAR-18-940** (Reissue of PAR-18-464)
  - Released Sept 27, 2018
  - A minor change in the receipt date to January 25, 2019 (due one month earlier)
  - Change from discreet dollars to a percentage (offers more flexibility)
  - No cap on the number of TL1 slots
- **KL2**
  - Confusion regarding recommended or maximum number of KL2 slots
  - This is being reconciled at NCATS
  - Will be issuing a notice clarifying there is no max on KL2 slots
- **CCIA FOA renewed for FY19**
- **Enhancing Network Capacity (2 receipt dates FY19)**
- **Competitive Supplements for FY20 awards**
  - The administrative supplement is for additional activity within scope of the original award
  - The competitive supplement allows you to expand beyond what the original scope of the award
  - The council clearance occurred in September
- **Future CTSA Program hub FOA**
  - Will be developing a formal RFI process to obtain feedback on the FOA

### Helping to End Addiction Long-term (HEAL) Update

- Current Status: Concept cleared by NCATS and NINDS Advisory Councils
- Congress gave NIH \$500 M last year. NINDS and NIDA both received \$250 M. The money will have some special reporting requirements as FY18 is 2-year money.
- Early phases of pain management - Phase 1, Phase 2 and abandoned assets from pharmaceutical companies and other approaches. We proposed an effectiveness research network. If there is a need for a Phase 3 study, a pharmaceutical company should be the sponsor.
- NCATS has been contacted by NHLBI (Division of Cardiovascular Science) about utilizing CTSA Program resources for conducting studies. They came to the conclusion that setting up a network, the establishment time, the amount of infrastructure costs that go into creating a network – after 2 or 3 studies or after the questions get answered - it all goes away. They recognize this is not a long-term strategy. The capability of having a virtual network that is fairly flexible is advantageous to them.

### NIH MIGRATION TO THE “CLOUD”

- Developing standardization of measures and outcomes will allow data to be mined in a more efficient manner. Data will no longer be siloed as interoperability comes into play. This is how we envision NCATS moving forward. We are also moving towards centralized computing services. This is not being driven by NCATS, NIH or even HHS, but rather it’s a US wide initiative that is migrating much of what the government does to the cloud, and there is an expectation on our part to comply. The capabilities:
  - Provides cyber security
  - Can buy cloud computing capabilities at low cost
  - No institutional constraints to access the cloud
  - Collaborative team science activities

- Place for shared resources
- Enterprise Google Suites is secure. Not mined by Google. Secure
- Federated Authentication for everyone.
- APP store shared tool
- Data Access capabilities
- Educational portal
- Public private partnership forums.
- Will look to the community to help us find uses for this.

## Domain Task Force Review and Discussion

Objective: Overview of the current work by the DTFs and discussion of how the DTF structure can be optimized to address important areas of translational science

### Methods and Processes - Brad Evanoff, MD

The Methods and Process DTF is currently reviewing the next steps for their existing work groups and pursuing input for areas of interest for new work groups.

The Methods and Process DTF created a Concept Map which shows ideas in relation to one another.

- Each point represents a brainstormed idea
  - There are 140 different ideas boiled down to 90 ideas.
  - They have added some additional ideas from 2016 but still haven't done in the 2 years. Using a complicated mapping exercise to look at the new activities that will be in order to try to engage membership and get some strategic sense of what they are doing as a DTF and target future workgroup development.

### Regulatory Science to Advance Precision Medicine Work Group

- Initial results from the 2017 Forum
  - Two manuscripts developed have been accepted as publications
  - Hosted a 2017 conference in conjunction with Pharma that was focused around a regulation of digital printing of medical devices and around some of the regulatory aspects of precision medicine
- 2018 Forum was held on September 27
  - Hosted a conference in Washington DC focused on digital health
  - Results of that conference are now being written up to be presented
  - Breakout sessions explored specific areas opportunities & challenges related to user interface of mobile health

### Institutional Readiness for Team Science Workgroup

- Great Team Science Contest garnered 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
  - Stories will be shared with the CTSA Program network for applying and developing new initiatives
  - Possibility of making this an annual event
- Promotion and Tenure Paper manuscript is currently under peer review.

- Major finding a great deal of variability within institutions across their tenure and non-tenured faculty pathways in terms of how a team science and collaborations are rewarded or not rewarded in the tenure process.
- Dataset from this national study is available to others who are interested in seeing the data.
- C. Austin asked if there were recommendations about the importance of translational sciences.
  - Yes. There will be recommendations at the end. Findings will be shared.
  - **ACTION:** Will provide NCATS a pre-published copy of the manuscript.

## Collaboration and Engagement - Joel Tsevat, MD

Collaboration and Engagement have 4 work groups that are in the process of sun-setting in Q4 of 2018 and 1 workgroup that has sunset.

### Researcher Training & Education and Community Capacity Building

- Joint workgroup with Workforce Development DTF
  - Developing recommendations for NCATS and the CTSA Program 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 are in development; undergoing thorough WG review
  - Survey goals are capturing barriers and facilitators to community engagement and capturing the processes and methods undertaken by CTSA's to measure impact of community engagement
  - Surveys will be sent to CTSA Program hub PIs and their Community Partners in early January 2019
- Sunset: By September 2019

### Dissemination & Implementation Science (D&I)

- Proposed a special issue on D&I Science to the Journal of Clinical and Translational Science (JCTS); awaiting confirmation. They have 2 manuscripts in preparation and 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

### Forthcoming Plans

- 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 - want to involve the community engage research
- Volunteers have been identified to lead each WG

- Holding elections to replace 3 lead team members who are rotating off
- Would like to add a community representative to the lead team and need to address provisions for doing this.
  - C. Austin referred to a discussion that happened at NCATS Day, an annual event hosted by NCATS to engage with communities, patient advocacy groups, etc. We spent time discussing the relationship between patient and community engagement. We had friction between these two groups, but barriers are coming down and both see the value in engagement. Given recent discussions, we all want the same thing in terms of methods and involvement. However, each of these communities are quite different. Are you expanding the definition of community to include various kinds?
    - Yes, we are open to it and maybe we need to reconfigure our work groups to address this area of community engagement.
    - Penny Burgoon, Patricia Jones, and Paul Harris could provide considerable insights.
    - Patient groups are usually people that have a disease without any treatment options and so are very focused on T1 and T2, whereas the community folks have needs for treatments, but not the resources to focus on their specific needs.
  - E. Boulware contributed that she works in this arena and with their PCORI Engagement Award, PCORI could be a good partner over the struggle of Patient and Community groups.
  - **ACTION:** Consider Forums with PCORI, patient and community groups.

## Integration Across the Lifespan - Dan Cooper, MD

We need to understand how we create a single unit that looks at this huge scope of lifespan research and try to engage folks across the lifespan. How do we create a single meeting where folks from such a wide and diverse group can all meet together?

### 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.
  - Shari Barkin met with Michael Kurilla to identify the best use of the DTF structure to most effectively utilize the strengths of the CTSA to advance lifespan research.
  - We will be holding an election for one of the Lifespan Lead Team slots, 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)
  - 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 CTSA's are identifying and addressing life course \$\$
  - Toolkits - Measures \$\$\$
  - Training the pipeline in Lifespan research/training \$\$\$
- 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?
- The Lifespan DTF believes the group would function much more effectively if there were concrete goals, create teams and put together plans.
- Initial discussion with the Informatics groups - wondering how can we preserve the data from the floppy disks that are virtually non-translatable? Perhaps we use the electronic health record after it's been around for 50 years to look across the lifespan to trace human beings across their lifespan? Informatics and the Lifespan teams think this is an important topic and not a moot point
- Creating a toolkit is intriguing to this group. A common fund study called Motor Path Molecular Transducers of Physical Activity looked at how to exercise affects health and will be recruiting 2,700 people (no age limit). They went to the Lifespan DTF and received some pointers on how to recruit. Are we able to train the concept of training?
- Would like to put together a map of the gene expression across the lifespan

#### 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 (focused on sickle cell disease and cystic fibrosis) is under review at the Journal of Clinical and Translational Science
  - The group will be Sunset Winter 2019
- C. Austin suggested that just like the patient and community engagement groups, perhaps the different age groups of pediatrics and geriatrics could use a committee's help to hone in on common themes. One of them is Chronological vs Biological age and getting back to the idea that we have data from the EhR so we can begin to really do lifespan research and follow a human being across a 60—70 year period. Need to identify the gap between what is meant by lifespan.

#### Workforce Development – Susan S. Smyth, MD, PhD

We have spent much time in discussing the value of our DTF. We have worked to provide a sense of community in the workforce by sharing best practices, receiving feedback from all the hubs and widespread adoption of best practices.

Our DTF has been serving as an idea incubator in identifying needs across the workforce that address new work groups that can collect data and development of processes that have gone on to have funding via administrative supplements that are developed across several hubs.

- 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)

#### 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.
- DISSIMINATION 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
- This workgroup started in 2010 and developed federated platform for education resources which led to the funding of Enlightened and the clinical research training which is focused on clinical research professionals resulted in the Diamond award.

#### 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)

## 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

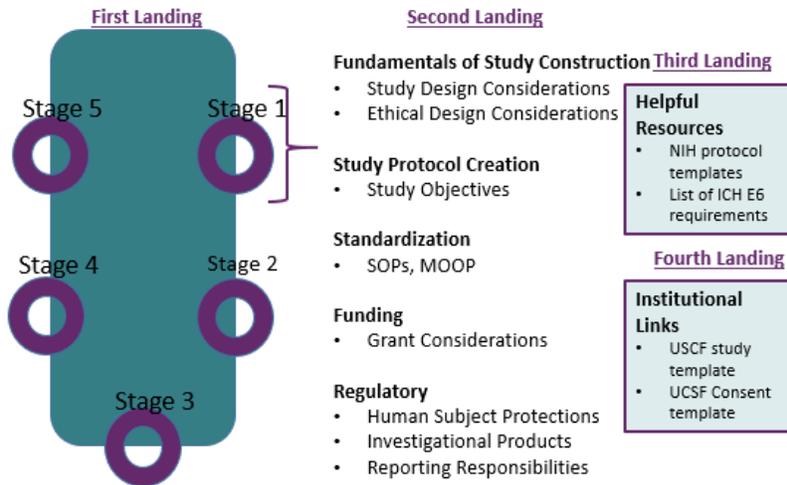
- map study operations and key roles, duties, and regulatory responsibilities
- embed links to timely information (e.g. CITI trainings, FDA & NIH tools/templates; DIAMOND discovery learning space resources)
- provide links to Hub-specific information

**DISSIMINATION 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



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 U24TR002200.

- The map has been developed to illustrate the Five Stages of Clinical research:
- Landing 1) When you land on this tool, you can click on the circle, initial or construction of the idea.
- Landing 2) Outline in the Cloud. Click on Stage One you'll go, to a second page and see a series of materials on study construction, protocols around the type, the roles for different individuals
- Landing 3) Will contain the NIH and hub specific links. Then you can access your hub specific links in different areas. (Still working on this to make each link available from online via the cloud. Will be hosting this on the CLIC website.

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
- **DISSIMINATION 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.

- Survey will be beta tested in fall and launched in the spring
- Will the Clinical Research Training be linked to the accreditation grant?
  - No, it will be used by investigators but I think will be heavily used by coordinators, managers.
- How will this be disseminated - this is a real implementation need? One of the investigators has applied for an internal funding from their institution to try to support this. A real need to implement, disseminate more broadly and through CLIC or CD2H mechanism.
- M. Zand asked who has been involved with ensuring the information is maintained and current? Need to make it interoperable and centralized to find everything, possibly link to the CD2h tools. Need to validate sustainability.
- M. Haendel - CD2H has been working with the DIAMOND infrastructure to support discovery, connectivity between the people, mentors and products so that things can actually be even field in many different access, but really helping the providers and actually be piped back to individual, have a website so that the whole system is being used. Actually create local dissemination. There's a much greater incentive to keep things up to date in that context as a whole ecosystem. The second point when people actually there's other competencies, educational resources being developed in other DTF and want to make sure how the different DTF structures relate to one another, and help support those other efforts.
- S. Smyth conveyed that this group is specifically taking the 4th landing will bring people to their own institutional specific resources for construction, protocol planning, startup implementation and study closeout.
- There is much controversy across the workforce and explains why it hasn't yet gotten tied into the accreditation.

## Informatics - Donald Lloyd-Jones, MD

### 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.
- 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

**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 31, 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 recruited.

## DTF Survey Results Discussion

Kathleen Brady, MD, PhD, Clare K. Schmitt, PhD, Martin S. Zand, MD, PhD

The CTSA Program Steering Committee Task Force on Enhancing the DTFs members are Kathleen Brady, Ebony Boulware, Brad Evanoff (Method/Processes DTF). Dan Cooper (Lifespan DTF, Melissa Haendel (CD2H), Donald Lloyd-Jones (Informatics DTF), Samantha Jonson (NCATS), Erica Rosemond (NACTS), Clare Schmitt (NCATS), Martin Zand, Joel Tsevat (Collaboration/Engagement DTF), Susan Smyth (Workforce DTF). CLIC Coordination - Catherine Fetherston, Scott McIntosh and Deborah Ossip.

The Task Force was created in November 2014.

- **Proposed: Retain function and rename to reflect function**
- **DTF Goals:**
  - 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 collaborative supplements
  - *PROPOSED: Revise structure and encourage cross-consortium collaborations*

### April 2018 Domain Task Force Packet/Updates

- 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, and 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

The DTF Survey - Key Responses (n=275) is generally supportive. The 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%) and “Right” Structure: 50% YES

\* *\*Yes includes only agree/strongly agree responses.*

The Issues Identified: communications, provide resources for DTFs; unfunded mandate, DTFs too broad; need focus, timelines, deliverables, strengthen Collaborative Efforts and 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

### 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
- The functions would remain the same, but will increase in some areas (i.e. discuss common interest gaps and opportunities).
- Represent the pods, some enhancement in the area of reviewing priority areas, the committees, the groups, and providing input on these priority areas, efforts and progress.
- Possibility to suggest PI webinars topics and serve as the planning committee for the annual meeting
- The Consortium Committee will retain the Administrators, KL2 and TL1 and keep the current functions (discussion forums, identify gaps and opportunities and generate and disseminate best practices.
- The DTF will transition in the Enterprise Committees and the functions will remain the same and promote collaboration across the key area identify gaps and opportunities and generate and disseminate best practices. Required output will be the annual report and CLIC is interested in putting together a brief template. We would like the Enterprise Committee member to give a verbal report to the SC on a call; so there will be a dialogue back and forth.
- The Steering Committee role would be to approve any executive committees (new or existing), review the annual report and topics.
- The Enterprise Committee (ECs) would have digital workspace and CLIC support. To protect CLIC resources, we should consider limiting the number, the size, and project duration of Enterprise Committees.

#### NCATS Proposals

- Elevate projects from DTFs/ECs into own space
- 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
- A proposal to the taskforce was to have substructure for the Enterprise Committees (i.e. work groups or discussion groups).
- The task forces (similar to the workgroup) functions are to consider and develop solutions around a specific translational science issue and create synergy across the consortium.
- Required output would be quarterly report
- Potential outputs could be papers, publications, workshops, conferences, and potentially funding through CCIA or supplements.
- Important to note that NCATS considers information from multiple sources for funding initiative topics.
- The Steering Committee would select challenge projects, help develop the taskforce team and review quarterly reports and provide input from these task forces.
- We would provide an NCATS POC, a digital workspace and CLIC support for calls, data analysis, and medical writers.

#### 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
- Bidirectional communication will take some efforts from the pod calls for feedback. We need to make it very easy for people to communicate and then click organizing that and disseminating it back.
- We will need community buy-in

#### 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

*(CLIC Forum launched two weeks ago).* It's a moderated forum where each of the current DTS have a space to have a conversation or an idea

- 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
- 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

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

Susan S. Smyth, MD, PhD

#### STARWORK Taskforce

This taskforce emerged out of conversations held during a SC call and at the 2017 Spring face-to-face meeting with regard to sustaining careers of our translational science clinical investigators. As most of our trainees are launching their careers as principle investigators, they typically begin in academics. Our focus will be in academics.

- 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 Collier, Rebecca Jackson, Samantha Jonson, Joan Nagel, Erica Rosemond, Doris Rubio, Joel Tsevat, Jason Umans, Emma Meagher, Kathryn Sandberg, Susan Smyth and Phil Kern

- Support: Karen Grabowski, CTSA Program SC Coordinator, CLIC, Heather Baker, Program Analyst, NCATS, Baidun Bayon, AAAS Fellow, NCATS

### KL2 Program Survey

The STARWORK Taskforce began its work in September 2018, and to fully understand and identify the barriers that exist, we chose the KL2 Scholars as our target population, and agreed that we needed to hear their experiences. We have decided to develop a KL2 program survey and look at how KL2 scholars are supported, collect data around debt reduction and look to present this information at the Spring Face-to-Face meeting in 2019. We are also looking at ways that we might be able to leverage other ICs, what we can learn from other disciplines; and how we're recognizing translational science from our investigator's perspective in the tenure and promotion process.

### The STARWORK Taskforce Tasks

The three areas below encompass the tasks to be completed.

- 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/Barrier

Below are the issues and barriers identified for further study.

- 1) Research support for translational scientists
  - a) How are KL2 Scholars supported after their KL2 ends?
  - b) Is a specific R pathway needed for the CTSA Program KL2 scholars?
  - c) Can other NIH institutes leverage the KL2 Program to advance the careers of translational scientists?
    - i) 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)
  - a) NIH Loan Repayment Program sufficient? What else is available?
- 3) Building Translational Science as a scientific discipline and field
  - a) Where does Translational Science "live" at academic medical centers?
  - b) What examples of building a discipline and field can we learn from? E.g. Genetics, Informatics, Data Science, Systems Biology, etc.
  - c) Recognizing Translational Scientists in the tenure and promotion process

### The timeline and deliverables include:

- 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)

Our second meeting on October 16<sup>th</sup>, involved discussions on the survey that will be administered to KL2 Scholars (This cohort will include 2008 – 2017 alumni individuals who have come off of their support from the KL2). The taskforce wanted to collect as broad of information as possible and analyze by year to understand the progression of issues that the group faces. NCATS will be providing the email addresses of the KL2 Scholars.

### Highlights from the Survey Questions

Some of the questions in the survey were derived out of work that Doris Rubio published on where she has collected information on KL2 trainees. The areas that we plan to capture characteristics of the KL2 scholars, include:

- *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*

### SC Discussion

Looking at the advanced draft of the KL2 survey, the SC members discussed the following points:

- Salary Question. This question is meant to get at whether their salaries were a barrier to pursuing careers as translational investigators.
- NCATS does have data on what has happened with the KL2 Scholars from an NIH perspective.  
**ACTION**: NCATS will provide emails of all KL2 scholars from IMPACII database (years: 2008-2017).  
**ACTION**: This list and emails will be confirmed by KL2 PIs with assistance from the KL2 PI Champions.
- Comparisons. Will allow us to start looking at things like time on a K tended to be longer than it is now as well as K to K and K to R transitions, as well as K to K comparisons.
- Other Potential Questions to consider asking:
  - How could the program could be improved?
  - What elements would you suggest adding to their career success?
  - How well did our program prepare you?
  - What could we do differently?
- Survey Population: Need a collective discussion on whether to approach those that FAILED.
  - In addition to KL2 Scholars, possibly find those people that we lost because it didn't work for them?
  - Need to rely on hubs to identify those people that didn't succeed.
  - Possibly ask the Dept. Chair why those people failed?
  - Careful, many questions are clinically focused.
- **ACTION**: Need a collective discussion on identifying SUCCESS. Other specific points regarding success included:
  - Some that dropped out have become very successful.
  - Be cautious about the score card approach
  - Reward structure is very critical to defining success. Need to include questions on the reward system
  - Have scholars write in and say what other ways they have contributed.
  - Have you participated implementation of new devices?
  - Need to have a business model that addresses the individual and defining success.

- What does success look like? Could be different for MDs, PhDs and MDPHds. These may not be the translational investigators that you're thinking about
- The rewards are at an individual level – promotion, tenured, individual accomplishments. Capture this from the scholars.
- Did your research experience help you with your medical practice?
- **ACTION:** need a collective discussion on identifying outcomes.
  - Collect data that would be informative around outcomes, not necessarily success because I agree all of us may define success differently.
- **ACTION:** need a collective discussion on how we are going to start tracking our broader impact.
  - Things that go beyond grants and publications, and impact the effects on health and disease?
- **ACTION:** need a collective discussion on the definition of a translational investigator.
  - Our concern was that anybody in our institution would right now say they are a translational investigator.
  - Pull out a little more clarity on where the primary focus was across the spectrum.
  - How do you train translational scientists?
- **ACTION:** need a collective discussion on lessons learned from other places.
  - I would say there are lessons to be learned in business schools.
  - Business schools teach how to work in teams.

Request for Approval and discussion about the survey questions.

- **QUESTION & DECISION:** We request your approval of understanding that we are still tweaking some of the questions in the survey, AND we would like to get approval to send the final survey out to the KL2 Scholar group. **The SC approved a survey to go to the KL2 Scholar Group and requested to review the survey prior to it being disseminated.**

## CTSA Program Steering Committee G-Suite Website Demo

Kenneth R. Gersing, MD, Samantha G. Jonson, MPS

K. Gersing and S. Jonson presented that as the federal government and the NIH is moving towards a cloud-based infrastructure and the most recent initiative to work with groups like Google, NCATS plans to roll out their initiative on providing a Google suite service to the Steering Committee.

The purpose is to keep information safe, confidential and in line with the Federal Information Security Management Act (FISMA). It will use federated logins.

The benefits include: a shared computing infrastructure, software analysis tools, shared data sets, investigator workspace, terminology services, G-Suite for Steering Committee, POD Suggestions Immediately open to all Steering Committee members, storage of articles, private discussion forums, communications workgroup, quick links to either NCATS or CLIC Websites.

They look to roll it out in early 2019, to NCATS, SC members, Pods and have it be mobile accessible and real time posting. S. Jonson will be sending out some directions.

## CTSA Program Steering Committee Structure

Kathleen Brady, MD, PhD, Christopher P. Austin, MD

As the Steering Committee members had a chance to review the Structure, Roles and Responsibility document, K. Brady and C. Austin led the discussion forward and posed two questions:

### 1. Do you all think there are too many Steering Committee members since the reconfiguration in 2014?

- “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.”
- With more than 10 -12 people on the call, there is a tendency to mentally check out, read emails and then it becomes anonymous. Most members like knowing why they are there and actively contribute.
- Size is fine for discussion and bouncing ideas off one another. As the consortium wants more communication, changing Pods, representing current DTFs – the size is perfect.
- **CONSIDER:** Size for decision making is difficult and it was suggested that a decision-making body might be helpful. Possibly create an Executive Steering Committee for decisions. When issues come up, it does help to flush out ideas within a smaller group.
- Believe the SC is much better than in past, the purpose is now becoming much clearer, and a larger number of people at the SC table ensures that PIs are more comfortable that their ideas are being heard.
- **DECISION:** Group is effective at bouncing ideas off one another, it is better than before, and members decide to keep the number of members as is.

### 2. Discussion Topic #2 – Administrator Appointment

The problem is that this role isn't really clearly identified in the grant itself and so we needed to flesh out a little bit more of the eligibility criteria. The administrator group is currently following criteria in their own special interest group.

- i. Serves as the key point of contact between the CTSA Program Leadership Program Directors
  - ii. Is well positioned to solve problems and provide input on ways to improve programs
  - iii. Enhances collaboration.
  - iv. Must demonstrate discretion
  - v. Deals with confidential and sensitive information.
- PI to nominate a person
  - May have more than one that does more financial, organizational.
  - Administrator is remarkable and possesses content knowledge, manages directors and has tremendous logistics.
  - **DECISION:** Steering Committee agrees there would be a benefit in having this role and agreed to go forward with the Administrator Nomination/Election Process.

## CTSA Branding: NCATS Designation of CTSA Centers

Barry S. Collier, MD and Martin S. Zand, MD, PhD

A concept that was brought up at the last Steering Committee meeting – CTSA Branding “OR” NCATS Designated CTSA Centers.

**1. Is this a concept the SC would recommend pursuing?** Discussion and comments included:

- Advantages: Same brand. It tells me something about the quality of the care that I'm going to get. Can we compare that with the notion of sustainability and funding? If the CTSA institutions meet certain criteria, it would get certain dollars. It helps support quality of translational science, not just making patients better today.
- Identifying stakeholders. We tried to think about some of the major stakeholders and how they might perceive the branding process.
  - Institutional leaders presumably they'd be interested in enhanced enrollment, getting high quality faculty, and attracting new patients.
  - The identity at our own institutions attract additional resources to support programs from the institution
  - For the patient advocacy groups, establish standard for identifying institutions of high quality and research
  - For the medical students, trainees and other healthcare professionals to enhance the prestige and attractiveness of careers and translational research and to be a benchmark for professional training in translational research
  - Enhance the identity with external stakeholders
  - It is for the PI to find a stable, sustainable and productive vision for the program that enhances the identity of CTSA and institution.
  - It is valuable to think about this from the standpoint of many different stakeholders. What the impact would likely be on them? What would be potentially perceived as benefits?
- Official Logo: NCATS designated CTSA Center. What would be required to have the official logo saying you are an NCATS designated a CTSA center? Could we launch a branding campaign that would be acceptable to the leadership?
- Complexity of Identity. The first CTSA Program award allowed the grantee to identify their hub as a department, a center or an institute, we now have a plethora of different designations. And so there's no uniformity.
- Is it a grant or program? People think of the CTSA as a grant, not as a program. And people think of programs very differently than they think about grants. We would need to recreate a *national uniform identity* that could be consistently branded. So first we're an institute and funded by institutional money. Then there's the hub award. As an institute we could have the little designation without having to change the name and would be able to prominently feature that designation.
- Angel Investors. I do think that part of the goal of the program is to be angel investors. We are angel investors of new ideas, education and in the workforce.
- The Community Engagement. The logo doesn't help the health system, but it needs to have brief clear messaging. If the Deans are not the right audience, perhaps it should be the community. If you have an advanced disease, or a rare disease, or a disease that does not have treatments coming up the pipeline, would

you rather go to a center that does not have access to clinical trials or to an NCATS designated CTSA center? I think we need to do community engagement with our hospitals reaching out to institutional leaders.

**2. How to handle minimum requirements, or do we have them at all?** Discussion and comments included:

- You have a CTSA award and that's it? What about maturity level? I bring up the minimum requirements as a suggestion because Cancer Centers have a minimum requirement of \$10,000,000 in the annual R01, R21 from NCI. Since we do not have that mechanism within NCATS, and if the comparison were made and there were some favorable way to do the attribution, it might help NCATS advocate for sustainable careers in the clinical and translational research. Additionally, the cancer centers benefit from the fact that the name of their grant and their identity in their home institution are identical and now we don't have that. This is an important point for follow-up as well.

**ACTION:** Need to perform due diligence and discuss with the CTSA Program consortium at tomorrow's Program meeting.

**ACTION:** Barry and Martin to put together a team and workspace and perform due diligence on the Branding Designation project. Determine members and consider questions above.

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

Christopher P. Austin, MD, Michael G. Kurilla, MD, PhD, Jane Atkinson, DDS

Funding of Appropriated \$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

There are three pillars to this approach (overdose, addiction, pain): 1) Find better treatments for overdose, 2) better approaches to addiction, and 3) pain management strategies.

With all hands-on deck, here are some of the 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*

#### Pain Management:

- The following was approved last summer.
  - 1) Pinpoint acute to chronic pain signatures to identify those at risk for transition to chronic pain and
  - 2) Discover and validate novel treatments for pain via:
- 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

#### Molecular Signature of Biomarkers:

- A big issue is that for people with acute pain, most of them did not develop chronic pain syndromes. Could we identify the molecular signature of a biomarker to identify those at risk of the transition to chronic pain now?
- Efforts are being made to developing human cell-based platforms for testing new treatments (iPSC-derived neurons for pain and reward pathways, 3-D Bio-printed Tissue Models, and 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 and development of investigational drugs ready for clinical testing.)

#### HEAL Pain Effectiveness Research Network:

- Current status is that the concept cleared by NCATS and NINDS Advisory Councils. We know that current pain management strategies are insufficient, including the long-term opioid use for chronic pain.
- Therefore, pain management is being addressed by establishing the HEAL Pain Effectiveness Research Network that will develop interventions and programs to manage acute and chronic pain.
- It will be necessary to leverage efforts of CTSA Program hubs/TIN to implement and execute clinical trials/studies of interest to multiple NIH Institutes, Centers and Offices.
- We will look to the support studies that provide evidence to inform practice-based guidelines as a catalyst for impact on our patients. Execution will include: 1) trials with standardized outcome measures enabling future meta-analyses, 2) data will be collected and stored centrally for future data sharing, and sites will not be restricted to a select group of network sites.
- The potential impact of the HEAL Pain-ERN is to 1) provide patients and practitioners with a suite of effective and data-driven strategies to alleviate pain, 2) demonstrate the flexibility of CTSA/TIN to rapidly facilitate clinical research of interest to NIH Institutes, Centers or Offices, and 3) develop standard measure and outcomes to allow comparison data across trials and may uncover new approaches for managing under-studied pain conditions.