NCATS Improving Health Through Smarter Science

CTSA Program Steering Committee

Monday, April 9, 2018

2:30 – 4:00 ET

CTSA Clinical & Translational Science Awards Program

NIH National Center for Advancing Translational Sciences

Agenda

Time	Topic	Moderator
2:30	Welcome	Christopher P. Austin Kathleen Brady
2:30 – 2:35	In-Person Steering Committee Agenda Update	Kathleen Brady
2:35 – 3:00	Common Metrics	Martin Zand (CLIC)
3:00 – 3:05	Approval: Communications Environmental Scan Survey	Debbie Ossip (CLIC)
3:05 – 3:55	Domain Taskforce Round Robin *(x~10 min each)* Collaboration/Engagement Informatics Integration Across the Lifespan Methods and Processes Workforce Development	 Joel Tsevat Donald Lloyd-Jones Dan Cooper Brad Evanoff Susan Smyth
3:55 – 4:00	Pod Discussions	All

National Center for Advancing Translational Sciences

In-Person Steering Committee Meeting Agenda

Kathleen Brady

CTSA Clinical & Translational Science Awards Program

CTSA Program Steering Committee (SC) Meeting

Marriott Wardman Park Hotel, Washington, DC
Lincoln Room #5
Wednesday, April 18, 2018

Agenda

7:30 – 8:00	**Registration**	
8:00 – 8:45	**Common Metrics Update**	**Moderated by Martin Zand**
	Objective: Status overview of the Common Metrics Initiative	
8:45 – 9:45	**Domain Task Force Discussion**	**Moderated by Erica Rosemond**
	Objective: Discussion of how the DTF structure can be optimized to address important areas of translational science within the 5 strategic goals of the CTSA Program.	
9:45 – 10:00	*Break*	
10:00 – 11:30	**2013 IOM Report and 2014 NCATS Council Working Group Report Retrospectives and Moving Forward**	
	10:00 – 10:20 Review of the Reports and Reflections on Accomplishments and Current (Ir)Relevance	**Christopher Austin**
	10:20 – 10:25 ModPod Reflections	**Barry Coller**
	10:25 – 10:30 Boulware Pod Reflections	**Ebony Boulware**
	10:30 – 11:30 Open Discussion: How can the CTSA Program consortium best address critical issues in clinical and translational research?	
11:30 – 11:45	**Wrap-Up/Prepare for Steering Committee Report Out at the CTSA Program Meeting [1:30 – 2:00]**	**All**
11:45	**Adjourn**	
11:45 – 12:00	Move to the Thurgood Marshall Ballroom; Grab lunch on your own	
12:00	CTSA Program Meeting begins	

Updated based on recurring feedback from pods.

National Center for Advancing Translational Sciences

Common Metrics

Martin Zand

Approval: Communications Environmental Scan Survey

Debbie Ossip

CTSA
Clinical & Translational Science Awards Program

CLIC
Center for Leading Innovation & Collaboration

Collaboration/Engagement DTF Update

Joel Tsevat, MD, MPH
UT Health San Antonio

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.

CTSA
Clinical & Translational Science Awards Program

CLIC
Center for Leading Innovation & Collaboration

Lead Team

- Sergio Aguilar-Gaxiola (UC Davis), Co-Lead
- Joel Tsevat (UTHSCSA), Co-Lead
- Louisa Stark (University of Utah)
- Syed Ahmed (MCW)
- Tabia Henry Akintobi (Emory)
- Patricia Jones (NCATS)
- Pam Whitcomb, DTF Coordinator (CLIC)

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.

CTSA
Clinical & Translational Science Awards Program

CLIC
Center for Leading Innovation & Collaboration

Goals

- Engaging stakeholder communities so they contribute meaningfully across the translational sciences spectrum
- Enabling team science to become a major academic model
- Ensuring that all translational science is performed in the context of collaborative team science and that shared leadership roles are the norm throughout the entire translational science process

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.

CTSA
Clinical & Translational Science Awards Program

CLIC
Center for Leading Innovation & Collaboration

Workgroups

1. Community Member Compensation – Sunsetted
2. Dissemination, Implementation and Knowledge Transfer
3. Joint Workgroup on Researcher Training & Education and Community Capacity Building
4. Developing Measures for Assessing and Improving Collaborations
5. Methods to Assess Community Engagement Strategies

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.

Community Member Compensation

- Developed a report summarizing current practices of community member compensation by CTSAs
- Developed guidelines for community member compensation for participating in DTFs (see DTF Governance and Operational Guidelines)
- Sunsetted in 2015

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.

Dissemination & Implementation (D&I)

- Report on initial survey results of D&I science activities across hubs – released March 2018
- Longer survey about D&I consultations, other resources, training, etc. being finalized
- Metrics for measuring D&I: Pilot-test metrics collection by volunteer CTSAs in 2018
- Create D&I consultation intake template
  - Complete environmental scan of individual D&I consultation templates by spring 2018
  - Develop D&I consultation intake template by fall 2018
- Manuscript(s) anticipated in fall 2018/winter 2019
- Sunset expected by end of 2018

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.

CTSA
Clinical & Translational Science Awards Program

CLIC
Center for Leading Innovation & Collaboration

Researcher Training & Education and Community Capacity Building

- Joint workgroup with WFD DTF
- Conduct pragmatic literature review of curricula and training resources to engaging communities → identified 99 articles
- Develop an inventory of existing curricula and training resources → identified 22 separate curricula
- Conduct gap analysis
  - Modified Delphi process → identified 9 competency domains
  - Focus on
    - Leadership
    - Regulatory support and knowledge
    - Ethics and responsible conduct of research
- Sunset anticipated at end of Q3 in 2018

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.

CTSA
Clinical & Translational Science Awards Program

CLIC
Center for Leading Innovation & Collaboration

Developing Measures for Assessing and Improving Collaborations

- Recommendations
  - For the Collaboration/ Engagement DTF
    - Update literature review biannually to identify new measures and new data on previously published indicators
    - Use standardized review protocol to review measures
  - For researchers and reviewers: studies assessing collaboration should describe measures and their reliability, validity, and generalizability
  - For NCATS
    - In the absence of robust measures, use interim measures
    - Support research to develop and test measures of collaboration and team science, with attention to partner and stakeholder relationships, the meaning of collaboration and engagement, and the quality and outcomes of collaboration
    - Develop a taxonomy of collaboration and engagement
- Manuscripts in preparation – anticipated by fall 2018
- Sunset anticipated fall 2018

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.

CTSA
Clinical & Translational Science Awards Program

CLIC
Center for Leading Innovation & Collaboration

Methods to Assess Community Engagement Strategies

- Systematic review of barriers and facilitators of community-engaged research
  - 617 articles identified: 49 included and 41 being evaluated for inclusion
  - Qualitative analysis underway
- Survey of hubs to ascertain barriers and facilitators and establish best practices planned for Q3 in 2018
- Sunset anticipated by March 2019

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.

CTSA Clinical & Translational Science Awards Program

CLIC Center for Leading Innovation & Collaboration

CLIC Center for Leading Innovation & Collaboration

CTSA Clinical & Translational Science Awards Program

Collaboration/ Engagement Domain Task Force
In-Person Meeting

Thursday, April 19, 2018
12:30 – 4:30 PM ET
Marriott Wardman Park Hotel | Washington, DC

AGENDA

TIME	TOPIC	PRESENTER(S)
12:00-12:30pm	**Registration**	
12:30-12:35	Welcome, Introduction and Meeting Objectives	*Co-chairs: Sergio Aguilar-Gaxiola, University of California, Davis and Joel Tsevat, University of Texas, San Antonio*
12:35-12:45	Overview of NCATS Initiatives	*Patricia Jones, NCATS*
12:45-12:50	Steering Committee/ Program Meeting Update	*Joel Tsevat, University of Texas, San Antonio*
12:50-1:30	Overview of Accomplishments/ Workgroup Updates	*Louisa Stark, University of Utah*
1:30-2:15	Table Discussion 1 – Team Science & Community Engagement	*Syed Ahmed, Medical College of Wisconsin*
2:15-2:30	**Break**	
2:30-3:15	Table Discussion 2 – Tools and Measures. What do we have and what do we need?	*Tabia Henry Akintobi, Emory University*
3:15-3:45	Group Discussion: Plan for moving the DTF forward -Making the DTF more productive -NCATS priorities -New Workgroup Suggestions	*Sergio Aguilar-Gaxiola, University of California, Davis and Joel Tsevat, University of Texas, San Antonio*
3:45-4:15	Summarization, Wrap Up and Next Steps	*Sergio Aguilar-Gaxiola, University of California, Davis and Joel Tsevat, University of Texas, San Antonio*
4:15-4:30	Open Networking	
4:30pm	Adjourn	

The University of Rochester Center for Leading Innovation and Collaboration (CLIC) is funded by the National Center for Advancing Translational Sciences at the National Institutes of Health under grant U24TR002260.
® The Clinical and Translational Science Awards (CTSA) is a registered trademark of DHHS

CTSA
Clinical & Translational Science Awards Program

CLIC
Center for Leading Innovation & Collaboration

UNIVERSITY of ROCHESTER MEDICAL CENTER

Informatics DTF & Working Group Review

Serving the CTSA Program through coordination, transparent communication, actionable metrics, network analytics and innovative collaboration tools.

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.

CTSA
Clinical & Translational Science Awards Program

CLIC
Center for Leading Innovation & Collaboration

Informatics DTF / WG Update

- The iDTF has been working well since inception.
- Generated a CTSA-wide informatics focused priority area analysis to identify working groups (WGs) resulting in the establishment of 4 WGs.
  - **Imaging Informatics (Sunsetted)** – First Goal was to survey CTSA hubs to determine the state of imaging informatics capabilities within the institutes.
    - ➢ Survey Results Presentation: https://rochester.box.com/s/69jzw3usvn62r0wr2ch4s83x9k9vhzt3
    - ➢ Determined there is a heterogeneous set of ad hoc solutions across institutes.
      - PACS systems adapted for research
      - Simple file systems
      - File exchange technology
      - Research imaging-specific tools like XNAT

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.

CTSA
Clinical & Translational Science Awards Program

CLIC
Center for Leading Innovation & Collaboration

Informatics DTF / WG Update

- Original WG update continued...
  - **EMR-based Research Recruitment (in collaboration with the Methods & Processes DTF – Sunsetted)** – They had multiple goals …
    - to develop best practices & recommendations regarding the use of EMRs to recruit potential research participants,
    - to develop educational materials targeting: IRBs, PCP/treating providers, & patients using EMR
    - Publication: A survey of practices for the use of electronic health records to support research recruitment published in the "Journal of Clinical and Translational Science" on September 19, 2017.
  - **Precision Medicine** (Disbanded due to overlap with the NIH national initiative)

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.

Informatics DTF / WG Update

- Original WG update continued...
  - **Sustainability Informatics Infrastructure** (Live) – Status: finalizing review & publication of white paper. Goal has been to examine the various components of institutional informatics resources in the context of sustainable funding & governance, identifying different informatics resources.
    - ➢ Surveyed all CTSA to identify the loci of institutional control & funding sources for these categories.
    - ➢ Will sunset in April 2018
    - ➢ Beginning of the next phase of a Sustainability WG in April 2018.

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.

CTSA
Clinical & Translational Science Awards Program

CLIC
Center for Leading Innovation & Collaboration

Informatics DTF / WG Update

- **Informatics Metrics** – the iDTF has worked closely with the Evaluation DTF and NCATS staff on the development & piloting of Informatics Metrics.
  - Conducted multiple discussions and surveys to identify both useful and feasible metrics for use at individual institutions.
    - Led to a focus on local data warehouses that could support cohort discovery at & across institutions.
  - Justin Starren, former Co-Lead of the iDTF, served on the Informatics Metric WG to convert the high-level metrics into concreate code.

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.

CTSA
Clinical & Translational Science Awards Program

CLIC
Center for Leading Innovation & Collaboration

Informatics DTF / WG Update

- **Current focus is the next generation of WGs and the coordination with CD2H interest groups to avoid topic and resource overlapping.**
  - Developed a list of priority areas after reviewing / comparing NCATS priorities, previously-determined priority areas for iDTF & CD2H interest group topics. This ranked list served as the basis for the March F2F iDTF Meeting agenda.
  - Goal: to identify a set of non-overlapping iDTF/CD2H WGs that advance the iDTF agenda.
  - A preliminary approach to determining if a suggested WG should be aligned with either iDTF or CD2H for support is to identify which WGs need what resources.

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.

Informatics DTF / WG Update

- **Suggestions for DTF Enhancements:**
  - Provide funding for human resources to complete WG aims
  - Formalizing coordination between iDTF and CD2H

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.

CTSA
Clinical & Translational Science Awards Program

CLIC
Center for Leading Innovation & Collaboration

Lifespan DTF Update

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

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.

CTSA
Clinical & Translational Science Awards Program

CLIC
Center for Leading Innovation & Collaboration

Lifespan DTF Accomplishments—April 9, 2018

CHAIR--Shari L. Barkin, M.D., M.S.H.S.
William K. Warren Foundation Chair in Medicine; Marian Wright Edelman Professor of Pediatrics; Director, Division of General Pediatrics
Vanderbilt University

Co-Chair—Dan M. Cooper MD
Associate Vice Chancellor Clinical and Translational Science
Professor of Pediatrics
UC Irvine College of Health Sciences

CTSA
Clinical & Translational Science Awards Program

CLIC
Center for Leading Innovation & Collaboration

Translational science is integrated across its multiple phases and disciplines within complex populations and across the individual lifespan.

CTSA
Clinical & Translational Science Awards Program

CLIC
Center for Leading Innovation & Collaboration

Lifespan DTF Workgroups

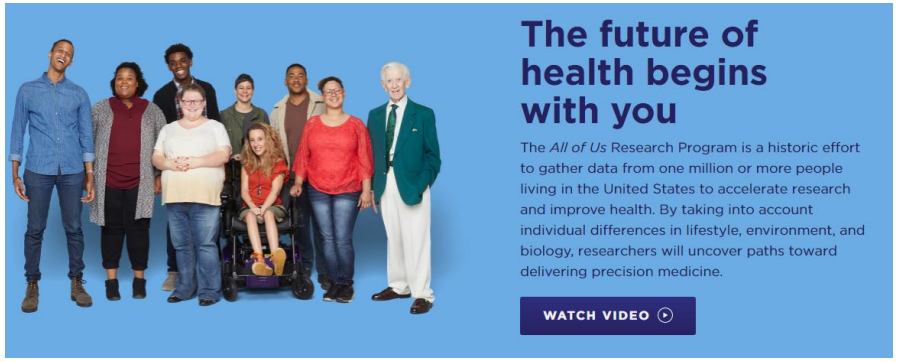
- Early life exposure
- Transitions across a single complex condition (such as sickle cell and cystic fibrosis)
- Older aging

CTSA
Clinical & Translational Science Awards Program

CLIC
Center for Leading Innovation & Collaboration

Lifespan DTF Accomplishments

We created conceptual framework to apply to lifespan research and used this to guide national initiatives such as Precision Medicine (All of Us) and the Environmental Influences on Child Health Outcomes (ECHO)



CTSA
Clinical & Translational Science Awards Program

CLIC
Center for Leading Innovation & Collaboration

Molecular Transducers of Physical Activity in Humans (MoTrPAC).

Common Fund Programs | Common Fund Research Funding | News & Media | Common Fund High

Molecular Transducers of Physical Activity in Humans

Common Fund » Common Fund Programs » Molecular Transducers of Physical Activity in Humans

Molecular Transducers of Physical Activity in Humans

For the Public

- Public Health Relevance
- Press Releases
- In the News

For Researchers

- Funded Research
- Funding Opportunities
- Meetings
- NIH Working Group
- Program Resources

Astronaut Dr. Peggy Whitson helps the MoTrPAC group!

Astronaut Dr. Peggy Whitson helped make a recruitment video for the MoTrPAC group. Check back soon to see the video. Thanks Dr. Whitson!

CTSA
Clinical & Translational Science Awards Program

CLIC
Center for Leading Innovation & Collaboration

Lifespan DTF Accomplishments

- Survey to assess existing resources for lifespan researchers
- This work has been accepted for publication

CTSA
Clinical & Translational Science Awards Program

CLIC
Center for Leading Innovation & Collaboration

Lifespan DTF Accomplishments

A webinar was held that included community organizations such as the March of Dimes and the Cystic Fibrosis Foundation to examine lifespan research contributions for diseases that last a lifetime. This work will be submitted as a white paper by March 201

CTSA
Clinical & Translational Science Awards Program

CLIC
Center for Leading Innovation & Collaboration

Lifespan DTF Recommendations for Continuous Improvement

There is consensus among the membership that absent a specific budget controlled by the DTF in collaboration with NCATS, the ability of DTF members to continue to achieve DTF goals consonant with the broad objectives of NCATS will be unsustainable.

Shari Barkin MD and Dan M. Cooper MD
Originally Approved by the DTF on September 17, 2017

CTSA
Clinical & Translational Science Awards Program

CLIC
Center for Leading Innovation & Collaboration

Specific Recommendation #1:
Lifespan DTF--sponsored focused meetings and conferences.

Rationale: The multi-institutional and multidisciplinary nature of the lifespan DTF has led to a number of potentially transformative action items

CTSA
Clinical & Translational Science Awards Program

CLIC
Center for Leading Innovation & Collaboration

Example: The creation of "Lifespan Clinical Research Toolkit" was conceived to offer a wide spectrum of investigators a set of best-practices in this emerging field that could guide study design and conduct for a myriad of novel research endeavors.

The Toolkit would include:

- Recruitment strategies that account for differences between biological and chronologic age
- Approaches to data maintenance over long time intervals
- Novel approaches to lifespan research utilizing EHRs
- Access to existing databases and registries that could enhance the lifespan impact of a particular study

Budget: 3 conferences per year, selected competitively. $12,000 per conference= $36,000

CTSA
Clinical & Translational Science Awards Program

CLIC
Center for Leading Innovation & Collaboration

Specific Recommendation #2:
Team Building Conferences to support child health focused investigator-initiated multicenter trials

Rationale: Building on the success of NCATS supported CHAMP (Child Health research Acceleration thru Multisite Planning) experience; our proposal is for the Lifespan DTF to support the catalysis of lifespan research clinical studies at their very earliest, critical stages.

CTSA
Clinical & Translational Science Awards Program

CLIC
Center for Leading Innovation & Collaboration

Example: Team building conferences in which competitively selected groups of researchers would have an initial face-to-face meeting to:

- Develop an organization plan
- Establish a data management strategy
- Identify specific short term goals
- Plan for extramurally funding thru grant mechanisms

Each selected team would, upon successful completion of the incubator tasks, be allocated a small pilot fund to enhance competitiveness for additional extramural funding.

Budget:

- 3 team building conferences per year @ $15,000 each = $45,000
- 3 pilot funds for each team at @$25,000 each = $75,000

CTSA
Clinical & Translational Science Awards Program

CLIC
Center for Leading Innovation & Collaboration

Specific Recommendation #3:
DTF Leadership and Administration

Rationale: The action items outlined above cannot be accomplished without skilled leadership and monitoring of metrics and milestones. We endorse the current leadership structure of co-chairs in which one co-chair is a CTSA PI and the other is selected from talented investigators with relevant experience. It is not possible in the challenging resource environment at all academic health centers, to ask the other co-chair to assume leadership responsibility without compensation

CTSA
Clinical & Translational Science Awards Program

CLIC
Center for Leading Innovation & Collaboration

Proposed DTF Leadership Budget:

- PI Co-Chair: Leadership remuneration included in parent CTSA
- DTF Co-Chair: 10% effort
- Administrative support: 1 full FTE

CTSA
Clinical & Translational Science Awards Program

CLIC
Center for Leading Innovation & Collaboration

Methods and Processes DTF Update

Brad Evanoff, M.D.
Washington University of St. Louis

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.

CTSA
Clinical & Translational Science Awards Program

CLIC
Center for Leading Innovation & Collaboration

Methods and Processes Domain Task Force:

1. Enable CTSA programs to function individually and together as a research engine to transform the way translational science is conducted.
2. Rapidly translate CTSA-generated new knowledge and technologies into health interventions in real world settings.
3. Develop technologies, methods, data, analytics and resources that change how translational scientists approach their work.
4. Generate and curate comprehensive data sets or other resources that catalyze science.

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.

EMR-Based Research Recruitment Working Group

Objective: Develop best practices / recommendations regarding the use of EHR's to recruit potential research participants.

Key Deliverable: Develop educational materials targeting IRBs, PCP/treating providers and patients regarding the recruitment process using EHR's. Develop white paper.

Status: Paper published in conjunction with iDTF: Obeid JS et al. A Survey of Practices for the Use of Electronic Records to Support Research Recruitment. JCTS (2017). Workgroup has been sunsetted.

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.

CTSA
Clinical & Translational Science Awards Program

CLIC
Center for Leading Innovation & Collaboration

Designing & Analyzing Clinical Trials for Personalized Medicine (DACTPerM) Working Group

Objective: Develop methodology and best practice guidelines for clinical trial design where treatments are being investigated or tested in several groups of patients, with the goal of matching patients to the treatments most likely to deliver benefit.

Key Deliverable: Produce and disseminate a white paper that will offer guidelines for designing and analyzing clinical trials for personalized medicine and testing heterogeneity of treatment effects.

Status: Workgroup has been sunsetted. White paper in progress.

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.

Institutional Readiness for Team Science Working Group

Objectives: Assess institutional support for team science at multiple CTSA institutions, develop a means to capture and publicize team science.

Key Deliverables: Document review of relevant materials (e.g., policies for promotion and tenure and indirect cost sharing);Survey of institutional leaders regarding available institutional resources and their opinions about team science; Great Team Science Contest

Status:

- Documents acquired from all CTSAs; preliminary data analysis performed
- The Great Team Science Contest - subcommittees have met; will launch soon with results announced at Fall CTSA meeting.

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.

CTSA
Clinical & Translational Science Awards Program

CLIC
Center for Leading Innovation & Collaboration

Regulatory Science to Advance Precision Medicine Working Group

Key Objectives: Identify and formulate specific regulatory science topics and opportunities to accelerate precision medicine. Conduct two Forums on Regulatory Science to Advance Precision Medicine that will provide recommendations to inform regulatory approaches and decision tools (and develop educational materials).

Key Deliverables: The Working Group will produce background materials will frame the specific issues for the two Forums, with white papers and educational resources to follow from the Forum. Share (or if necessary develop) state-of-the-science papers in specific areas that will further advise the Forum and be disseminated more broadly.

Status: First Forum held 9/2017; Papers in progress; Second Forum planned 9/2018

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.

Regulatory Science to Advance Precision Medicine Forum

First Forum: (PhRMA Foundation, UR CTSI and UVa VCTRS)

- Regulatory considerations for 3D printing of medical products (in combination with cell products)
- Technologies and approaches that integrate and analyze genomic, proteomic, metabolomic, and/or epigenetic data for precision medicine

Second Forum: 9/27/18 at PhRMA Foundation (DC): Topic = Digital Health

- Software: algorithms and data analytics approaches - how to assess/validate?
- Sensors: static and mobile
- Address: emerging science/R&D, regulatory considerations, data - storage & use, ethics, privacy

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.

CTSA
Clinical & Translational Science Awards Program

CLIC
Center for Leading Innovation & Collaboration

Pithy DTF Feedback

- The barriers to doing something meaningful in a Work Group are very high - unfunded collaboration to achieve consensus in >50 groups.
- A big time sink for those who lead the workgroups, a modest time sink for those who participate meaningfully, and a total waste of everyone's time that some feel compelled to be "engaged" but don't meaningfully participate.
- Although this group will have a deliverable in the form of a paper that will highlight potential barriers to team science (most of which we already know), this will have little impact without an in-depth analysis of what works and doesn't, next-step action items, best practices for institutions to follow, etc.

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.

CTSA
Clinical & Translational Science Awards Program

CLIC
Center for Leading Innovation & Collaboration

Suggestions for DTF Enhancement

- Use DTF as organizing platform for applying for grants (such as NCATS Collaborative Innovation Award) to support projects that need resources beyond those required for white papers or surveys
- Consider opportunities for trans-DTF workgroups suited to M&P
- Develop a formal evaluation process of the DTF effort – outputs and impacts
- Develop best practices for Work Groups that would streamline the process
- Smaller groups and in-person meetings would be more productive.
- Clearly identified problems/gaps (possibly identified by CTSA leadership) for the group to address would be more productive.
- An implementable end product or an implementable answer to a specific question (e.g., how can the NIH/CTSA promote team science) should be the deliverable.
- Consider an Evaluation DTF; all CTSA's struggle with how to evaluate meaningfully

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.

CTSA
Clinical & Translational Science Awards Program

CLIC
Center for Leading Innovation & Collaboration

Methods & Processes Domain Task Force In-Person Meeting

Thursday, April 19, 2018, 8:30 AM – 11:30 AM ET
Marriott Wardman Park Hotel | Washington, DC
Room: Lincoln Room #4 (Exhibition Level)

TIME	TOPIC	PRESENTER
8:00 -8:30 am	Registration Meet & Greet Session – Continental Breakfast available	
8:30 – 8:35 am	Welcome, Introductions & Meeting Overview	Brad Pollock Brad Evanoff
8:35- 8:45 am	NCATS News & Updates	H. Timothy Hsiao
8:45 – 8:50 am	Steering Committee Update	Brad Evanoff
WORKING GROUP UPDATES		
8:50 – 9:20 am	Institutional Readiness for Team Science Working Group	Rebecca Moen Debbie DiazGranados
9:20 – 9:50 am	Regulatory Science to Advance Precision Medicine Working Group	Scott Steele Joan Adamo
9:50 – 10:05 am	Break – beverages will be provided	
10:05 – 10:10 am	Presentation: • Collaborative Business Development	H. Timothy Hsiao
10:10 – 11:20 am	Discussion: • Evolution of Methods & Processes DTF Working Groups	All
11:20 – 11:30 am	Next Steps and Closing Remarks	Brad Pollock Brad Evanoff

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.

CTSA
Clinical & Translational Science Awards Program

CLIC
Center for Leading Innovation & Collaboration

UNIVERSITY of ROCHESTER MEDICAL CENTER

Domain Task Force Update to Steering Committee

Serving the CTSA Program through coordination, transparent communication, actionable metrics, network analytics and innovative collaboration tools.

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.

CTSA
Clinical & Translational Science Awards Program

CLIC
Center for Leading Innovation & Collaboration

DTF – Workforce Development Value

- Created a collaborative cohort of interested individuals

↓

- Provide opportunity to share best practices across hubs
- Provide a sense of community for CTS education, training, and workforce development

↓

- Provide a mechanism to leverage the power of the Consortium to impact the CTS workforce

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.

CTSA
Clinical & Translational Science Awards Program

CLIC
Center for Leading Innovation & Collaboration

DTF – Workforce Development Focus

- Holistic approach to the entire spectrum of the workforce

- **Horizontal integration** across the investigator lifespan

pre / post-doctoral (TL1) ⟷ early faculty (KL2) ⟷ beyond

- **Vertical integration** across the entire workforce

trainees ⟷ investigators

CTS team members

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.

CTSA
Clinical & Translational Science Awards Program

CLIC
Center for Leading Innovation & Collaboration

DTF – Workforce Development Update

- 4 active working groups (WG)

- 2 funded studies developed from WG
  - N-Lighten Network, a semantically anchored federated educational resources sharing platform (WG 2)
  - DIAMOND, clinical research coordinator training and development of competency assessments (WG3).

- DTF provides stakeholder feedback and facilitates more widespread adoption.

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.

CTSA
Clinical & Translational Science Awards Program

CLIC
Center for Leading Innovation & Collaboration

DTF WG1 – TL1 Survey

Translational Science Impact Statement

- Survey the scope of activities supported by the CTSA to promote the training and career success of clinical and translational investigators prior to their having faculty appointments. Identify and disseminate best practices for preparing trainees for careers in translational science. Develop a basic dataset that may be useful for future identification of practices that have the most impact on clinical and translational research training.

Project Timeline

- We have been working for about 4 months to develop a survey. The work has been slowed by the complexity of addressing similar but non-identical concerns for pre-doctoral, postdoctoral and short-term training. We also have been careful to incorporate lessons learned from issues that arose during the KL2 survey. We hope to have a pre-survey completed and the final survey ready for release by late summer or early autumn.

Sunset Criteria

- The plan is to: 1) complete the survey, 2) analyze the data and 3) prepare and publish a report on our findings for the CTR community. When these are accomplished our work will be complete.

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.

CTSA
Clinical & Translational Science Awards Program

CLIC
Center for Leading Innovation & Collaboration

DTF WG2 – Federated Education Platform: Harmonizing Competencies

Translational Science Impact Statement

- The Harmonizing Competency group is answering a call to harmonize competencies (97) identified by the CTSA KFC in 2011 to reduce overlap and improve their usefulness across academia, industry, government, and philanthropy organizations. We are working from the concept of Personalized Pathways developed within the CTSA Consortium to acknowledge that not all learners need to achieve the same level of mastery in all the domains specified in the core competencies. Rather, to optimize the efficacy of and efficiency in training, we will offer guidance to develop a tailored IDP approach for a learner's desired career path, or "phenotype".

Project Timeline

Jan-Nov 2016
Identification of:
- Career Phenotypes
- Mastery level Definitions

Dec 2016
- IRB Submission

Jan 2017
- Pilot Survey testing to HC member-ship

Feb 2017
- Validate/ Update Survey Instrument

March 2017
- Complete Workforce DTF invited to complete survey

Aug 2017 – Jan 2018
- Analysis and Discussion of survey results

March – April 2018
- Manuscript development

Sunset Criteria

- Disseminating methodology and results via publication and posting the new tailored knowledge, skills and attributes (KSA) for different career pathways on the CLIC public-facing website.

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.

DTF WG3 – Clinical Research Training for Investigators

CTSA
Clinical & Translational Science Awards Program

CLIC
Center for Leading Innovation & Collaboration

Translational Science Impact Statement

- Complementing trainings on clinical research, we need to build proficiency in the "how to" of performing clinical research. Process workflows to guide researchers through the stages of the study lifecycle will help develop the logistical know-how to effectively execute studies from protocol development to study closeout. Our Work Group is developing interactive workflows to: (1) map study operations and key roles, duties, and regulatory responsibilities at each step, (2) embed links to timely information along the way (e.g. CITI trainings, FDA & NIH tools/templates; DIAMOND discovery learning space resources), and (3) provide links to Hub-specific instructions, forms, and check-lists from individual CTSAs so their researchers can employ them—*in real time*—as they progress through the workflows

Project Timeline

Tasks	Apr	May	June	July	Aug	Sept	Oct	Nov
Subgroups finalize Stage & Thread process outlines: key personnel, step-by-step tasks, regulatory duties								
Decide work flow format: Stage & Threads build and populate work flows with outline content								
Compile links to relevant FDA & NIH tools, CITI trainings, Diamond resources for Study Stages & Threads								
Build inventory of work Group members institution links to Hub-specific instructions, forms & Check-lists								
Edit, finalize, and approve Stage-Thread composite matrix and content								
Integrate content and links into work flow and active learning modules								
Present to DTF for approval, follow-up with CLIC on informatics platform (possibly Informatics DTF?)								
Project Completion								

Sunset Criteria

- Completion of Stage-Thread matrix and content and dissemination through CLIC or CD2H OR lack of progress as defined by not meeting project milestones within 2 months of proposed date

the Clinical and Translational Science Awards (CTSA)
nstitutes of Health (NIH), Grant U24TR002260.

CTSA
Clinical & Translational Science Awards Program

CLIC
Center for Leading Innovation & Collaboration

DTF WG4 – Best Practices for Mentoring and Supporting KL2

Translational Science Impact Statement

- Provide program-reported information of current organization, leadership, programmatic foci, practices and impact of KL2 programs
- Provide program-level aggregate data on short- and mid-term scholar outcomes related to career path, trajectory, and productivity and relate these outcomes to program characteristics and practices •Identify additional KL2 programmatic features and measures of interest to the translational research training programs which have not been tracked successfully, uniformly and with acceptable participant burden in the past.

Project Timeline

- We designed, iteratively tested and refined, administered and have completed our survey, with 90% response by KL2 program directors and administrators. Initial data reduction, cleaning, and analysis identified several challenges in the dataset as well as domains of general interest for which limited data are readily available to most programs. Two waves of analysis have been shared with the full DTF as well as with the newly-constituted KL2 directors group and final analyses are in progress. Plan is to present to full DTF and to KL2 PDs at spring face-to-face meeting, manuscript submission, and sharing of data for further analyses. Lessons from KL2 survey are contributing to more efficient design of TL1-focused survey.

Sunset Criteria

- Following completion of currently planned analyses, publication of the main analyses and conclusions, and archiving of data in an accessible manner to facilitate future use by the DTF, the main work of the subgroup will be complete. We will continue to work with the TL1 survey subgroup on conduct of the TL1-focused survey, reporting of its results, and archiving of those data. Work of the full working group will then be complete.

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.

CTSA
Clinical & Translational Science Awards Program

CLIC
Center for Leading Innovation & Collaboration

DTF – Workforce Development Enhancement Strategies and Next Steps

- Promote sharing and dissemination of resources that have been developed
  - (1) greater use of IGNITE presentations and posting of these opportunities on CLIC with links to the proposing CTSA hubs and
  - (2) adoption of a federated educational platform for educational resource discovery and access.
- Consider ways to harmonize across T32 and K12 programs (non-NCATS)
- DTF has developed robust mechanism for proposing ideas from ground-up; would benefit from additional top-down charge and direction from steering committee.

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.

CTSA
Clinical & Translational Science Awards Program

CLIC
Center for Leading Innovation & Collaboration

DTF – Workforce Development Enhancement

- We believe that each CTSA hub has developed many unique educational resources, approaches and tools that will enable the career development for the translational science workforce.
- In order to enhance efficiency, increase accessibility and adoption to unique resources and minimize redundancies, we believe that the DTF must be engaged in promotion of sharing and dissemination of these resources through two approaches:
- (1) greater use of IGNITE presentations and posting of these opportunities on CLIC with links to the proposing CTSA hubs and
- (2) adoption of a federated educational platform for educational resource discovery and access.
- This former facilitates cross-CTSA efforts to translate ideas from 1 hub to assessment of its generalizability then dissemination more broadly whereas the latter can also serve as a way to disseminate resources from the CTSA Consortium including the output from WG and funded efforts across CTSA hubs and to the larger clinical and translational science community.

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.

CTSA
Clinical & Translational Science Awards Program

CLIC
Center for Leading Innovation & Collaboration

DTF – Workforce Development Update

- The Workforce Development DTF has focused on supporting working groups and sharing best practices that impact the training and career development for the full spectrum of the clinical and translational scientific workforce, ranging from investigators [from pre and postdoctoral trainees and early career faculty (KL2 program)] to research coordinators/nurses and other members of the research team.
- In addition to supporting and sharing updates on the progress of the 4 active working groups as described below, two funded studies (the N-Lighten Network, a semantically anchored federated educational resources sharing platform (linked to DTF WG 2) and DIAMOND, clinical research coordinator training and development of competency assessments, grew out of previous DTF efforts and remain aligned to DTF goals and complement efforts of working groups (WG2 for N-Lighten and WG3 for DIAMOND).
- As these projects progress, the DTF will serve to provide critically important stakeholder feedback to the projects to ensure that these projects meet the CTSA educational community needs and to facilitate more widespread adoption. To share best practices and to enhance dissemination and adoption of unique programs, approaches and tools for career development across CTSA hubs, the DTF includes IGNITE presentations (short 3-4 slide presentations highlighting the problem addressed, the approach and outcomes and steps for dissemination) on DTF calls.
- A brief summary of each of these opportunities is then placed on the DTF website to facilitate engagement.
- Finally, with the development of the KL2 and TL1 PI groups, the focus of the DTF is to complement the efforts of these groups by integrating efforts that support training across the entire career pipeline and across the entire workforce.

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.

Pod Feedback Discussion

All

Pod Structure Feedback Report

[Feb 2018]

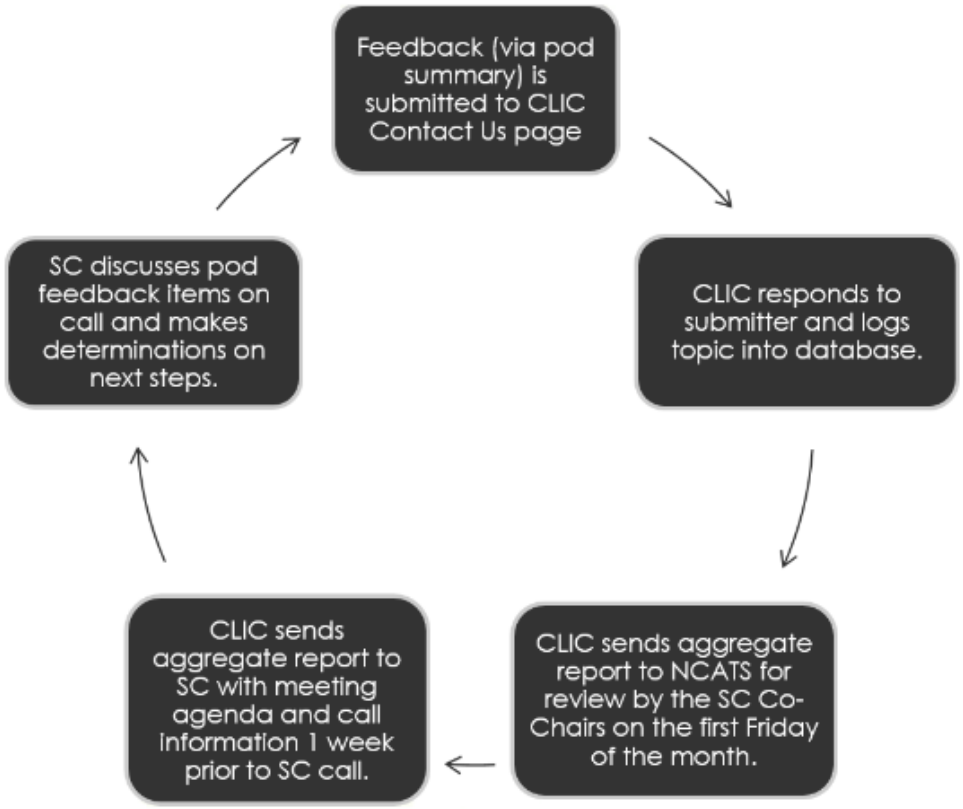
STEERING COMMITTEE DISCUSSION

The Communications Workgroup to the Steering Committee reviewed this report on January 31, 2018. This full CTSA Program Steering Committee reviewed this report on February 12, 2018.

The Steering Committee has decided to move forward with the following:

- Pods to continue to hold calls preferably 1-2 months or every 4-6 weeks.
- Pods can determine their own recurrence that works best for their pod group.
- See proposed pod feedback structure below.
- NCATS will add dedicated time on the agenda to review pod feedback on SC calls.

POD FEEDBACK STRUCTURE



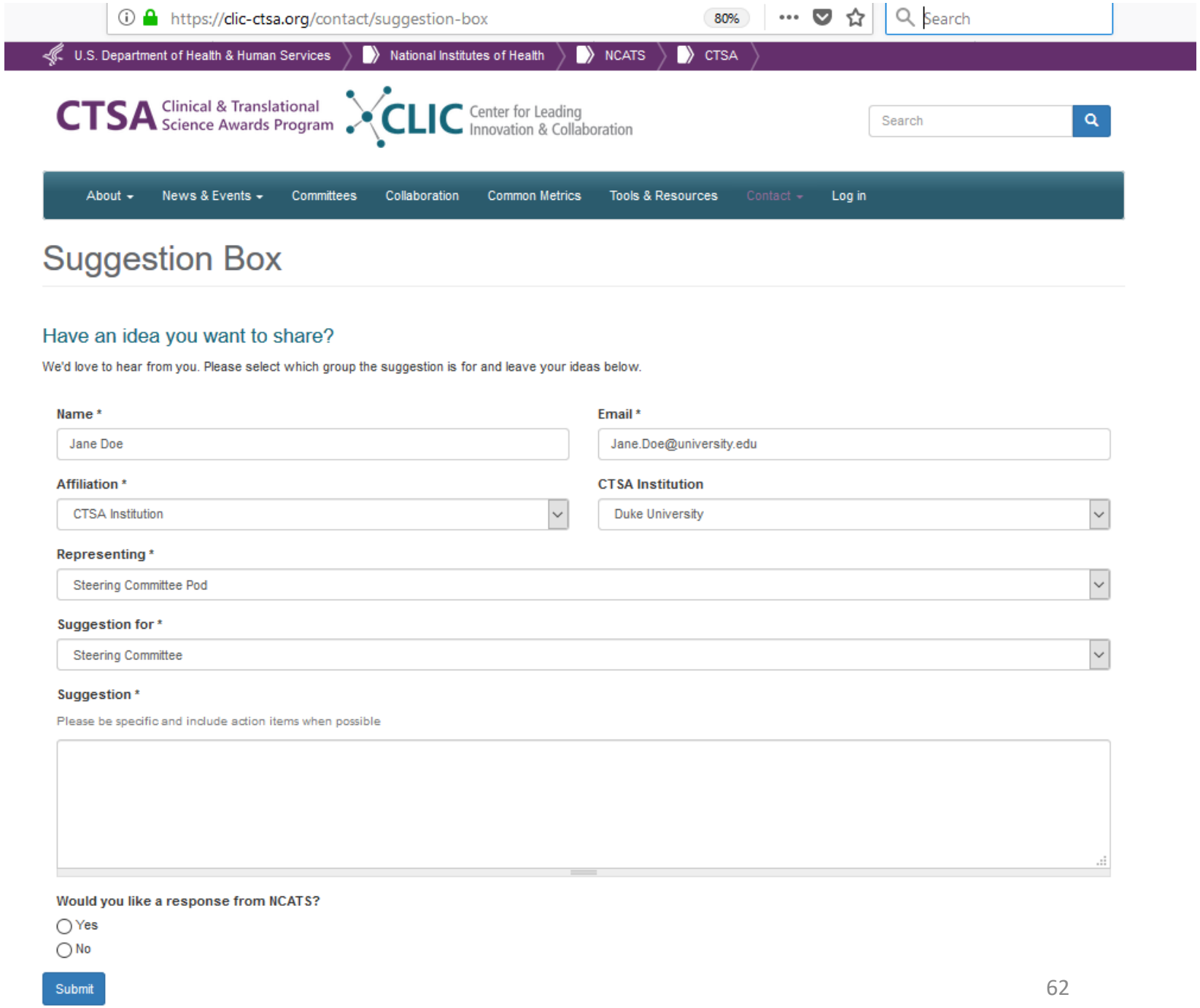
Prepared by CLIC_February 2018

The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health's National Center for Advancing Translational Sciences.

National Center for Advancing Translational Sciences

Pods

- Pods should send their pod feedback to the SC Co-Chairs via the CLIC suggestion box.
- CLIC provides monthly report to NCATS at the end of the month
- Bullet points of major issues/ concerns of topics discussed
- Detailed meeting summaries are not necessary



National Center for Advancing Translational Sciences

Thank you!

See you in DC.