CTSA Program Steering Committee

November 26, 2018

3:00 – 4:30 ET

Agenda

3:00 – 3:05	Welcome	Kathleen Brady, Christopher Austin
3:05 – 3:15	NCATS Update	Christopher Austin
3:15 – 3:25	Steering Committee Taskforce on Sustaining the Translational Science Workforce (STARWORK) Update	Susan Smyth
3:25 – 3:30	DTF Work Group Update	Clare Schmitt, Kathleen Brady
3:30 – 4:05	Common Metrics Initiative: 2018 Activities and Beyond	Martin Zand, Deborah Ossip (CLIC)
4:05 – 4:30	*Note: Pod Feedback and Discussion was tabled to the next call scheduled for:* *Monday, December 11, 2018, 2:30 – 4:00 pm ET.*	*Discussion facilitated by:* *Christopher Austin* *Kathleen Brady* *Michael Kurilla*

National Center for Advancing Translational Sciences

NCATS Director's Update – FY 2019 Budget

- Congress tried new approach this year
  - Labor/HHS/Education bill usually saved until end, due to contentious provisions
  - This year -- Congress combined Defense bill with Labor/HHS/Education bill into a "minibus"
    - Included priorities for both Republicans and Democrats
    - Did not contain any "poison pills"
    - Also included Continuing Resolution (CR) for any appropriation bills that did not pass
- Two different minibuses cover 5 of the 12 annual appropriation bills
  - Energy-Water, Military Construction-VA, and Legislative Branch: became law on Sept. 21
  - ***Defense and Labor-HHS-Education: became law on Sept. 28***
- Seven remaining appropriation bills not passed
  - Affected agencies operating under a Continuing Resolution (CR) through 12/7/18 (after mid-term elections)
  - If nothing happens by 12/7/18, there could be a partial gov't shutdown, but NIH would still be open

NIH
National Center for Advancing Translational Sciences

FY 2019 Budget Process

- Minibus: Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019
- Budget Amounts
  - NIH: $39.084 billion ($2 billion increase, or 5.4%, above FY18)
  - NCATS:

	FY 2017 ($M)	FY 2018 ($M)	FY 2019 ($M)
NCATS	**705.9**	**742.4**	**806.4**
CTSA	516.1	542.8	559.8
CAN	25.8	25.8	“up to 80.0”

Seeking New Steering Committee Members

NCATS is seeking nominations for new CTSA Program Steering Committee (SC) members! **We have 5 total slots available – 4 UL1 PIs and 1 Administrator SC member.** If you would like to self-nominate or suggest a fellow PI, please submit the PI name, institution, and brief explanation (no longer than 1 paragraph) to Samantha Jonson (Samantha.Jonson@nih.gov) by **Friday, November 30th**.

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

- A PI must be officially named in the Notice of Grant Award of an active CTSA Program hub
- An Administrator is the key point of contact between their institution's CTSA Program leadership and Program Directors, and NCATS personnel
- An "active" award is defined as a hub award that is not in a No-Cost Extension (NCE). A PI or Administrator whose hub award in an NCE is not considered eligible as there is insufficient time remaining in the award project period for initiation of an appointment.
- For both PIs and Administrator, their hub award must have at least 3 years remaining during the project period
- An eligible PI has not served on the SC since December 2014

To learn more about the roles and responsibilities, please visit this web page.

National Center for Advancing Translational Sciences

Driving Innovation: NCATS Programs to Support Small Businesses & Research Organizations

Are you an entrepreneur launching a biotech or healthcare technology business and finding the funding landscape to be complex? Learn about programs and resources from the National Institutes of Health's National Center for Advancing Translational Sciences (NCATS), including its Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs.

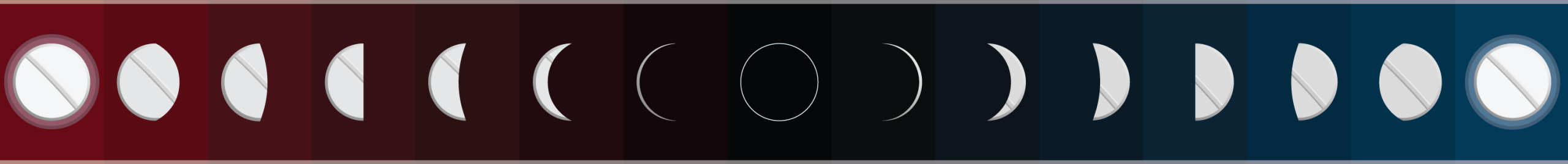
Register today to join NCATS, Vermont BioSciences Alliance and the University of Vermont College of Medicine I-Trep program and DRIVEN Accelerator Hub on **Tuesday, Nov. 27, 2018, 2:00 – 3:00 p.m. ET**, for a webinar featuring:

- NCATS focus areas to advance clinical research and translational sciences
- SBIR and STTR program overview
- Other resources and programs, including NCATS' Therapeutics for Rare and Neglected Diseases (TRND) and Bridging Interventional Development Gaps (BrIDGs) programs
- Tips for submitting a successful application
- Upcoming opportunities and deadlines

NIH
National Center for Advancing Translational Sciences

The Opioid Crisis and the Future of Addiction and Pain Therapeutics: Opportunities, Tools, and Technologies

February 7-8, 2019 • Natcher Auditorium • NIH Campus • Bethesda, MD



Session Topics

- Novel targets and pathways in pain and addiction
- Lessons learned from clinical successes and failures
- Assays to improve predictive therapeutic efficacy and abuse/addiction liability
- New technologies and methodologies
- NIH capabilities and initiatives
- Biomarkers to enable clinical trials

Sponsored by

NIH National Center for Advancing Translational Sciences

THE ASSAY GUIDANCE MANUAL

Register by Friday, January 11 at:

https://events-support.com/events/NCATS-Pain-Addiction-Symposium

NIH National Institute on Drug Abuse

NIH National Institute of Neurological Disorders and Stroke

Led by the National Center for Advancing Translational Sciences (NCATS), National Institutes of Health, this Helping to End Addiction Long-term (HEAL) Initiative workshop is a component of the NCATS Human Cell-Based Screening Platforms and Novel Drugs to Treat Pain, Addition and Overdose project. For more information on NCATS' role in the NIH HEAL Initiative, visit https://ncats.nih.gov/heal.

Other Upcoming HEAL-Related Events

January 30 - 31, 2019
A Critical Evaluation of Animal Pain Models Workshop
Bethesda North Marriott Hotel and Conference Center, Rockville, Maryland

This meeting will convene experts in the field of animal models for pain and experts in translational development of pain therapeutics to discuss screening programs in the preclinical process for determining if a compound should be developed to treat pain in the clinical setting.

February 6, 2019
Natural Products and Pain: The Search for Novel Non-Opioid Analgesics
NIH Campus Natcher Building 45 Balcony B

The goal of the workshop is to facilitate the identification of novel non-opioid natural products with efficacious and non-addictive analgesic properties. The workshop will also discuss research barriers for the study of such natural products for pain treatment and management. The discussion will focus on how to identify promising leads based on traditional medicine; how to discover and identify active natural products; and how to characterize the mechanisms through which they act. The talks will be organized around promising known non-opioid classes of natural products from various sources and will walk through their discovery and challenges that have been encountered in their development. The workshop is targeted to researchers engaged in basic and mechanistic research in the fields of natural products and/or pain signaling. We hope that through this workshop we will provide novel and important contributions to the goal of finding solutions to the current pain and opioid crisis.

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

Update to CTSA Program Steering Committee

November 26, 2018

Status Report - Activities

Issue / Barrier	Update
1. **Research support for translational scientists:**	
• Collect info from KL2 Scholar Stakeholders on challenges: KL2 Scholar Survey	• Doris Rubio circulated draft survey, comments received and updated, presented to SC, SC wants to see it again; discussion ongoing; Doris Rubio leading updated draft
• ICs leveraging the CTSA Program training and education resources	• Barry Coller (Discussion TBD)
• How are KL2 Scholars supported after their KL2 ends?	• Data presented at the Workforce DTF F2F meeting – Spring 2018 (summary slide follows)
• Is a specific R pathway needed for the CTSA Program KL2 scholars?	• Review current data on KL2 subsequent grants (Joan and Heather – discussion today)
2. Debt Reduction:	
• Assessment of the KL2 Scholars success rate with the NIH LRP • Enhancing communication about resources for the NIH LRP for the KL2 Scholars	KL2 Directors Meeting – Nov 13 – Discussed – See ACTION items
3. Building Translational Science as a Scientific Discipline and Field:	
• Landscape analysis of Programs PhDs in Translational Science	Data Collection in Progress (Baindu)
• Where does Translational Science “live” at academic medical centers? • What examples of building a discipline and field can we learn from? e.g. Genetics, Informatics, Data Science, Systems Biology, etc. • Recognizing Translational Scientists in the tenure and promotion process	?? Does this need a larger in person meeting (suggest CLIC un-meeting?)

National Center for Advancing Translational Sciences

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

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

Debt Reduction: Discussion

- KL2 PI Directors discussed analysis conducted by NCATS on the success of KL2 Scholars in the NIH Loan Repayment Program
- Analysis indicates the KL2 scholars have an excellent rate of success in LRPs compared to overall NIH cohort
  - From 2006-2017, of the 1784 unique KL2 Scholars, 736 applied to the NIH LRP and 578 were awarded (78.5% success rate over these years)
  - Yearly NIH success rate is ~50%
- Most KL2 Scholars apply to ICs other than NCATS (in line with the focus of their research)
  - From 2006-2017, 55 Scholars were assigned/applied to RR/TR for LRP and 47 received LRP awards
  - Note that NCATS in FY18 invested ~$2.5 million in the LRP (middle of the pack for investment by NIH ICs)

Debt Reduction: ACTION

- Disseminate NIH LRP information and resources broadly to the consortium:
  - KL2 PIs propose to conduct regional Workshops on NIH LRP using Institution specific data from Ericka Boone (follow-up from Tom Pearson's presentation during KL2 PI Directors meeting)
  - Commitment from NCATS to communicate release of FOAs and deadlines through appropriate consortium listservs (KL2, TL1, Workforce, newsletter, PI, etc)
  - Enhance LRP information and resources on the NCATS website
- Create a webinar for the CTSA Program scholars
  - Invite Ericka Boone – Director of LRP to present to KL2 PIs and Scholars and archive the webinar

Domain Task Force Work Group Update

Currently Scheduling Next Meeting!

CTSA
Clinical & Translational Science Awards Program

CLIC
Center for Leading Innovation & Collaboration

Common Metrics Initiative: 2018 Activities & Beyond

Steering Committee Call

November 26, 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

Agenda

- Overview of the Common Metrics Initiative Progress
- CMI 2.0
- Pod Exercise

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

Overview of the CMI 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.

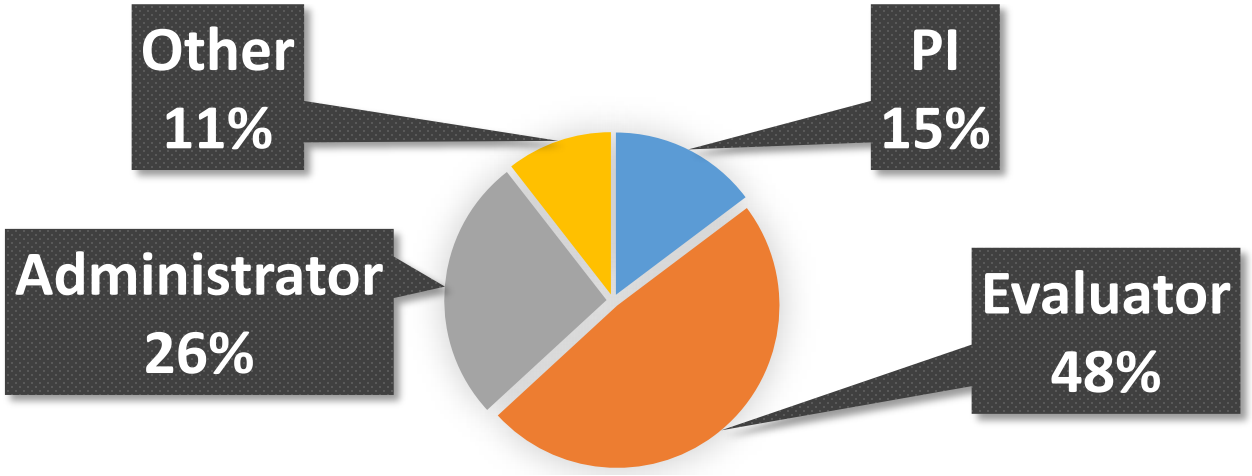
CTSA
Clinical & Translational Science Awards Program

CLIC
Center for Leading Innovation & Collaboration

Hub Participation in Survey

95 Number of Surveys Received

60 Number of Unique Hubs Responding



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

Addressing in the next report based on feedback

- Hubs want TTC plan examples – those trending in the right direction
- Simpler graphics
- Better definitions
  - Easy to read/interpret
  - How data were identified
- Complete data: hub location of data in scorecard

- Full report available on CLIC website (login required)
  - https://clic-ctsa.org/content/2016-common-metrics-hub-survey-report-feedback

CTSA
Clinical & Translational Science Awards Program

CLIC
Center for Leading Innovation & Collaboration

Goal

To provide both a quantitative and qualitative longitudinal perspective of the Common Metrics data for 2015, 2016, and 2017.

Objectives

1. To show hub quantitative trend values relative to consortium data.
2. To illustrate changes in hub data relative to consortium since 2016 going into 2017.
3. To identify qualitative factors involved in turning the curve since 2016.
4. Generate questions and hypotheses, allow exploration - “What if...”

CTSA
Clinical & Translational Science Awards Program

CLIC
Center for Leading Innovation & Collaboration

Communication Plan: Next Report

Stakeholder Groups:

- Steering Committee
- PI Webinar
- Common Metrics Executive Committee
- CTSA Program Evaluators

The goal of presenting at these calls is twofold:

1. to engage the community in the CM report process, and
2. to seek comments and feedback to ensure visualization clarity and improve descriptions of our visualizations

Target Report Date: February 28, 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

Quantitative Methodology

- Obtain 2017 CM Data Extract on 10/1/2018
- Clean the data
- Calculate Median, IQR for all Numerical Data 2015 - 2017
- 2015 -2017 longitudinal plots for each hub
- Identify "exemplars"; Change in metric value from 2016 - 2017

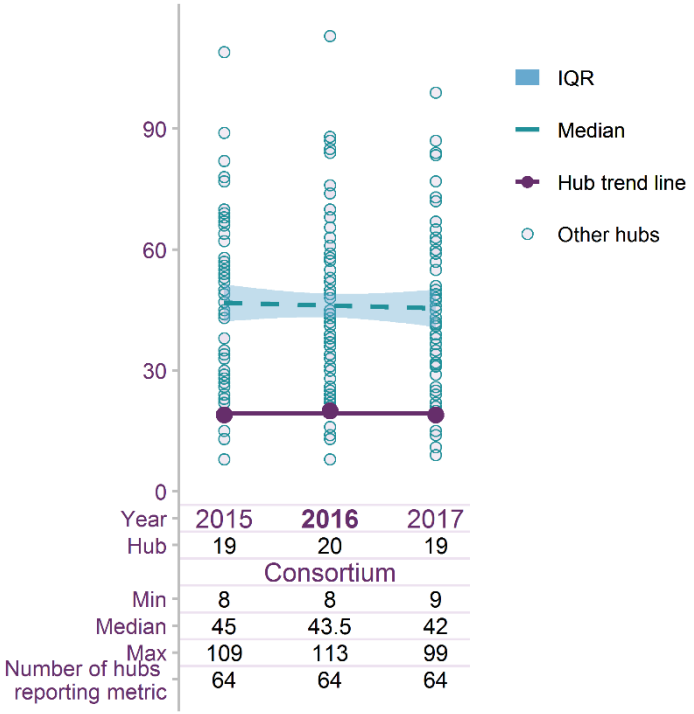
The University of Rochester Center for Leading Innovation and Collaboration (CLIC) is the coordinating center for the Clinical and Translational Science Awards (CTSA) Program, funded by the National Center for Advancing Translational Sciences (NCATS) at the National Institutes of Health (NIH), Grant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

CTSA
Clinical & Translational Science Awards Program

CLIC
Center for Leading Innovation & Collaboration

Quantitative Results

2015 -2017 Longitudinal Plots



	'16-'17 Change
Hub	-1
	Consortium
Min	-34
Median	-2
Max	25
Number of hubs reporting in '16 and '17	64

2016 – 2017 Change in Metric Value

For all numerical metrics:

- Illustrate year over year trend for your hub as well as the consortium
- Your hubs annual reported results as well as the consortium

For all numerical metrics show:

- Change in reported value from 2016 – 2017
- Identify “exemplars” – hubs with the most change in the “right direction”

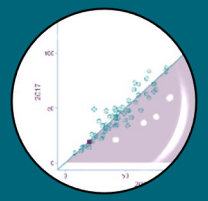
The University of Rochester Center for Leading Innovation and Collaboration (CLIC) is the coordinating center for the Clinical and Translational Science Awards (CTSA) Program, funded by the National Center for Advancing Translational Sciences (NCATS) at the National Institutes of Health (NIH), Grant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

CTSA
Clinical & Translational Science Awards Program

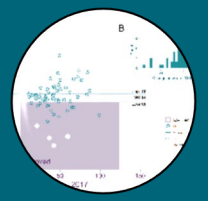
CLIC
Center for Leading Innovation & Collaboration

Qualitative Methodology

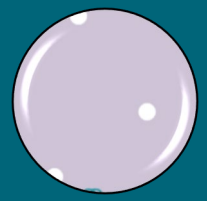
2016 – 2017 hub exemplars (all metrics):



Determined slope change between 2016-17



Use Hubs where slope is above 95% confidence interval



Selected top 5 hubs with highest slope

Provide analyzed TTC Plans

TTC Plans Reviewed:

1. Days to IRB Approval (Median)
2. Percent of Pilots with at Least 1 Publication
3. Percent of TL1 Grads Engaged in Clinical Translational Research
4. Percent of KL2 Grads Engaged in Clinical Translational Research

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

TTC Plan Analysis

- Identify common themes/practices among de-identified exemplar hubs.
- May include analysis through QDA Miner software / Inter-Rater Reliability.
- Best practices of de-identified exemplar hubs will be shared in reports sent to NCATS and hubs.

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

CMI 2.0

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 Goals for the CTSA CMI 2.0

Nearer term

- Optimize the CMI processes
- Grow the CMI to new metrics
- Routinely disseminate and discuss aggregated data and findings
- Identify needs of external stakeholders and show how the CTSA Program metrics demonstrate value

Longer term

- Increase sustained engagement of individual hubs in the CMI
- Effectively engage consortium in CMI

CTSA
Clinical & Translational Science Awards Program

CLIC
Center for Leading Innovation & Collaboration

CMI 2.0: Goal of the Assessment Period

- Take a pulse on how well the metrics are implemented and utilized at each hub
- Engage with the consortium on ways to improve the metrics and the initiative overall.
- Determine a process on how to move progressively forward with the initiative with the goal of measuring how well the consortium is doing as a collective across the metrics.

CTSA
Clinical & Translational Science Awards Program

CLIC
Center for Leading Innovation & Collaboration

Development of CMI 2.0

Potential Data Collection Methods:

- Focus groups
- Roundtables
- Think Tank – 2018 AEA

Key Stakeholders:

- PIs
- Administrators
- CTSA Evaluators
- NCATS
- Others

CTSA
Clinical & Translational Science Awards Program

CLIC
Center for Leading Innovation & Collaboration

Pod Exercise

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

Goal

Obtain PI level input on designing CM 2.0 to grow and strengthen the initiative beyond a focus on hub-based metric results and utilization.

Request: Send RedCap link to your Pod groups.

Common Metrics Initiative 2.0 PI Survey

Deadline: Seeking feedback by **December 14, 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

Questions

- What priority should we give to the development of Consortium level metrics for use by the network and for external stakeholders; recommendations for Consortium level metrics?
- What should be the priority for the next set of metrics?
- Hubs have different levels of engagement with the CM, what could be done to add value to the CM at the hub level?

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

CMI Timeline

Informatics Final Phase 1 Office Hour – December 10, 2018

Informatics Phase I completion – December 31, 2018

Informatics Phase 2 – February 4, 2019

Informatics Phase 2 completion – March 31, 2019

Accrual Median Metric Development Team
- December 7, 2018
- January 23, 2019

Targeted 2017 Hub Report
- February 28, 2019

2017 Hub Report Webinar
- March 18, 2019
- March 21 OR 26, 2019

RBA Tool Review – April 8, 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.

Next Meeting: In Person on December 10, 2018

See you soon!