CTSA Program Webinar

Wednesday, April 22, 2020
2:00 PM – 3:00 PM ET
<table>
<thead>
<tr>
<th>Time</th>
<th>Topic</th>
<th>Presenter</th>
</tr>
</thead>
<tbody>
<tr>
<td>2:00 PM - 2:20 PM</td>
<td>Welcome NCATS and CTSA Program Updates</td>
<td>Michael G. Kurilla, M.D., Ph.D.</td>
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<tr>
<td>2:20 PM - 2:20 PM</td>
<td>Introduction to: On the Importance of Enhancing Diversity in the CTSA Program</td>
<td>Erica Rosemond, Ph.D.</td>
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<td>2:20 PM - 2:35 PM</td>
<td>NIH Scientific Approach to Inclusive Excellence</td>
<td>Hannah Valantine, M.D.</td>
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<td>2:35 PM - 2:45 PM</td>
<td>Administrative Supplements for Retention and Continuity of Career Development and First Time Research Project Grant Recipients</td>
<td>Pritty Joshi, Ph.D. Melissa Ghim, Ph.D.</td>
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<tr>
<td>2:45 PM - 2:55 PM</td>
<td>Enhancing Diversity through CTSA Program Consortium Strategies – CTSA Program Insights to Inspire Series</td>
<td>Raquel Ruiz, MAEd</td>
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<tr>
<td>2:55 PM - 3:00 PM</td>
<td>Closing Comments</td>
<td>Michael G. Kurilla, M.D., Ph.D.</td>
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CTSA Program Updates

Michael Kurilla
COVID-19 Updates
CTSA Program COVID Response

• Central **CTSA COVID Portal** on CLIC

• **CTSA COVID-19 Discussion Forum**

• Collaboration between CTSA Program TIN, CD2H, and CLIC
  • Common clinical platform for communication and dissemination

• Involved in numerous clinical activities
  • Clinical trials (many)
  • Observational studies
Central CTSA COVID Portal on CLIC

Coronavirus Disease 2019 (COVID-19)

For up-to-date information regarding COVID-19 please go to the CDC Website.

Background

In response to the recent outbreak of the coronavirus disease 2019 (COVID-19), the CTSA and CLIC Program have created several communication venues for members of the CTSA Program to share information and identify potential research collaborations focused on COVID-19. Learn more about coronaviruses from the National Institute of Allergy and Infectious Diseases (NIAID) as well as the World Health Organization (WHO). The Center for Disease Control and Prevention (CDC) is responding to the outbreak. The CDC is updating its site as new information becomes available where you can find information about the outbreak, travel information, preventing the spread, and protection from COVID-19.

Collaborate and Share Information

NCATS and CLIC are partnering to facilitate discussions around COVID-19. Specific research or translational discussions should use the CTSA Program Response to COVID-19 Discussion Forum to discuss and identify efforts to manage the Coronavirus outbreak. Learn more about how to join a Discussion Forum and join in on the conversation on COVID-19. You can also view the NCATS Getting Started resources for using the OP.

Please share your hubs, events, news, educational content, and other resources about COVID-19 by posting them on the CLIC website using the tag “COVID-19”. View all posted hub information about COVID-19 on the COVID-19 tag page. For information on how to share content, please check out the CLIC Library video: Sharing Content. We have provided a comment section below for short inter-consortium communications about hub efforts around COVID-19.

Center for Data to Health (CD2H)

In collaboration with several HHS agencies, the CTSA program, and distributed clinical data networks, CD2H has created the National COVID Cohort Collaborative (NCCC), a centralized, secure, limited access portal to access COVID-19 clinical data. The NCCC page and the accompanying CD2H+COVID portal has been established to provide the additional assets needed to rapidly develop the analytics that clinical centers and physicians need.

COVID Case Report Forms and Phenotyping Standards contains a list of known CRFs for triage, intake, and patient-focused phenotype/metadata collection efforts

Specific Funding Opportunities

Current NIH funding opportunities specific to COVID-19 can be found on the NIH Information for NIH Applicants and Recipients of NIH funding specific to COVID-19. Also, consider applying to the CLIC Synergy Paper RFA. Learn more about Synergy Papers and review the open RFA.

Clinical Trials

For the latest information about currently recruiting COVID-19 related clinical trials, please visit the COVID-19 Clinical Trials feed. This is a curated list from clinicaltrials.gov.

Collaborative Research Efforts

Due to the rapidly changing research efforts in response to COVID-19 pandemic, NCATS and the CTSA Program Coordinating Centers have created a publicly accessible clinical research information platform with the aim of providing a centralized location of preclinical and investigational research studies. The goal is to facilitate collaboration between investigators and reduce duplicate trials. To share information, log in to CLIC site and submit any COVID-19 research that is occurring at your institution.

You can also view the list of COVID-19 research studies submitted by institutions around the country.

COVID-19 Resources for Trainees and Researchers

SHARE Education and Career Development Resources: Share (video tutorial) any content that would benefit CTSA Program trainees and scholars during the COVID-19 outbreak. Be sure to include the COVID-19 tag with your resource.

SEARCH for Education Content: The Education Clearinghouse is a centralized space where the CTSA community can find and share a variety of education and workforce development resources for a broad range of audiences.

DISCUSS Needs and Collaborate: Join the Education and Career Development CTSA Discussion Forum.
Notice of Special Interest: CTSA Program Applications to Address COVID-19 Public Health Need (NOT-TR-20-011)

- Particular interest in projects focusing on the use of informatics solutions to diagnose cases and the use of CTSA-supported core resources (e.g., advanced scientific instruments, highly-specialized facilities, and regulatory expertise) to facilitate research on COVID-19 and advance the translation of research findings into diagnostics, therapeutics, and vaccines.
  - Administrative Supplements to UL1, U01, and R21 awards (thru PA-18-591)
    - Page limits: In general, research portion limited to 6 pages
  - Collaborative Innovation Awards to U01 and R21 awards (thru PAR-19-099 & PAR-19-100)
  - Competitive Revisions for UL1 awards for each of the non-administrative supplement awards (thru PAR-19-337)

- Pending updates – stay tuned
WE NEED YOU!

• The response of CTSA Program investigators to the COVID-19 crisis has been remarkable

• It’s critical that CTSA awardees share efforts to build synergistic collaborations and be recognized by the wider audience for their contributions

• Ways to Share
  • Provide regular updates & highlights to your Program Officer
  • **CTSA COVID Portal** on CLIC
    • Participate in COVID Discussion Forum
    • Enter COVID-19 research under “Collaborative Research Efforts”
    • More ways coming!
GRANTS GUIDANCE

• Coronavirus Disease 2019 (COVID-19): Information for NIH Applicants and Recipients of NIH Funding

• Additional NCATS-Specific Guidance Under Development
CTSA Program Administrative Updates & Opportunities
Notice of Special Interest: Clinical and Translational Science Award (CTSA) Program Administrative Supplements (NOT-TR-20-014)

Add dedicated quality assurance/quality control position to perform quality reviews of CTSA-related submissions to NCATS, submissions to the eRA Human Subjects System, and management of the overall process

- Administrative Supplements to UL1 awards (through PA-18-591)
- Due Date: May 4, 2020 (and onwards)
- Budget request limited to salary, fringe, F&A for one dedicated quality assurance/quality control position
- Questions: contact your Program Officer
Administrative Updates & Opportunity

- Guidance on Prior Approval Requests
  - Cost Extensions
    https://ncats.nih.gov/funding/grantees/approval#extensions
  - Foreign Components
    https://ncats.nih.gov/funding/grantees/approval#foreign-components

- Notice of Special Interest (NOSI): Administrative Supplements for Development of Training Modules in Genomic Medicine for Health Care Professionals NOT-HG-20-020 (supp to UL1)
  - Due May 1, 2020; supplement to UL1; budget $125,000 TC/year; can request up to 2 years of support
Human Subjects Research (HSR) Process Change

- **NOT-TR-20-019**: Change in NCATS Prior Approval Process for New CTSA Program Pilot Projects that Involve HSR
- **Purpose**: Significantly reduce award recipient burden in the administration of pilot projects and accelerate the clinical and translational research project process
- **Scope**: UL1 Pilot Projects with HSR that are supported with direct CTSA grant funding and/or voluntary committed cost share (only some changes apply to projects funded under KL2 awards)

**Major Points**
- New domestic HSR UL1 Pilot Projects deemed by the IRB or recipient institution to be non-NIH-defined Clinical Trial minimal risk or exempt (45 CFR 46) studies **ONLY require prior notification** and submission to HSS
- Still need **Official Prior Approval** Receipt & Entry of Studies into HSS Required Prior to Study Start: a.) new UL1 CTSA Program Pilot Projects that include HSR deemed by the IRB to be Greater Than Minimal Risk or meet the criteria for a NIH-defined Clinical Trial or include a foreign component, and b.) **all KL2 Scholar Projects** that involve HSR
- Streamlined Addendum Form and fewer required documents (for both UL1 Pilot Projects and KL2 projects)
CTSA Program Enhancements
Enhancing the CTSA Program

- Current FOA ([PAR-18-940](#)) expires August 2021

- Request for Information (RFI): Enhancing the Clinical and Translational Science Awards (CTSA) Program ([NOT-TR-19-027](#))
  - Responses were received by October 25, 2019

- Town Hall was tentatively scheduled for after the April CTSA Program group meetings and ACTS Meeting; date TBD
Demonstrating the Value of the NCATS CTSA Program

The current public health emergency has accelerated the merging of two interests:

- NCATS’ and hubs’ desire to demonstrate Program Impact
- Hubs’ desire to decrease/streamline required CM activities, which has become an acute issue

FY20 focus

- Common Metrics Initiative
  - Modify expectations for current CMI activities
  - Communicate the successes of the CMI and dissemination of best practices [Insights to Inspire (I2I) series, publications on the process and discovered best practices, etc.]
  - Transition collection and analysis of hub-level metrics to the hubs
- Data to Demonstrate Impact (D2DI): Initiate new program
- Document COVID-19 response and accomplishments
- CLIC will roll out additional details on these aspects
# Common Metrics Initiative: FY20 Modifications

<table>
<thead>
<tr>
<th>Common Metrics (CM)</th>
<th>Plan</th>
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<tr>
<td>Informatics</td>
<td>Modified reporting timeline/expectations under development</td>
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<tr>
<td>Careers in Clinical &amp; Translational Research</td>
<td>Modified reporting timeline/expectations under development</td>
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<tr>
<td>Median Accrual (expanded pilot)</td>
<td>Modified reporting timeline/expectations under development</td>
</tr>
<tr>
<td>Median IRB Review Duration</td>
<td>Halt reporting of the following Common Metrics and associated Turn the Curve Plans, effective immediately <em>(sites are free to collect and/or develop TTC plans and use for hub operations and continuous quality improvement planning)</em></td>
</tr>
<tr>
<td>Pilot Funding Publications and (Optional) Subsequent Funding</td>
<td>Halt reporting of the following Common Metrics and associated Turn the Curve Plans, effective immediately <em>(sites are free to collect and/or develop TTC plans and use for hub operations and continuous quality improvement planning)</em></td>
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New Program: Data to Demonstrate Impact (D2DI)

- Begin to identify CTSA Program consortium-level metrics
- Measure the impact to improve the translational research process
- Explore new methodologies
- Leverage mixed methods analysis, which includes quantitative and qualitative measures to demonstrate impact
Capture the Impact of the CTSA Program in Addressing the COVID-19 Public Health Need

• Focus the collection of the CTSA Program impacts on addressing COVID-19 as an example of how the program prepares and responds to a public health crisis

• Report format under development

• Completion/submission: perhaps initial version due in 6 months are so; update in 12 months?
“If you’re going through hell, keep going”

WINSTON CHURCHILL
On the Importance of Enhancing Diversity in the CTSA Program

Erica Rosemond, Ph.D.

Deputy Director, CTSA Program, Division of Clinical Innovation
Introduction to: On the Importance of Enhancing Diversity in the CTSA Program

Goals of the Presentations:

• Highlight NIH activities on enhancing diversity and retention in the biomedical workforce
• Advertise the upcoming Common Metrics Insights to Inspire blog and webinar series

Expected Outcomes of the Presentations:

• Information dissemination
• Engagement and interest in attending the Summer 2020 Insights to Inspire webinar series focused on engaging and retaining underrepresented persons and women in clinical and translational research
NIH Scientific Approach to Inclusive Excellence

Hannah Valantine
NIH’s Scientific Approach to Inclusive Excellence

CTSA Meeting
April 22, 2020
Hannah A. Valantine, M.D.
NIH Chief Officer for Scientific Workforce Diversity
Why Diversity Matters: Capitalizing on the Opportunity

- Excellence, Creativity, Innovation
- Broadening Scope of Inquiry: Health Disparities
- Changing Demographics: Types of Diversity
- Global Research Preeminence
What is the problem?

Underrepresentation in influential scientific workforce positions
Diminishing Representation of Women and URG Scientists

Representation in the Biomedical Sciences, 2015 - 2016

Women - Underrepresented
Women - Well-represented
Men - Underrepresented
Men - Well-represented

CTSA Research Institutions: Women Department Chairs 2019 (%)

National Average (Dept. Chairs) = 19%

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<tr>
<th>Institute</th>
<th>Percentage</th>
<th>N</th>
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<tbody>
<tr>
<td>Stanford</td>
<td>37%</td>
<td>11</td>
</tr>
<tr>
<td>Harvard</td>
<td>21%</td>
<td>14</td>
</tr>
<tr>
<td>Penn</td>
<td>20%</td>
<td>5</td>
</tr>
<tr>
<td>Wash U</td>
<td>20%</td>
<td>5</td>
</tr>
<tr>
<td>UCSF</td>
<td>19%</td>
<td>5</td>
</tr>
<tr>
<td>Hopkins</td>
<td>18%</td>
<td>6</td>
</tr>
<tr>
<td>UCLA</td>
<td>18%</td>
<td>4</td>
</tr>
<tr>
<td>Cornell</td>
<td>16%</td>
<td>5</td>
</tr>
<tr>
<td>NYU</td>
<td>13%</td>
<td>4</td>
</tr>
<tr>
<td>Columbia</td>
<td>8%</td>
<td>2</td>
</tr>
<tr>
<td>NIH</td>
<td>20%</td>
<td>6</td>
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At funded CTSA institutions or their associated medical colleges.
Institutional Transformation and Culture Change

Programs are necessary but not sufficient

Promote Transparency and Accountability

Link to Institutional Values and Reward Systems

- Systematic review and transparency of hiring and promotion procedures, policies
- Transparency: collect and publicize aggregate diversity metrics
- Provide tools to Divisions, Departments for enhancing recruitment and retention
- Evaluation of impact
NIH Institutional Approaches to Inclusive Excellence

• Identity diverse talent pool – systematic unbiased approach
• Trans-NIH searches for tenure track positions
• Implicit-bias mitigation
  – NIH SWD Interactive Toolkit
• Distinguished Scholars Program
  – Build a self-reinforcing community of PIs committed to diversity and inclusion
• NIH Equity Committee
  – Transparency and accountability
NIH Scientific Workforce Diversity Toolkit

The U.S. scientific research enterprise - from basic laboratory research to clinical and translational research to policy - requires intellect, creativity, and diverse skill sets and viewpoints.

Diversity
... enhances excellence, creativity, and innovation
... broadens the scope of biomedical inquiry
... addresses health disparities
... ensures fairness in our highly diverse nation
Expanding Diversity of NIH Candidate Pools:

**Junior Career Stage (Postdoc and Assistant Professors)**

~ 842 total, top 1/3\textsuperscript{rd} culled
4-10 years post-doctorate
Authorship in top journals
  10+ publications: 516
  100+ citations: 667
  200+ citations: 534

Updated July 19, 2019
Expanding Diversity of NIH Candidate Pools:

**Junior Career Stage (Postdoc and Assistant Professors)**

~ 842 total, top 1/3\textsuperscript{rd} culled
4-10 years post-doctorate
Authorship in top journals
  10+ publications: 516
  100+ citations: 667
  200+ citations: 534

Updated July 19, 2019
Expanding Diversity of NIH Candidate Pools:

**Junior Career Stage (Postdoc and Assistant Professors)**

- **Gender**
  - Male: 41%
  - Female: 59%

- **Race Ethnicity**
  - African American: 26%
  - Asian: 22%
  - Hispanic/Latino: 16%
  - Native American/Alaskan Native: 6%
  - Other: 1%
  - White/Caucasian: 29%

Updated July 19, 2019
Reducing Implicit Bias and Its Impacts
Cognitive Debiasing

Research suggests that cognitive debiasing does work in some cases, and proper training and interventions can help reduce certain biases:

- Raise awareness (Devine et al. 2017)
- Broaden images of success (Gocłowska et al. 2013)
- Consistency in judgment and evaluation criteria
- Avoid ambiguity and time pressure
- Practice speaking up when bias perceived

** A Gender Bias Habit-Breaking Intervention Led to Increased Hiring of Female Faculty in STEMM Departments.
*** Counter-stereotypic thinking decreases stereotyping and increases creative ideas
Best Practices for Enhancing Faculty Diversity

- Use tools to identify candidates from diverse backgrounds
- Recruitment begins before position is available
- Job descriptions might influence who apply
- Seek implicit-bias education

- Hiring committee should reflect diverse perspectives and backgrounds
- Criteria before applicant evaluation
- Adequate time for evaluation
- Articulate reasons for decisions
- Structured interviews
Distinguished Scholars Program (Faculty cohort NIH IRP)
• PIs with demonstrated commitment to inclusive excellence
• Professional development and mentoring

NIH programs: Portfolio analysis
• NIH investment to date primarily targeted individuals (e.g., fellowships) and/or “distributed” cohorts of individuals within specific disciplines.
• NIGMS MOSAIC, NHLBI PRIDE

Non-NIH programs
• Harold Amos Scholars (Robert Wood Johnson)
• Pew Biomedical Scholars
• Hanna H. Gray Fellows (HHMI)
• NSF ADVANCE
2018 cohort, 13 scholars:
• 8 female and 5 male
• 6 Hispanic
• 2 African/African-American

2019 cohort, 15 scholars:
• 11 female and 4 male
• 1 Hispanic
• 4 African/African-American
NIH Equity Committee
Metrics for Annual Evaluation

- Tenured and tenure-track investigators analyzed separately
  - Demographic data,
  - Salaries, resources for hiring

- Equity of review practices
  - BSC and ad hoc reviewers, promotion, and tenure committees

- Efforts to correct identified problems

- Efforts to promote diversity, equity, inclusion
  - Diversity of speakers at seminars hosted by the IC
  - Promote awareness of implicit bias
  - Best practices for search committees and outreach
  - Award nominations

- Input on how Office of Intramural Research and SWD can support the ICs
Great minds think differently …

@NIH_COSWD
Administrative Supplements for Retention and Continuity of Career Development and First Time Research Project Grant Recipients

Pritty Joshi, Melissa Ghim
Administrative Supplements for Retention and Continuity of Career Development and First Time Research Project Grant Recipients

Pritty Joshi, Ph.D., Office of Extramural Research
Melissa Ghim, Ph.D., Office of Research on Women’s Health
April 22, 2020
What is the problem that we are trying to solve?

Academic STEM Career Progression by Gender and Race, 2015


Women Assistant Professors Lag Behind the Growth in Ph.D. Recipient Pool

Adapted from Gibbs, K. D., et al. (2016). Decoupling the minority PhD talent pool and assistant professor hiring in the medical school basic science departments in the US.
K to R Transition Represents a Particularly Vulnerable Career Stage

• Women comprised just 31% of the (initial) NIH RPG pool from 1991-2010 (Hechtman, Moore, Schulkey, Miklos, Calcagno, Aragon, Greenberg: PNAS 2018 115 7943-48)

• Previous evaluations of K awardees found that male K awardees applied for & received subsequent NIH grants at higher rates than their female counterparts

• These data highlight the need to retain women in the NIH-funded workforce during critical transition periods (e.g., postdoc to faculty)

• Surveys of postdoctoral scientists indicate that family responsibilities are a major driver for women opting out of academic research
Percentage of Male or Female K Award Recipients Transitioning to R01-equivalent Awards

- Female K award recipients with subsequent R01 Equiv/
  Total pool of Female and Male K recipients with R01 Equivs
- Male K award recipients with subsequent R01 Equiv/
  Total pool of Female and Male K recipients with R01 Equivs

Fiscal Year:

- 2000
- 2001
- 2002
- 2003
- 2004
- 2005
- 2006
- 2007
- 2008
- 2009
- 2010
- 2011
- 2012
- 2013
- 2014

Percentage:

- 0
- 10
- 20
- 30
- 40
- 50
Funding Rate of PIs Transitioning from K to R01-equivalent Awards Among Those Who Apply: Male and Female

Female K award recipients with subsequent R01 Equiv/
Total pool of Female and Male K recipients with R01E applications (K to R Applicant Pool)

Male K award recipients with subsequent R01 Equiv/
Total pool of Female and Male K recipients with R01E applications (K to R Applicant Pool)

Fiscal Year

Percentage

Funding Rate for Men
Funding Rate for Women
Women individually hold fewer grants, submit fewer applications, and are less successful in renewing grants, making their research career trajectories less stable, especially during critical life events.
Research Continuity & Retention of Individual NIH Mentored Career Development (K) Award Recipients (NOT-OD-20-054)

**Overarching goal**: to support transition & retention of investigators from mentored career development to research independence & to minimize departures from biomedical research workforce at critical junctures

**What it does**: provides temporary **supplemental research support** to help sustain the investigator’s research during critical life events

**Supplement may be used to hire additional personnel**: to promote the continuity of the career development research project during a period when the PD/PI experiences an issue which impacts progress or productivity

**Eligibility**: Individual *K* awardees who are late-stage post doctorates, instructors, early stage-tenure-track or non-tenure-track faculty & recipients of individual mentored *K* awards are encouraged to apply
Continuity of Biomedical and Behavioral Research Among Recipients of First-Time NIH Independent Research Awards (NOT-OD-20-055)

**Overarching goal:** to enhance the transition & retention of investigators from first independent RPG award to renewal of their first RPG award or 2nd independent RPG award

**What it does:** provides temporary **supplemental research support** to help sustain the investigator’s research **during critical life events**

**Supplement may be used to hire additional personnel:** to promote the continuity of the research project during a period when the PD/PI experiences an issue which impacts progress or productivity

**Eligibility:** First-Time Recipients of independent RPG awards (DP1, DP2, DP5, R01, R00, R15, R21, R35, RF1, and U01) experiencing a critical life event
Lessons Learned from the NIH BIRCWH K12 Program

• Building Interdisciplinary Research Careers in Women’s Health (BIRCWH)-Institutional mentored career development grant program
• Junior-level faculty are the focus; called Scholars, who receive a minimum of 2-years training
• Aspects of BIRCWH are particularly conducive to developing the research careers of women: interdisciplinary, team science, strong goal-oriented mentorship, mentorship teams
• Resulted in extraordinary outcomes, including training more than 700 Scholars from 2000-2019. Evaluation of 2010-2015 cohort indicates 55% PhDs, 30% MDs, and 12% MD/PhDs; 84% are women and 16% are men. Current evaluation is underway.
Family-Friendly NIH programs and policies

Other significant examples

• ESI Status extension policy for childbirth (NOT-OD-18-235)
• BRAIN Initiative K99/R00 eligibility extension policy for childbirth (NOT-OD-20-011)
• Providing opportunities to describe delays in expanded NIH biosketch (NOT-OD-11-045 and NOT-OD-11-050)
• NIH grants policy for childcare on conference grants (PA-18-648)

FAQs: https://grants.nih.gov/faqs#/nih-family-friendly-initiatives.htm
Contact us

Mentored K Administrative Supplement Program for Continuity & Retention (NOT-OD-20-054)
Joshi Pritty, PhD, pritty.joshi@nih.gov

First-time RPG Administrative Supplement Program for Continuity (NOT-OD-20-055)
Melissa Ghim, PhD, melissa.ghim@nih.gov

Building Interdisciplinary Research Careers in Women’s Health (RFA-OD-19-020)
Lisa Begg, DrPH, RN, beggl@od.nih.gov
Enhancing Diversity through CTSA Program Consortium Strategies – CTSA Program Insights to Inspire Series

Raquel Ruiz
CTSA Program Common Metric: Careers in Clinical and Translational Research

Enhancing Diversity through Consortium Strategies
 Insights to Inspire Series
Insights to Inspire – Blogs and Webinars

• An opportunity for CTSA Program hubs to highlight their innovative and unique strategies implemented to improve on a given Common Metric.
  • Share lessons learned
  • Foster innovation
  • Encourage collaboration across institutions
  • Provide actionable intelligence
  • Inspire change

https://clic-ctsa.org/common-metrics-initiative
CTSA Program Common Metric: Careers in Clinical and Translational Research

• Purpose:
  • Measure and develop strategic management plans to enhance the extent to which CTSA Program hubs and the Consortium as a whole are training and supporting scientists to remain engaged in clinical and translational research into the future

• The Metric:
  • The number and percent of institutional scholars and trainees who completed the KL2 and TL1 programs, respectively, who are currently engaged in clinical and translational research
  • Of those who are currently engaged in clinical and translational research, the number and percent of underrepresented persons and women

• Expected Outcomes:
  • Increase the number of underrepresented persons and women who hold clinical research leadership positions
  • Strengthen recruitment/retention strategies and tactics at institutions
  • Enrich the diversity of research teams

• To Date:
  • Metric data has been collected from the hubs for 4 years (2015-2019)
“We also need to implement education and training programs to provide the required knowledge, skills and attitudes to aspiring translational scientists at the undergraduate, graduate, early career and established career levels. NCATS is taking an intentional team-based and experimental approach to translational science education.”

Chris Austin. June 2019. Establishing Education and Training for the Young Field of Translational Science
Retrieved from https://ncats.nih.gov/director/year/2019
What is Insights to Inspire 2020 (I2I 2020)?

- CLIC’s approach to sharing how hubs have improved their Careers in Clinical and Translational Research metrics
- An opportunity for institutions to share what they have learned with regard to Underrepresented persons (URP) and Women
Careers Metric Value to Research

- Increase the number of URPs and women who hold clinical research leadership positions
- Strengthen recruitment/retention strategies and tactics
- Improve the perception of the value of clinical trial participation within marginalized communities
- Strengthen research team productivity
- Enrich the lives of marginalized populations
Insights to Inspire

- Hubs that have demonstrated quantitative improvement in their 2018 data were asked to share their “Story Behind the Curve”
- Continue to explore the metric on Careers in Clinical and Translational Research, focused on how hubs engaged persons from underrepresented groups and women in clinical and translational research
- Stories will focus on five themes:
  - Diversity and Inclusion
  - Recruitment
  - Application & Screening
  - Mentoring & Training
  - Follow-up & Surveys
Insights to Inspire: 2020 Timeline

- **Kickoff on the CTSA Program webinar**
  - April 22

- **Interview featured hubs**
  - March - May

- **Publish blogs**
  - June - October

- **Conduct a webinar for each theme**
  - July - November

- **Publish “From Insights to Action”**
  - December
Featured Hubs
Top 4 Hubs by Metric

- Metric measures analyzed
  - KL2 URP/Women
  - TL1 URP/Women
- Invited to submit stories
- Some interviews conducted
  - Publish blog
  - Include in “From Insights to Action”
Top 4 Hubs
Submit Your Insights

Common Metrics Initiative
- Common Metrics Initiative
- All Common Metrics
- Common Metrics Reporting
- CMI Leadership
- CM FAQ
- Evaluators Group
- Insights to inspire
- Webinars

Insights to Inspire

The Insights to Inspire (ITI) is a series of blogs and/or webinars highlighting the innovative and unique strategies implemented by a CTSA Program institution to improve on a given Common Metric. The insights gained may inspire hubs to use this actionable intelligence to move the needle on the metrics.

The goals of the ITI are to:
- Foster innovation and new ideas
- Encourage collaboration across institutions
- Inspire action

Show your Insights

CLIC News
- Insights to Inspire: Catapulting the Careers of Future Translational Scientists

CLIC News
- Insights to Inspire: The 4 Stages of a Successful Pilot Funding Publication Program

CLIC News
- Insights to Inspire: 4 Strategies for Improving IRB Turnaround Times
The University of Rochester Center for Leading Innovation and Collaboration (CLIC) is the coordinating center for the Clinical and Translational Science Awards (CTSA) Program, funded by the National Center for Advancing Translational Sciences (NCATS) at the National Institutes of Health (NIH), Grant U24TR002260.

CLIC Updates

Martin Zand
Deborah Ossip
CTSA Program Working Group Application – Round Three

• What is required in the application?
  • Individuals/Groups need to propose and deliver well-defined projects or deliverables that fill identified translational gaps and/or further the CTSA Program objectives in high priority areas within clinical and translational science.

• Who can submit an application?
  • Any group or individual within the CTSA Program

• Who will receive CLIC support?
  • Any Working Group approved by the CTSA Program Steering Committee

• How does someone apply?
  • Log onto the CLIC website and complete the form found at the top of Groups page.

Application Deadline: Sunday, May 31, 2020, (no later than 11:59 pm EST)

<table>
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<tr>
<th>System Live</th>
<th>Proposals Due</th>
<th>SC Review</th>
<th>Earliest WG Start</th>
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<tr>
<td>2019 Initial Round</td>
<td>Oct 31</td>
<td>Nov 15-Dec 8</td>
<td>Jan 1</td>
</tr>
<tr>
<td>Oct 1</td>
<td>Oct 31</td>
<td>Nov 15-Dec 8</td>
<td>Jan 1</td>
</tr>
</tbody>
</table>
| Future Submission Timeline
| Sep 1 | Sep 30 | Dec | Jan 1 |
| Jan 1 | Jan 31 | Mar | Apr 1 |
| May 1 | May 31 | Jul | Aug 1 |
NCATS and the CTSA Program Coordinating Centers have created a publicly accessible clinical research information platform with the aim of providing a centralized location of pre-clinicaltrials.gov investigational research studies.

• Any hub can view/post information on research studies happening at your hub
  • Amplify research efforts
  • Look for collaborations
  • Reduce redundancy

https://clic-ctsa.org/covid-19
Coordinate reuse of Case Report Forms / Instruments

Many intake / triage Case Report Forms (CRFs) being used

• CTSA drafted & national and international resources – possibility for alignment

• Improve interoperability with other standards such as CDISC & GA4GH

• Enhance interoperability with EHRs and data sharing

https://covid.cd2h.org/
2020 Synergy Paper RFA

Purpose - advance the field of translational science and to cultivate collaborative research, while providing co-authors with the support to meet their academic goals of producing high quality scientific publications.

- collaborative manuscript developed by 3 or more CTSA Program hubs
- address substantial challenges in clinical or translational research
- Synergy Paper teams receive
  - project support from CLIC
  - funds toward copy editing and publishing costs

• Learn more: https://clic-ctsa.org/collaboration/clic-synergy-papers
• Contact: synergy_papers@clic-ctsa.org
The goal of this Un-Meeting will be to gather individuals interested in exploring ideas and methods for evaluating non-pharmacological interventions.

…trial designs, methods, and standards established to support regulatory approval of pharmacological interventions frequently result in conflicting or negative studies despite strong epidemiological evidence of benefit

….no consensus on best practices exists on the design of studies of non-pharmacologic interventions

Approaches to Evaluate Non-Pharmacological Interventions in Clinical Research
Saturday August 8, 2020, 8:00 am - 3:00 pm
University of Rochester Medical Center, Rochester NY
CLIC / NCATS Communication Channels

Sharing Content: CLIC Website

- News (Consortium News & WOW! Factor stories): clic-ctsa.org/news
- Events: clic-ctsa.org/events
- CLIC Funding opportunities (RFAs):
  - Synergy Papers: https://clic-ctsa.org/collaboration/clic-synergy-papers
  - UnMeetings: https://clic-ctsa.org/collaboration/clic-un-meetings
- CLIC Education & Career Development Gateway
  - Educational tools (Education Clearinghouse): clic-ctsa.org/education
  - Career & training opportunities (Opportunities Board): https://clic-ctsa.org/opportunities-board

Twitter

- NCATS: twitter.com/ncats.nih.gov
- CLIC: twitter.com/CLIC_CTSA
- Hashtag: #CTSAProgram

CLIC Contact Us

- Have a question and not sure where to direct it?: clic-ctsa.org/contact

Newsletters

- CTSA Ansible: Subscribe Here
- CLIC News Roundup: Subscribe Here
- NCATS e-Newsletter: ncats.nih.gov/enews

Mike’s Blog

- https://clic-ctsa.org/news/mikes-blog
CTSA Program Initiative Channels

ACT Network
- Website: http://www.actnetwork.us/National
- Subscribe to newsletter: https://bit.ly/2HQGsM5

IREx
- Website: https://www.irbexchange.org
- Subscribe to newsletter: https://bit.ly/2TtQG7b

National Center for Data to Health (CD2H)
- Website: https://ctsa.ncats.nih.gov/cd2h/
- To Join: CD2H Onboarding

Recruitment Innovation Center (RIC)
- Website: https://trialinnovationnetwork.org/recruitment-innovation-center
- Subscribe to newsletter: https://bit.ly/2OpEDHc

SMART IRB
- Website: https://smartirb.org
- Subscribe to newsletter: https://bit.ly/2JFbiK3

Trial Innovation Network (TIN)
- Website: https://trialinnovationnetwork.org
- Subscribe to newsletter: https://bit.ly/2TXHQDZ
Questions?
Reminders

• The next scheduled webinar will be **Wednesday, May 25th**, 2:00 PM – 3:00 PM Eastern Time.

• Registration URL: https://rochester.zoom.us/webinar/register/WN_Bz2g-rQqTV6gJLi614aXgA

• ctsa_program_webinar@clic-ctsa.org

• https://clic-ctsa.org/groups/ctsa-program-group