

CTSA Program Steering Committee

Monday, September 10, 2018

2:30 – 4:00 ET

Agenda

2:30	Welcome	Kathleen Brady, Christopher Austin
2:30 – 2:45	NCATS Update	Christopher Austin
2:45 – 2:55	Steering Committee Taskforce on Sustaining the Translational Science Workforce (STARWORK) Update	Susan Smyth
2:55 – 3:10	DTF Workgroup Update	Kathleen Brady, Clare Schmitt
3:10 – 3:20	Fall Program Meeting Update	Clare Schmitt
3:20 – 3:30	Fall Steering Committee Meeting Brainstorm	Kathleen Brady, Christopher Austin
3:30 – 4:00	Pod Discussions	All



NCATS Director's Update – FY 2019 Budget

Status and Prospects of Labor-HHS-Educ appropriation bill:

- Summer - Both House and Senate **Appropriations Committees** passed their own bills
 - Provide differing amounts for NIH, NCATS, and CTSA Program (see previous SC meeting slides)
- August 24 – **Full Senate** passed a combined Defense and Labor-HHS-Educ bill
 - Includes priorities for both Republicans and Democrats, and no “poison” pills
- This week? – **Full House and Senate** are “confereencing” to work on a compromise combined bill
 - Note: Full House never passed its Labor-HHS-Educ bill, but agreed to go to conference
- Late September – If conference combined bill is developed:
 - Needs to be passed by both House and Senate
 - Needs to be signed by President – previously threatened veto if funding for border wall not provided

Overall Government (12 Appropriation bills) Status

- Compromise spending bills being worked on:
 - Energy-Water, Military Construction-VA, and Legislative Branch
 - Defense and **Labor-HHS-Education**
 - Interior-Environment, Financial Services, Agriculture, and Transportation-HUD
- On hold:
 - Homeland Security - includes border wall funding, so probably postponed until after mid-term elections
 - Commerce-Justice-Science and State-Foreign Operations – unknown regarding when these will be taken up



Helping To End Addiction Long-term (HEAL) Initiative

- Launched by NIH in April, 2018
- Led by Francis Collins (NIH), Walter Koroshetz (NINDS) and Nora Volkow (NIDA)
- Appropriation of \$500 million in the FY18 Consolidated Appropriations Act
 - \$250 million to NIDA
 - \$250 million to NINDS
- Emphasis on “all hands on deck” / Trans-NIH effort
- Overarching priority areas:
 1. Treatments for opioid misuse and addiction
 2. Pain management



Announcement of Research Plan

VIEWPOINT

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

Francis S. Collins, MD, PhD
National Institutes of Health, Bethesda, Maryland.

Walter J. Koroshetz, MD
National Institute of Neurological Disorders and Stroke, National Institutes of Health, Bethesda, Maryland.

Nora D. Volkow, MD
National Institute on Drug Abuse, National Institutes of Health, North Bethesda, Maryland.

Extraordinary focus by all segments of society is required to respond to the nation's opioid crisis. Now is the time to channel the efforts of the scientific community to deliver effective—and sustainable—solutions to this formidable public health challenge. Recognizing this opportunity, Congress added \$500 million to the base appropriation of the National Institutes of Health (NIH), starting in fiscal year 2018.¹ The NIH will invest these much-needed resources to support science that advances national priorities for addiction and pain research² with a bold new trans-NIH initiative called Helping to End Addiction Long-term (HEAL).³ In this Viewpoint, we outline the initial components of this cross-cutting, interdisciplinary program.

More than 25 million US adults are affected by daily pain.⁴ More than 2 million individuals in the United States have an opioid use disorder (OUD), most starting with opioid analgesics prescribed to them or procured from diverted medications, but once addicted, often shifting to illicit heroin or synthetic opioids.⁵ The scope of this crisis is staggering, but scientific advances offer strategies that can help the nation overcome it.

At the National Rx Drug Abuse and Heroin Summit in April 2018, leaders from both the public and private sectors affirmed that research is essential to the effort to end this public health crisis. It will take "all hands on deck" to make this happen, which is why HEAL seeks to foster innovative partnerships with other government agencies, academic institutions, industry, communities, and patient advocates. Through a year-long series of engagements with individuals from these groups, the NIH has developed an innovative, action-oriented research plan for HEAL that is focused on 2 primary areas: improving treatments for opioid misuse and addiction as well as enhancing strategies for pain management (Table).

Although there are effective medications for OUD (methadone, buprenorphine, and naltrexone), only a small percentage of individuals in the United States who would benefit receive these medications. Even among those who have initiated these medications, about half will relapse

Table. Research Plan for the NIH HEAL Initiative

Opportunities	Components
Improving Treatments for Opioid Misuse and Addiction	
New treatments for addiction	Identify new targets, develop new medications/immunotherapies; reformulate existing medicines Improve overdose reversal medicines Develop new therapies for opioid-induced respiratory depression
Optimization of effective treatments for addiction	Enhance NIDA Clinical Trials Network for opioid research Establish Justice Community Opioid Intervention Network Initiate HEALing Communities Study
NOWS	Expand ACT NOW pilot study; use results to conduct clinical trials to determine best practices for clinical care of NOWS
Enhancing Pain Management	
Better understanding of chronic pain	Establish Acute to Chronic Pain Signatures program
New nonaddictive pain treatments	Identify new targets for pain treatment Engineer preclinical testing platforms to profile potential nonaddictive treatments
Public-private HEAL Partnership to speed movement of nonaddictive treatments through clinical pipeline	Enhance data and asset sharing Validate biomarkers to inform neurotherapeutic and pain clinical research Establish clinical trials network to support and accelerate trials of nonaddictive pain therapies

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

counter opioid-induced respiratory depression, and novel medications and immunotherapies to treat OUD and prevent and reverse overdoses.

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

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Other Updates

- Steering Committee Governance document is currently in review with NCATS and SC Co-Chairs
 - Will be circulated to the full SC for feedback
- Administrator Steering Committee role
 - Will follow the same solicitation process as for the PI
 - Looking to fill the position prior to the October face-to-face meeting
- Opioid Medication Training Initiative
- Pod Feedback



Funding Opportunities

Laura Sugarwala
Sr. Engagement Mgr.

CTSA

Clinical & Translational
Science Awards Program

Un-Meetings

- Apply to host an attendee-driven event without traditional rules and structure
- One hub will receive funds, planning guidance and materials, and high-level coordination from CLIC



Application deadline: **October 15, 2018**

- Learn more: <https://clic-ctsa.org/funding/un-meeting-request-applications>
- Contact: unmeetings@clic-ctsa.org

Synergy Papers

- Apply to collaborate on a manuscript that showcases a new or transformed assessment or perspective relative to translational science
- Receive funds and administrative support from CLIC



Application deadline: **November 5, 2018**

- Learn more: <https://clic-ctsa.org/funding/synergy-paper-request-applications>
- Contact: synergy_papers@clic-ctsa.org

CLIC
Center for Leading
Innovation & Collaboration

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

Susan Smyth, M.D., Ph.D.

*TL1 PI Representative to the CTSA Program Steering Committee
Lead CTSA Program Steering Committee Taskforce: STARWORK*



Steering Committee Taskforce on Sustaining Careers of the Translational Science Workforce (STARWORK)

- **Charge:**

- To identify ways to improve the environmental landscape to sustain the careers of the translational science workforce, with particular emphasis on clinical investigators at academic medical centers

- **Members:**

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

- **Support:**

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

The STARWORK Taskforce will:

1. Identify barriers that exist to sustaining the translational science workforce,
2. Provide guidance for interventions / investments to achieve the best possible environment to sustain the translational science workforce, and
3. Generate a white paper that articulates the vision for the ideal environment to sustain the careers of investigators performing translational science.

Specific issues/barriers that have been raised include:

- Research support for translational scientists
 - How are KL2 Scholars supported after their KL2 ends?
 - Is a specific R pathway needed for the CTSA Program KL2 scholars?
 - Can other NIH institutes leverage the KL2 Program to advance the careers of translational scientists?
 - Examples of ICs that have leveraged / provided supplements to the KL2 to date: NIDCR, NIBIB and NICCH
- Debt from medical school and extended training
 - NIH Loan Repayment Program sufficient? What else is available?
- Building Translational Science as a scientific discipline and field
 - Where does Translational Science “live” at academic medical centers?
 - What examples of building a discipline and field can we learn from? E.g. Genetics, Informatics, Data Science
 - Recognizing Translational Scientists in the tenure and promotion process

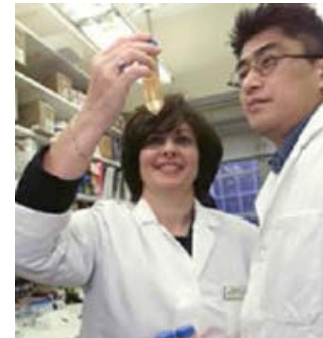
Timeline and Deliverables:

- **Timeline:**

- Meet 1x a month starting in September
- Preliminary thoughts provided at the Fall 2018 Steering Committee Meeting
- Target date for deliverables: March
 - Steering Committee Meeting (F2F)
 - KL2 PI Meeting (F2F)

- **Deliverables:**

- Guidance
- White paper



References / Activities in consideration:

- [Physician-Scientist Workforce \(PSW\) Report 2014](#)
 - Charged with analyzing the current composition and size of the physician-scientist biomedical workforce and making recommendations for actions that NIH should take to help sustain and strengthen a robust and diverse PSW ([update June 2017](#)):
 - Expand Loan Repayment Program and amount of loans repaid
 - Support pilot programs to improve/shorten physician research training
 - Leverage the existing resources of the CTSA Program to obtain maximum benefit for training and career development of clinician scientists
- [21st Century Cures Act](#) (Dec 2016)
 - Legislation provides NIH with critical tools and resources to advance biomedical research across the spectrum, from foundational basic research studies to advanced clinical trials of promising new therapies.
 - [NIH Next Generation Researchers Initiative](#) (2017)
 - To address longstanding challenges faced by researchers trying to embark upon and sustain independent research careers, and to take steps to promote the growth, stability and diversity of the biomedical research workforce
 - Recent [update](#) at NIH ACD June 2018

Questions?



Domain Task Force Workgroup Update

Kathleen Brady, Clare Schmitt



Domain Task Force Working Group Update

Date	Task
July 2	Survey disseminated to PIs, administrators, DTF Teams and DTF working group members; targeted reminders will be sent out twice
July 16	Survey closes
August 13 August 29	Report prepared by CLIC Report circulated to the DTF Work Group members
September 12	Work group meets to discuss proposed changes
October 22	Discussion at Fall In-Person Steering Committee Meeting
October 23	Presentation at CTSA Program Meeting

Working group members

DTF Leads

Ebony Boulware
 Kathleen Brady
 Bradley Evanoff
 Dan Cooper
 Melissa Haendel
 Donald Lloyd-Jones
 Susan Smyth
 Joel Tsevat
 Martin Zand

NCATS

Samantha Jonson
 Erica Rosemond
 Clare Schmitt

CLIC Coordination

Catherine Fetherston
 Scott McIntosh
 Debbie Ossip



In-Person Program Meeting Update

Clare Schmitt



2018 Fall CTSA Program Meetings

- **Oct 22**

- Steering Committee
- Administrators' Meeting
- Networking & Poster Session
 - Announcement of The Great CTSA Team Science Contest Winners

- **Oct 23**

Morning

- **CLIC-Common Metrics Session**
- Updates from NCATS
- Report from SC DTF Task Force
- SMARTIRB
- ACT

Afternoon

- Integrating Clinical Care & Research
- **Interactions with NCATS Div of Preclinical Innovations**
- Opportunities for Hub Engagement with CD2H
- **Trial Innovation Network Session**
- NCATS CTSA Program “Designation”

More Info

<https://clic-ctsa.org/events/2018-ctsa-program-fall-meeting>



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In-Person Steering Committee Meeting Update

Kathleen Brady, Christopher Austin



2018 Fall CTSA Program *Draft* Steering Committee Meeting Agenda

10:00 – 12:30	Domain Task Force Discussion
12:30 – 1:00	Lunch Break
1:00 – 2:00	Sustaining Careers of the Translational Science Workforce (STARWORK) Update
2:00 – 5:00	???

Unique Registration link: <https://redcap.clic-ctsa.org/surveys/?s=3CPLJW8L73>



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Next Meeting: In Person on October 22, 2018

See you soon!

