NCATS Improving Health Through Smarter Science

CTSA Program Steering Committee

Monday, February 12, 2018

2:30 – 4:00 ET

CTSA Clinical & Translational Science Awards Program

National Center for Advancing Translational Sciences

Agenda

Time	Topic	Moderator
2:30	Welcome	Kathleen Brady Christopher P. Austin
2:30 – 2:45	NCATS Update	Christopher P. Austin
2:45 – 3:15	Communications Workgroup to the SC Update	Moderated by: Kathleen Brady
3:15 – 3:20	Informatics Domain Taskforce Update	Donald Lloyd-Jones
3:20 – 3:35	Brainstorming: April Face-to-Face Steering Committee Agenda	All
3:35 – 4:00	Discussion on topics from the pods:	All

NCATS Update

Christopher P. Austin

Budget Update

- Last week's budget deal provides overall budget amounts for defense and non-defense for FY 18 and FY 19
  - No specific amounts for each agency

FY 2018

- Congress using budget deal amounts to finalize appropriation bills
- Until then, we are operating under another Continuing Resolution (CR) through March 23
  - Funds provided at slightly below FY 2017 level
- Standard NIH Policy
  - Existing awards to be issued at 90% of committed amount; Likely restored once full-year budget received
  - New awards may be issued below requested amount

FY 2019

- President's Budget released a few hours ago
- Requests $35.5 billion for NIH ($1.4 billion above FY18 CR level)
  - Includes $750 million for Opioid research
- Requests $685 million for NCATS ($16 million less than FY18 CR level)
  - NCATS' budget justification to be posted on website once we have approval

Upcoming Events

Rare Disease Day 2018
February 28, 2018
https://www.rarediseaseday.org/

Rare Disease Day at NIH
Masur Auditorium, NIH Campus
March 1, 2018
https://events-support.com/events/NIH_Rare_Disease_Day

CTSA Program Steering Committee Meeting
Marriott Wardman Park, Washington, DC
April 18, 8:00 am – 12:00 pm

CTSA Program Meeting
Marriott Wardman Park, Washington, DC
April 18, 1:00 pm – 5:00 pm
https://clic-ctsa.org/events/spring-ctsa-program-meeting

April 19, 2018

- 8:00 am – 10:00 am KL2 Meeting
- 8:30 am – 11:30 am Methods & Processes DTF Meeting
- 10:00 am – 2:00 pm Workforce Development DTF Meeting
- 12:30 pm – 4:30 pm Collaboration/ Engagement DTF Meeting
- 2:00 pm – 4:00 pm TL1 Meeting

Association for Clinical and Translational Science Conference
Marriott Wardman Park, Washington, DC
April 19 - 21, 2018
http://www.actscience.org/

CTSA Clinical & Translational Science Awards Program

Spring 2018 CTSA Program Meeting

Marriott Wardman Park Hotel Washington, DC - Thurgood Marshall Ballroom
Wednesday, April 18, 2018

11:30 - 12:00 pm	**Registration**
12:00 – 12:15 pm	**Welcome, Introduction, Meeting Goals** Michael G. Kurilla, M.D., Ph.D.
12:15 - 1:00 pm	**NCATS and CTSA Program Updates** Christopher P. Austin, M.D. and Michael G. Kurilla, M.D., Ph.D.
1:00 – 1:30 pm	**CTSA Program Steering Committee Updates** Kathleen Brady, M.D., Ph.D. and Christopher P. Austin., M.D.
1:30 – 2:30 pm	**CLIC Updates: Communications, Common Metrics and Collaboration** CTSA Program Coordinating Center for Leading Innovation and Collaboration (CLIC) Martin Zand, M.D., Ph.D. and Deborah Ossip, Ph.D.
2:30 – 3:00 pm	**Networking Break**
3:00 – 4:00 pm	**Clinical Trials Registration and Reporting** Valery Gordon, Ph.D., M.P.H. and Anthony Keyes, M.B.A., P.M.P.
4:00 – 5:00 pm	**Collaborative Innovation Awards** TBD
5:00 – 5:15 pm	**Closing Remarks** Michael G. Kurilla, M.D., Ph.D.

As discussed on January SC call.

2018 Spring CTSA Program Planning Committee:

Name	Affiliation	Name	Affiliation
Martin Zand	CLIC	Christopher P. Austin	NCATS
Debbie Ossip	CLIC	Michael G. Kurilla	NCATS
Jeanne Holden-Wiltse	CLIC	Mary Purucker	NCATS
Pamela Whitcomb	CLIC	Erica Rosemond	NCATS
Jeanne Paiko	CLIC	Pablo Cure	NCATS

NIH National Center for Advancing Translational Sciences

Update on Opioid Efforts - NIDA Collaboration

- Close collaboration with NIDA
- Former DCI Deputy Director (Redonna Chandler) transitioned to NIDA this month and will coordinate the NCATS collaboration
- Established a Working Group of the CTSA Program Steering Committee
- Examples of projects being developed:
  1. Phenotyping patients in the ER with overdose
  2. Best practices for training surgeons on optimal prescribing of opiates post-operatively
  3. Determining community-based approaches for taking back unused opiates
  4. Research to develop and disseminate effective models of care to address OUD in high-target medical settings
- Open Opportunity through the CCIA awards (PAR-18-244, reissue of PAR-15-172)
  - NOT-TR-18-013: Expands the list of high priority translational research opportunities to conduct novel clinical research studies intended to develop and test models of care for **Opioid Use Disorders** within medical settings including primary care, emergency departments, and neo-natal units.
  - Submit for March 8, 2018 and subsequent due dates
  - Contact: PJ Brooks pjbrooks@mail.nih.gov

Building a Pilot Local Clinical Research Network
National Institutes of Health (NIH)
Invitation List
Dec. 1, 2017

Organization	Participants	Title
Children's National Health System	Kurt Newman, MD	President and CEO, Children's National Health System
	Mark L. Batshaw, MD	Physician-in-Chief and Chief Academic Officer, Children's National Health System
	David M. Wessel, MD	Executive VP and Chief Medical Officer
	Lisa Guay-Woodford, MD	Director, Center for Translational Science
	Gary L. Rogers, MD	Division Chief, Plastic and Reconstructive Surgery
Duke University	Robert M. Califf, MD	Professor of Medicine, Vice Chancellor for Health Data Science, Duke University, Duke University School of Medicine
Georgetown University School of Medicine	Joseph G. Verbalis, MD	Chief of Staff
George Washington University School of Medicine	Jeffrey S. Akman, MD	Vice President for Health Affairs and Dean GW School of Medicine and Health Sciences
	Gary Simon, MD, PhD	Vice Chairman of the Department of Medicine
	Alison Hall, PhD	Associate Dean for Research Workforce Development, School of Medicine and Health Sciences
Howard University	Hugh E. Mighty, MD	Dean College of Medicine
Inova Fairfax Health System	John E. Niederhuber, MD	CEO, Inova Translational Medicine Institute
Johns Hopkins Medicine	Paul B. Rothman, MD	Dean Medical Faculty and CEO Hopkins Medicine
	Adrian Dobs, MD, MHS	Director, Johns Hopkins Clinical Research Network
Medstar Health Research Institute	Neil J. Weissman, MD	President of MedStar Health Research Institute
University of MD School of Medicine	E. Albert Reece, MD, PhD, MBA	Dean, University of Maryland School of Medicine
	Stephen N. Davis, MBBS	Professor and Chair of Medicine, and VP for Clinical and Translational Science
	Terry B. Rogers, MD/PhD	Professor and Assistant Dean for Research Affairs
	Robert L. Ord, MD, DDS	Professor and Chair, Oral-Maxillofacial Surgery
	Louisa A. Peartree, MBA	Senior Associate Dean for Finance and Resource Management
University of Pennsylvania	Emma A. Meagher, MD	Senior Associate Dean and Chief Clinical Research Officer, U. Penn/Penn Medicine
CHOP	Richard Aplenc	Asst Professor, Dept of Pediatrics
University of Virginia	David S. Wilkes, MD	Dean, School of Medicine
Virginia Commonwealth University	Michael Rao, PhD	President, VCU
	F. Gerald Moeller, MD	Division Chair for Addiction Psychiatry, Director of the Institute for Drug and Alcohol Studies, Director of Addiction Medicine
	Marsha D. Rappley, MD	VP for Health Sciences and CEO, VCU Health Systems
	Francis L. Macrina, PhD	VP for Research and Innovation
USUHS	Yvonne Maddox, PhD	VP for Research
	Arthur L. Kellermann, MD, MPH	Dean, F. Edward Hebert School of Medicine, Uniformed Services University of the Health Sciences
Walter Reed National Military Medical Center	Capt John R. Rotruck, MD	Chief of Staff
	Cmdr Robert A. Liotta, MD	Director for Education and Training Research
	Capt Saira N. Aslam, MD	Director for Medicine
	Cmdr Hasan Hobbs, MD	Director for Healthcare Operations
	Col Joseph A. Brennan, MD	Professor of Surgery
USAMRMC	Mark T. Dertzbaugh, PhD	Civilian Deputy
NIH	Francis S. Collins, MD, PhD	Director, NIH
	Lawrence A. Tabak, DDS, PhD	Principal Deputy Director, NIH
	Michael Gottesman, MD	Deputy Director for Intramural Research
	James K. Gilman, MD	CEO Clinical Center
	John I. Gallin, MD	Chief Scientific Officer, Clinical Center and NIH Associate Director for Clinical Research
	Christopher P. Austin, MD	Director, NCATS
	Diana E. Bianchi, MD	Director, NICHD
	Jodi Black, PhD	Deputy Director Extramural Research
	Patricia Flatley Brennan, RN, PhD	Director, NLM
	Janine A. Clayton, MD	Associate Director for Research on Women's Health
	William A. Gahl, MD, PhD	Clinical Director, NHGRI
	Joshua A. Gordon, MD, PhD	Director, NIMH
	Patricia A. Grady, PhD, RN	Director, NINR
	Stephen I. Katz, M.D., PhD	Director, NIAMS
	Griffin P. Rodgers, MD, MACP	Director, NIDDK
	Paul A. Sieving, MD, PhD	Director, NEI
	David Shurtleff, PhD	Acting Director, NCCIH
	Anne Zajicek, MD, Pharm.D.	Office of Clinical Research
	David Eckstein, PhD	Office of Clinical Research
	Barbara M. McGarey, JD	Deputy Associate General Counsel

Central Initiative: Clinical Research Training

- Leverage our current clinical research curriculum and training programs, and consider additional training courses
  - 3 three core courses of the current curriculum are introductions to
    - Principles and Practice of Clinical Research
    - Principles of Clinical Pharmacology,
    - Ethical and Regulatory Aspects of Clinical Research
- A two-week summer course in clinical research is offered for PhD candidates and recent PhD graduates
- Host our sabbatical program in clinical research management, done in collaboration with the Office of the DHHS Secretary's Office of Human Research Protections, the Food and Drug Administration and the NIH Institutes and Centers
- NIH is interested in convening a small group of interested representatives from the Academic Medical Centers, including representatives from the CTSAs, to discuss what additional courses might be offered or expanded

Communications Workgroup to the SC Update

POD Feedback Discussion

Kathleen Brady

Pod Feedback Report

N = 66 respondents

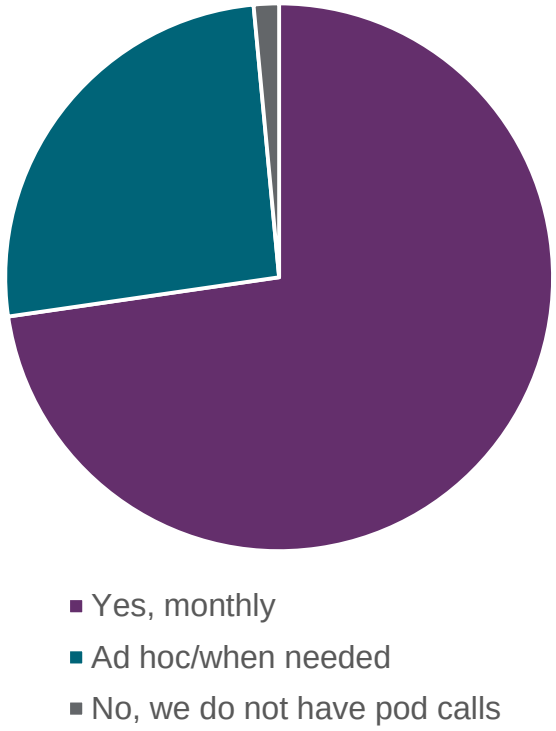
PIs = 49

- Pod leader = 14
- Pod member = 35

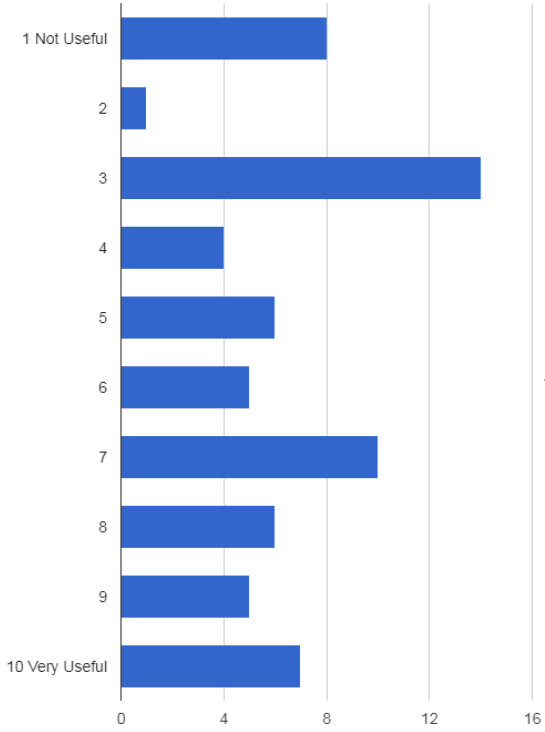
Administrator = 15

Other = 15

Do you attend monthly calls?



How useful are the pods?



Full Sample Mean = 5.47 (SD=2.87)
PI Pod leader Mean = 5.50 (SD=2.20)
PI Pod member Mean = 5.77 (SD=2.89)
Administrator Mean = 4.93 (SD=3.53)

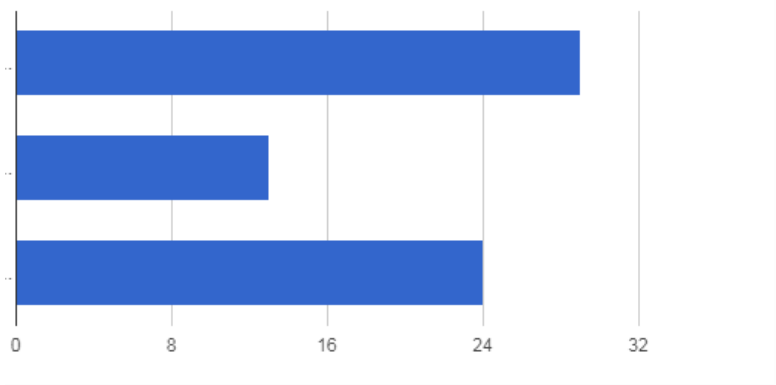
Pod Feedback Report

Do you recommend…

a) Keeping the pod structure "as is" (29, 43.9%),

b) Changing the frequency to "as needed" (13, 19.7%)

c) Replacing the pod mechanism with an alternative communication mechanism(s) (24, 36.4%)



Suggested Alternative Mechanisms…

…open session with all PIs and Admins participation every two months to start with. open discussion and updates with material sent beforehand

… an asynchronous blog-like platform at the level of the National Consortium.

Web based input to steering committee and CTSA leadership to be discussed at steering committee meetings.

How about using something like the NIH "on-line study section" system? The pod leader would put some information or some discussion questions on a web site that would be accessible by Pod members. There would then be a ~3 day window to reply, and generate a back/forth online discussion.

Pod Feedback Report

Common Themes

- Needs to be more bi-directional communication with SC, including input. Allow pods to contribute to future SC meetings agendas, and give feedback to SC prior to such meetings, suggest topics, etc.

- Several respondents suggested self-organization – such as to have pod members choose or elect the SC member or create pods based on common interests. They feel the pod membership structure if confusing – pod membership should be developed from more naturally occurring shared interests/affiliations/regions/time-zones.

Communications Workgroup to the Steering Committee Discussions

- Pods to continue to hold calls preferably 1-2 months or every 4-6 weeks.
- Pods can determine their own recurrence

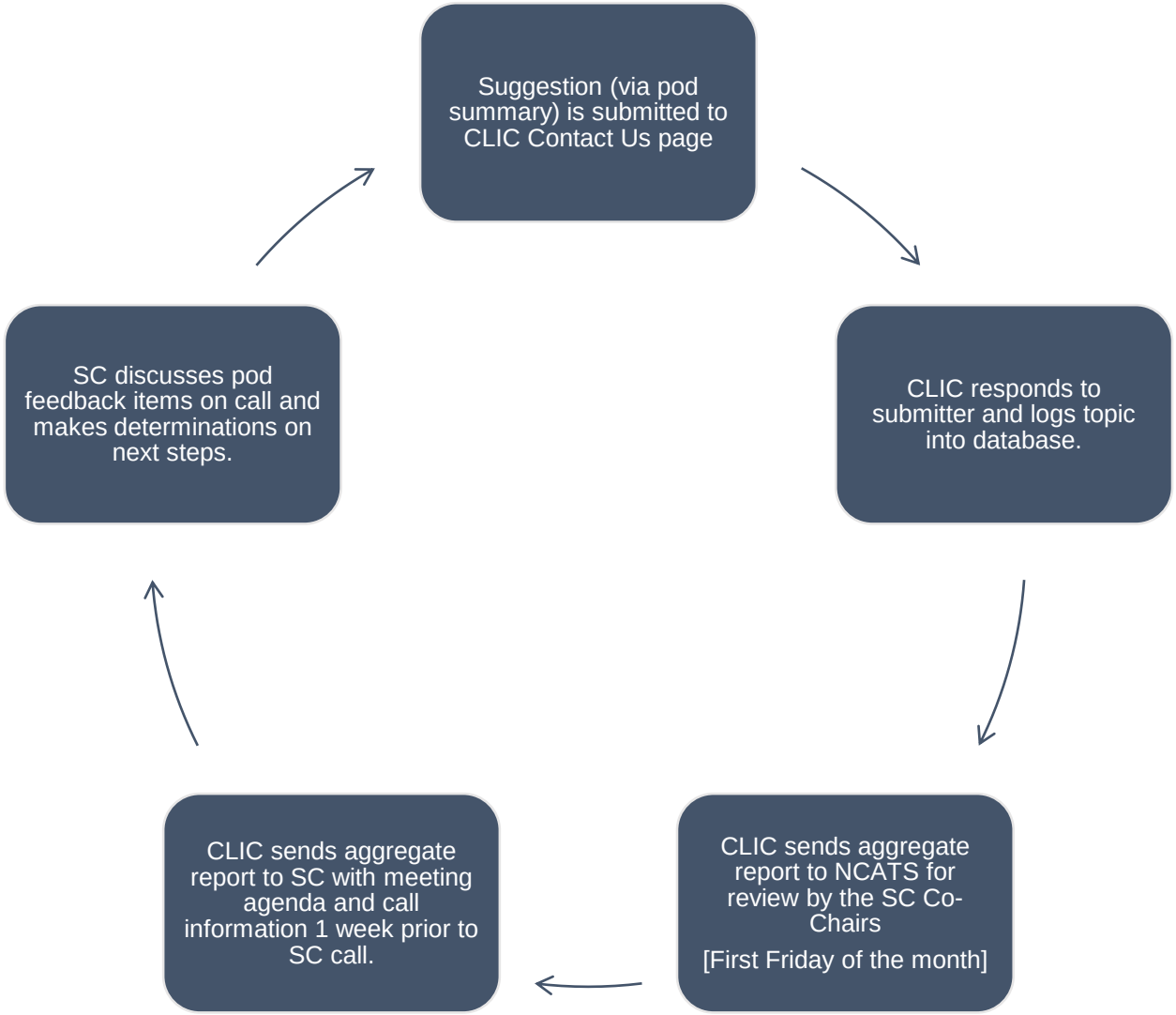
Enhancing Bi-Directional Communications

- CLIC will develop a submission portal on the "Contact Us" subpage of the CLIC website that allows suggestions to come in from various audience (individual PI members, SC/Pod leaders, administrators)
- CLIC will keep a list of topics that the SC is currently looking at and add new items
- CLIC will post the pod feedback report on the CLIC website for transparency to the consortium
- NCATS will add a dedicated time on the agenda to review an aggregate report of feedback

Pod Reorganization? – Geographical Considerations

- Need input on this specific question; not enough data
- CLIC to develop a poll and circulate to the consortium on whether to regionalize pods
- Leave the poll open for 2 days after PI call for those unable to attend the call
- If a regional reorg is determined, this would take effect next year (CY2019)

Pod Feedback Structure



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Informatics Domain Taskforce Update

Donald Lloyd-Jones

Brainstorming: April Face-to-Face Steering Committee Agenda

All

Brainstorm: CTSA Program Steering Committee Agenda

- 4 Hour Meeting (8 – 12 PM)
- 1 Hour to be focused on Domain Task Forces

Spring 2018 CTSA Program Steering Committee Meeting

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

7:30 – 8:00	**Registration for SC Meeting**
8:00 – 9:00	**Domain Taskforce Discussions** TBD
9:00 – 10:00	***1 Hour Slot*** *TBD*
10:00 – 10:15	*Break*
10:15 – 11:15	***1 Hour Slot***
11:15 – 12:00	***45 Minute Slot***

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Discussions on Topics from the Pods

All

POD DISCUSSIONS

- Whether nurses caring for patients in clinical studies have GCP-level skills in conducting clinical research.
- The CTSA Program should act as a convener for research pharmacists to share experiences and best practices in addressing:
  - a) the increasingly stringent (and costly) requirements for obtaining and compounding research drugs;
  - b) transport of research pharmaceuticals across State barriers; and
  - c) maximizing the safety of administering investigational agents.
- The CTSA Program should investigate the impact of EPIC's creation of COSMOS on other CTSA-supported networks.
- Topics from the floor

Thank you!

Next Call: March 12, 2018

2:30 – 4:00 ET