

CTSA Program Steering Committee

Monday, July 9, 2018

2:30 – 4:00 ET

Agenda

2:30	Welcome	Christopher Austin
2:30 – 2:40	Director's Update	Christopher Austin Mike Kurilla
2:40 – 3:30	Review Action Items List <ul style="list-style-type: none">• DCI and Cancer Center Meeting Update• Workforce Development Workgroup	All
3:30 – 3:45	Methods and Processes DTF Project Approval: Great CTSA Team Science Contest	Debbie DiazGranados Bill Trochim
3:45 – 4:00	Brainstorming Agenda Topics: <ul style="list-style-type: none">• October 22nd CTSA Program Steering Committee• October 23rd CTSA Program Meeting Agenda <p>Both meetings will be held in Crystal City, VA. More information here.</p>	Samantha Jonson Clare Schmitt



NCATS Director's Update – FY 2019 Budget

House - Appropriations Subcommittee on Labor/HHS/Educ

- June 14 - passed Bill (<https://appropriations.house.gov/files/?CategoryID=34777>)
 - Bill Details:
 - NIH: \$38.3 billion (+ \$1.25 billion)
 - NCATS: \$751,219,000 (+ \$8.9 million)
 - CAN: up to \$30,000,000
 - CTSA: \$542,771,000 (+ \$0)
 - Report Details:
 - “The Committee expects NIH to fund CTSA’s at not less than the level provided in FY 2018.”
 - “Rural Health Outcomes and Health Disparities--...The Committee requests an update on the actions within the CTSA Program to improve rural health outcomes and health disparities in the FY 2020 [budget request].”
- July 11 - Full Appropriations Committee to vote on Bill
 - Multiple amendments expected to be proposed by Democrats

Senate - Appropriations Subcommittee on Labor/HHS/Educ

- June 26 - passed Bill (<https://www.appropriations.senate.gov/subcommittees/labor-health-and-human-services-education-and-related-agencies>)
 - Bill Details:
 - NIH: \$39.1 billion (+ \$2.0 billion)
 - NCATS: \$806,787,000 (+ \$64,353,000)
 - CAN: up to \$80,000,000
 - CTSA: \$560,031,000 (+17.3 million)
 - Report Details:
 - “The Committee encourages the NCATS to fund, through the existing CTSA Program hubs, expanded efforts to improve translational research that address health disparities and the significant burden of conditions that disproportionately affect minority and special populations...”
- June 28 – Full Appropriations Committee approved all 12 FY19 appropriations bills.



Open Mike

Helping connect you with the NIH perspective, and helping connect us with yours

Posted on [July 3, 2018](#) by [Mike Lauer](#), [Michael Kurilla](#), and [Jane Atkinson](#)

The NCATS Trial Innovation Network – A Resource Supporting High Quality and Cost Effective Clinical Trials Available to You

Well-conducted randomized trials are considered the best method of providing evidence about the safety and efficacy of treatments to improve health. Each year, NIH Institutes and Centers spend an estimated \$3-4 billion supporting clinical trial activities. These activities require high-level understanding of human biology, of manufacturing and pre-clinical research, and of regulatory requirements. The process of translating a new therapeutic from discovery to practice can be robust, but ... at the same time is long and expensive – and despite the challenges inherent in complex, multi-disciplinary research sometimes too long and too expensive.



Dr. Michael Lauer is NIH's Deputy Director for Extramural Research, serving as the principal scientific leader and advisor to the NIH Director on the NIH extramural research program.

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Domain Task Force Survey Overview



Date	Task
July 2	Survey disseminated to PIs, administrators, DTF Teams and DTF workgroup members; targeted reminders will be sent out twice
July 16	Survey closes
August 13	Report prepared by CLIC and NCATS
August - September	Taskforce and NCATS deliberates and assesses
October 8	Presentation to SC
October 23	Presentation at CTSA Program Meeting



Supplements – Responsive to NOT-TR-18-022

Priority Research Areas

- Priority Research Areas described on the [consortium website](#) that were considered for supplemental funding, but not limited to:
 - Planning / Pilot Grants to support:
 - Opioids
 - CTSA Program Collaborative Innovation Suite of Awards
 - Education and/or training materials/resources
 - Research Software Applications
 - Software Messaging Standards and Balloting
 - Rare Disease Research
 - Instrumentation



Supplements – Responsive to NOT-TR-18-022

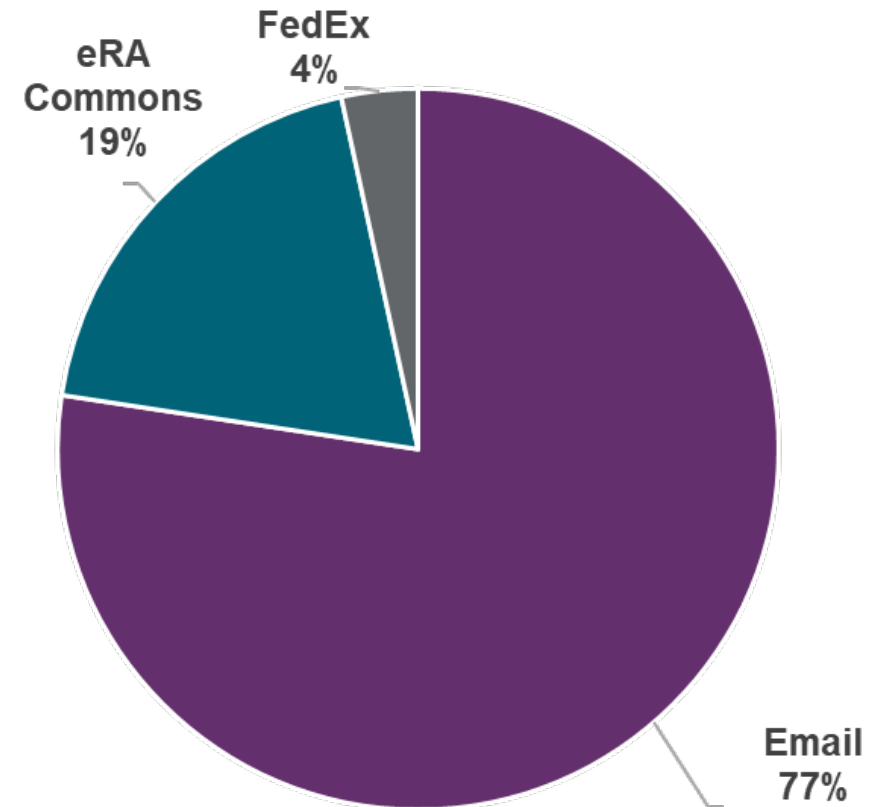
Earliest Anticipated Start Date

- Supplement project and budget periods are limited to the remaining active budget period that started in FY18 for the existing parent award.
 - Examples:
 - For parent awards with FY18 budget periods that started on April 1, 2018, supplement applicants could request a project period from July 1, 2018, through March 31, 2019.
 - For parent awards with FY18 budget periods that start on July 1, 2018, supplement applicants could request a project period from July 1, 2018, through June 30, 2019.
- Earliest anticipated start date is July 1, 2018
- Issuance of awards will be on a **rolling basis**, as funds become available (until end of September 2018), with earliest anticipated start date of July 1, 2018 and onwards
 - Issuance of award may occur AFTER July 1st but may be back dated for a July 1st budget start date



Supplements – Responsive to NOT-TR-18-022 Submission Process

- Process of submitting supplements
 - <https://grants.nih.gov/grants/administrative-supplements.htm>
- 3 ways to submit supplements:
 - × **Electronic requests submitted through Grants.gov**
 - ✓ **Electronic requests submitted through the eRA Commons**
 - [eRA Commons Administrative Supplement Module User Guide](#)
 - ✓ **Paper-based applications**
 - This means EMAIL!
 - Use [PHS 398 forms](#) to create PDF to email
- Troubleshooting:
 - eRA Help Desk: 1-866-504-9552
 - Web: <http://grants.nih.gov/support> (Preferred method of contact)
 - Email: commons@od.nih.gov (for Commons Support)



Pending Action Items

(Not listed in priority order.)

Task	Name	Description	Action	Target Completion Date	Owner
1	CTSA Program U54 Review Processes	SC members brought up the issue of the review process in comparison to the Cancer Centers review and that no PIs are on the review panels.	DCI leadership met with the NCI Cancer Center Director regarding branding and review panel.	Update to be provided on July SC call	Mike Kurilla
2	Future CTSA Program Meetings	Proposed for Fall: Day 1: Administrators and SC overlap; Day 2: Program Meeting	SC will discuss upcoming meeting agendas on July SC call	Discussion to held on July SC call	Steering Committee
3	Workforce Development Concerns	Concerns: 1) the next stage of career for KL2s as NCATS does not have an R portfolio; 2) retaining physician scientists; 3) debt load of physician scientists;	Workgroup is currently meeting	TBD	Susan Smyth
4	Support of administrators	SC recommended that we support the administrators	NCATS and CLIC will support the administrator meetings. CLIC will organize an in-person meeting in conjunction with the CTSA Program meeting this coming October.	MAY 2018 - COMPLETE	Erica Rosemond
5	FOA feedback	Develop a broad-reaching feedback mechanism on previous FOA	NCATS is developing a comprehensive multi-stakeholder plan and will report back to the SC at a later time.	TBD	Mike Kurilla
6	Suggestion Box	Need to have submissions and responses open to the consortium	CLIC will implement the discussion board which will allow for others to provide asynchronous comments regarding topics.	Fall 2018	Martin Zand
7	Talking Points for Institutional Administration	Talking points for PIs for the institutional administration on the value of being a part of the CTSA Program consortium	NCATS will develop revised talking points. NCATS staff will reach out to the SC for input. More details to come.	TBD	TBD
8	Steering Committee Task Force on the Domain Task Force	Develop a survey to determine possible changes/enhancements to the DTF structure.	Workgroup to present survey data on August 13 call.	November 2018	Kathleen Brady
9	IT Platform for Collaboration	Develop a space where SC can house working documents, discussions, polling, etc.	NCATS working on log-in federation for NCATS G-Suite Enterprise system.	August 2018	Sam Jonson

Steering Committee Workforce Development Taskforce

Tentative Goal of the SC Taskforce - to identify ways in which NCATS and the CTSA Programs can work collaboratively with policy and decision makers in government, academics, and elsewhere to improve the environmental landscape for supporting the development of the translational science workforce, with particular emphasis on physician-scientists and clinician investigators.

The focus will be on the environment in which most of the translational science trainees land initially, namely academic medical centers.

Specific issues that have been raised include:

- (1) mechanisms to offset debt from medical school and extended training;
- (2) lack of specific R pathway for KL2 scholars;
- (3) Other items

Membership of taskforce: (* not yet invited)

- Susan Smyth
- Rebecca Jackson (Ohio State)
- Barry Coller (Rockefeller)
- Phil Kern (UK)
- Joel Tsevat (UTHSCSA)
- Doris Rubio (UPMC) *
- Emma Meagher (Univ Penn) *
- TBD others

Questions

1. Is the scope correct / appropriate?
2. What is the expectation for deliverables?
3. What is our time line?
4. Will there be an implementation arm?
5. What will be the evaluation process?
6. Membership
 - 2 individuals are not on SC or lead DTF - is this ok?
 - Do we need to do a broad announcement to the entire DTF to solicit names for the committee or is invitation-only acceptable ?



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Institutional Readiness for Team Science

The Great CTSA Team Science Contest

Deborah DiazGranados - VCU
William Trochim - Cornell



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The Great CTSA Team Science Contest

What It Is. The purpose of this contest is to find the best ideas in all of CTSA-land for encouraging better team science. The CTSA hubs have been operating for as long as ten years and many hubs have been trying out and testing novel ideas for how to encourage better collaboration and teamwork in biomedical research. We want to find the best examples of things that have worked or seem especially promising.

Who Can Play. Any person associated with a CTSA hub is eligible. It can be the PI, a participating researcher, a community member associate, a hub staff member, etc.



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The Great CTSA Team Science Contest

How to Play. It's simple. Think of something that you've seen done at your hub's institution(s) that you think has helped to advance team science. It could be a program, a support service, an event, or anything else. We've set up a simple website where you will be asked to supply three things about your team science innovation:

The Headline (15 words or less!). Concoct a short headline for an imaginary newspaper article about the team science innovation. For example, a headline might be something like "Come Together: A Program for Launching Biomedical Research Teams".

The Paragraph (150 words max!). Provide the bare essentials that summarize the "story" of your team science innovation. This should include the basic "five-W's": Who, What, Where, When, and Why, and as much of the 'How' as you can fit (see here for more suggestions on how to think about writing this).

The Hub. You'll be asked to identify the hub you are associated with.



The Great CTSA Team Science Contest

The Judging. We have assembled a crack team of the best team science researchers and managers in all of CTSA-land. Multiple judges will be asked to read each contest submission and rate it for things like: Originality, Importance, Feasibility, Impact. These will be analyzed by our top-flight team of biostatisticians and the highest-rated submissions will be declared the gold, silver and bronze award winners in each category.

The Prize. The winners will receive absolutely no prize money, no additional grant funds and, in fact, nothing of any monetary value whatsoever! They won't get a medal or a trophy. Instead, they'll get something every CTSA desires and finds so hard to achieve – ***bragging rights!*** The winning hubs will be announced at a major CTSA event and the results forever recorded on the world-wide internet somewhere.



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The Great CTSA Team Science Contest

Most Significant Change Methodology (Trochim)

- Relatively new method based on a qualitative, participatory approach, with stakeholders involved in all aspects of the evaluation.
- Shift away from conventional quantitative, expert driven evaluation methods toward a qualitative participant driven approach, focusing on the human impact of interventions.
- Involves the generation of significant change stories by various stakeholders involved in the intervention.
- These are stories of significant changes caused by the intervention.
- The more significant of these stories are then selected by the stakeholders and in depth discussions of these stories take place.
- These discussions bring to the stakeholders' attention the impacts of the intervention that have the most significant effects on the lives of the beneficiaries.

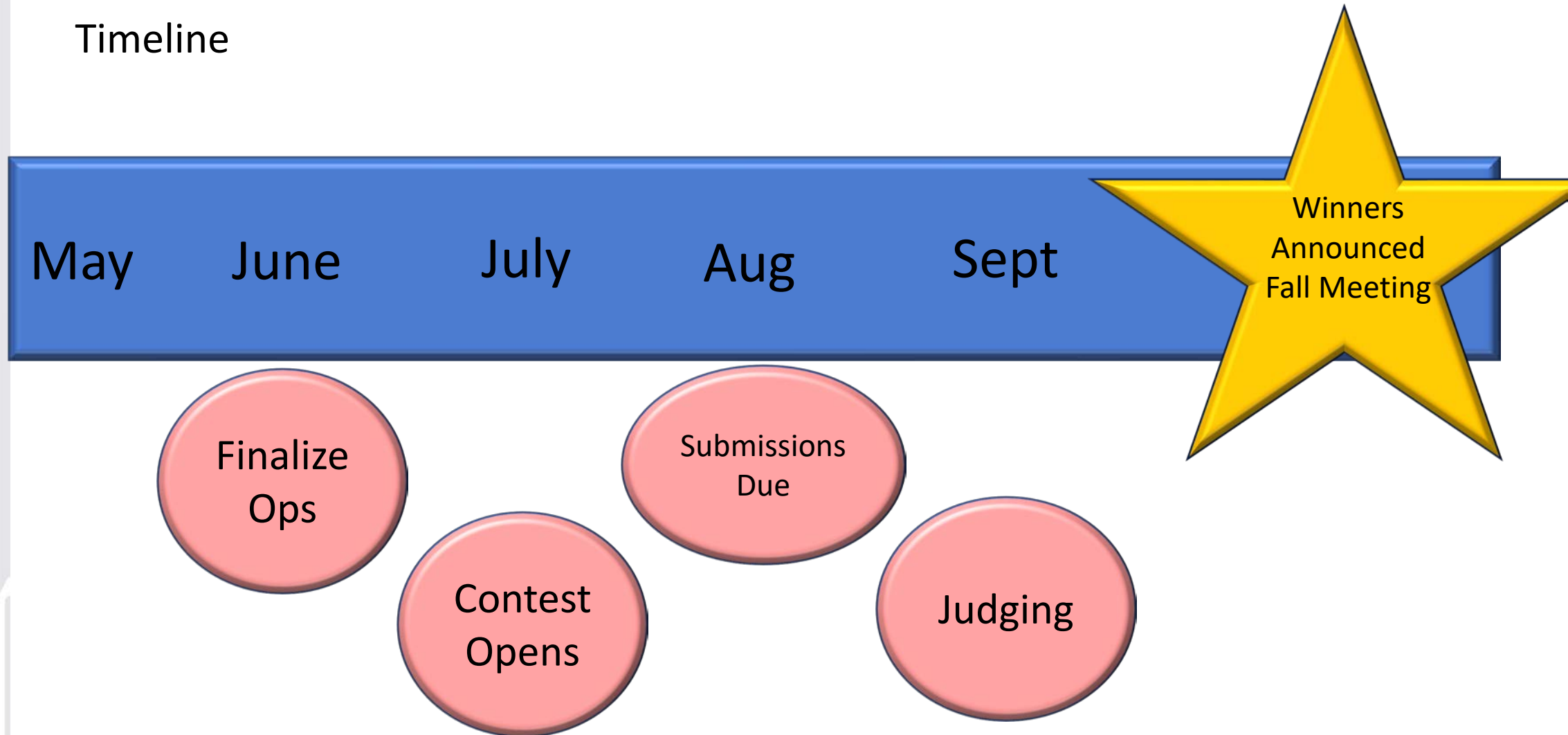


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https://en.wikipedia.org/wiki/Most_significant_change_technique#cite_note-2

The Great CTSA Team Science Contest

Timeline



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Why is this unique?

- Focus on interventions that promote/support team science
- Real world examples
- “Catalog” of ideas
- Low burden of response
- Not PI-dependent
- Opportunity for creativity and a little fun (?)
- Methodology simple and could be used for other areas



Brainstorming Agenda Topics

October 22nd CTSA Program Steering Committee

- Start time?
- How long?
- Agenda topics?

October 23rd CTSA Program Meeting Agenda

- Scheduled Presentations
 - SMART IRB
 - ACT
 - CD2H
 - CLIC



Next call: August 13, 2018

