

CTSA Program Webinar

03/22/2023







Agenda

TIME	TOPIC	PRESENTER(S)
2:00 pm ET	Welcome	Rebecca L. Laird, MDiv, MBA Assistant Director, CLIC
2:01 pm - 2:10 pm	NCATS & CTSA Program Updates	Michael G Kurilla, MD, PhD Director, Division of Clinical Innovation
2:10 pm – 2:35 pm	HRSA Regional Pediatric Pandemic Network	Joelle Simpson, MD, MPH The Pediatric Pandemic Network, MPI Mark Batshaw, MD The Pediatric Pandemic Network, MPI
2:35 pm – 2:55 pm	Clinical Trials Management Ecosystem Maturity Model Update	Justin Starren MD, PhD Working Group Lead
2:55 pm – 3:00 pm	CLIC and CCOS Updates	Deborah Ossip, PhD MPI, CLIC Stephan Bour, PhD CCOS, PI
3:00 pm ET	Adjourn	





NCATS/CTSA Program Updates

Michael Kurilla, MD, PhD

Director, Division of Clinical Innovation NCATS

March 22, 2023



Appropriations - FY 2023

- **Consolidated Appropriations Act, 2023** (P.L. 117-328)
 - ➤ Signed by President 12/29/22

\$ (in millions)	FY 2022	FY 2023	
NCATS	Enacted	Enacted	Difference
Total	882.3	923.3	+41.0 (4.6%)
CTSA	606.6	629.6	+23.0 (3.8%)
Non-CTSA	275.7	293.8	+18.1 (6.6%)

CAN* Up to \$60M Up to \$70M



^{*}All CAN projects are funded through the non-CTSA budget.

Notices of Interest

- NOT-OD-23-098: Notice of Special Interest: Administrative Supplements to NIH-funded T32 and TL1 Training Grants to Better Integrate Behavioral and Social Sciences (BSS) with other Health-Related Sciences
 - To be eligible, the parent award must be active (i.e., not be in an extension period), and the activities proposed in the supplement must be accomplished within the remaining active budget period that started in FY23 for the existing parent award.
 - Application Due: May 1, 2023
 - Contact: Erica L. Spotts, PhD., Office of Behavioral and Social Sciences Research (OBSSR), Email: spottse@od.nih.gov
- NOT-TR-23-007: Notice of Information: NCATS Prior Approval Process for New CTSA Program UM1 and K12 Scholar Projects that Involve Human Subjects Research
 - CTSA Program Website for grantees update to reflect this new notice (<u>New Projects with Human Subjects Research</u>)



CTSA Program Research Supplements to Promote Diversity, Re-entry and Re-integration

NEW RECEIPT DATE: SEPTEMBER 15, 2023

- CTSA Program-Specific Guidance for Diversity, Re-entry and Reintegration Research Supplements: https://ncats.nih.gov/ctsa/funding/diversity-reentry-reintegration/guidance
 - Please ensure that packages are complete by adhering to this guidance
- Prospective applicants and their mentors are strongly encouraged to contact
 their respective NCATS program officer and/or the scientific contact listed
 below during the initial preparation of a supplement application and prior to
 its submission to discuss the goals and objectives of the supplement application.
 - Scientific Contact: Andrew Louden, Ph.D. @ andrew.louden@nih.gov
 - Grants Management Contact: Leslie Le @ leleslie@mail.nih.gov



Request for Information (RFI): Advancing Clinical and Translational Science through Accelerating the Decentralization of Clinical Trials

- **Information Requested:** This RFI invites stakeholders throughout the scientific research, advocacy, clinical practice, industry, patient and lay communities, including the general public, to comment on how DCTs may be designed to be more effective, efficient and equitable to bring more interventions to all people, faster.
- Possible areas for comment include, but are not limited to:
 - Application of research methods in decentralized clinical trials (DCTs)
 - Resources, Infrastructure, and Enabling Technologies
 - Community Engagement
 - Workforce Development
 - Partnerships and/or Collaborations
 - Study Participation and Adherence
 - Data integration, quality, accessibility, and reproducibility
 - Privacy and Regulatory Considerations
- Response Date: May 12, 2023
- POC: Chris Hartshorn: christopher.hartshorn@nih.gov
- https://grants.nih.gov/grants/guide/notice-files/NOT-TR-23-006.html





Update to Guidance of Conference Grants Supported with Funding from the CTSA Program

- Conference grants supported with funding from the CTSA Program must:
 - be from a primary CTSA institution or a CTSA partnering institution (see list on the CTSA Program UM1 Budget Request Tables page,
 - address the CTSA Program goals (listed on the <u>About the CTSA</u> <u>Program</u> page), and
 - have consortium-wide impact and/or are intended for participation by multiple CTSAs.
- CTSA supported conference grants must comply with NCATS-specific <u>Conference</u> <u>Grant Information</u>.



Steering Committee Pod Discussions Through February 2023

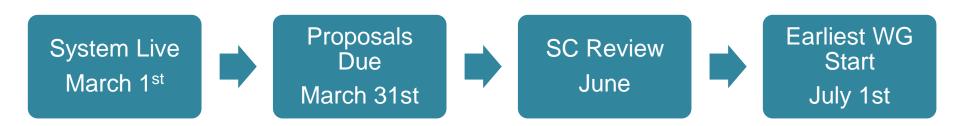
- Discussion of utilization of ENACT and other platforms like N3C and TriNetX
 - Developed into the first Steering Committee crowd-sourced topic for further discussion on the March 27 meeting (led by Karen Johnston, Steve Reis and Melissa Haendel)
- Future vision and plans for N3C
 - Further discussed at the Steering Committee on March 20 and will be the main topic for the April CTSA Program webinar on April 26
- Concern expressed about the widening of the gap in funding for a "living wage" for predoctoral and postdoctoral fellows
 - Advisory Committee to the NIH Director Working Group on Re-envisioning NIHsupported Postdoctoral Training (<u>ACD Postdoc WG</u>)
 - NOT-OD-23-084: Request for Information (RFI): Re-envisioning U.S.
 Postdoctoral Research Training and Career Progression within the Biomedical Research Enterprise (Closes April 14, 2023)



Solicitation of CTSA Working Group Proposals

The CTSA Program Steering Committee encourages the consortium to create Working Group proposals that align with the following areas:

- Learning health and research systems
- Best practices for navigating the Science of Translation
- Causes of rising midlife mortality in America (Case & Deaton, PNAS, 2015)
- Climate change and health
- National training curricula in CTS
- Diversity, equity, inclusion, and accessibility
- Enhancing the impact of clinical trials





Submission Page: https://clic-ctsa.org/groups/working-groups-proposal-information

Advancing the Clinical Translational Science Enterprise

CTSA Roundtables Part II

- March June 2023
- Part of NCATS' initiative to strengthen trust and improve communication with the CTSA community.
- Next series of roundtables to hear from multiple CTSA communities about scientific opportunities and challenges across the CTS enterprise.
- Help inform the NCATS strategic plan.





NCATS 2024 Strategic Plan

Current NCATS Strategic Plan (Fall 2016): https://ncats.nih.gov/strategicplan

If you have feedback for the NCATS 2024 strategic plan, please send comments to:

NCATS2024StrategicPlan@nih.gov



Upcoming Dates to Remember

Next CTSA Program Webinar

April 26, 2023; 2-3 PM ET. Register here.



NGATS

COLLABORATE. INNOVATE. ACCELERATE.













The Pediatric Pandemic Network (PPN)

Lead PIs:
Mark Batshaw MD
Charles Macias MD, MPH
Chris Newton MD
Joelle Simpson MD, MPH

Introducing PPN

VISION

Improving health outcomes of children and the resiliency of children, families and communities impacted by emergencies, disasters and pandemics.























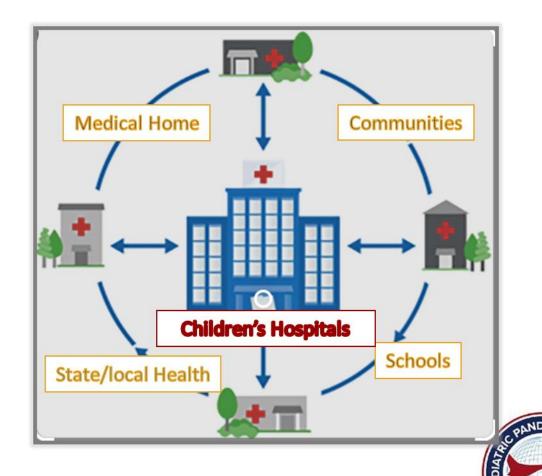
Goals

- 1. Introduce the Pediatric Pandemic Network
- 2. Identify opportunities for partnership with CTSA programs



Mission

In collaboration with the Nation's children's hospitals and their communities, the Network will coordinate, prepare, respond, and disseminate high-quality, equitable, research based pediatric care in future disasters, emergencies, and pandemics.



PPN Goals



Increase children's hospitals **partnerships** with local, state, regional, and national emergency preparedness systems

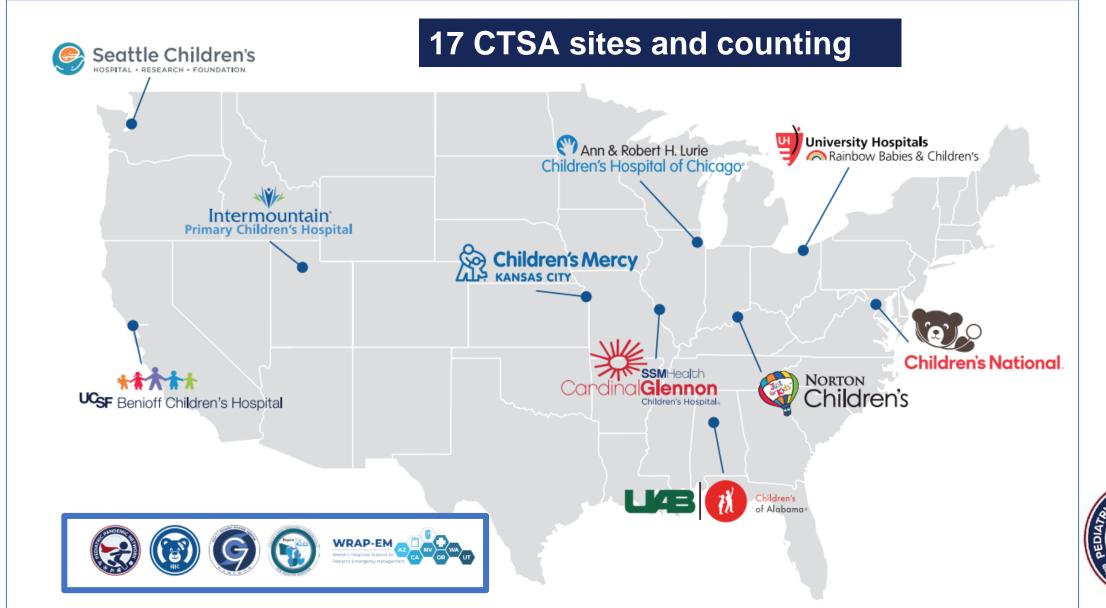
Collaborate with community partners to address disparities and ensure **health equity**

Improve the <u>pediatric emergency readiness</u> of health care systems, including hospital and prehospital systems

Increase the capability of <u>telehealth</u> systems to address the unique needs of children and families

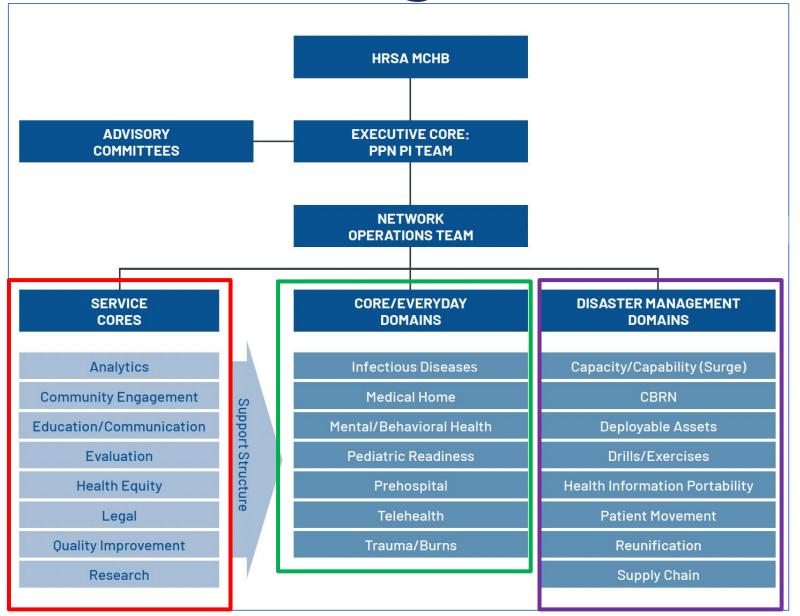
Accelerate the real-time dissemination of research-informed pediatric care

PPN Hub Sites and Key Partners



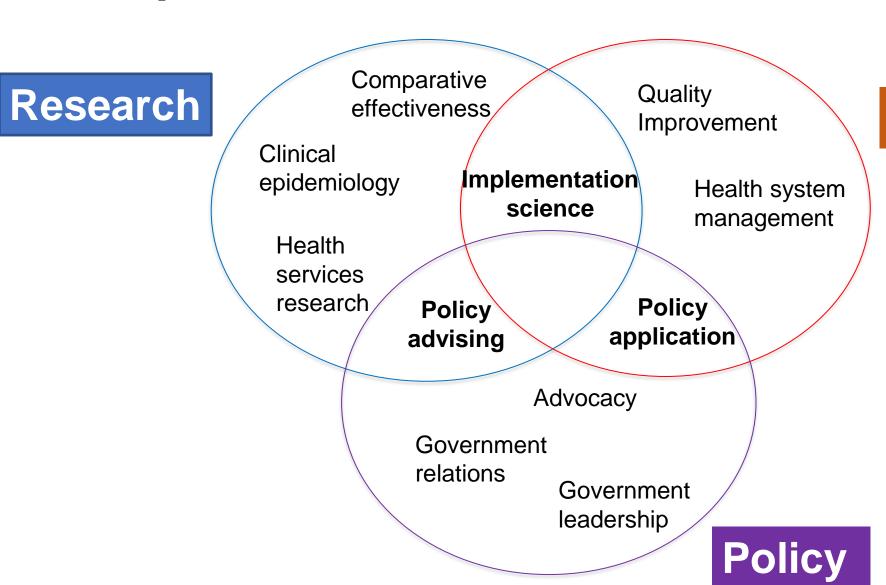


PPN Structural Organization





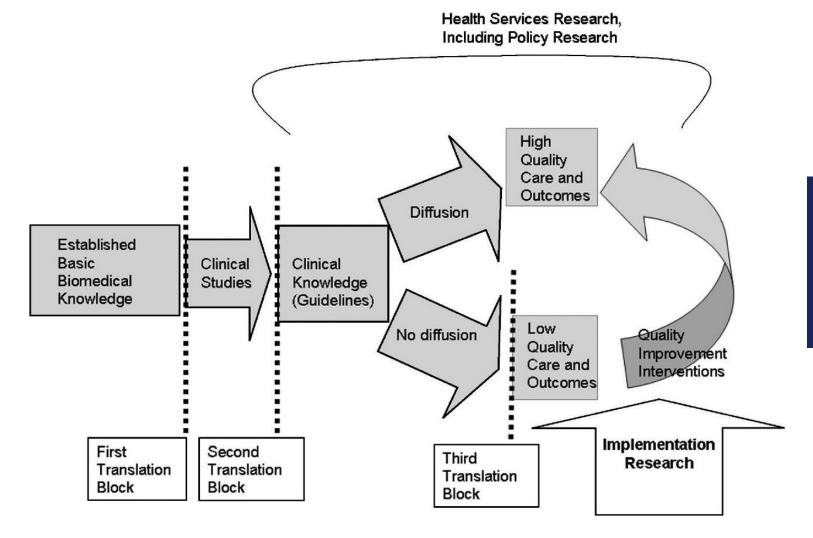
System operations and Health Services Research



Management



Translational Research



Need to use evidence based or research informed strategies to broadly diffuse best practices to achieve high quality care and outcomes



Potential Partnerships of CTSA and PPN

Current work:

Disaster science curriculum Pilot studies program

Disaster science (examples):

- Inquiry on association between everyday readiness and disaster/pandemic readiness
- Linkage between disaster science work in adult and pediatric populations

Research applications:

- Health Services research
- Improvement Science
- Community engagement in research
- Health equity approaches to research

Research environment:

Developing research infrastructure and support during pediatric health emergencies, disasters or pandemics



Contact information



Website: https://pedspandemicnetwork.org

Email: Pediatricpandemicnetwork@gmail.com



Acknowledgments & Disclaimer

The Pediatric Pandemic Network is supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) as part of grant awards U1IMC43532 and U1IMC45814 with 0 percent financed with nongovernmental sources.

The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by HRSA, HHS, or the U.S. Government. For more information, please visit HRSA.gov.





Clinical Trials Management Ecosystem Maturity Model

Justin Starren, Northwestern University Feb. 2023



Clinical Trials Management Ecosystem Maturity

About Members Meetings Deliverables Status Report Message Board

Leadership



Justin Starren
Director, Center for Data Science and Informatics
Northwestern University At Chicago

Adam Wilcox, University Of Washington



Center

Jane AtkinsonDirector, Trial Innovation Network
NCATS



Leonie Misquitta NCATS

Members

Nicholas Anderson, University Of California Davis	Jane Atkinson, NCATS	Michael Becich, University Of Pittsburgh At Pittsburgh
Bryan Belmer, Medical College Of Wisconsin	Tell Bennett, University Of Colorado Denver	Sarah Erskine, Coordination, Communications and Operations Support (CCOS)
Lauren Fitzharris, Coordination, Communications and Operations Support (CCOS)	Jonathan Gelfond, University Of Texas Health Science Center	Ramkiran Gouripeddi, University Of Utah
Rachel Hillhouse, University Of Rochester	Kerry James , Coordination, Communications and Operations Support (CCOS)	Boyd Knosp, University of Iowa
Hongfang Liu, Mayo Clinic	Farhan Mahmood, Icahn School Of Medicine At Mount Sinai	Jomol Mathew, University Of Wisconsin-Madison
Leonie Misquitta, NCATS	Julie Schwan, MS, University Of Rochester	Anthony Solomonides, University Of Chicago
Justin Starren, Northwestern University At Chicago	Megan Stewart, Coordination, Communications and Operations Support (CCOS)	Jeffery Talbert, University Of Kentucky
Bradley Taylor, Medical College Of Wisconsin	Firas Wehbe, Northwestern University At Chicago	Chunhua Weng, Columbia University Health Sciences

Meredith Zozus, University Of Texas Health Science



Maturity Models

- Framework to assess and guide planning
- "Maturity" refers to the degree of formality and optimization of processes and capabilities.
- Developed in 70's for manufacturing
- Capability maturity models for software engineering developed in 90's



Why Bother?

- Within the institution
 - Enhanced Organizational Learning
- Benchmarking
- Prioritization & Planning
- Money
- Developing new models

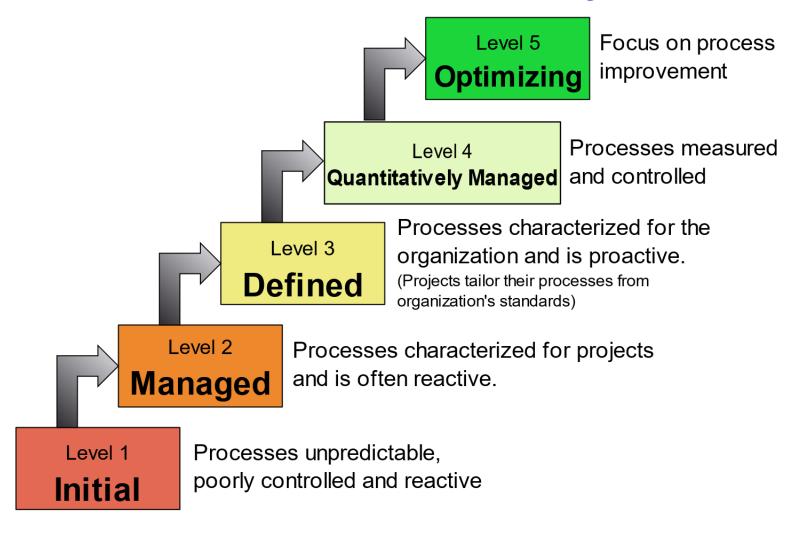






30

Characteristics of the Maturity levels





31

Goal

Develop a multi-axial Clinical Trials Management Ecosystem (CTME) Maturity model.

- Hubs will have improved understanding of the components and complexity of technical and organizational issues related to Clinical Trials Management.
- Establish consortium wide benchmarking for CTME.
- The CTME Maturity Model will empower informatics leads to present and advocate for CTM technology to institutional leadership.
- The CTME Maturity Model will address a missing component to the current suite of CTSA maturity models
- Using the CTME Maturity Model will enable informatics leads to identify and remove barriers to effective CTM at hubs.
- The long-term impact will be improvement in the quality and comprehensiveness of CTME at CTSA hubs.



Step 1: Define Axes

Axis
Study management
Regulatory and Audit management
Financial management
Investigational product management
Subject Identification & recruitment
Subject management
Data
Reporting analytics & dashboard
System integration and interfaces
Staff training & personnel management
Organizational maturity and culture



Axis descriptions 1-3

Study management:

Protocol development, routing, and review, CRF development, contract management, IRB submissions and approvals

Regulatory and Audit management:

Electronic study binder, IRB

Financial management:

Charge capture, budgeting, and pricing





Axis descriptions 4-7

Investigational product management:

Medical equipment, drugs, biomaterial management, research pharmacy, etc.

Subject management:

Patient study calendar, quality control- AE, and cohort management-patient ranking, screening, eligibility, etc.

Subject Identification & recruitment:

Cohort identification, screening, eligibility, consenting, etc.

Data capture and CRF:

Separate for now. May combine with subject management after more definition.





35

Axis descriptions 8-11

Reporting analytics and dashboard:

Report generation, visualization, and dashboards

Staff training and personnel management:

Training resources for staff

System integration and interfaces:

eIRB, Barcode system, ERP

Organizational maturity and culture:

CRTO



36

Step 2: Define levels for each axis

- Developed REDCap survey to solicit candidate statements for each maturity level for each axis.
- Collaborative discussion and refinement of each statement.
 - 1-7 statements per level.
- Level discussions were more extensive and nuanced than anticipated.
- Final level-discussion zoom Feb 17.





37

Progress to Date

Activity	Status	Date
Axes Defined	100%	Mar. 22
Level 1 & 5 Defined	100%	July 22
Intermediate Levels Defined	100%	Feb. 17
Redcap Survey Tool	40%	May 23
Initial CTSA Hub Survey	0%	Oct. 23
Paper	0%	Nov. 23





Related Informatics Maturity Activities

- IEC Maturity Update Mar. 2022
- Maturity Workshop AMIA Fall Symposium, Nov. 2022
- AMIA Maturity Discussion Forum Jan. 2023
 - Submitted charter for conversion to full AMIA Workgroup Feb. 2023
- Birds-of-a-Feather Session AMIA Summit, April 2023
- Maturity Workgroup MEDINFO, July 2023



Discussion and Questions

Justin.starren@northwestern.edu

CTM Maturity Workgroup:

https://clic-ctsa.org/groups/clinical-trials-management-ecosystem-maturity

Draft Maturity Definitions:

https://docs.google.com/document/d/1kYsHzTlt7LQEXiVyeK8yL2_H5uGo7UFD/edit?usp=sharing&ouid=114229323777532070106&rtpof=true&sd=true





40

CLIC and CCOS Updates

Deborah Ossip, PhD CLIC MPI

Stephan Bour, PhD CCOS, Pl





41

Spring 2023 In-Person CTSA Program Group Meetings

Thursday, April 20, 2023

- UL1 Principal Investigator Meeting from 11am-noon.
 - Separate registration- Register <u>here!</u>
- Steering Committee Meeting 1:30-6pm- Please register <u>here</u>

Friday, April 21, 2023

- In-Person CTSA Group Meetings 9am-4pm- Register here.
- Registration closes Monday, April 3rd

Reminder: Virtual participation will be limited to streaming presentations and monitoring the chat. Breakouts, networking sessions, etc., will not be streamed.



Working Group Proposals Due March 31, 2023

CLIC and CCOS will support the next cycle of Working Groups
Proposals in March 2023

- The proposal submission period will be between March 1st 31st.
- All proposals should be submitted no later than March 31st.

Information and the application are available at:

https://clic-ctsa.org/groups/working-groups-proposal-information



Save the Date: 2023 Fall Program Meeting

• **Date:** November 6-8, 2023

• Location: Double Tree (Crystal City) Washington, DC

3-Day Meeting

- Day 1: Administrators and Steering Committee Meeting
- Day 2-3: Program meeting

CCOS Transition Highlights – CCOS Website

- CCOS Website Design is underway
 - Page mockups for public-facing website are done
 - Review / approval by NCATS leadership ongoing
- CCOS Private Portal also being designed
 - New information model
 - Access permissions based on user roles
 - State of the art search engine
- Please contact CCOS to learn more or for a demo of the new website

Themed Issue Call for Manuscripts





Decentralized research: realizing the promise of virtual clinical trials

This themed issue of JCTS will cover the current state of knowledge around decentralized trials, disseminate the innovations and approaches that are being successfully deployed, and will highlight the regulatory, ethical, and methods developments needed to accelerate the migration of research from the hallowed halls of healthcare into the homes of patients and their families. Through this open call, we are soliciting manuscripts that contribute to understanding and improving the decentralized research process



Deadline for Submission due March 30, 2023

Well-Being in Clinical and Translational Science

We are issuing a Call for Papers for a special themed issue of the Journal of Clinical and Translational Science (JCTS) that will focus on evidence-based practices and interventions to support well-being and retention in the CTS workforce

Deadline for Submission due April 1, 2023



Integration of Social Determinants of Health with Clinical and Translational Science NEW

We are issuing this Call for Papers for a special themed issue of the Journal of Clinical and Translational Science, which will focus on studies that address social determinants of health (SDoH) in clinical and translational science.

Deadline for Submission: July 31, 2023





Reminders

- The next scheduled CTSA Program Webinar:
 - Date: April 26, 2023
 - Time: 2:00-3:00pm Eastern Time.
 - New Series Registration Link (July 2022 June 2023)
 https://rochester.zoom.us/webinar/register/WN_JrgtrbvmSZmbURZTyN5Yog
- Group coordinator:
 - ctsa_program_webinar@clic-ctsa.org
- CTSA Program Webinar meeting archives/information:
 - https://clic-ctsa.org/groups/ctsa-program-group







CLIC/NCATS Communication Channels

Sharing Content: CLIC Website

- News (Consortium News & Mike's Blog): <u>clic-ctsa.org/news</u>
- Events: <u>clic-ctsa.org/events</u>
- Education & Career Development Gateway: https://clic-ctsa.org/education-careers
 - Education Clearinghouse: <u>clic-ctsa.org/education</u>
 - Opportunities Board: https://clic-ctsa.org/opportunities-board
 - Diamond: https://clic-ctsa.org/diamond
- Funding opportunities (RFAs):
 - Synergy Papers: <u>https://clic-ctsa.org/collaboration/clic-synergy-papers</u>
 - Un-Meeting https://clic-ctsa.org/collaboration/clic-un-meetings

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: <u>Subscribe Here</u>
- NCATS e-Newsletter: ncats.nih.gov/enews





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: N3C & CD2H Login/Registration

Recruitment Innovation Center (RIC)

- Website:
 https://trialinnovationnetwork.org/recruitment-innovation-center
- Subscribe to newsletter: https://bit.ly/20pEDHc

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



