Technical Assistance Webinar For:
Clinical and Translational Science Award Program

During the presentation send your questions to:

UM1 and RC2: CTSAFOAQuestions@mail.nih.gov

K12, T32 and R25: CTSATrainingFOAsQuestions@mail.nih.gov

October 12, 2022

Introduction

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Director, Division of Clinical Innovation

October 12, 2022

NCATS Division of Clinical Innovation
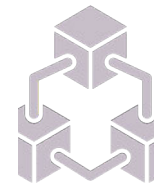## *Innovating Clinical and Translational Science*

Plans, conducts, and supports research to *develop new methods* that enhance clinical processes

Plans, conducts, and supports research to *evaluate existing approaches and technologies* in the clinical spectrum
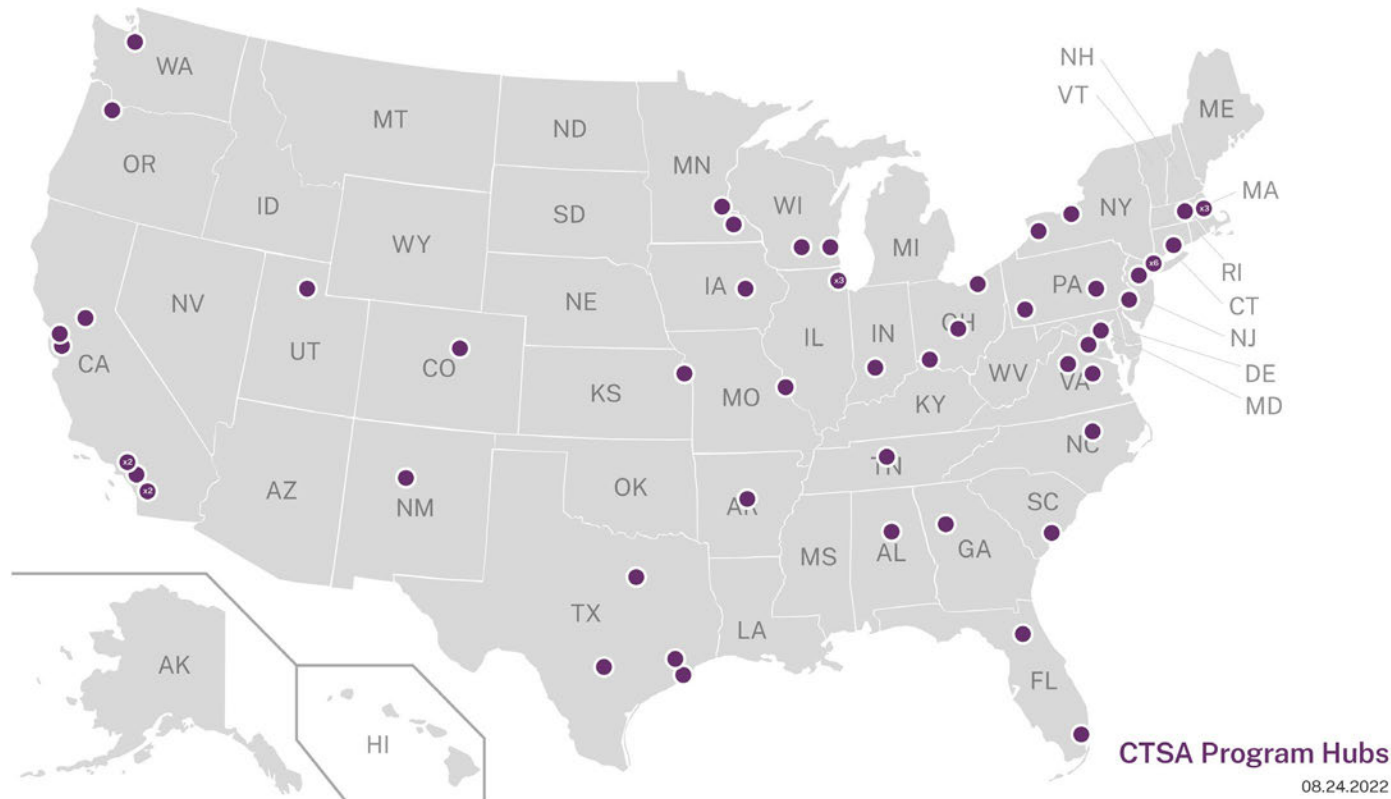
Allocates resources to clinical and translational infrastructure and investigators

Supports training programs relevant to clinical phases of translational science

NCATS Clinical and Translational Science Awards (CTSA) Program

CTSA Program Hubs
08.24.2022

➢ National network of medical research institutions and their partners/collaborators

➢ In fiscal year 2022, NCATS invested $606M in the CTSA Program to speed translation of research discoveries into improved patient care

CTSA Program Focus

Develop, demonstrate, and disseminate innovations that turn science into health faster

Provide a national resource for the rapid response to urgent public health needs

Promote impactful partnerships and collaborations

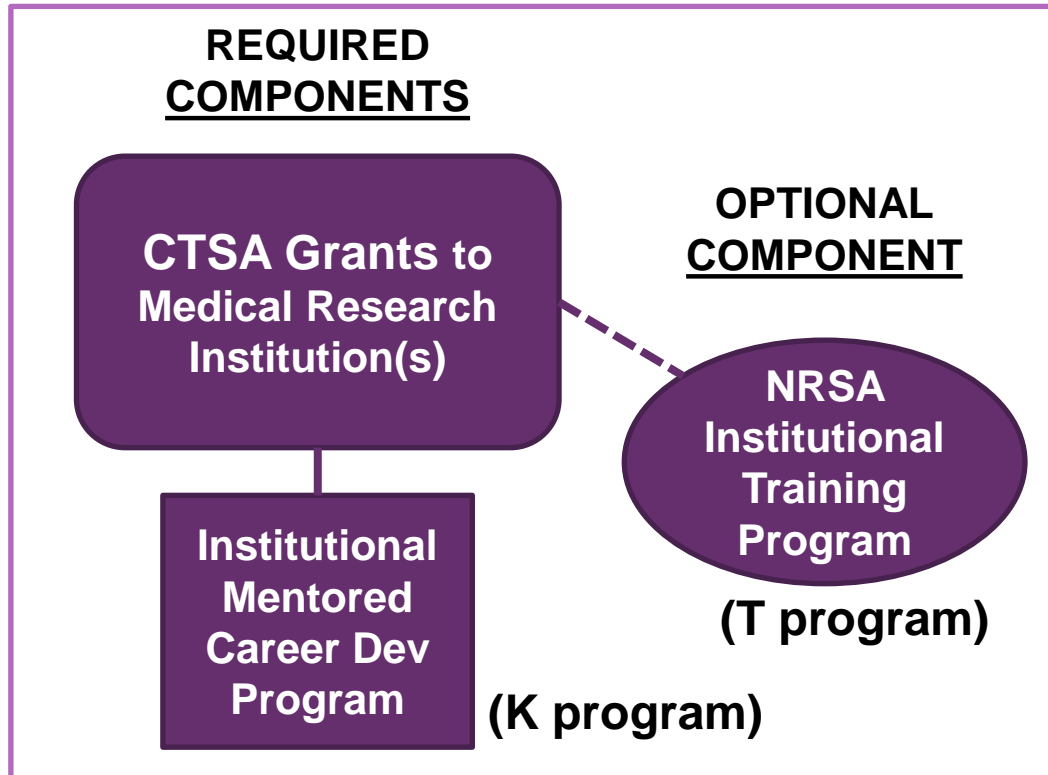Promote training and career support

Address health disparities

Nurture field of translational science

CTSA Program in FY22

63 CTSA Program Hub Grants in FY22

REQUIRED COMPONENTS

CTSA Grants to Medical Research Institution(s)

OPTIONAL COMPONENT

NRSA Institutional Training Program

(T program)

Institutional Mentored Career Dev Program

(K program)

CONSORTIUM-WIDE ACTIVITIES

Operations (website, logistics and meetings)

Data Interoperability & Bioinformatics

Trial Innovation Network (TIN)

PROGRAM FUNDING OPPORTUNITIES

➢ **Collaborative Innovation Awards**

➢ **Supplements**
- **Dissemination**
- **Particular interest areas (e.g., opioids, rural health)**
- **Individual diversity & career re-entry**

National Center for Advancing Translational Sciences

Solicitation of Input and Feedback

Pre-Publication (Planning Stages and Council Meeting):

- Public & Consortium members
  - Request for Information (RFI; thru late Oct 2019)
  - Stakeholder Feedback Session [Video](#) & [Slides](#)
- Listening to various CTSA Groups
- Peer Reviewers of CTSA Program applications
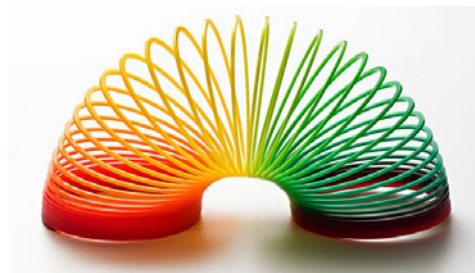- NCATS

Post-Publication:

- CTSA Program Steering Committee and Pods
- Coalition for Clinical and Translational Science
- Individual Responses
- Listening to various CTSA Groups
- CTSA Emails:

  - NCATS_CTSA_Program@mail.nih.gov (general inquiries and feedback)
  - CTSAFOAQuestions@mail.nih.gov (UM1 and RC2)
  - CTSATrainingFOAsQuestions@mail.nih.gov (K12, T32, R25)

Modifications Responsive to CTSA & Stakeholder Feedback

Simplification of Grant Mechanism & Harmonization with NIH Mechanisms

Increase Hub Flexibility & Hub Specialization Opportunities

Expand Hub Funding Options

Hub / Grant Structure

Additional Programmatic Modifications

Research Resources
Informatics
Consulting Services
Funding
Regulatory Support
CTSA
Community Engagement
Training

Award Calculation

Evolution of the Suite of CTSA FOAs

U54
One Complex Application

REQUIRED

One Overall Impact Score

CTSA Hub Grants to Medical Research Institution(s) (UL1)

Institutional Mentored Career Dev Program (KL2)

OPTIONAL

NRSA Institutional Training Program (TL1)

Pre-doc Post-doc Short-term

New
Multiple Separate Applications

REQUIRED

Each application: Individual Impact Score

CTSA Hub Grants to Medical Research Institution(s) (UM1) **+** **Institutional Mentored Career Dev Program (K12)**

OPTIONAL

Specialized Innovation (RC2)

Post-doc (T32) **Pre-doc (T32)** **Short-term (R25)**

INFLEXIBLE → FLEXIBLE

NIH National Center for Advancing Translational Sciences

Program Evolution

Hub / Grant Structure

Current: Hub = U54

- One combined application (U/K/T)
- Hub (U) & required career application (K) & optional T
- Reviewed and scored as a package
- Funding: all or none

New: Hub = UM1

- Separate applications
- Hub (UM1) & required career application (K12) & optional companion applications (T32, R25, RC2)
- Reviewed and scored separately
- Funding: flexible

For illustration purposes:

➢ *Former* CTSA Program Funding – No Flexibility

U Score	K (±T) Score	Overall U54 Score	Consequence*
Fundable range	Fundable range	Fundable range	Funding of all components
Fundable range	Non-Fundable Range	Non-Fundable Range	No funding; entire package must be resubmitted
Non-Fundable Range	Non-Fundable Range	Non-Fundable Range	No funding; entire package must be resubmitted

➢ *Current* CTSA Program Funding – Added Flexibility

U Score	K (±T) Score	Overall U54 Score	Consequence*
Fundable range	Fundable range	N/A	Funding of all components
Fundable range	Non-Fundable Range	N/A	Funding of U; K and optional applications must be resubmitted
Non-Fundable Range	Fundable Range	N/A	No funding of U; optional applications held until U funded

* Funding in any fiscal year is based on merit and subject to available funds

UM1: K12 Required Application

- NOT-TR-22-022: Released February 25, 2022:
  - The K12 Physician Scientist Award Program required UM1 companion application **must be submitted** in accordance with the UM1 and K12 FOAs application submission dates under the following scenario:
    - Initial Concurrent submission of both a UM1 application to PAR-21-293: Clinical and Translational Science Award and a K12 application to PAR-21-336
  - The K12 Physician Scientist Award Program required companion application **may be resubmitted** in accordance with the applicable FOA application submission dates under the following scenarios:
    - concurrently with the resubmitted UM1
    - while the UM1 application is under review consideration
    - after the UM1 application is funded
    - while the UM1 is under consideration for funding
  - While the K12 Physician Scientist Award Program required companion application must be submitted concurrently with the initial UM1 application or resubmitted at any time the submitted UM1 new or resubmission application or award remains active, the K12 Physician Scientist Award Program required companion application will only be awarded if the UM1 is awarded.

PAR-21-336 - K12 Physician Scientist Award Program (PSA)

UM1: Companion Applications

- **NOT-TR-22-008: Released November 15, 2021:**
  - Companion optional applications (RC2, R25, T32s) may be submitted in accordance with the applicable FOA application submission dates under the following scenarios:
    - concurrently with the UM1
    - while the UM1 application is under review consideration
    - after the UM1 application is funded
    - ***while the UM1 is under consideration for funding***
  - While optional companion applications may be submitted concurrently with the UM1 application or at any time the submitted UM1 new or resubmission application remains active, optional companion applications will only be awarded if the UM1 is awarded.

- **Companion Funding Opportunities:**
  - PAR-21-340 - Limited Competition: High Impact Specialized Innovation Programs in Clinical and Translational Science for UM1 CTSA Hub Awards (RC2 Clinical Trials Not Allowed)
  - PAR-21-339 - Limited Competition: NCATS Clinical and Translational Science Award (CTSA) Program Research Education Grants Programs (R25 - Clinical Trial Not Allowed)
  - PAR-21-338 - Limited Competition: Ruth L. Kirschstein National Research Service Award (NRSA) Postdoctoral Research Training Grant for the Clinical and Translational Science Awards (CTSA) Program (T32 Clinical Trial Not Allowed)
  - PAR-21-337- Limited Competition: Ruth L. Kirschstein National Research Service Award (NRSA) Predoctoral Research Training Grant for the Clinical and Translational Science Awards (CTSA) Program (T32 Clinical Trial Not Allowed)

Timelines of Submission of a set of CTSA Applications

- NIH policy states that any application that has undergone review remains active (and under consideration for funding) for up to 14 months after Council.

- Note that the 14-month window for funding eligibility also applies to resubmitted applications; that is, receipt of a resubmitted application constitutes the starting point for the 14-month eligibility window.

- Unfunded Application Notification: NIH will send centralized automated correspondence to applicant organizations notifying them of NIH's intent not to fund the indicated applications (approximately 14 months after the application's council date) (NOT-OD-18-197)

Example Submission:

- **Required applications:**
  - UM1 and K12 (required companion application) submitted May 13, 2022 (January 2023 Council). These applications will be under consideration until May 2024 (for up to 14 months after Council).
- **Optional companion applications:**
  - T32 (predoc) and T32 (postdoc) are submitted September 16, 2022
  - R25 is submitted January 13, 2023
  - One RC2 application submitted January 13, 2023
  - One RC2 application submitted May 17, 2024 (This is the last receipt date that any companion application may be eligible because the next receipt date is September 13, 2024, which is after the 14-month window that the UM1 could be under consideration for funding.)

NOT-TR-22-008, released November 15, 2021

Program Evolution

Award Calculation

Current

- Total NIH funding of the Applicant and Partners over previous **1-year**
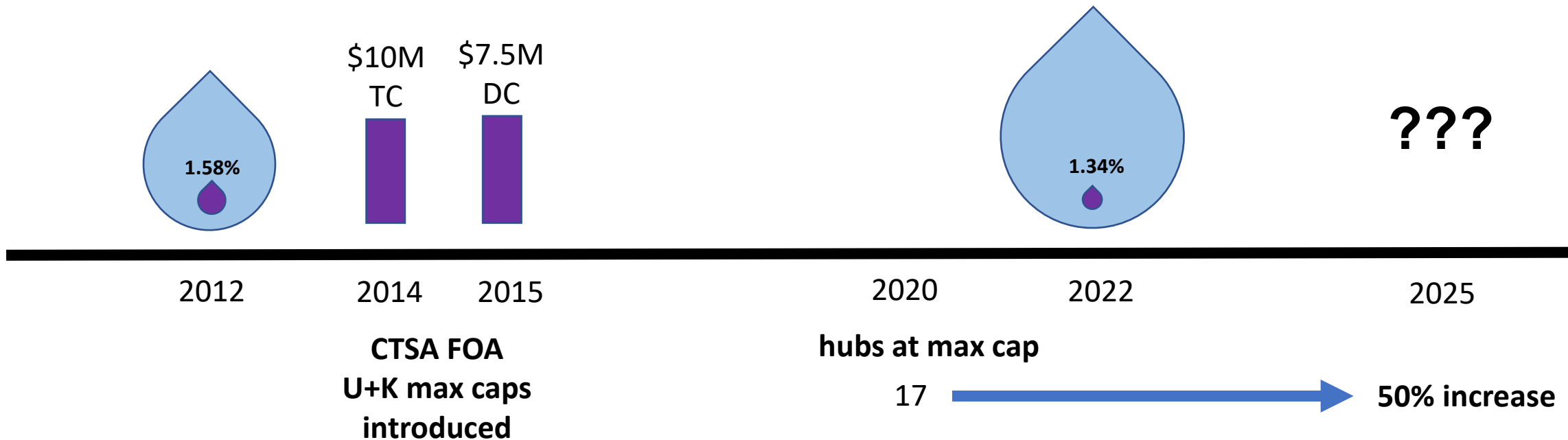- Minimum, maximum, and sliding scale tied to 2.5% of NIH funding of Applicant plus all Partners

New

- Rolling average of previous **5-year** total NIH funding of the Applicant plus any Partners
- 4 funding request categories

Award Budgets: Past, Present & Future

Overall NIH budget has outpaced the CTSA budget growth (2012 – 2022)

$10M
TC

$7.5M
DC

1.58%

1.34%

???

2012

2014

2015

2020

2022

2025

**CTSA FOA
U+K max caps
introduced**

hubs at max cap

17 ——————————————➤ **50% increase**

CTSA budget ●
NIH budget ●

Bottom line: Current 'tie' is not sustainable

Notice of Change to PAR-21-293 Clinical and Translational Science Award (UM1 Clinical Trial Optional) in Award Information

NOT-TR-22-025 (FY23 Awards)

Hub Tier	Size Eligibility Budget Tiers for FOA Applicants (FOA receipt dates May 13, 2022, September 16, 2022)	Maximum Direct Cost Budget Requests for UM1
	5-year average of the most current NIH Direct Cost (DC) Funding of the applicant institution, PLUS 5-year average of the most current NIH Direct Cost (DC) funding of any partner(s)* (based on FY2016-FY2020 NIH Fund data)	UM1
A	>$300,000,000	$6,500,000
C	$220,000,000 - $300,000,000	$5,000,000
T	$135,000,000 - $219,999,999	$3,600,000
G	<$135,000,000	$2,600,000

Institutional NIH Direct Cost (DC) Funding Table FY16-20
FY16-FY20_NIH_DC_Funding-all_Orgs-FINAL.xlsx

NOT-TR-22-033 (FY24 Awards)

Hub Tier	Size Eligibility Budget Tiers for FOA Applicants (FOA receipt dates January 13, 2023, May 12, 2023, September 15, 2023)	Maximum Direct Cost Budget Requests for UM1
	5-year average of the most current NIH Direct Cost (DC) Funding of the applicant institution, PLUS 5-year average of the most current NIH Direct Cost (DC) funding of any partner(s)* (based on FY2017-FY2021 NIH Fund data)	UM1
A	>$320,000,000	$6,500,000
C	$235,000,000 - $320,000,000	$5,000,000
T	$145,000,000 - $234,999,999	$3,600,000
G	<$145,000,000	$2,600,000

Institutional NIH Direct Cost (DC) Funding Table FY17-21
FY17-FY21_NIH_DC_Funding-all_Orgs-FINAL.xlsx

Award Budget Requests for CTSA Applications

Receipt Dates of January 13, 2023, May 12, 2023, September 15, 2023 ([NOT-TR-22-033](NOT-TR-22-033)) for FY24 Funding

Hub Tier Size	5-year avg of NIH DC of applicant institution PLUS NIH DC of any partners*	UM1 Budget (Direct Cost)	K12 Budget (Direct Cost)	T32 predoc slots	T32 postdoc slots
A	>$320M	$6.5M	$1.5M	10	5
C	$235M - $320M	$5.0M	$1.0M	8	4
T	$145M - $234,999,999	$3.6M	$900,000	6	3
G	<$145M	$2.6M	$700,000	4	2

Calculated from the 5-year average of the most current NIH Direct Cost (DC) Funding of the applicant institution, PLUS 5-year average of the most current NIH Direct Cost (DC) funding of any partner(s) (based on FY2017-FY2021 NIH Funding data)

https://ncats.nih.gov/ctsa/funding/CPUBRT

CTSA FOAs Released

- One UM1 hub applicant institution can submit the following applications concurrently with the UM1, while the UM1 application is under review consideration, after the UM1 application is funded or while the UM1 is under consideration for funding (NOT-TR-22-008):

- **REQUIRED APPLICATION:**
  - Institutional Research Career Development Award (K12) PAR-21-336

- **COMPANION OPTIONAL APPLICATIONS:**
  - Institutional NRSA Predoctoral Award (T32) PAR-21-337
  - Institutional NRSA Postdoctoral Award (T32) PAR-21-338
  - Research Education Grant (R25) PAR-21-339
  - High Impact Specialized Innovation Programs in Clinical and Translational Science for UM1 CTSA Hub Awards (RC2) PAR-21-340

- The required K12 and any companion optional applications will be awarded only if the UM1 application is awarded.

Reminder to Applicants

- **Please Note:**
  - The primary source of all information regarding ANY funding opportunity announcement is the funding opportunity itself and any notices linked therein.

    PLEASE READ THE FOA, APPLICATION INSTRUCTIONS AND ALL NOTICES

- **Resources:**
  - Application Information for PAR-21-293: Clinical and Translational Science Award (UM1 Clinical Trial Optional) https://ncats.nih.gov/ctsa/funding/application-information-par-21-293
  - CTSA Program UM1 Budget Request Tables https://ncats.nih.gov/ctsa/funding/CPUBRT
  - CTSA Program Summary Data Guide https://ncats.nih.gov/ctsa/funding/CPSDG
  - Application Information for CTSA Program Research Training and Career Development Awards https://ncats.nih.gov/ctsa/funding/ctsa-research-training-career-development-awards

- **Questions?**
  - UM1 and RC2: CTSAFOAQuestions@mail.nih.gov
  - K12, T32 and R25: CTSATrainingFOAsQuestions@mail.nih.gov

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- NIH Events Management

Next Up: Technical Assistance for the UM1 FOA

During the presentation send your questions to: CTSAFOAQuestions@mail.nih.gov