National Institutes of Health (NIH)
National Center for Advancing Translational Sciences (NCATS)
Clinical and Translational Science Awards (CTSA) Program
Feedback Information Session

Michael G. Kurilla, MD, PhD

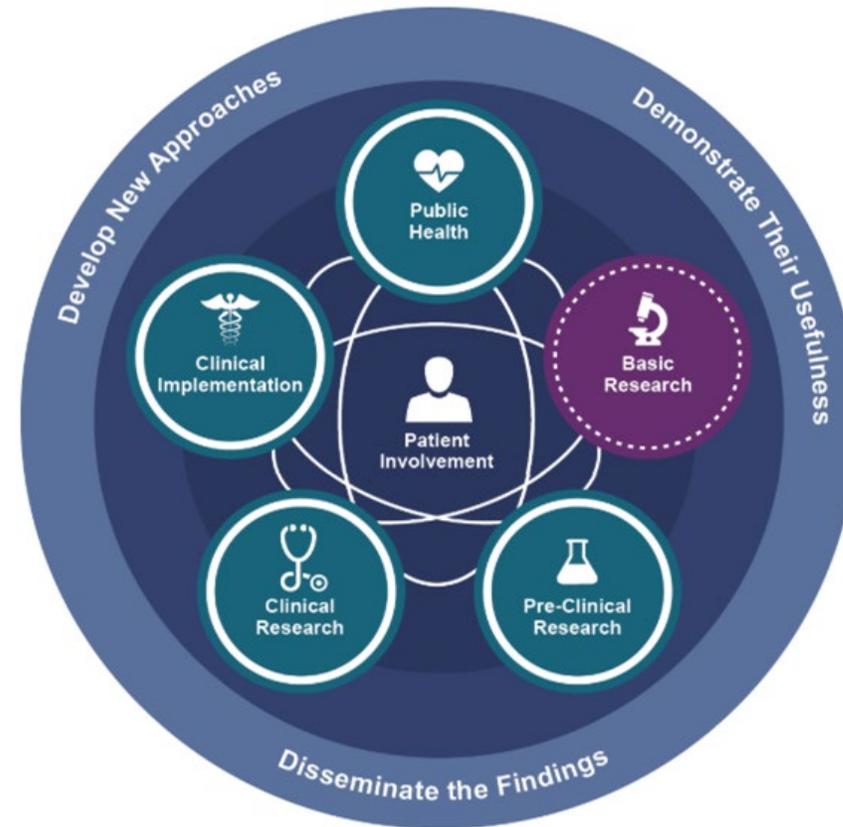Director, NCATS Division of Clinical Innovation

National Center for Advancing Translational Sciences (NCATS)

o One of the 27 Institutes and Centers at the National Institutes of Health (NIH), NCATS strives to bring more treatments to more patients more quickly.

o Rather than specific diseases, the focus is on foundational, broadly-applicable gaps and opportunities across the health research spectrum.

o Conducts and supports research on both the scientific and operational aspects of translational science leading to more predictive and successful development of new medical interventions, such as drugs, diagnostics, and medical devices, for all human diseases.

What we do

NCATS leverages the power of data, new technologies and teamwork to develop, demonstrate, and disseminate innovations that reduce, remove or bypass costly and time-consuming bottlenecks in translational research.

**NCATS Director
Christopher P. Austin, MD**

NCATS Division of Clinical Innovation (DCI)

o Innovates extramural clinical and translational science through development of novel processes, sharing of best practices, collaboration, and harmonization of research approaches at the local, regional and national levels

o Disseminates expertise, tools, training, and clinical research innovations for effective treatments, while supporting a diverse translational science workforce

o Administers the NCATS Clinical and Translational Science Awards (CTSA) Program

DCI Director
**Michael G. Kurilla, MD-PhD**

NCATS Clinical and Translational Science Awards (CTSA) Program

o One of the largest programs at the NIH

o National network of medical research institutions, their partners and collaborators working together to speed translation of research discoveries into improved patient care by tackling system-wide problems in clinical and translational research that no single team can overcome

NCATS CTSA Program

In fiscal year 2020, NCATS invested $578M in the CTSA Program, currently comprising 60 medical research institutions that share the common vision of improving human health by transforming clinical and translational science.

National Center
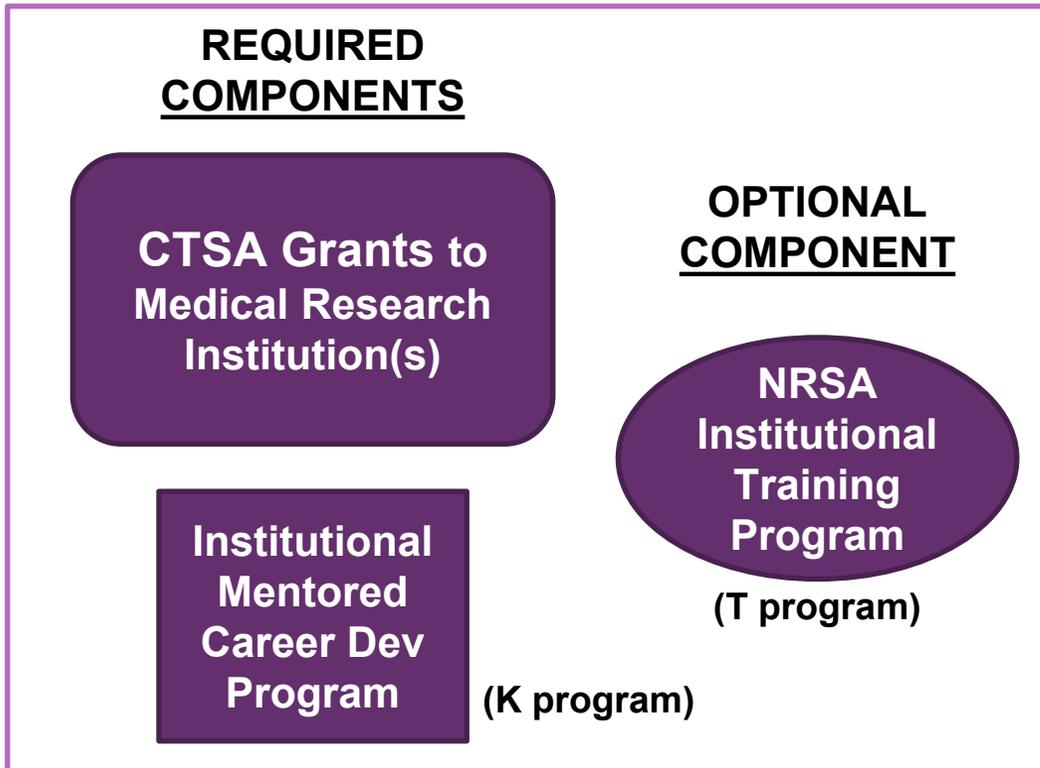for Advancing
Translational Sciences
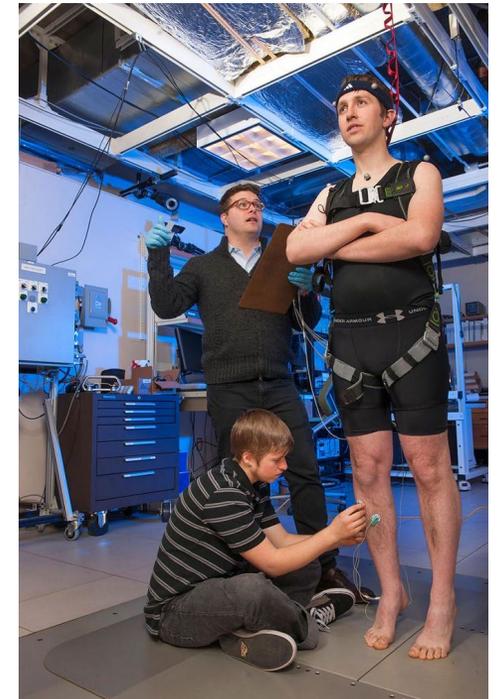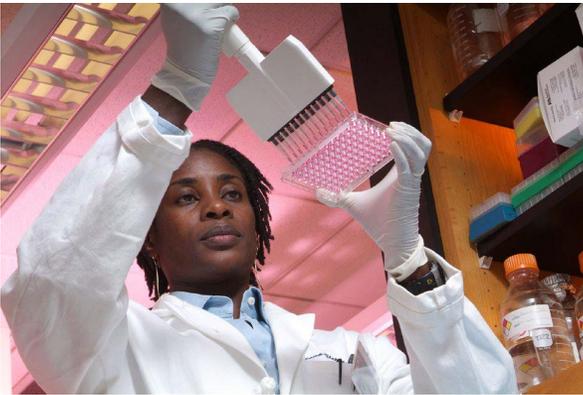
Current CTSA Program goals

- Train and cultivate the translational science workforce

- Engage patients and communities in every phase of the translational process

- Promote the integration of special and underserved populations in translational research across the human lifespan

- Innovate processes to increase the quality and efficiency of translational research, particularly of multisite trials

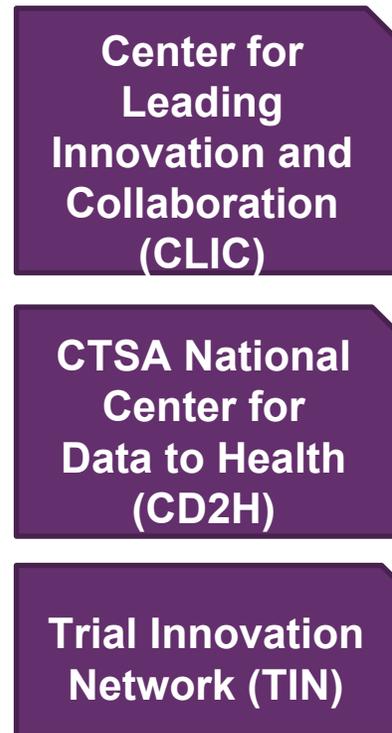- Advance the use of cutting-edge informatics

National Center for Advancing Translational Sciences

CTSA Program at a glance

60 CTSA Program Hub Grants in FY20

REQUIRED COMPONENTS

CTSA Grants to Medical Research Institution(s)

Institutional Mentored Career Dev Program

(K program)

OPTIONAL COMPONENT

NRSA Institutional Training Program

(T program)

CONSORTIUM-WIDE ACTIVITIES

Center for Leading Innovation and Collaboration (CLIC)

CTSA National Center for Data to Health (CD2H)

Trial Innovation Network (TIN)

PROGRAM FUNDING OPPORTUNITIES

➢ **Collaborative Innovation Projects**

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

National Center for Advancing Translational Sciences

CTSA Program consortium activities

o **Trial Innovation Network (TIN)**
  - Innovate the process of design and conduct of clinical trials & studies

o **Streamlined, Multisite, Accelerated Resources for Trials (SMART) IRB Platform**
  - Supports and facilitates the initiation of multisite clinical research

o **Accrual to Clinical Trials (ACT)**
  - Improve the process for the identification of participants for clinical trials

o **Collaborative Innovation Suite of Awards**
  - Enhance collaboration across the CTSA Program

o **Common Metrics Initiative**
  - Demonstrate and improve the impact of the CTSA Program

NIH National Center for Advancing Translational Sciences

Approaches for obtaining input on the CTSA Program

o **Peer Reviewers**
  - General feedback from CTSA Program review panel

o **Public & CTSA Program Consortium members**
  - Request for Information (October 2019)

o **NCATS**
  - Working Groups

Input on the CTSA Program from the public and CTSA Program consortium members: Request for Information (RFI)*

- **October 2019**

  - Sought input from stakeholder communities on how the NCATS CTSA Program might be strengthened to deliver on its promise to develop, demonstrate, and disseminate innovative approaches, methodologies and interventions that translate into improved human health

  - Received >100 comments

  - Diverse submitters: academics (individuals and institutions); advocacy groups; medical and scientific societies; a not-for-profit, integrated health system; and an NIH institute.

*Input requested for information and planning purposes only; individual responses not provided.

Input on the CTSA Program: Recurring themes from all sources

o Increase flexibility and diversity across hubs to leverage strengths & drive innovation

o Share Best Practices, tools, & materials

o Develop uniform guidance for research, training, and education

o Standardize & facilitate data collection

o Enhance ways to support and reward teams

o Expand funding opportunities and mechanisms

o Simplify the Funding Opportunity Announcement (FOA)

Grouped comments submitted in response to the RFI and/or general peer review panel feedback

General Input*

o Establish minimum requirements, standards, and programmatic milestones that each hub would fulfil at the local and national levels

o Simplify; decrease number of required cores

o Reconsider current budget determination parameters, which are weighted towards volume of basic research

o Consider reorganization of components

o Variable views on value to the hub/institution of the existing CTSA Program Common Metrics Initiative to demonstrate and improve performance

o Consider new formats for reporting progress

o Improve Prior Approval process

*Sources: Public comments submitted in response to RFI & general peer review panel feedback

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Barriers and solutions to improve use of basic research findings to inform clinical care*

o Foster interoperability and standards

o Share tools, algorithms, and best practices

o Enhance informatics support, e.g., ontology standards & interoperability

o Provide shared GMP/GLP facilities; Biostatistics, Epidemiology, and Research Design (BERD); regulatory consulting resources

o Allow awardees (hubs) to specialize

o Develop and share expertise registry to facilitate collaboration

o Consider funding mechanisms to support public-private partnerships

o Enhance links with other NIH components, e.g., consider co-sponsoring specific scientific problems with other NIH institutes & centers

Source: Public comments submitted in response to RFI

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- **Community Engagement, Health Disparities, and Dissemination***

  - Leverage existing structures, e.g., All of Us, PCORnet
  - Evaluate NIH single IRB policy

- **Pilot Project Programs***

  - Develop common purpose, criteria, and measures of impact
  - Share best practices
  - Develop a pilot project data collection instrument to collect data about pilot projects using a standardized approach that mirrors the pilot data requested in the annual progress reports

Sources: Public comments submitted in response to RFI

Workforce Development*

o Expand training to the broader Clinical & Translational Science workforce (beyond the K & T programs)

o Expand available funding mechanisms

o Increase flexibility

o Share best practices & tools

o Develop training standards

o Expand & enhance experiential learning opportunities beyond industry

Source: Public comments submitted in response to RFI

Applications, Grants Management, & Peer Review*

- Consider a different format for these complex applications, including streamlined tables, elimination of redundancy

- Manage the increasing numbers of letters of support

- Clarify progress related to the grant versus the institution

- Facilitate assigning an overall score to the U, K, & T components

- Remove the K & T applications and review separately

- Decouple award funding cycles for linked UL1, KL2, and TL1 grants

- Align KL2 and TL1 awards with the academic calendar

- Consider a standing study section

Sources: Public comments submitted in response to RFI & general peer review panel feedback

Other Comments*

- Utilize administrative supplements or other funding mechanisms to address priorities

- Challenge noted: balancing local efforts with Consortium efforts

- Measuring impact of the CTSA Program

  - Identify and consider existing measurement & evaluation methods and tools

  - Adopt a uniform platform for data collection

  - Focus on CTSA Program-level impact

  - Clarify expectations

Source: Public comments submitted in response to RFI

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Outside NCATS' Purview or Currently Not Feasible*

- Remove carryover funding restrictions for Pilot Projects (funds generally are prohibited from crossing grant years)

- Dramatically increase funding

- Adopt many attributes of the NIH Cancer Institute Cancer Centers, e.g., perform pre-review site visits to applicant sites

- Create a standing study section; challenges:
  - Broader scope of the award
  - Required scale of partners and collaborators results in massive conflict of interest issues

Source: Public comments submitted in response to RFI

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Misconceptions*

Comment: NCATS does not allow CTSA PIs or key personnel to serve on CTSA application review committees*

NCATS response:

- o NCATS welcomes study section participation by CTSA Key Personnel: https://ctsa.ncats.nih.gov/governance-guidelines/guidelines/reviewer-suggestions/

- o 63% of the reviewers who served between 2015-2019 were identified by NCATS Review Staff as Key Personnel participating in a CTSA application during the same period. E.g., Core Lead or Co-Lead; KL2 Director/Co-Director/Leadership; and TL1 Director or Co-Director. (not eligible to serve when own institution competing)

- o Availability is an issue; about 20-25% of invited panelists accept the invitation serve

- o CTSA U54/UL1 PIs as reviewers pose substantial conflict of interest issues

- o Conflicts of interest presents a challenge with increased collaboration among CTSA investigators

Source: Public comment submitted in response to RFI

Misconceptions*, continued

Comment: The creation of Consortium Resources (e.g., CLIC, TIN, CD2H) and Collaborative Innovation Awards (CCIAs) have resulted in significant decreases in individual hub budgets

NCATS response:

- Thanks to Congress, the Program's budget has increased every year since NCATS began to receive program-specific appropriations (FY2014) and received funds in FY2016 to support the program's networking capacity and innovative collaborative projects. This has enabled NCATS to address dissemination and implementation, and collaboration, key characteristics of the CTSA Program, via CCIA awards to hubs.

- As the program ramped up and fulfilled the original intention of a national program, award amounts were stabilized to accommodate additional sites across the country.

**Source: Public comment submitted in response to RFI*

Additional thoughts from NCATS regarding input on the CTSA Program

- NCATS appreciates the comments that the CTSA Program is highly valued and viewed as an essential component at academic medical institutions

- NCATS' unique niche among NIH institutes and centers (ICs) is it's focus on the clinical and translational science, or CTS, space of T2-T4 research to build on the basic research supported by other NIH ICs that focus on specific diseases/organs

- NCATS & other NIH ICs leverage and build upon one another's research findings

- One of NCATS' goals is to support CTS research in a variety of institutions with appropriate resources & support

- NCATS is interested in utilizing a range of mechanisms to advance the CTS research field and develop career paths for the CTS workforce