

CTSA Program Webinar

March 26, 2025



Agenda

TIME	TOPIC	PRESENTERS
2:00 PM ET	Welcome	Lauren Fitzharris, M.P.H., P.M.P. CCOS
2:01 – 2:10 PM	NCATS/CTSA Updates	Michael Kurilla, M.D., Ph.D. NCATS
2:10 – 2:15 PM	CCOS Updates	Kerry James, M.P.H., P.M.P. CCOS
2:15 – 2:30 PM	Learning About the Science of Translation: Identifying Best Practices to Accelerate the Translational Process Through Case Studies Working Group	Clara Pelfrey, Ph.D. Case Western University Deborah DiazGranados, Ph.D. Virginia Commonwealth University
2:30 – 3:00 PM	Influential Scholarship: Clinical and Translational Science Trainees at the Intersection of Academic Impact and Public Attention	Eric Nehl, Ph.D. Nicole Llewellyn Emory University
3:00 PM	Adjourn	





NCATS/CTSA Program Updates

Michael G. Kurilla, MD, PhD

Director, Division of Clinical Innovation NCATS

March 26, 2025



Senate Confirms New NIH Director!

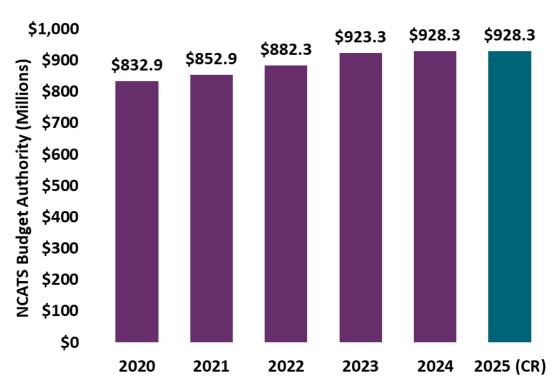
- Jay Bhattacharya, BA, MA (economics), MD, PhD (economics)
- Professor of medicine (Stanford), with courtesy professorships in both economics and health research and policy
- His research focuses on population health and well-being, with particular attention to the impact of government programs, biomedical innovation, and economic factors





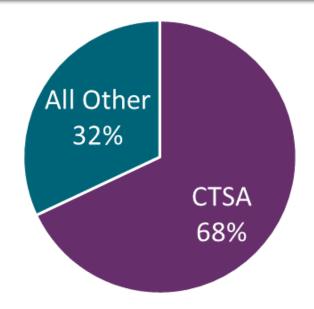
NCATS Budget

Funding History



FY 2026 President's Budget: \$XXX.X million

FY25 Budget by Activities



NCATS Appropriations



https://ncats.nih.gov/about/budget



CTSA Consortium Updates

- Diversity, Equity, Inclusion and Accessibility Enterprise Committee:
 - NCATS thanks the EC members for their service on this committee.
 - This Enterprise Committee has been sunset.
 - Communication took place with the lead team and sent to the committee membership.



Updates on the CTSA Spring Group Meetings

- We sincerely appreciate the EC's hard work and dedication into planning their meetings. Your efforts do not go unnoticed, and we are grateful for your commitment to the CTSA Program.
- Due to significant delays in obtaining NIH approvals, NCATS has reluctantly elected to cancel
 the Spring CTSA Group Meetings scheduled for April 14-17, 2025 (inclusive of ECs and
 Steering Committee)
- No virtual option will be available
- Translational Science 2025 meeting hosted by ACTS is still scheduled as planned
- ACTS has graciously agreed to provide an opportunity for CTSA U-PIs to meet informally during ACTS and other groups if they choose (more details will follow)
- NCATS and CCOS are evaluating the possibility of adding EC meetings to the Fall 2025 CTSA
 Program meeting agenda, which would provide an opportunity for the entire CTSA consortium
 to come together. We will provide more information as soon as it becomes available.







NIH Grants and Funding Information Status

- NIH grants and funding policies and processes are evolving as NIH aligns with new agency priorities. Keep on top of the latest status of changes impacting NIH grants administration and funding. It is updated as new information becomes available; check back regularly for updated information.
- https://grants.nih.gov/policy-and-compliance/implementation-of-new-initiatives-and-policies/nih-grants-and-funding-information-status
- On this page:
 - Communications
 - Applications
 - Some funding opportunities have been closed and others have been updated to align with agency priorities.
 - Applicants must carefully reread funding opportunities for any changes prior to submission and adjust their applications accordingly.
 - Review
 - Awards
 - Reporting



Upcoming Changes



Common Forms for Biographical Sketch and Current and Pending (Other) Support

NIH is adopting the Biographical Sketch Common Form and the Current and Pending (Other) Support Common Form in 2025.



Postponed

NIH's adoption of the Common Form for Biographical Sketch and a new Biographical Sketch Supplement originally scheduled for May 25, 2025 is postponed. Continue to use NIH-specific format pages until further notice.



https://grants.nih.gov/policy-and-compliance/implementation-of-new-initiatives-and-policies/common-forms-for-biosketch

3/17/25 - V3.0 Agreement, Reliance System & Website Go Live

SMART IRB Agreement V3.0 & Indemnification Addendum

- V3.0 Agreement must be signed for any new reliance arrangement
- Indemnification Addendum is optional

New SMARTIRB.org website

- New agreement and accompanying resources posted
- New look for the Participating Institutions Page
- Updates resources to reflect V3.0
 Agreement

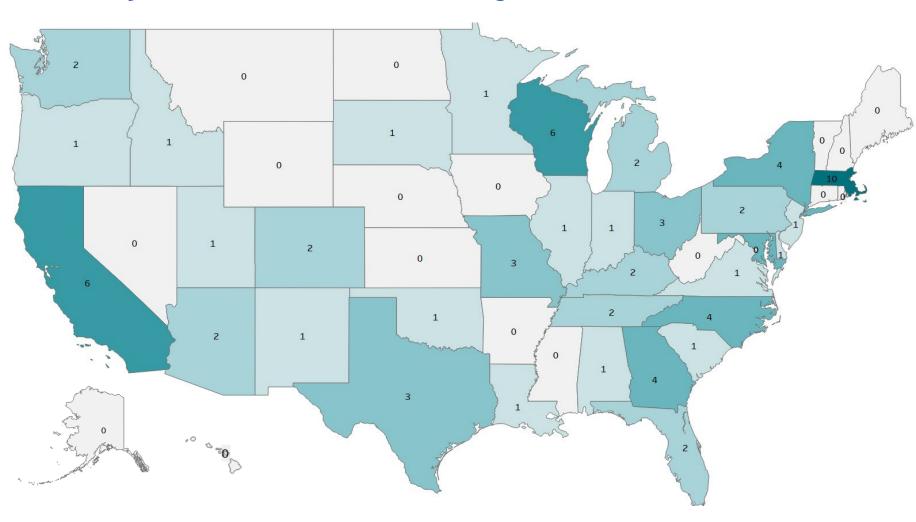
New Reliance System

- Replaces the previous Joinder and Online Reliance Systems
- Must be used to execute V3.0
 Agreement

Ready to Launch: Week 1 Retrospective (3/17-3/21)

78 Institutions across 33 states joined Version 3.0 during week 1!

- NIH: the 1st signatory
- 27 CTSA Hubs
- 50 Universities/AMCs
- 18 Hospital Systems
- 5 Commercial IRBs
- 30 Institutions awaiting signature
- 109 Signatories to date (as of 03/25)!



Upcoming Dates to Remember

Next CTSA Program Webinar

April 23, 2025; 2-3 PM ET.

Register here for the 2025 series



NGATS

COLLABORATE. INNOVATE. ACCELERATE.











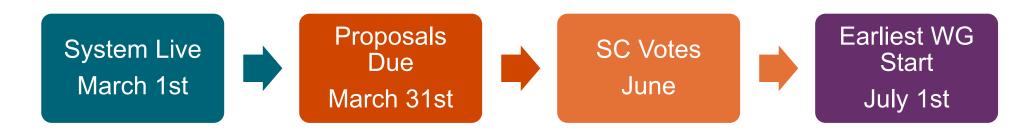
CCOS Updates

Kerry James CCOS

Next Cycle for Working Group Proposals

Working Groups Proposal Submission portal for Cycle XIV open on CCOS website during the month of March 2025

- The proposal submission period will open on March 1st
- All proposals should be submitted no later than March 31st at 3pm ET



Cancellation of Spring 2025 CTSA Group Meetings

- Due to significant delays in obtaining NIH approvals, the Spring CTSA Group meetings have been cancelled; no virtual option will be available.
 - The Translational Science 2025 meeting hosted by ACTS is still scheduled as planned. For more information, see <u>Translational Science</u>.
 - NCATS and CCOS are evaluating the possibility of adding EC meetings to the Fall 2025 CTSA Program meeting agenda, which would provide an opportunity for the entire CTSA consortium to come together.
 - We will provide more information as soon as it becomes available.

The hard work put into planning these meetings is greatly appreciated. Thank you for your commitment to the CTSA Program.

Requests for Informal Networking at ACTS

- CCOS has confirmed with ACTS that meeting rooms are still available for groups during the originally scheduled CTSA Group meeting dates/times.
- ACTS requests that groups reach out to Kim Stelmaszak
 (kStelmaszak@actscience.org) directly to arrange an informal meeting by
 Friday, March 28th if possible.
- Requests will not be considered if received after April 1st.
- ACTS and CCOS will work together to communicate final arrangements to CTSA groups.

Since these meetings are informal and not NCATS/CCOS sponsored, only meeting space has been secured; no onsite meeting support will be provided through CCOS.

Requests for Informal Networking at ACTS

Current Schedule for Informal Networking for CTSA Groups during ACTS:

April 14th

8am - 11am ET WFD/KPIs/TPI Meeting

2:15pm - 4:45pm ET BIDS EC Meeting

April 17th

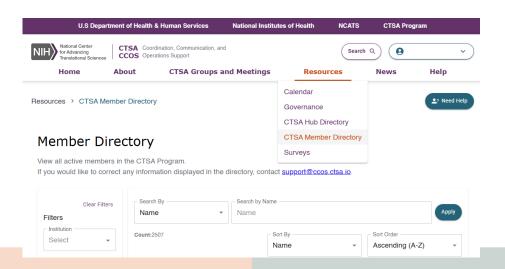
1pm-3pm ET U-PI Meeting

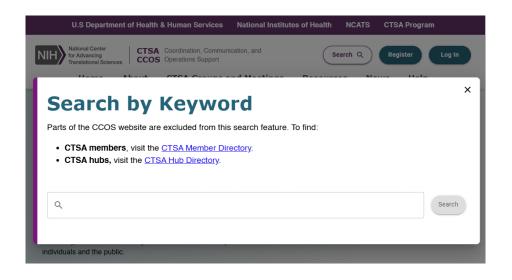
Thank You to ACTS for their generous support of the CTSA program

New Features on CCOS Website

CTSA Member Directory

Easily find and connect with fellow CTSA members based on their group memberships. This feature will help you expand your network, identify potential collaborators, and engage with peers across the CTSA hubs.





Search Function

Our enhanced search functionality simplifies navigation, allowing you to quickly locate the information and resources you need. Access support materials and stay informed about the latest updates. Found on Home Page.



Last Call for Submissions

Do you have an idea for the next Collaborative Workshop Topic? Is your hub interested in being the co-host?

Submit your proposal by March 31, 2025

CTSA Program hubs interested in co-hosting with CCOS & NCATS in the early spring of 2026 are invited to respond to the solicitation with their hub's suggested topic

Questions? Contact us at collaborative_workshop@ccos.ctsa.io



CCOS Website Account

Getting Started

Get step-by-step guidance on getting started including how to create a CCOS account and how to log in can be found here:

Getting Started Page

Account Access Includes:

- Meeting Materials/Archives
- Collaborative Workspaces
 /Discussion Forums
- CTSA Hub Directory

Questions? Please email support@ccos.ctsa.io

Next CTSA Webinar

The next webinar is **Wednesday**, **April 23, 2025**; 2-3 PM ET

Register <u>here</u>

Please register and add the new invite to your calendar

Thank you!



Translational Science Case Studies

Full Title: Learning about the science of translation: Identifying best practices to accelerate the translational process through case studies





Translational Science Case Studies Co-Chairs



Clara M. Pelfrey, Ph.D

Evaluation Director

Clinical and Translational Science Collaborative (CTSC)

Professor, Case Western Reserve University

clara.pelfrey@case.edu

Deborah DiazGranados, PhD

Director of Evaluation

Wright Regional Center for Clinical and Translational Science

Associate Professor, Virginia Commonwealth University

diazgranados@vcu.edu





A bit of History...

History of Case Studies Group:

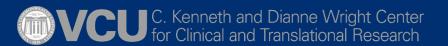
- 1. We developed a process for conducting TS case studies (Dodson, et.al., 2020, doi:10.1017/cts.2020.514)
- 2. Lobbied JCTS to create a new manuscript category to accommodate this unique kind of evaluation research. New manuscript category is the *Translational Science Case Study*.
- 3. Subsequently published several individual TS case studies in the JCTS,
- 4. First TS Case Study was published in 2021.

How can we accelerate the translational process? ... by doing comparative case studies of *successful translation* to learn the critical facilitators which enabled the research to move forward as well as the challenges and *how they were overcome*.



Goals

- To conduct comparative case studies (cross-case analysis) of translational science case studies
- To publish at least one paper on the findings of this cross-case analysis
- To generate new knowledge about the translational process by investigating and comparing successful translational science cases
- To produce widely applicable knowledge about the translational process, including critical facilitators, overcoming roadblocks, and highlighting impacts
- To develop a best practices guideline for overcoming roadblocks and speeding the pace of translational science.



Anticipated Impact

- Dissemination enabling infrastructure development, education and professional development.
- 2. Better understand TS facilitators and challenges allowing CTSA hubs to improve forward advancement of translational science, shortening the time to human health impacts.
- 3. Understanding facilitators and challenges allows CTSA hubs to develop and disseminate common solutions.
- **4. Promotes continuous quality improvement** (CQI) by identifying barriers to conducting TS, which can be addressed with education, training, partnerships, collaborations, funding and new grant mechanisms.
- 5. Demonstrate the impact of TS on human health and the critical role of the CTSA consortium.
- 6. Provide **important information that could benefit many potential stakeholders**, including researchers, research teams, institutions, CTSA hubs, funders, Congress, and the public.



Members & CTSA Hubs

50 members/contributors* from 30 unique CTSA hubs

First name	Last name	Collaborating Institutions	First name	Last name	Collaborating Institutions
Clara	Pelfrey	Case Western Reserve University	Kenneth	Hargreaves	UT Health San Antonio
Lixin	Zhang	Case Western Reserve University	Dan	Cooper	U California, Irvine
Lisa	Welsh	Tufts University	Margaret	Schneider	U California, Irvine
Jillian	Harvey	Medical University of South Carolina	Amanda	Woodworth	U California, Irvine
Rechelle	Paranal	Medical University of South Carolina	Allison	Orechwa	U. Southern California (USC)
Elias	Samuels	University of Michigan	Nicki	Apaydin	U. Southern California (USC)
Ellen	Champagne	University of Michigan	Christina	Buckel	Washington U, St. Louis
Debbie	DiazGranados	Virginia Commonwealth University	Jessica	Presley	U Arkansas for Medical Sciences
Andrea	Molzhon	Virginia Commonwealth University	Alexandra	Jauregui- Dusseau	U Arkansas for Medical Sciences
Joe	Hunt	Indiana University	Jennifer	Croker	University of Alabama at Birmingham
Sarah	Wiehe	Indiana Univ.	Carolyn	Oliver	University of Alabama at Birmingham
Leah	Pope	Columbia University/NY State Psychiatric Institute	Wendy	Novicoff	U Virginia
Harold	Pincus	Columbia University/NY State Psychiatric Institute	Melissa	Peskin	UT Health Houston CTSA
Zainab	Abedin	Columbia University/NY State Psychiatric Institute	Cecelia	Patino-Sutton	University of Southern California
Chris	Pulley	University of Minnesota	Maran	Subramanian	U lowa CTSA
Marie	Kenny	University of Minnesota	Jennifer	Moses	U Florida
Boris	Volkov	University of Minnesota	Kayla	Kuhfeldt	Boston U
Jessica	Sperling	Duke University	Alyson	Eggleston	Penn State CTSI
Joseph	McClernon	Duke University health System	Douglas	Gabenstetter	Medical College of Wisconsin
Perusi	Benson	Duke University health System	Michael	Widlansky	Medical College of Wisconsin
Stella	Quenstedt	Duke University health System	Jamie	Ostroff	Memorial Sloan Kettering Cancer Center-Weill Cornell
Corey	Snelson	U Washington, Seatle	Amber	Osterholt	U Illinois, Chicago
Patricia	Moussatche	Stanford University	Matt	Honore	Oregon Health & Science University
Maryam	Gholami	U California San ညဖစ္သဝ (ຟດຣອ)	As	rc C. Kenr	ปะใ ปลุ่ม Dasi e Wright Center
Rebecca	Stachurski	University of Kentucky Clinical and Translational Science Collaborative	An	Volkink for Clini	oal otah Translational Research

Cross-Case Analytic Groups

Cases about Improving Health

An intervention, solution, or approach to improve health is:

to work at one site...

Group A

... and implemented beyond research *Group B*

Cases about Improving Research

An intervention, solution, or approach to improve research is:

to work at one site...

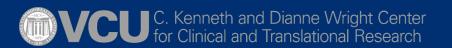
Group C

...and implemented at other site(s) *Group D*



Progress & Accomplishments

- Recruitment of new WG members. Methods: 1). Shared the opportunity via our CTSA hubs social media pages, 2.) Via the evaluators listserv. 3.) CCOS shared the posts from LinkedIn on their social media page. Result: 50 participants from 30 unique CTSA hubs.
- We collaborated with other groups that have posted Translational Science Case Studies: 1.) NIH Office of Science Policy, 2.) NIEHS, 3.) Washington University Translational Science Benefits Model (TSBM) case studies, 4.) Duke University CTSA
- We created a Coding Committee for Qualitative Coding (9 members): 1.) Determining the best method for coding, 2.) The unit of analysis will be the case study templates, promoting consistency, 3.) Meets monthly at a different time than the WG meeting, 4.) Report their progress to WG monthly.



Progress & Accomplishments

- Created an Interview Committee (6 members): 1.) Responsible for filling in the gaps in case studies, e.g., the facilitators and challenges, 2.) Have identified 12 case studies that require further interviews, 3.) 7/12 interviews have been conducted (58%).
- Upon request, NCATS set up a collaborative workspace in Google Drive. <u>This has also benefited all other CCOS WG and NCATS affinity groups</u>. This enables: 1.) Groups can collaborate nationally by using the collaborative workspaces, 2.) All members have access, 3.) By creating folders, members can upload their case study templates, 4.) Committees can post their progress.
- **Created 2 ways to collaborate**: 1.) <u>Full participation members</u> moved forward with IRB approval through the SMART IRB #3536, with CWRU as the IRB of record, 2.) <u>Case study "contributors"</u>: Interested in contributing a case study, but not interested in conducting interviews, coding or manuscript writing. These members agreed that they would be *acknowledged in the manuscript* rather than be authors.



Progress on Deliverables 1 & 2

Deliverable 1: Conduct at least one successful TS case study, (e.g., classification of the type of case study, analysis of the barriers & facilitators during the process of translation (Each participating hub).

- 44 case study templates completed or mostly completed. 44 cases/30 hubs = 146% of the number of participating hubs.
- Opportunity to learn interviewing techniques by other members. All Full Participation members who are going to join have joined the CWRU IRB protocol (16 hubs) or have engaged their own IRB process at their own hubs. All hubs were fully able to participate by the end of October 2024.

Deliverable 2: Create a collection of successful TS case studies from other institutions and CTSA hubs, includes cases from multiple frameworks: TSBM, NIEHS TR Framework, Payback Framework.

- o Adapting case studies from the <u>NIH OEPR</u> website to our template, with their permission.
- With permission, using publicly available <u>TSBM Case Studies</u>. Interview Committee assigned specific TSBM cases to members; in the process of interviewing the PIs and other stakeholders.
- Have adapted several <u>NIEHS</u> case studies to our case study template.



Progress on Deliverables 3 & 4

Deliverable 3: Conduct additional interviews with PIs and other stakeholders to fully understand the facilitators, challenges, techniques for overcoming barriers and societal benefits (e.g., impact).

- Conducting interviews of PIs and other stakeholders on the case studies.
- Coding Committee <u>reviewing cases and determining which need interviews</u> (12 cases this far).
- <u>Performed interviews</u> in 7/12 (58%). Remaining interviews will be completed in the next 1-4 months.
 <u>Members continue to post new case studies</u>. Committee has also been <u>discussing additional cases</u> that could be included.

Deliverable 4: Participate in cross-case analyses to identify barriers/roadblocks and how they were overcome as well as facilitators of successful translation. Example: comparisons across many different types of case studies (e.g. drugs, devices, diagnostics, novel therapies, behavioral interventions) to produce widely applicable knowledge that could apply to many kinds of TS or might be highly specialized for one or more specific kinds of TS. Steps involved:

- <u>Coding strategy</u>: Rigorous & Accelerated Data Reduction (RADaR), Wilkins, 2017, Int.J.Qual. Methods)(*Done*)
- Develop initial codebook (In process)
- Completing the coding analysis (TBD)
- Participating in cross-case comparisons (TBD)





Deliverables 5-7 (TBD)

Deliverable 5: To develop a theoretical model or a best practices guideline for overcoming TS roadblocks and speeding the pace of translational science (The WG).

Deliverable 6: Disseminate the generalizable and actionable learnings in at least one scientific publication (The WG).

Deliverable 7: Disseminate findings beyond publication to scientific and lay audiences (The WG).



Thank you! Questions?

Clara M. Pelfrey, Ph.D clara.pelfrey@case.edu

Deborah DiazGranados, PhD diazgranados@vcu.edu





Influential Scholarship: Clinical and Translational Science Trainees at the Intersection of Academic Impact and Public Attention

CTSA Program Webinar March 26, 2025

Nehl EJ, Pelfrey CM, DiazGranados D, Dave G & Llewellyn NM











Publications to Public Impact

 How does the support that CTSA hubs provide lead to translational outputs and outcomes?











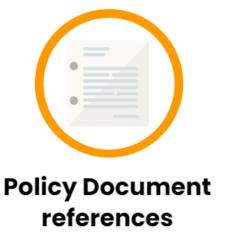




Publications to Public Impact

 How does the support that CTSA hubs provide lead to translational outputs and outcomes?



















Publication Influence

We assume that publications have influence outside of academia. But do we really know?



Key question: How can we use cutting-edge bibliometrics to evaluate how science supported by our hubs has gone beyond academia?











Method

- Supported investigators (including KL2 Scholars/TL1 Trainees) are asked to cite CTSA grants in resulting publications
- We identified publications that cited CTSA grants using NIH RePORTER & PubMed
- We queried resulting publications in Dimensions, Altmetric Explorer & Overton databases

















Linking CTSA Research to Health Policy

- First publication to demonstrate consortium-wide policy impact using cutting-edge bibliometrics
 - Llewellyn, N.M, Weber, A., Pelfrey, C., DiazGranados, D. & Nehl, E. J. (2023)
 Translating Scientific Discovery into Health Impact: Innovative Bibliometrics Bridge
 CTSA-Supported Publications to Policy, *Academic Medicine*





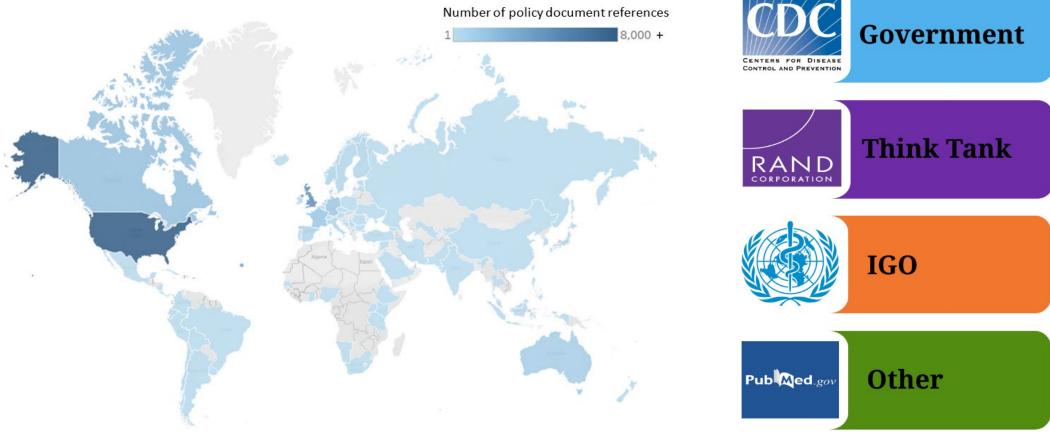








>120K CTSA publications have been used in global policy literature













What kinds of publications are most likely to influence policy?

• Factors that independently predict uptake in policy literature:



个 Clinical Relevance





↑ Academic Influence



↑ Public/Community Attention



The New York Times











Examples



<u>Article</u>: "Maternal Influenza Immunization and Reduced Likelihood of Prematurity and Small for Gestational Age Births: A Retrospective Cohort Study" *PLOS Medicine*, 2011

- Referenced 26 times by: WHO, PubMed Guidelines, Gov.uk, etc.
- E.g.: 'Safety of immunization during pregnancy: a review of the evidence: Global Advisory Committee on Vaccine Safety' WHO, 2014



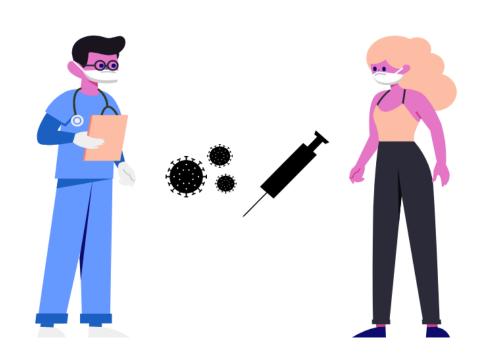








Examples



<u>Article</u>: "An mRNA Vaccine against SARS-CoV-2 — Preliminary Report" - *NEJM*, 2020

- Referenced 24 times by: CDC, Dept. of Homeland Security, etc.
- E.g.: 'Grading of recommendations, assessment, development, and evaluation (GRADE): Moderna COVID-19 vaccine' CDC, 2020











Academic Medicine publication received significant attention

6

Georgia CTSA @Georgia CTSA · 6m

At #2023FallCTSAmtg, Dr. Kurilla @ncats_nih_gov highlights study led by @GeorgiaCTSA showing how CTSA-supported research has been used in public health & policy literature to advance translation. Thanks to partne @CWRUSOM & @VCU_CCTR #CTSAProgram

→ journals.lww.com/academicmedici...



Over 600 views on X

NCATS reposted your post







JoniRutter and 2 others liked your post











CTSA Impact on Policy



CTSA publications 2006 - 2021:

Linking CTSA Trainee Research to Altmetrics

• First project to demonstrate public impact of CTSA trainees consortium-wide, using cutting-edge bibliometrics







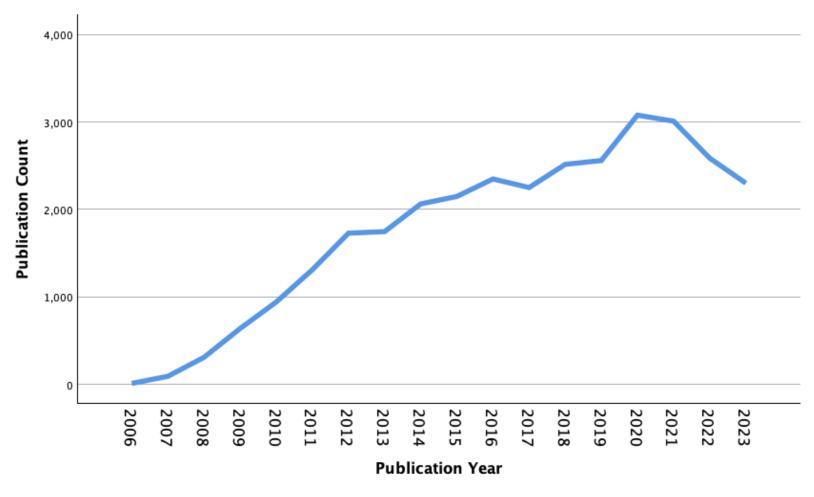






Growing Productivity

Over **30,000**publications cited CTSA KL2 and/or TL1 support from 2006 to January 2024







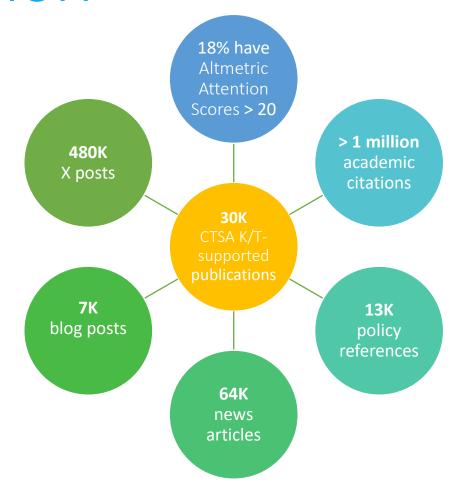






Altmetric Attention

CTSA publication influence across public spheres













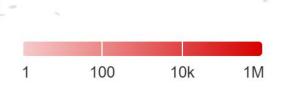
News Demographics from Altmetric Explorer

Data for all research outputs with 25,000 identifiers













There have been **75,877 news stories** about this content by **63,051 unique news outlets** in **116 specified countries**.





What makes an Academic Influencer?

COVID-19 (30%)

Diet & Exercise

Drug Overdose

Genetics

Alzheimer's/Mental Health

Disease Risk and Burden

Public Health









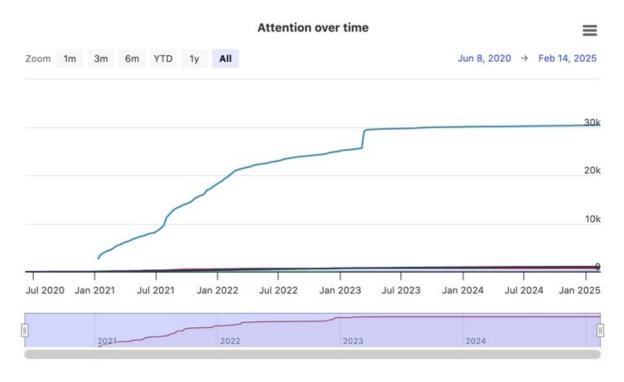


Examples

 Article: An Evidence Review of Face Masks against COVID-19. Proc Natl Acad Sci U S A. 2021 Jan 26;118(4):e2014564118

- Altmetric Attention Score: 17,221
 - Referenced nearly 20K times on social media, in 750 news stories & 42 blogs, 1,500 Mendeley downloads
 - In the top 5% of all research outputs scored by Altmetric







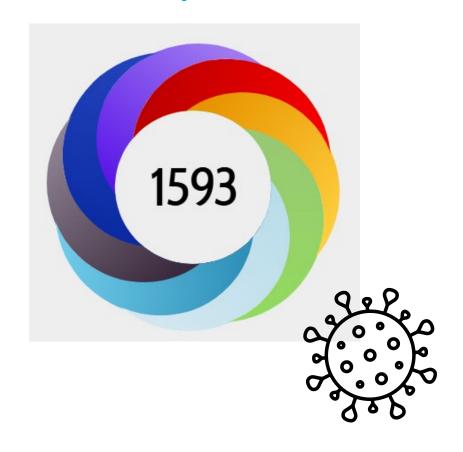








Examples



Article: "Long-term Health Consequences of COVID-19" - JAMA, November 2020

- Work by a Georgia CTSA MSCR graduate and KL2 Scholar
- Over 800 academic citations, RCR: 24.6
- Altmetric Attention Score: 1,593 including 56 news outlets, over 1,500 social media users, and 6 policy citations, E.g.: 'Clinical Management of COVID-19' WHO, 2023











What Kinds of Publications Gain Public Attention?

个JIF

↑ Downloads

Published after 2020

个 RCR

个 Policy citations

个 APT











In Sum

- CTSA Goal: "Develop, Demonstrate, and Disseminate" innovations
- A key goal of dissemination is to communicate science advances beyond academia to the public
- Bibliometrics are a promising way to track and evaluate the impact of the CTSA program through the applications of supported publications outside academia











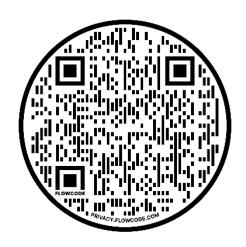


Thank You!

Eric Nehl, PhD & Nicole Llewellyn, PhD enehl@emory.edu, nicole.llewellyn@emory.edu

Learn More! Georgia CTSA Evaluation & Continuous Improvement webpage:

https://georgiactsa.org/about/what-we-do/evaluation-continuous-improvement.html













Reminder: April 2025 CTSA Webinar

The next webinar is April 23, 2025; 2-3 PM ET

