# Tufts Clinical and Translational Science Institute

covid-19 response data science science and community collaborations innovative broadly-engaged team science new initiatives and programs to improve clinical care and health expertise in quantitative methods biostatistics, epidemiology, research design, data sciences, artificial intelligence, machine learning, and health informatics synergistic centers to accelerate clinical and translational science informatics leadership analytic tools quality of care improvement **ANNUAL REPORT 2022** trust in research dissemination and implementation community-academic coalition interdisciplinary research positive health impact funders, partners, collaborators, researchers, stakeholders covid-19 response data science science and community collaborations innovative broadly-engaged team science new initiatives and programs to improve clinical care and health expertise in quantitative methods biostatistics, epidemiology, research design, data sciences, artificial intelligence, machine learning, and health informatics synergistic centers to accelerate clinical and translational science informatics leadership analytic tools quality of care improvement increased our focus on broadly-engaged science and community collaborations to advance and grow trust in research new communityacademic coalition interdisciplinary research positive health impact

#### **Our Partners and Collaborators**

Tufts CTSI's partners and collaborators include an engaged network of hospitals and medical practices, academic institutions, health sciences institutions, community stakeholders, and industry. Each brings unique insights to our support of clinical and translational research, and makes major contributions to that work.

#### 12 Tufts Schools and Centers

Cummings School of Veterinary Medicine

Fletcher School of Law and Diplomacy

Friedman School of Nutrition Science and Policy

Institute for Clinical Research and Health Policy Studies (ICRHPS) at Tufts Medical Center

Jean Mayer USDA Human Nutrition Research Center on Aging (HNRCA)

Jonathan M. Tisch College of Civic Life

Graduate School Biomedical Sciences

School of Arts and Sciences

School of Dental Medicine

School of Engineering

School of Medicine

Tufts Center for the Study of Drug Development

#### 6 Tufts-Affiliated Hospitals

**Baystate Medical Center** 

Lahey Hospital and Medical Center

Maine Medical Center

Newton-Wellesley Hospital

St. Elizabeth's Medical Center

Tufts Medical Center

#### 6 Academic Partners

Brandeis University

Massachusetts General Hospital (MGH)

nstitute of Health Professions

Massachusetts Institute of Technology (MIT)

Northeastern University

**RAND** Corporation

The Jackson Laboratory

#### 6 Industry/Non-Profit Partners

Blue Cross Blue Shield of Massachusetts

Massachusetts Biotechnology Council (MassBio)

Massachusetts Biotechnology Education

Foundation (MassBioEd)

Novartis

Pfizer, Inc.

Point32Health

#### 8 Community-Based Partners

Asian Community Development Corporation (ACDC)

Asian Task Force Against Domestic Violence (ATASK)

Asian Women for Health

Boston Chinatown Neighborhood Center (BCNC)

Center for Information and Study on Clinical Passage Participation (CISCPR)

Research Participation (CISCRP)

Greater Boston Chinese Golden Age Center (GBCGAC)

Museum of Science, Boston (MoS)

Tufts Medicine Integrated Network

# **Our Mission**

The mission of Tufts Clinical and Translational Science Institute (CTSI) is to stimulate innovative broadlyengaged team science across the translational research spectrum to improve clinical care and health.

We support the conduct of innovative research: from pre-clinical development to initial human studies (T.5), bench research to the bedside (T1), bedside to clinical practice (T2), clinical practice to widespread clinical practice and care delivery (T3), and public benefit and policy (T4). We help improve clinical care and health by providing education, consultations, services, and direct support.

We are supported by a Clinical and Translational Science Award (CTSA) from the National Center for Advancing Translational Sciences (NCATS), part of the National Institutes of Health (NIH). Tufts CTSI was founded in 2008, supported by three sequential CTSA grants, currently NCATS award UL1TR002544.

## The Aims of Our Third NIH CTSA Grant

Our current grant began in May 2018 with the following aims:

**Aim 1:** Create an environment, resources, and services to stimulate and support the full spectrum of clinical and translational research (CTR) by leveraging the diverse expertise and assets of Tufts CTSI partners.

**Aim 2:** Cultivate broadly-engaged team science, actively including stakeholders, to promote relevant and impactful translation for diverse populations and across the lifespan.

**Aim 3:** Develop, demonstrate, and disseminate innovations in methods, research process improvement, and evaluation, to advance CTR locally and nationally.

**Aim 4:** Advance methods and performance of multisite clinical trials within the Tufts CTSI Clinical Research Network, the NCATS Trial Innovation Network, and in other multi-institutional networks.

**Aim 5:** Provide outstanding education, training, and mentoring, tailored to different roles and disciplines, to advance a diverse CTR workforce, and share these resources nationally.

# MESSAGE FROM THE DEAN

ufts Clinical and Translational Science Institute (Tufts CTSI) is at an inflection point in 2022. We are in the final year of our third NIH Clinical and Translational Science Award (CTSA) grant, having been activated to new levels of service and support of researchers during the COVID-19 pandemic, all the while continuing our mission to



support innovative broadly-engaged team science across the translational research spectrum. We are also looking ahead in anticipation of the fourth CTSA grant which will bring new initiatives and programs to improve clinical care and health while maintaining existing Tufts CTSI resources and services. In the meanwhile, it is good to reflect on activities that have come to the front of our work in the past few years.

In responding to the COVID-19 pandemic in the last three years, we engaged all of Tufts CTSI services to support the Tufts clinical and research community in addressing needs brought

on by the pandemic. Our Clinical and Translational Research Center (CTRC) became the central venue for COVID-19 research at Tufts Medical Center. This included two large remdesivir inpatient studies, other COVID treatment and vaccine studies, and, by a cross-Tufts University team, the first trial in humans for COVID-19 of niclosamide, an inexpensive long-used medication for tapeworm. We set up and managed a National COVID-19 Survivors Registry to connect researchers with volunteers who want to support COVID-19 studies. We were also one of the first CTSAs to submit data to the National COVID Cohort Collaborative (N3C) to aid a data-driven response to, and research on, COVID-19.

We are making strides in our impact on data science. The Biomedical and Health Data Science Collaborative (BHDSC) at Tufts CTSI brings together our expertise in quantitative methods, including biostatistics, epidemiology, research design, data sciences, artificial intelligence, machine learning, and health informatics into a group of synergistic centers to accelerate clinical and translational science. Locally, we were intimately involved in creating unique research capacities in Tufts Medicine's newly acquired Epic electronic health record. Globally, our Informatics leadership is active in the international Observational Health Data Sciences and Informatics (OHDSI) community to develop analytic tools for enabling research and improving the quality of care.

Over the past few years, we have increased our explicit focus on broadly-engaged team science and community collaborations to advance and grow trust in research. A concept that originated with us, Tufts CTSI includes broadly-engaged team science as one of our foundational pillars of success. As an organization we are committed to involving a broad array of stakeholders in health research, from project inception to completion, and then dissemination and implementation. We were delighted this year to publish the book, "Broadly Engaged Team Science in Clinical and Translational Research" which documents a range of activities, perspectives, and practices on building broadly-engaged team science.

We also successfully disseminated our model of community-engaged clinical and translational research from our long-standing Addressing Disparities in Asian Populations through Translational Research (ADAPT) program to a new communityacademic coalition, Collaboration for Research Equity Sustainability & Trust (CREST), dedicated to improving the health of Black and Brown Bostonians.

We see the advances in interdisciplinary research and positive health impacts through the efforts from Tufts CTSI. In support of this, I am immensely grateful to our funders, partners, collaborators, researchers, stakeholders, and especially the heart of Tufts CTSI, our incredible team of faculty, directors, managers, and staff for sustaining our success. I look forward to our work together in our mission to have impact on health.

Very best wishes,

## Our Programs, Resources, and Services

Addressing Disparities in Asian Populations through Translational Research (ADAPT)

Biostatistics, Epidemiology, and Research Design (BERD) Center

Clinical and Translational Research Center (CTRC)

Comparative Effectiveness Research (CER)

Collaboration for Research Equity, Sustainability, and Trust (CREST)

Data Safety and Monitoring Board (DSMB)

Education, Training, and Career Development

**Evaluation and Continuous** Improvement (ECI)

**Funding Opportunities and Voucher Programs** 

**Human Nutrition Research Center** on Aging Metabolic Research Unit (HNRCA MRU)

Informatics

Integrating Underrepresented Populations in Research (IUPR)

Junior Faculty Research Career **Development Forum** 

Massachusetts Institute of Technology Clinical Research Center (MIT CRC)

Multi-site Clinical Research Center (MCRC)

One Health

Recruitment and Retention Support Unit (RRSU)

Regulatory Knowledge and Support

Research Process Improvement (RPI)

Science Communication

Stakeholder and Community Engagement (SCE)

Stakeholder Expert Panel (SEP)

T.5 Capacity in Medical Devices

Team Science: Research Collaboration Team and Navigators

Trial Innovation Network (TIN)

Translational Science Expert Panel (TSEP)

For more information, please visit tuftsctsi.org

# **Bringing Broadly-engaged Team Science to the World**

ollowing up on the concept of broadly-engaged team science that we introduced in 2017, in 2022, Tufts CTSI worked to illustrate the application of this principle and practice across the research enterprise, especially across Tufts CTSI and its partners, in the form of a book. Published in March 2022 by Springer, edited by Tufts CTSI faculty Debra Lerner, MSc, PhD; Marisha E. Palm, MSc, PhD; and Thomas W. Concannon, PhD, Broadly Engaged Team Science in Clinical and Translational Research is a collection of perspectives and best practices to help researchers and stakeholders to build diverse, inclusive teams.

The term broadly-engaged team science refers to the inclusion of diverse stakeholders, including community members, in all aspects of research. This starts with the posing of research questions and defining meaningful outcomes, to conducting the research, interpreting its findings, and disseminating the results. Our broadly-engaged team science approach brings the traditions of team science, multi-stakeholder engagement, and community engagement together into a single model

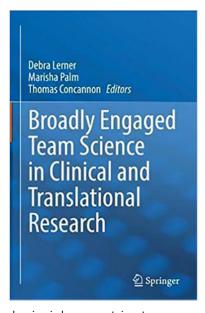
The idea of broadly-engaged team science has powerful potential to change the way that translational research is done, making it more inclusive and relevant.

for engaging diverse stakeholders in all aspects and phases of clinical and translational research and science. Tufts CTSI believes this is essential for the effective translation of research into health impact and health equity. However, challenges to broad engagement in research persist, particularly in the early translational stages. Lack of engagement and/ or systemic exclusion of

certain populations in basic, pre-clinical, and early translational research lays the foundation for inequities in later translational research and in health outcomes. It is critical that broad engagement occurs throughout the translational spectrum.

This year our Community and Stakeholder Engagement (CSE) leaders sought to increase investigator adoption of broadly-engaged team science. As a first step we surveyed applicants to the Pilot Studies Program about their experience with developing a CSE plan as part of the application process and interviewed awardees and stakeholders about implementing the plan. The findings fueled a rich discussion within Tufts CTSI about how to

more effectively support adoption of CSE. This included ensuring "fit-for-purpose" CSE across the translational spectrum, providing case examples from CSE planning through implementation, engaging early translational researchers to address perceived barriers, emphasizing science communication skills, and adopting a career development perspective.



Guided by our foundational principles, we strive to build trust through transparent bidirectional communication, intentionally developing community partnerships with an emphasis on relationship building through shared goals and values. We create collaborative engagement and partnership structures for stakeholders. especially those with historically-marginalized identities, to co-drive the research agenda and participate as equal contributors. Our partners and collaborators foster innovation by providing diverse expertise, contexts, and engagement with populations that create opportunities to develop and test generalizable scientific advances. To ensure relevance in approaches and priorities, we involve stakeholders across sectors who bring multiple perspectives and experiences to our work. We believe that effective engagement across the translational spectrum cannot be achieved through narrowly-defined methodologic approaches, and that approaches must be designed to suit distinct research environments, intended research products, and relevant stakeholders.

Looking to the future, Drs. Lerner, Palm, and Concannon are currently working on a number of ways to support the dissemination of broadly-engaged team science, including presenting at relevant conferences and national workgroups, engaging chapter authors and community members to share their stories with a wider audience via short video clips, and drafting a manuscript that talks about broadly-engaged team science with examples across the translational spectrum.

Broadly-engaged team science can be recommended to Clinical and Translational Science Awards (CTSA) programs seeking to make *all biomedical research* more outward facing.

# Leadership for Informatics Solutions and the Tufts Analytics Platform

ufts CTSI Informatics Core's mission is to accelerate research in translational medicine and make personalized patient care possible using state-of-the-art methods in data science and artificial intelligence. We have a unique array of expertise that enables our ambitious work.

Realizing the promise of clinical and translational research to improve health care delivery, advance health equity, and inform policy requires a modern, mature, and sophisticated informatics and analytics infrastructure. It must support research in diverse environments, standardizing and aggregating various data types, while also managing the scale and complexity of modern data acquisition, transformation, and analysis.

Tufts CTSI provides a robust institutional informatics infrastructure, enabling research teams to maintain their focus on scientific discovery and analyses rather than on data wrangling. Our infrastructure and support systems are dynamic, to keep pace with the changing and interdependent fields of health informatics, bioinformatics, statistics, and data science. Our systems are expandable, to accommodate new data types and analytic methods, and scalable, to support efficient and methodologically rigorous multi-site/institutional research. These defining traits allow us to explore novel methods and operational principles, harmonize datasets, and create pipelines for data sharing and analytics.

During the COVID-19 pandemic, and beyond, Tufts CTSI provided national and international leadership to realize the promise of interoperable health-related data across data types and organizations. For example, we collaborated with the international Observational Health Data Sciences and Informatics (OHDSI) community to develop the technical and governance infrastructure to improve evidence generation from clinical data, and together with Tufts CTSI partner, Northeastern University, launched the OHDSI Center at the Roux Institute to foster reproducible research with open science. Through leadership on multiple OHDSI Workgroups, we are helping to develop extensions, ontologies, and concept-mapping for the Observational Medical Outcomes Partnership (OMOP) Common Data Model (CDM) that will allow the inclusion of more data types. Recent efforts enable integration of tumor registry, oncology, intensive care unit data for observational

William Harvey MD, MSc, FACR, Co-Director, Informatics





Andrew Williams. PhD, Co-Director, Informatics

research and analytics. These improvements are disseminated and implemented internationally at sites that use the OMOP CDM. Our leadership supports timely adoption of informatics innovations, including being among the first CTSAs to submit data to the National COVID Cohort Collaborative (N3C) to aid a data-driven response to COVID-19.

Another example of Tufts CTSI Informatics' contributions is the creation of the Tufts Analytics Platform (TAP) as a Hub resource to accelerate inquiry and hypothesis generation across the full translational spectrum, including supporting the collaboration between Tufts CTSI and Tufts Medicine of its Patient-centered Learning Health System. TAP supports the use of artificial intelligence and machine learning (AI/ML) for 1) data scientists interested in model development and best practices; 2) statisticians interested in augmenting traditional statistical approaches; 3) subject matter experts for predictive model development and analysis; and, 4) to further assist researchers in integrative analysis by allowing them to explore links between clinical, omic-, and chemical features of health conditions of study.

The TAP team is a collaborator and a primary contributor on the NIH National Center for Advancing Translational Science (NCATS) Biomedical Data Translator program a multi-year effort to develop a comprehensive information system that integrates multiple types of existing data sources. These sources may include objective signs and symptoms of disease, drug effects, and intervening types of biological data relevant to understanding pathophysiology. The fully realized Translator will be designed to enhance human reasoning and enable a significant shift from the current symptom-based diagnosis of disease classification to one that is based on a set of molecular and cellular abnormalities that can be targeted by various preventive and therapeutic interventions.

# Tufts CTSI Informatics embraces diversity, innovation, and drive.

# **Driving Stakeholder Engagement with ADAPT and CREST**

ufts CTSI's community-academic coalitions focus on addressing health disparities. More than 10 years ago, we established **Addressing Disparities** in Asian Populations through Translational Research (ADAPT) in partnership with community organizations in Boston's Chinatown in which the Tufts Health Sciences campus resides. In 2021, we launched the Collaboration for Research Equity, Sustainability, and Trust (CREST) which is focused on health equity in Black and Brown communities in three Boston neighborhoods.

ADAPT's core mission is to build authentic communitybased participatory research partnerships and conduct community-prioritized research that translates into improved service delivery, advocacy, or policy change. Early on, our ADAPT community partners identified problem gambling in the Asian community as a priority issue. Building off the November 2018 Translational Research Day (now called Translational Science Day) on addiction, ADAPT hosted a workshop on problem gambling, which laid the groundwork for the Asian Center for Addressing Research, Education, and Services (Asian CARES), a community-based coalition focused on Asian communities in Greater Boston.

With Tufts CTSI support, Asian CARES secured funding from the Massachusetts Gaming Commission to conduct an in-depth qualitative study to understand how problem gambling manifests in Asian families and to inform the development of culturally and linguistically appropriate tools and resources for prevention and early intervention of problem gambling.

The Asian CARES report findings and recommendations were disseminated primarily through presentations by the study's co-PIs and authors, Ben Hires, CEO of BCNC, Dr. Carolyn Heang Leung Rubin, then Tufts CTSI Director of ADAPT, Mia Colby, and Yoyo Yau, BCNC Chief Program Officer at local and national events. These included the report launch event at First Parish in Malden, MA, in October 2021, the National Conference on Gambling Addiction in Boston in July 2022, and the Tufts CTSI/ ADAPT Asian Health Symposium in September 2022. The report was publicized in local and international outlets such as GBH and GGB News, a weekly online newsletter produced by the publishers of Global Gaming Business magazine, the leading trade magazine in the gaming industry. The report was also highlighted on the Massachusetts Department of Public Health and the Tufts CTSI websites.



▲ MyDzung Chu, PhD, MSPH, Director, Addressing **Disparities in Asian Populations through Translational Research** 



Linda Hudson, SCD, MSPH, Associate Director, **Integrating Underrepresented Populations in Research** (IUPR), Director, **Collaboration for** Research Equity, Sustainability, and Trust (CREST)

Most recently, on September 30, 2022, more than 75 community members, researchers, clinicians, and community advocates attended Tufts CTSI's 7th Annual Asian Health Symposium: "Unpacking the Root Causes of Problem Gambling in the Asian Community: From Research to Action" at the Tufts Health Science Campus. There is additional information in our recently published peer-reviewed article, "Unpacking the Root Causes of Gambling in the Asian Community: Contesting the myth of the Asian gambling culture" in the Frontiers in Public Health academic journal.

While CREST and ADAPT's populations of interest differ in race and ethnicity, our constituencies experience similar inequities in health services and inclusion in health research.

Since 2021, CREST has focused on community-driven research priorities in largely Black and Brown communities in the Boston neighborhoods of Roxbury, Mattapan, and Dorchester. Comprised of six core members and two affiliates, CREST has engaged in a process of prioritization of concerns based on publicly-available data which includes mental health, chronic disease prevention, and promotion among other social/structural determinants of health. The major pillars of the CREST mission are research, education, and advocacy. Using these core values in the prioritization process, CREST is developing its annual strategic plan development and review process. In addition, recognizing the mutual trust and alignment of vision and purpose, ADAPT and CREST have formed a communityto-community partnership and co-learning opportunity to jointly support and promote community-driven research.

In 2022, the Greater Boston Section of the National Council of Negro Women (GBSNCNW), a CREST partner, partnered with the Tufts Friedman School of Nutrition to create a semester-long webinar program. The students hosted monthly webinars covering a wide range of nutrition topics. The program provided an opportunity for the students to connect with the community and make culturally-relevant meals.

On May 23, 2022, CREST held its first public event, "An Evening with CREST: Improving the Health of our Black and Brown Communities" at Roxbury Community College. Community members and academic partners



Binta Barry, MS, **Senior Project** Manager, Integrating Underrepresented Populations in Research

discussed the importance of redefining ownership of the research process and study results. In addition, panelists shared their experiences developing a climate of mutual trust as the key to building sustainable community-academic partnerships. The event also highlighted the importance of sharing study findings in a meaningful way and translating study results into impactful actions.

Members of CREST are engaged in training and facilitation opportunities sponsored by departments in Tufts University/Tufts CTSI and are using those skills in addressing health and wellness issues within their constituencies.

Stakeholder-engaged research provides an authentic and ethical process for inclusion of those most impacted by the outcomes from conception to dissemination. It is foundational to addressing health inequities by participating in a process of co-creation, co-learning, and shared decision-making between researchers and potential participants.

The collaborative process envisioned within stakeholder-engaged research promotes the utilization of expertise and knowledge from all involved, centering the focus of the impacted populations. Given the history of egregious and harmful research practices, specifically perpetrated on communities of color, stakeholder-engaged research provides a pathway to processes grounded in principles of justice and equity.

# **Embedding Clinical and Translational Science in the "Clinical Moment"**

n order to generate evidence that is applicable to realworld care, studies must be broadly inclusive of the full range of patients and settings. As part of our mission to promote more generalizable results, the Tufts CTSI Clinical Research Network (CRN) includes a wide range of settings, rural, urban, and suburban community hospitals. In the past five years, our CRN steadily increased participation in Trial Innovation Network (TIN) studies, with five activated studies, two pending site activations, and 17 pending site selection decisions for 11 studies, making us one of the most active TIN participants in the national CTSA Consortium. Another example of diverse setting is the Tufts University School of Dental Medicine Practice-Based Research Network, which extends research to patients at a range of private practices.

For research to be generalizable, besides including settings that have diverse populations, all eligible patients should be included. Traditionally clinical trials have had very selective participation, which means that their results are not applicable to more diverse groups. Addressing this is a major thrust of our effort to embed research into the "clinical moment," that moment in which the patient and clinician are making their assessments and treatment decisions. As part of our role in the Johns Hopkins-Tufts University Trial Innovation Center, we have explored methods for doing this. One has been our device-based clinical research platform, which helps enroll patients when a diagnostic device is used — e.g., an electrocardiograph. Not only can the device's results mandate treatment, it also can flag that patient as a possible research participant, rather than the usual way of enrolling based on research staff and special clinical sites. We are working to embed this approach across Tufts Medicine, and then, in other partners' sites nationally. Another way we are embedding research into the clinical moment is the use of N-of-1 trials — individual patient trials that collect data to find out what treatment is very best for that patient. Using our principles of broadly-engaged team science, we are engaging stakeholders including patients, clinicians, hospitals, insurance payors, and pharmacy benefit managers, with the goal of creating a system for the use of N-of-1 trials that are embedded in the health care ecosystem.

To make real the embedding of research into real-world care, with the commitment of the Tufts Medicine health system's leadership and methodologic and logistic support from Tufts CTSI, we established a Patientcentered Learning Health System (PCLHS) in 2021. We call it "patientcentered" as a reminder



Denise Daudelin, RN, MPh, Director, Research **Process Improvement** 

that we prioritize the patient and the delivery of personalized medical care. Tufts PCLHS projects are identified and prioritized by the Tufts Medicine PCLHS Steering Committee, led by the Tufts Medicine Chief Academic Officer, Dr. Helen Boucher. The Steering Committee includes health system, component (e.g., hospitals and home care services), and function (e.g., informatics, service lines, pharmacy) leaders; patients, providers, and community members; and Tufts CTSI leaders and methodologists.

The Tufts CTSI PCLHS Consultation Team guides the implementation of prioritized projects and the incorporation of best practices from other learning health systems, including our Tufts CTSI partner, Kaiser Permanente. The objective is to identify and implement evidence-based innovations that yield improvements in health care quality, safety, value, and equity. The inaugural PCLHS project is a collaboration between Tufts CTSI and Tufts Medical Center's CardioVascular Center to use machine learning to better understand the predictors of hospital readmission for patients with heart failure.

One of the most pressing concerns in health care is the slow translation of effective interventions into health care. Dissemination and Implementation Science and Practice help us understand how to overcome barriers to translation and ensure that implementation of new discoveries meets the unique needs of patients, clinicians, and varied health care settings.

Tufts CTSI has a strong Research Process Improvement program which works with research teams to optimize study conduct, and the CTS Program to improve the effectiveness of the services and educational experiences we offer.

# **Tufts CTSI Responds to COVID-19**

ufts CTSI was well-positioned to provide services and institutional knowledge to support researchers and the health care community in responding to the coronavirus pandemic. At the onset of the pandemic, with the closing of all Tufts Medical Center research except that on COVID-19, Tufts CTSI was responsible for all COVID-19 studies through its Clinical and Translational Research Center (CTRC). Also, Tufts CTSI staffed and ran the processes for the Tufts Medical Center COVID-19 Oversight Committee that reviewed and approved all research during that period, which was co-chaired by the Tufts CTSI Dean and the Tufts Medical Center Chief Scientific Officer.

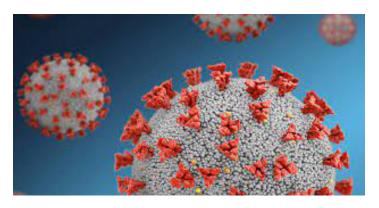
In addition to taking on these emergency responsibilities for COVID-19 research, Tufts CTSI immediately created pilot funding opportunities to support COVID-19 research, launched a few weeks after the initial statewide call to shelter in place and guarantine. Besides the Tufts CTSI COVID-19 Pilot Studies Program, the CTRC Voucher Program offered an expedited process called CTRC Sample Processing during COVID-19 to support sample processing for federal and other non-profit studies.

We also promoted the wide range of COVID-19 research funding that rapidly became available. especially at NIH, and supported applications by Tufts Medical Center and Tufts University investigators. Examples of NIH-funded studies from these efforts were a randomized, placebo-controlled effectiveness trial of niclosamide, an effectiveness trial of remdesivir, and a groundbreaking trial that used sarilumab in COVID-19 patients.

In addition, Tufts CTSI facilitated research through the COVID-19 Clinical Trial Rapid Start-Up and Symposium Plus Programs to get projects from an idea or design into trials as quickly and safely as possible. Once projects were off the ground, Tufts CTSI provided services to help with the sample processing during study trials and through sessions with our other service centers, such as our Biostatistics, Epidemiology, and Research Design (BERD) Center and Research Electronic Data Capture (REDCap) virtual drop-in hours. Tufts CTSI also launched an initiative in early 2021 to promote multi-site studies and utilization of the national CTSA Trial Innovation Network (TIN), alongside its existing support of the TIN in early COVID-19 research.

We also developed research databases and other tools for researchers to utilize





in studying the pandemic. We continuously provided electronic modes for data capture such as the REDCap application. Tufts CTSI participated in the National COVID Cohort Collaborative (N3C), through which we contributed to data collection as well as the distribution of tools and training associated with the N3C, the National COVID-19 Survivors Registry, and assisted with the dissemination of the Massachusetts COVID-19 Confidence Survey, approximately one year after the initial shutdown.

Due to the logistical and safety challenges presented by COVID-19, we quickly saw the need for remote options for research training. In 2021, Tufts CTSI's Professional Education team launched several COVID-19-related trainings on I LEARN, Tufts CTSI's interactive learning platform featuring non-degree professional education and training opportunities on a range of topics in clinical and translational research. These included workshops to help researchers better communicate with each other, such as giving researchers skills and frameworks to work with their collaborators. We also shifted support services to online platforms, such as the Development, Implementation and AssessMent of Novel Training in Domain-based competencies (DIAMOND) portal.

The work continued in 2022, as a clinical research team led by Harry Selker, MD, MSPH, Dean of Tufts CTSI, published the results of the first randomized placebo-controlled clinical trial of the effectiveness of niclosamide, an inexpensive oral medication long-used worldwide for treatment of tapeworms in people of all ages, in COVID-19 patients in JAMA Network. As a preliminary Phase 2 trial, it showed positive signals for reduction in viral shedding and symptoms that need to be followed-up in a larger study.

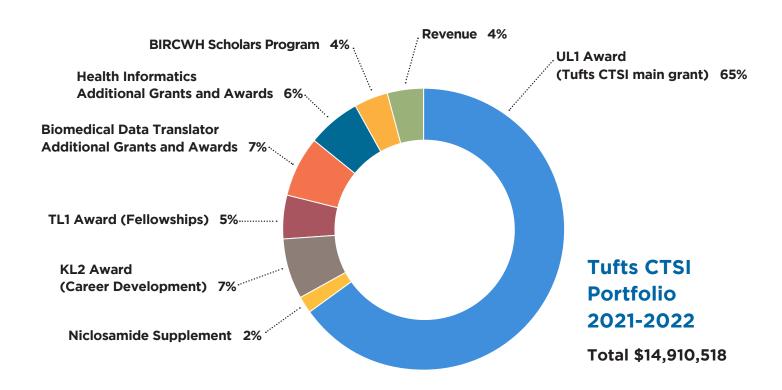
Adept and agile, Tufts CTSI stands ready to assist researchers in responding to the ever-changing coronavirus pandemic.

# Selected Tufts CTSI Program Highlights

- We quickly pivoted to respond to the COVID-19 public **health emergency**, including:
  - Supporting more than 175 active COVID-19 studies with more then 260 research services and 150 electronic data capture accounts.
  - Collaborating on core team to develop the National COVID Cohort Collaborative (N3C), harmonizing clinical data across 72 organizations.
- From 2009-2020, we awarded 104 Pilot Studies grants for innovative, interdisciplinary research, which generated more than \$57M of subsequent funded research and 146 publications. An additional 15 grants awarded in 2021-2022 are actively producing and disseminating results.
- We developed a OneHealth veterinary data warehouse and research center overseeing 40 veterinary trials and more than 1,000 research visits annually.
- We engaged more than 800 community members and other stakeholders in cultivating a culture of communication for inclusiveness and enhanced public trust in clinical research.
- Our Clinical and Translational Science Awards (CTSAs) have been cited in more than 575 academic journal articles.

#### In 2021:

- Our Navigators and content experts provided more than 900 research services in 2021.
- The Biostatistics, Epidemiology, and Research Design (BERD) Center fielded 335 service requests and provided their expertise to investigators during 53 Drop-in Sessions.
- The Clinical and Translational Research Center (CTRC) supported 81 clinical studies, involving pediatric, adult, and geriatric participants in research.
- Our Informatics team fielded 66 requests to mine existing clinical data to determine feasibility, and support achievement, of participant recruitment for specific studies.
- The Professional Education Team delivered 32 seminars, workshops, and symposia events to a total of 691 attendees, providing 87 training hours to researchers. In addition, 724 learners engaged in self-paced courses or archived events on the updated Tufts CTSI I LEARN platform.



# 2022 Tufts CTSI Funding Recipients

Tufts CTSI offers funding for innovative, high impact, translational science pilot projects and for the career development of junior faculty affiliated with our partners and collaborators. Congratulations to our recent recipients.

# ■ Career Development Award (KL2) Program

Tufts CTSI offers a KL2 Career Development Award for highly-qualified junior faculty to conduct multi-disciplinary clinical/patient-oriented research for two or three years. This NIH-funded program is designed to foster collaborative research across Tufts-affiliated hospitals/campuses and across disciplines. Our YR4 May 2021—April 2022 scholars are:

- · Jana Leary, MD, Tufts Medical Center
- Wendy McCallum, MD, MS, Tufts Medical Center
- Eric Anderson, PhD, Maine Medical Center
- Marieke Rosenbaum, DVM, MPH, Tufts Cummings School of Veterinary Medicine
- Maya Nadimpalli, PhD, Tufts University, School of Engineering

### TL1 Fellowship Program

The TL1 Fellowship Program offers research training for scholars and clinicians with an interest in clinical and translational research. These prestigious, NIH-funded programs provide stipends and full tuition for the Clinical and Translational Science (CTS) Graduate Program. Fellows earn a Certificate or MS in CTS, with the possibility of a PhD. Our Y4 fellows are:

- · Dara Azuma, MD, Tufts Medical Center
- Charles Cummings, MD, Tufts Medical Center
- Laura Nicolais, MD, Maine Medical Center
- Natalie Pawlak, BS, Tufts University, School of Medicine
- Jessica Penney, MD, Tufts Medical Center
- Emma Price, DVM, Tufts Medical Center
- Allison Reaves, MD, Tufts Medical Center
- Andy Wang, AB, Tufts University, School of Medicine
- · Alexis Webber, MD, Tufts Medical Center

#### Tufts CTSI Pilot Studies Program

The Pilot Studies Program funds projects led by interdisciplinary, multi-institutional, translational and clinical research teams. The program aims to improve population health by funding projects that allow investigators to develop and disseminate novel tools or methods, and/or to generate sufficient preliminary data for a larger follow-on study. The Principal Investigators for the Y4 awarded projects are:

- Ambika Bajpayee, PhD, MEng, Northeastern University Project: Long-acting Local Anesthesia to Treat Pain from Osteoarthritis
- Christine Bishop, PhD, AM, Brandeis University Project: Medicaid Enrollees' Receipt of Home- and Community-based Services: Allocation and Impact
- Srivalleesha Mallidi, PhD, MS, Tufts University School of Engineering
  - Project: Free-hand Ultrasound and Photoacoustic Imaging for Monitoring Oral Cancer Lesions
- Elizabeth Peacock-Chambers, MD, MS, Baystate Medical Center
  - Project: Development and Feasibility Assessment of a Train-the-Trainer Model to Improve Access to an Evidence-based Parenting Intervention for Mothers in Recovery from Substance Use Disorder

- Ellen Roche, PhD, MS, Massachusetts Institute of Technology
  - *Project:* A Novel Device for the Treatment of Obstructive Sleep Apnea: A Pilot Clinical Study
- Kinna Thakarar, DO, MPH, Maine Medical Center **Project:** Improving Discharge Decision-making Among Vulnerable Hospitalized Patients with Injection Drug Use-associated Infections
- Benjamin Wessler, MD, FACC, Tufts Medical Center Project: A Benchmark De-identified Echocardiogram Database for Studying Automated Diagnoses

# **Tufts CTSI Events Gallery**

Each year, Tufts CTSI hosts educational seminars, workshops, symposia, and an annual research conference at the Tufts Health Sciences Campus in Boston. Here are some images from our most recent offerings.

24th Annual Clinical and Translational Science Graduate Program Symposium (May 6, 2022)



CTS Graduate Program Director David Kent MD, CM, MSC, kicks off the symposium.



Caroline Hsu, MD, MS, answers a question after presenting "Acute and Chronic Dialysis during the Coronavirus Disease 2019 (COVID-19) Pandemic."



The poster session was a great opportunity to get a group shot of our students, faculty, staff, and leadership!

### An Evening with CREST: "Improving the Health of our Black and Brown Communities" (May 23, 2022)



Carl Baty, Executive Director, Rounding the Bases; and Christine Sinclair, former IUPR Project Manager.



Binta Barry, IUPR Senior Project Manager; Jonathan Garlick, DDS, PhD, Director of Science Communications; Zion Iverson, former IUPR Project Coordinator; and Arnetta Baty, CREST partner.



Andrew Sharpe, Founder and CEO of the Authentic Caribbean Foundation Inc.; Rosaline Lowe, member of Roxbury Main Streets; Thomas Concannon, PhD, Co-Director of Community and Stakeholder Engagement; Judith Thermidor, Resident Wellness Director at CSI Support & Development Services.

# 7th Annual Asian Health Symposium: "Unpacking the Root Causes of Problem Gambling in the Asian Community: From Research to Action" (September 30, 2022)



Ben Hires, Chief Executive Officer, Asian CARES Co-Principal Investigator, Boston Chinatown Neighborhood Center (BCNC), delivers keynote remarks.



Attendees discuss questions about casino marketing at their tables.



Anna Tse, one of the two interpreters, provided Tufts CTSI's first-ever live interpretation service for Cantonese/Mandarin speaking participants.

# Tufts | CTS| Tufts Clinical and Translational Science Institute

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