

**Tufts**

**CTSI**

Tufts Clinical and  
Translational Science Institute

**ANNUAL REPORT 2018**



# 10 Years of Partnership and Progress

TRANSLATING  
RESEARCH INTO  
BETTER HEALTH

## MESSAGE FROM THE DEAN

Time flies!

As we conclude our second five-year NIH Clinical and Translational Science Award (CTSA), we celebrate 10 years since the creation of Tufts Clinical and Translational Science Institute (CTSI), and the good news of being funded for another five years.



Over the past decade, we have brought together purposely-selected partners and existing and new programs and activities with a singular focus on how best to contribute to clinical and translational research. We have done this based on our particular skills, partnerships, and opportunities. This has allowed us to provide unique and outstanding services, resources, education, and mentorship as a hub for our New England partners and CTSA nationally as a participant in many CTSA collaborations and as a leader of CTSA Consortium initiatives. We have also augmented Tufts CTSI's role in the Consortium by being one of the three national CTSA Trial Innovation Centers (TICs).

In our new CTSA grant, which started May, 2018, we will expand our offerings by amplifying longstanding partners' contributions and by adding the special assets of new partners. In doing so, we will retain the same principles:

1. Actively collaborate.
2. Practice broadly-engaged team science.
3. Support the full spectrum of translational research.
4. Continually assess and iteratively improve research processes.
5. Reflexively look to develop, demonstrate, and disseminate new methods and approaches.
6. Advance rigorous role-specific education and training.

In preparation for the future of clinical and translational research, we have focused on transforming our organization from the original CTSA mission of being an institutional integrated home for clinical and translational science (CTSA 1.0) to now also including responsibilities to the national CTSA Consortium as a vital part of the CTSA Trial Innovation Network (CTSA 2.0). As you will see in this report, these efforts include increasing our capacity for multi-site clinical studies, building the informatics infrastructure for the information-sharing needed to conduct such studies, and evaluating our performance to execute our key functions with excellence. We've been very busy since our last report, and we hope you will be pleased with our progress.

To everyone who has been with us since the beginning, thank you for your dedication and perseverance! We are proud of everything we've accomplished together. To those who are discovering us for the first time, welcome to the family! In partnership and collaboration, we will transform the research enterprise to improve the public's health.

Very best wishes,

**Harry P. Selker, MD, MSPH**  
Dean, Tufts CTSI

### 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

Education, Training, and Career Development

Informatics

Integrating Special Populations

One Health

Pilot Studies Program

Regulatory Knowledge and Support

Research Process Improvement

Stakeholder and Community Engagement

T.5 Capacity in Medical Devices

Team Science: Research Collaboration Team and Navigators

Trial Innovation Network Multi-site Clinical Research Center

Translational Science Expert Panel

**For more information, please visit [www.tuftsctsi.org](http://www.tuftsctsi.org)**

### Our Mission

Tufts CTSI accelerates the translation of research into clinical use, medical practice, and health impact. Our mission is to identify, stimulate, and expedite innovative clinical and translational research, with the goal of improving the public's health. To reach this goal, we link scientists and scholars from a wide range of disciplines with clinical investigators, policy makers, and industry and community leaders to collaborate in conducting innovative clinical and translational research. We cultivate this collaboration and innovation by offering education, research expertise, and financial support to investigators.

One of more than 50 Clinical and Translational Science Award (CTSA) hubs in the national CTSA Consortium, Tufts CTSI was established in 2008 with our initial grant from the National Institutes of Health, National Center for Advancing Translational Sciences (NCATS).

Our second five-year grant period concluded in April 2018; our third five-year CTSA grant began in May 2018.

### The Aims of Our Second NIH CTSA Grant

The aims of our just concluded grant were:

**Aim 1:** Strengthen Tufts CTSI overall by:

- ORGANIZING and leading our partners in their commitment to a shared home for clinical and translational research.
- EXPANDING efficient access for all partners to a full spectrum of high-quality resources in a way that promotes collaborative clinical and translational research across disciplines and institutions.
- ADVANCING the field of clinical and translational research through local and national leadership and development of novel methods.
- PROVIDING innovative and targeted education and training across the spectrum of translational research, from bench to bedside (T1), bedside to practice (T2), practice to public health (T3), and practice to public policy (T4).

**Aim 2:** Operationalize and implement the clinical and translational research home and its infrastructure, services and programs, including its central office personnel, administrative and financial management systems, committees, and other necessary structures.

**Aim 3:** Sustain and grow innovative resources, services, and policies that support and promote collaborative, cross-disciplinary, full-spectrum translational research.

**Aim 4:** Develop and broaden the clinical and translational research workforce through education and training across the T1-T4 spectrum, with a specific focus on addressing translational gaps between bench to bedside and from bedside to widespread impact on health.

Tufts CTSI's partners and collaborators include an engaged network of hospitals and medical practices, academic institutions, health sciences and other academic institutions, community stakeholders, and industry. Each brings unique insights to our support of clinical and translational research, and make major contributions to that work. In the last ten years, our partnerships have grown and evolved to reflect the changing landscape of research. Institutions that have joined us since our last report are marked with an asterisk.

### 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 at Tufts Medical Center  
Jean Mayer USDA Human Nutrition Research Center on Aging  
Jonathan M. Tisch College of Civic Life  
Sackler School of Graduate 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

### 7 Tufts-Affiliated Hospitals

Baystate Medical Center  
Lahey Hospital and Medical Center  
Maine Medical Center  
New England Baptist Hospital  
Newton-Wellesley Hospital  
St. Elizabeth's Medical Center  
Tufts Medical Center

### 4 Academic Partners

Brandeis University  
Massachusetts Institute of Technology\*  
Northeastern University  
RAND Corporation

### 5 Industry/Non-Profit Partners

Baim Institute for Clinical Research\*  
Blue Cross Blue Shield of Massachusetts  
Eli Lilly and Company\*  
The Jackson Laboratory\*  
Pfizer, Inc.  
Tufts Health Plan

### 11 Community-Based Partners

Action for Boston Community Development  
Asian Community Development Corporation  
Asian Task Force Against Domestic Violence  
Asian Women for Health  
Boston Chinatown Neighborhood Center  
Center for Information and Study on Clinical Research Participation  
Greater Boston Chinese Golden Age Center  
Health Resources in Action  
Massachusetts Biotechnology Council\*  
MGH Institute of Health Professions\*  
Museum of Science, Boston  
New England Quality Care Alliance

## Partnership and Progress: Looking Ahead

Looking ahead to our next CTSA grant, we will expand our offerings by amplifying long-standing partners' contributions and adding special assets of new partners, retaining the same principles: 1) support the full spectrum of translational research; 2) practice broadly-engaged team science; 3) actively collaborate; 4) continually assess and iteratively improve processes; 5) reflexively look to develop, demonstrate, and disseminate new methods and approaches; and 6) advance rigorous role-specific education and training.

### The Aims of our Third NIH CTSA Grant:

**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.

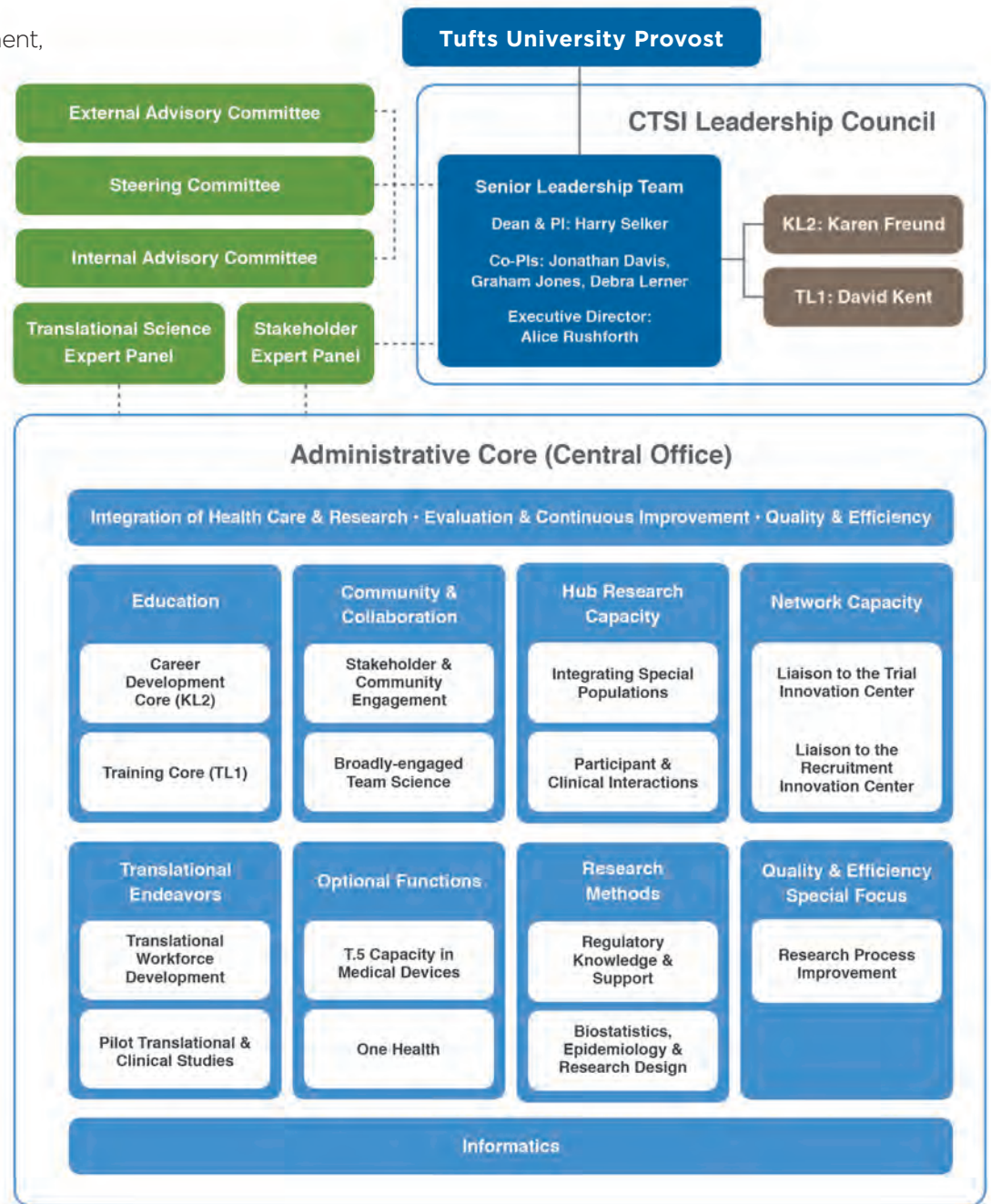
**Aim 3.** Develop, demonstrate, and disseminate **innovations in methods, research process improvement, and evaluation**, to advance CTR locally and nationally.

**Aim 4.** Advance methods and performance of **multi-site 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.

We restructured our organization to support these core principles and new aims.



## Partnership Highlights

Partnership and collaboration are integral to Tufts CTSI's identity. Convening experts across departments, institutions, and the CTSA Consortium, we constantly find new ways to stimulate projects, conduct studies, and educate the research workforce.

### **SYMPOSIUM PLUS: Advancing Innovative, Interdisciplinary Team Research Projects**

To promote team science and help nascent research ideas become fundable projects, we hosted four Symposium Plus events in 2016-2017. Our Symposium Plus framework is a four-stage cycle of activities that includes solicitation of projects, project pitches and discussion, proposal development, and project follow-up.

Researchers from across the Tufts CTSI partnership are invited to submit proposals related to the theme of each symposium. For each event, four or five proposals are selected, and investigators present their project ideas and receive feedback from technical experts, biostatisticians, and audience members. After the symposium, they work on forming teams and identifying at least one funding mechanism for which they will submit a proposal. In some cases, project teams receive modest Tufts CTSI pilot grants to generate data that can be used to develop applications for larger grants. Based on positive feedback from participating investigators, we are gathering data to publish a paper on the Symposium Plus model.

We hosted Comparative Effectiveness Research (CER) Symposium Plus in June 2016 and June 2017; a One Health Symposium Plus in October 2016; a Stakeholder and Community Engagement Symposium Plus in March 2017; and a Sensors, Devices, and Biomarkers in Medicine Symposium Plus in April 2018.



**Linda B. Hudson, ScD, MSPH of Tufts University School of Medicine presents at the March 2017 Symposium Plus.**

### **TRIAL INNOVATION CENTERS: Facilitating Optimal Conduct of Clinical Trials**

In June 2016, a joint application by Johns Hopkins and Tufts Universities was selected as one of three National Center for Advancing Translational Sciences (NCATS) CTSA Consortium Trial Innovation Centers (TICs). The JHU-Tufts TIC facilitates optimal conduct of clinical trials with three major objectives: 1) operational excellence, 2) astute application of the best science, and 3) innovation and application of new methods that will advance the field of clinical research. The three TICs and the Recruitment Innovation Center (RIC) are engaged with NCATS to build the national CTSA Consortium's multi-site clinical trial infrastructure and capacity, provide consultations to investigators interested in conducting multi-site studies at CTSA

institutions, and conduct multi-site trials using TIC and RIC infrastructure, resources, and services. The Tufts TIC team has provided seven major consultations since January 2017 and a number of Tufts CTSI researchers, including those from health economics and policy, and biostatistics (BERD), as well as cardiologists and oncologists from Tufts Medical Center, were involved in these consultations. The consultations take an average of four months to complete. While most are working toward a submission deadline to an NIH Institute or Center, some are industry-sponsored studies. The consultations involve developing a final protocol and statistical analysis plan, conducting study feasibility assessment, and developing a study budget. Recruitment plans and community engagement studios are also carried out in collaboration with the RIC.

The TICs will continue to engage in a number of infrastructure-building collaborative demonstration projects, two of which Tufts is leading. These are 1) the development of clinical trial performance metrics in collaboration with the Tufts University Center for the Study of Drug Development, and 2) the development and dissemination of innovations in trial design and execution, such as: efficacy-to-effectiveness (E2E) and efficacy and effectiveness too (EE2) trials, and device-based trial cohort discovery.

### **DIAMOND: Working Together to Develop Comprehensive Research Training**

In July 2017, the CTSA's at University of Michigan, Tufts University, The Ohio State University, and University of Rochester were awarded a three-year Collaborative Innovation Award (U01), *Development, Implementation and Assessment Of Novel Training in Domain-based Competencies* (DIAMOND), to develop a comprehensive training curriculum that equips investigators and clinical research coordinators with the necessary skills to more effectively, efficiently, and safely execute clinical trials.

Led at University of Michigan, the main goal of the DIAMOND project is to foster competency-based training nationally among junior investigators and other clinical research professionals, primarily study coordinators, by creating a one-stop web portal containing CTSA-shared training, curricula and assessment tools, and networking opportunities. Enhancing training opportunities across the CTSA Consortium is critical to preparing study teams with the necessary skills to design and conduct clinical trials more effectively, efficiently, and safely.

Over the next three years, the DIAMOND project will deliver a sustainable, collaborative discovery learning space for clinical research professionals working in CTSA institutions or partners that includes shared competency-based clinical research training offerings, assessments, networking, and a unique ePortfolio system to encourage workforce development and connection.

Since our inception, Tufts CTSI has strived for progress in facilitating research that will have impact on health.

### TRANSLATIONAL RESEARCH DAY: Using Technology to Impact Health

Tufts CTSI hosted its third Translational Research Day in November 2017. The theme of the event was the impact of biomarkers and sensors on personalized medicine, with speakers from Tufts Medical Center, Tufts University, the Massachusetts Institute of Technology (MIT), Northeastern University, and the US Food and Drug Administration (FDA). The day, attended by 165 people, also featured panel discussions and a poster session.

After Translational Research Day, Graham Jones, PhD, Tufts CTSI Associate Director and Director of Research Collaborations, and Jill Maron, MD, MPH, Executive Director of the Tufts Medical Center Mother Infant Research Institute, published a commentary manuscript, “How Sensors, Devices, and Biomarkers Can Transform Precision Medicine: Perspectives from a Clinical and Translational Science Institute,” in *Clinical Therapeutics*. A companion Tufts CTSI Symposium Plus event was held in April 2018 to catalyze new team research on this theme.



Tufts University School of Engineering’s Donna Slonim, PhD, and Tufts CTSI Executive Director Alice Rushforth, PhD.

### CTSA COMMON METRICS INITIATIVE: Measuring Progress Across the CTSA Consortium

The 2013 Institute of Medicine Report on the CTSA Program called for measurable strategic goals and uniform actionable performance metrics that would support assessment and improvement of the effectiveness and impact of CTSA. To address this, NCATS and the CTSA embarked on an aggressive initiative to develop and apply metrics and strategies nationally across all CTSA to maximize the Consortium’s impact.

In 2015, Tufts CTSI was awarded a supplemental grant to lead and evaluate the implementation of the Common Metrics and the use of the Results-Based Accountability (RBA) framework throughout the National CTSA Consortium. In August 2017, we were awarded a second supplemental grant to continue in this leadership role.

The project team was led by Tufts CTSI Dean and Principal Investigator Harry Selker, MD, MSPH, with the implementation and dissemination activities overseen by Research Process Improvement Director Denise Daudelin, RN, MPH, and the evaluation research study led by Director of Organizational Impact Debra Lerner, MS, PhD, and Evaluation Director Lisa Welch, PhD.

We worked closely with NCATS to implement the Common Metrics and RBA framework for the first three Common Metrics (on IRB review time, research education success, and pilot award

productivity), and to pilot test a new clinical trial accrual metric. We are now completing the formal evaluation of the implementation and adoption of the Common Metrics. This involved training, coaching, and providing technical support to 250 staff and 32 Principal Investigators across 64 institutions nationally; developing and conducting follow-up surveys; and designing and launching a qualitative component to better understand the context, barriers, and facilitators of implementing the Common Metrics framework across the CTSA Consortium. At the end of 2017, we transitioned the Common Metrics implementation and technical assistance activities and resources to the new CTSA Coordinating Center, the Center for Leading Innovation and Collaboration (CLIC), at the University of Rochester.

### SPOTLIGHT: Clinical and Translational Science Graduate Student Alison Brown, PhD, MS

Alison Brown, PhD, MS is a researcher on the rise. In May 2017, immediately after earning her PhD in Food Policy and Applied Nutrition from the Friedman School of Nutrition Science and Policy at Tufts University, she enrolled in Tufts CTSI’s Clinical and Translational Science Graduate Program as a certificate student and a Tufts CTSI TL1 Postdoctoral Fellow, working with KL2 Program Director Karen Freund, MD, MPH and her research team.

Dr. Brown’s research interests and experience include the intersection of epidemiology, clinical, and community initiatives to address racial/ethnic health disparities in the US. As a postdoctoral fellow, she is working to broaden her understanding of health science research as it relates to health disparities, and how health insurance instability influences the management of diabetes among various racially and ethnically diverse patients.

“Improving our understanding and characterization of health disparities in the health care sector will help shape how we effectively address these disparities,” she said.

During her fellowship, a paper related to Dr. Brown’s dissertation, “Ethnic Heterogeneity among Blacks, Diet Quality, and Hypertension Risk: A Mixed Methods Approach,” was accepted for publication by the *American Journal of Clinical Nutrition*. Her study examined the ethnic diversity in the US Black population and how this related to diet quality and hypertension risk, in which the data showed that foreign-born Blacks had better diet quality and lower risk for hypertension than their US-born counterparts. This research is timely considering the national immigration policy debate, and provides more evidence on why the ethnic and cultural diversity of the US Black population needs to be considered, appreciated, and explored in public health research and programs.

“Blacks in the US experience some of the highest rates of diet-related diseases,” said Dr. Brown. “With funding constraints for public health programming and research, these findings can help to prioritize interventions for the most at-risk and vulnerable.”

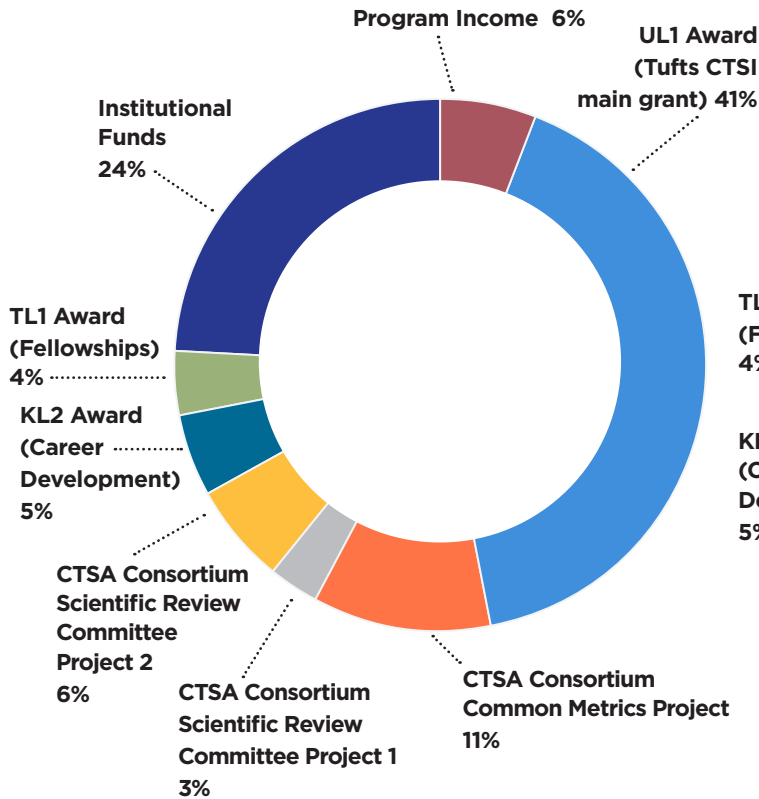
The future continues to look bright for Dr. Brown. In 2018, she received a “40 Under 40 Leaders in Health Award” from the National Minority Quality Forum.



# Tufts CTSI Resources

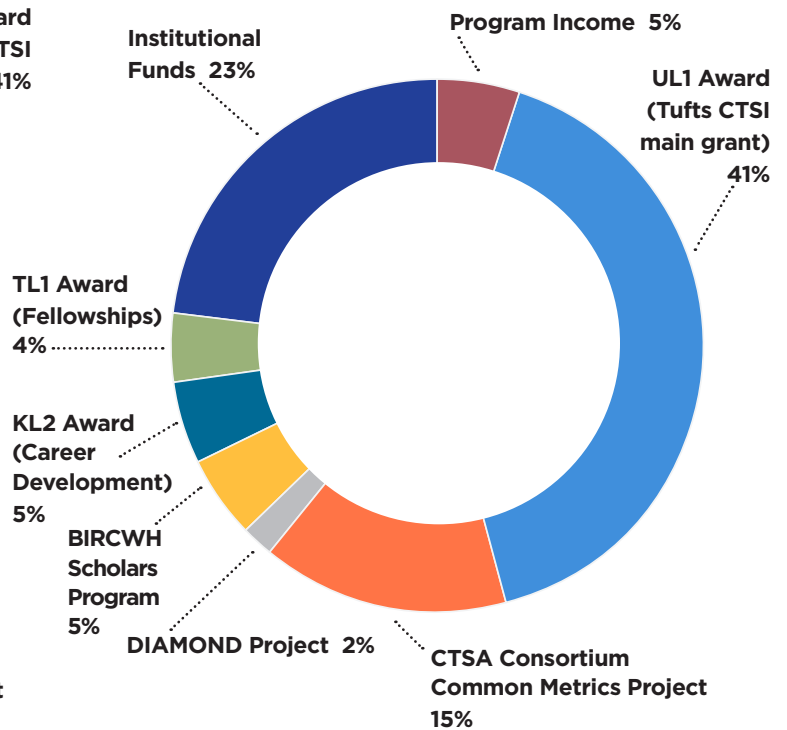
TUFTS CTSI FUNDING BY SOURCE  
**2ND GRANT PERIOD, YEAR 4**  
 May 2016 - April 2017

**Total \$10,827,090**



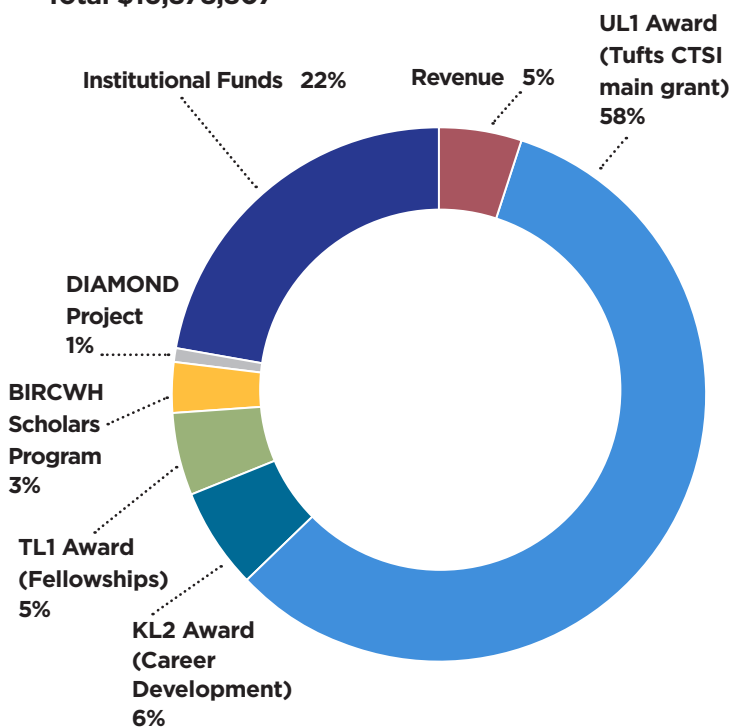
TUFTS CTSI FUNDING BY SOURCE  
**2ND GRANT PERIOD, YEAR 5**  
 May 2017 - April 2018

**Total \$10,893,040**



TUFTS CTSI FUNDING BY SOURCE  
**3RD GRANT PERIOD, YEAR 1**  
 May 2018 - April 2019

**Total \$16,878,807**



## Tufts CTSI Program Highlights

### 10 years of impact:

- Since 2009, we've awarded **85 grants** for innovative, interdisciplinary research through our Pilot Studies Program.
- The Clinical and Translational Science (CTS) Graduate Program has conferred degrees and certificates to **186 trainees** since joining the Sackler School of Graduate Biomedical Sciences in 1999. **98% of graduates** from 2012-2017 remain engaged in translational research.
- REDCap has more than **2,800 registered users** and an average of **260 logins per day**.

### Supporting research at every phase in 2016-2017:

- Lead navigators triaged more than **340 service requests** and provided over **90 consultations**.
- The Biostatistics, Epidemiology, and Research Design (BERD) Center assisted with **176 pre-award projects** and provided **107 drop-in consultations**.
- The Clinical and Translational Research Center (CTRC) supported **74 clinical studies**.
- The Professional Development Team offered **32 events** (seminars, workshops, symposia) attended by more than **735 people**.

# KUDOS & CONGRATULATIONS

## ■ TL1 Fellowship Program

Our exciting, NIH-funded TL1 research training programs provide pre- and post-doctoral fellowships. Fellows earn a Certificate or MS in Clinical and Translational Science, with the possibility of a PhD.

- Paul Adjei, MD, Tufts Medical Center
- Alison Brown, PhD, MS, Friedman School of Nutrition Science and Policy
- Jonathan Brown, BS, MIT
- Alissa Dangel, MD, Tufts Medical Center
- Gaurav Gulati, MD, Tufts Medical Center
- Michael Jonczyk, MD, Tufts Medical Center
- Anita Kumar, MD, Tufts Medical Center
- Vaibhav Kumar, MBBS, Tufts Medical Center
- Jana Cerullo Leary, MD, Tufts Medical Center
- Anthony Karabanow, MD, Tufts Medical Center
- David G. Li, BS, Tufts University School of Medicine
- Daqin Mao, PhD, Tufts Medical Center
- Anna Meader, MD, Maine Medical Center
- Natalia Olchanski, MS, Tufts Medical Center
- Bridget Perry, PhD, MGH Institute of Health Professions
- Xi Qian, PhD, Tufts University School of Medicine
- Ramy Rashad, BS, Tufts University School of Medicine
- Maria Rodriguez Berrios, ND, Tufts Medical Center
- Henry Rogalin, PhD, Tufts University School of Medicine
- Alexandra Sack, DVM, MPH, Harvard T.H. Chan School of Public Health
- Alexander Xu, BS, Tufts University School of Medicine

## ■ Tufts CTSI Pilot Studies Program

The Pilot Studies Program funds proposals for innovative, high-impact, translational science projects with a focus on building interdisciplinary, multi-institutional research teams including investigators from the basic, clinical, and/or applied sciences.

- Heather Clark, PhD, Northeastern University
- Kathryn Connaghan, PhD, Northeastern University
- Kimberly Dong, DrPH, RD, Tufts University School of Medicine
- Chris Dulla, PhD, Tufts University Sackler School of Graduate Biomedical Sciences
- Christina Economos, PhD, Tufts University Friedman School of Nutrition Science and Policy
- Caroline Genco, PhD, Tufts University Sackler School of Graduate Biomedical Sciences
- Christopher Hasson, PhD, Northeastern University
- Linda Hudson, ScD, ScM, MSPH, Tufts University School of Medicine
- Kumaran Kolandaivelu, MD, PhD, Massachusetts Institute of Technology

## ■ Welcome to the Team

Our diverse faculty members represent many of our partner institutions. Recently appointed Tufts CTSI faculty include:

- Jennifer D. Allen, ScD, MPH, MSN, Tufts University School of Arts and Sciences
- Ndiyamaka Amutah-Onukagha, PhD, Tufts University School of Medicine
- Elena Byhoff, MD, MSc, Tufts Medical Center
- Mei Chung, PhD, MPH, Tufts University School of Medicine
- Elazer Edelman, MD, PhD, SM, SB, Massachusetts Institute of Technology
- Abby Fleisch, MD, MPH, Maine Medical Center
- Peter D. Friedmann, MD, MPH, FASAM, FACP, Baystate Health
- Edward J. Hackett, PhD, MA, Brandeis University
- Paula (Gigi) Hirsch, MD, Massachusetts Institute of Technology
- David S. Huckins, MD, Newton-Wellesley Hospital
- Stratis Ioannidis, PhD, MSc, Northeastern University
- Tania Konry, PhD, Northeastern University
- Arthur Kramer, PhD, Northeastern University
- Anita J. Kumar, MD, MS, Tufts University School of Medicine
- Amy LeClair, PhD, MPhil, Tufts Medical Center
- Peter Levine, PhD, Tisch College of Civic Life
- Jeanne Madden, PhD, Northeastern University
- Teresa May, DO, Maine Medical Center Research Institute
- Melissa P. McInerney, MPP, PhD, Tufts University School of Arts and Sciences
- Derek Merck, PhD, Brown University
- Lisa Merck, MD, MPH, FACEP, Brown University
- Dominique Michaud, ScD, Tufts University School of Medicine
- Christina Mulé, PhD, NCSP, LP, Tufts Medical Center
- Errol R. Norwitz, MD, PhD, MBA, Tufts Medical Center
- Quinn Pack, MD, MSc, Baystate Health
- Jessica Pollard, MD, Maine Medical Center
- Michaela Reagan, PhD, Maine Medical Center Research Institute
- Scot Remick, MD, FACP, Maine Medical Center
- Angie Mae Rodday, PhD, MS, Tufts Medical Center
- Clifford Rosen, MD, Maine Medical Center Research Institute
- Robert Sege, MD, PhD, Tufts Medical Center
- Mihaela S. Stefan, MD, PhD, FACP, Baystate Health
- Dennis Steindler, PhD, Jean Mayer USDA Human Nutrition Research Center on Aging
- Jay Steingrub, MD, Baystate Health
- Thomas Stopka, PhD, MS, Tufts University School of Medicine
- Cindy Thomas, PhD, MSPH, PA, Brandeis University
- Paul Visintainer, PhD, Baystate Health

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