



MIAMI CLINICAL &  
TRANSLATIONAL  
SCIENCE  
INSTITUTE

# ANNUAL REPORT

FISCAL YEAR 2020

UNIVERSITY  
OF MIAMI







The U statue on the Foote University Green.  
Photo: University Communications



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## LETTER FROM THE DIRECTOR

Welcome to the Miami CTSI Annual Report. At the beginning of FY20, we had no idea of the challenges the world would be facing at fiscal year-end. It has been a year of adaptability, determination, and teamwork. I am only highlighting a few achievements in this welcome note and invite you to continue reading the report to learn about our accomplishments.

Our work in FY20 was made possible through unwavering support from the Miller School of Medicine and University of Miami Provost. Our achievements are enabled through strong relationships and alignment with institutional research offices.

In FY20 we were also highly engaged in the CTSA Consortium, working with CTSA institutions across the country on innovative projects, including a lay-friendly clinical research portal and expansion of the I-Corps Entrepreneurship Training Program. In January, I also began my three-year term as a CTSA Steering Committee member, charged with identifying and recommending best practices and policies to advance clinical and translational research and facilitating collaborations.

This year, the Miami CTSI added three new mentored translational scholars – one awarded through federal funds and the other two in partnership with academic departments. We funded six new pilot awards – two co-sponsored by the NCI-designated Sylvester Comprehensive Cancer Center and one co-sponsored by the University of North Carolina CTSA. Other notable CTSI-sponsored awards include: a ULINK award to address occupational hearing loss that brought together a team of researchers from across schools; three Magic Leap Awards to teams utilizing mixed/augmented reality in clinical settings; and two Public Voices fellows to amplify minority perspectives in the media.

In FY20 we held our first full scale Research Mentoring training program, developed in partnership with the University of Colorado CTSA. The CTSI continued to showcase outstanding team science through the Dean Henri Ford's Interdisciplinary Research Seminar Series, and our state-of-the-art CTSI Training Center was a hub for research training and events across the university, hosting over 160 events this year.

We also expanded CTSI tools that facilitate participant recruitment in clinical research. The Consent to Contact for Research program, which links interested patients with studies for which they may be eligible, had over 119,000 patients as of May 2020 and had 21 studies approved for use. We also expanded URIDE, our de-identified clinical data tool, to house more than 15 million encounters representing 1.26 million unique patients.

The last quarter of FY20 brought the onset of the COVID-19 pandemic. Along with much of the country, we pivoted to remote work and virtual events. We swiftly awarded three COVID-19 research projects through Emerging Disease Awards. Working with institutional partners, we enabled methods to support virtual clinical research, including HIPAA-compliant Zoom, eConsent training, and eRegulatory Binder. We also launched Translational Tuesdays, an instantly popular weekly moderated webinar highlighting COVID-19 research advances.

Finally, I want to recognize the dedication and flexibility demonstrated by CTSI faculty and staff during this uniquely challenging year. I am proud of our work and know that we will rise to meet any challenges FY21 may bring.

With sincere gratitude,

**DR. RALPH L. SACCO, MD, MS**  
DIRECTOR AND PRINCIPAL INVESTIGATOR

## CTSI MISSION

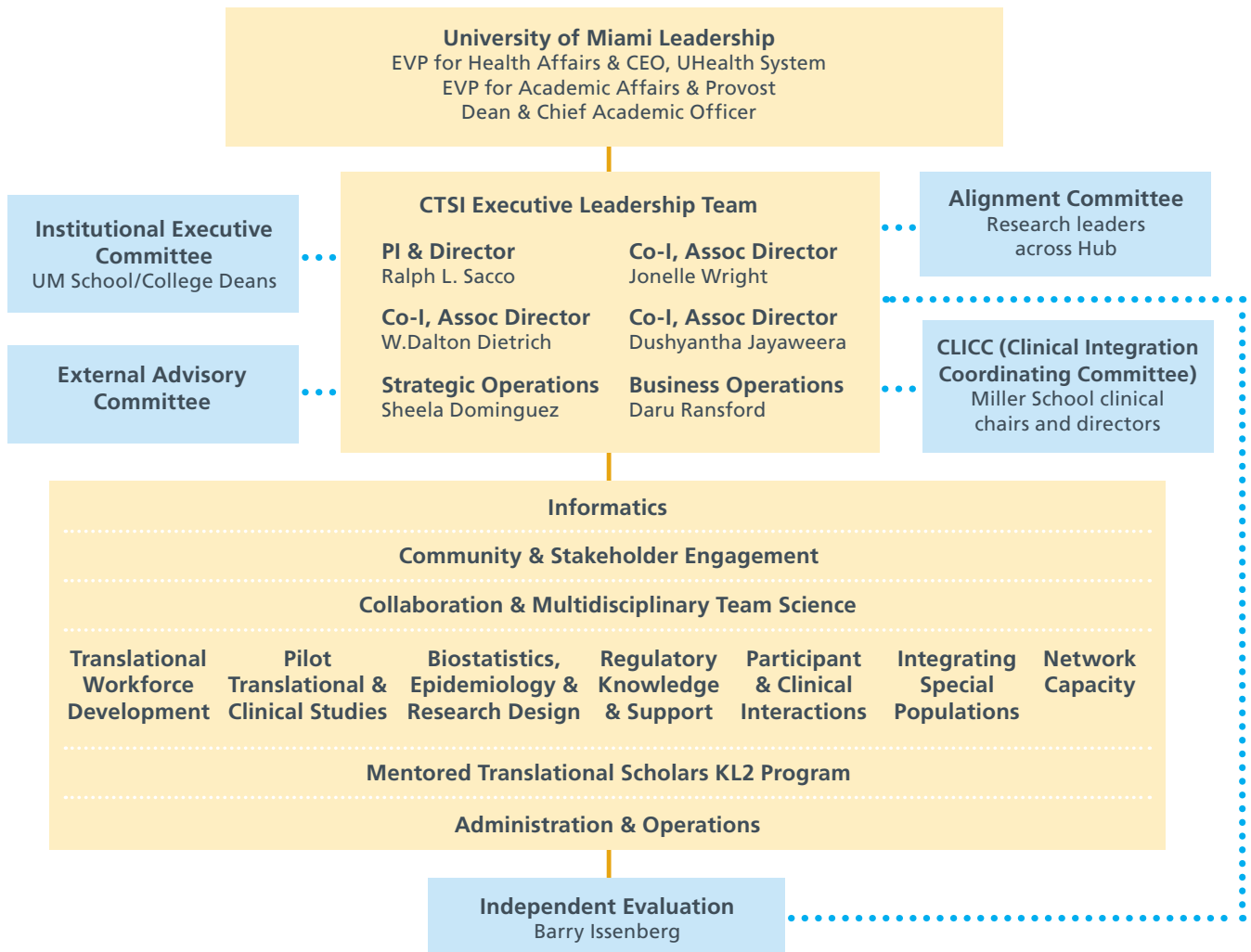
The mission of the Miami Clinical and Translational Science Institute (CTSI) is to be indispensable as the scientific home for clinical and translational (C/T) research, transforming University research infrastructure to advance excellence in culturalized C/T research.

## INSTITUTIONAL PARTNERSHIP

The Miami CTSI actively works with University of Miami leaders to align with Miller School of Medicine, UHealth System, and University research strategic plans. To that end, the CTSI formally reports to University of Miami academic and health system leaders, providing bidirectional, dynamic feedback and mutual prioritization of research focus areas and activities.

In addition to funding from the National Center for Advancing Translational Sciences, in FY20 the Miami CTSI was supported by UHealth System and Miller School of Medicine leadership, as well as the University of Miami Provost.

## CTSI STRATEGIC STRUCTURE



## MIAMI CTSI HUB

The Miami CTSI Hub is comprised of six partners that create a dynamic platform for clinical and translational research. Hub Partners expand outreach and share resources and expertise in workforce development, technology, and community-engaged research.

CTSI partners include the entire University of Miami, Jackson Health System, Miami VA Healthcare System, OneFlorida Clinical Research Consortium, Health Choice Network, and Health Council of South Florida.

## CTSI GOVERNANCE

### INSTITUTIONAL EXECUTIVE COMMITTEE

**Roni Avissar** (Dean, RSMAS)  
**Leonidas Bachas** (Dean, Arts & Sciences)  
**Victoria Behar-Zusman** (Professor, Nursing & Health Studies)  
**Daniel Berg** (Interim Dean, Engineering)  
**Norma Kenyon** (Vice Provost, Innovation)  
**Erin Kobetz** (Vice Provost, Research)  
**Guillermo Prado** (Vice Provost, Faculty Affairs & Dean, Graduate School)  
**CTSI Executive Leadership Team**

### ALIGNMENT COMMITTEE

**Katuska Barbery** (Director, Clinical Research, Jackson Health System)  
**Erin Kobetz** (Vice Provost, Research)  
**Peter Paige** (Chief Clinical Officer/Chief Physician Executive, Jackson Health System)  
**Carl Schulman** (Executive Dean, Research Miller School of Medicine)  
**José Szapocznik** (CTSI Founding PI)  
**CTSI Executive Leadership Team Research Administration Representative**

### CLINICAL INTEGRATION COORDINATING COMMITTEE

**Maria T. Abreu** (Vice-Chair for Research, Medicine)  
**Eduardo Alfonso** (Chair, Ophthalmology)  
**Joshua Hare** (Director, Interdisciplinary Stem Cell Institute)  
**Erin Kobetz** (Vice Provost, Research)  
**Stephen Nimer** (Director, Sylvester Comprehensive Cancer Center)  
**Michael Paidas** (Chair, Obstetrics & Gynecology)  
**Vittorio Porciatti** (Vice-Chair for Research & Director, McKnight Vision Research Center)  
**Judy Schaechter** (Chair, Pediatrics)  
**Fred Telischi** (Chair, Otolaryngology)  
**Omaida Velazquez** (Chair, Surgery)  
**Roy Weiss** (Chair, Medicine)  
**Stephan Züchner** (Chair, Human Genetics)  
**CTSI Executive Leadership Team**

### EXTERNAL ADVISORY COMMITTEE FY20

**Peter J. Embi, MD, MS, FACP, FACMI**  
 President & CEO, Regenstrief Institute; Sam Regenstrief Professor of Medicine and Associate Dean for Informatics and Health Services Research, Indiana University School of Medicine; Associate Director of Informatics, Indiana CTSI; Vice President for Learning Health Systems, IU Health

#### Patricia Ann Furlong, MS

Founder, President & CEO, Parent Project Muscular Dystrophy

#### Jill G. Joseph, MD, PhD, MPH

Professor Emeritus, University of California Davis Betty Irene Moore School of Nursing

#### David Nelson, MD

Director (FY20), UF Clinical and Translational Science Institute; Senior Vice President for Health Affairs, University of Florida, President, UF Health

#### Harold Pincus, MD

Associate Director, Irving Institute for Clinical and Translational Research; Professor and Vice Chair, Department of Psychiatry, Columbia University; Director of Quality and Outcomes Research, New York-Presbyterian Hospital

#### David S. Stephens, MD

Chair, Department of Medicine, Stephen W. Schwarzmann Distinguished Professor of Medicine, Emory University School of Medicine; Vice President for Research, Woodruff Health Sciences Center, Emory University

## CTSA FY20 COLLABORATIONS



The Clinical and Translational Science Awards (CTSA) Program supports a national network of research institutions that work together to improve and accelerate the translational research process for turning research discovery into interventions that improve patient care and public health outcomes. As part of this consortium, we engaged in several collaborations with other CTSA institutions in FY2020.

### 1. Indiana Clinical and Translational Sciences Institute

Submitted a collaborative supplement application with the Indiana CTSI to NCATS focused on effective dissemination, communication, and cross-promotion of translational research.

### 2. Georgia Clinical and Translational Science Alliance

Led the Opioid Epidemic session at the 2020 Southeast Regional Clinical and Translational Science Conference organized by the Georgia CTSA.

### 3. University of Colorado

Collaborated with the University of Colorado CTSI to implement a junior faculty mentoring program at the University of Miami with 28 mentor-mentee teams participating in the inaugural workshop.

### 4. University of North Carolina at Chapel Hill

Awarded a collaborative pilot award with the North Carolina Translational and Clinical Sciences Institute and the project began in FY2020.

### 5. University of Alabama at Birmingham

Received a competitive revision award for national dissemination of the I-Corps@ NCATS program led by the University of Alabama Center for Clinical and Translational Science. UM is one of the participating sites in the I-Corps@NCATS Program.

### 6. University of Kansas

Collaborated with University of Kansas Frontiers to pilot a program with the Dartmouth Institute Microsystems Academy to test a Quality Improvement "Team Coaching" model for clinical trials teams.

### 7. University of Florida

As a partner of the OneFlorida Clinical Research Consortium led by the University of Florida CTSI, UM researchers can query a statewide clinical research network and database of over 15 million patient records to identify cohorts using aggregate and de-identified patient-level health data, intervene with patients at the point-of-care and conduct pragmatic clinical trials and other interventional studies.

### 8. University of Pittsburgh

Participated as a site in the Accrual to Clinical Trials (ACT) network, a federated network of sites from the CTSA Consortium that share Electronic Health Record (EHR) data to increase participant accrual to the nation's highest priority clinical trials.

### 9. University of Michigan Ann Arbor

Collaborated with the Michigan Institute for Clinical and Health Research to implement an online portal (clinical trial search tool) to improve community participant recruitment outside of our health system into clinical trials, including healthy participants.

### 10-14. CTSA Trial Innovation Network (TIN) Trials:

The TIN focuses on operational innovation, operational excellence and collaboration to address critical roadblocks in clinical trials and to accelerate the translation of novel interventions into life-saving therapies.

In FY 20, UM participated as a site in five TIN trials led by:

- 10. Duke University
- 11. Johns Hopkins University
- 12. New York University Langone Medical Center
- 13. Ohio State University
- 14. Columbia University

# ANNUAL (FY20\*) AND LIFETIME\*\* OPERATIONAL HIGHLIGHTS

## MIAMI CTSI FUNDING (ALL SOURCES)

**\$6.2m** FY20      **\$47.3m** Lifetime

## CTSI FY20 TEAM

 **32**  
Faculty

 **37**  
Staff

 **11**  
Students

 **58**  
External Collaborators

## PILOT AWARDS

**\$225,000**

CTSI Award

**\$40,000**

U-LINK Award

U-LINK: University of Miami Laboratory for Integrated Knowledge

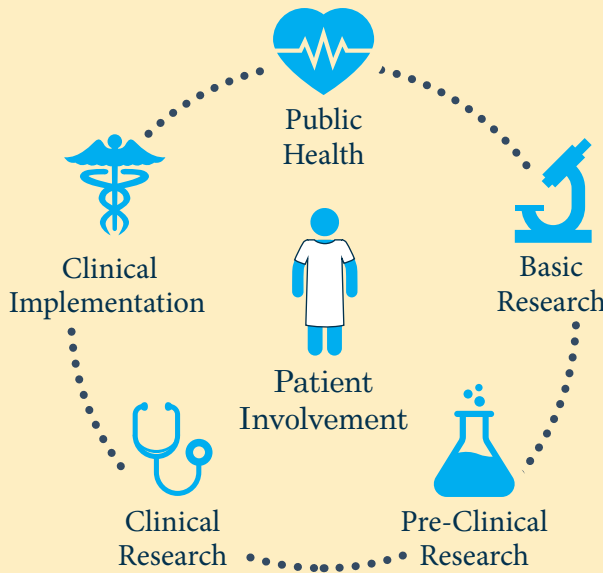
**\$30,000**

Magic Leap Awards

**\$13,000**

Public Voices Fellowships

Public Voices: Year-long fellowship aimed at increasing the impact of women and minorities in public discourse.



**16:1** Lifetime ROI\*\*\* on CTSI Internal Awards

## CAREER DEVELOPMENT/KL2 AWARDS

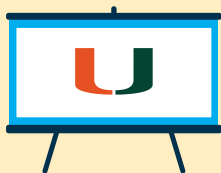
**\$539,220**

FY20 Awarded Scholar Funding

**\$3.9m**

Lifetime

## CONNECTION FOR RESEARCH CAREER ENHANCEMENT



**06**  
Networking events across UM campuses



**101**  
Total Attendees

\*Fiscal Year (FY)20 spans June 1, 2019 - May 31, 2020, \*\*FY13-20. Miami CTSI was established in FY13. \*\*\*external funding received



# CTSI FY20 AT A GLANCE

## CONSENT TO CONTACT

**119,000<sup>+</sup>** UHealth patients that agreed to be contacted for research at the end of FY20

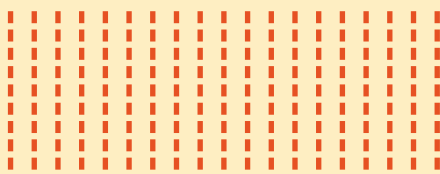
**56%**  
FEMALE

**44%**  
MALE

**28**  
Trials queried

**15**  
Approved

## RESEARCH USING ELECTRONIC MEDICAL RECORDS (EMR)



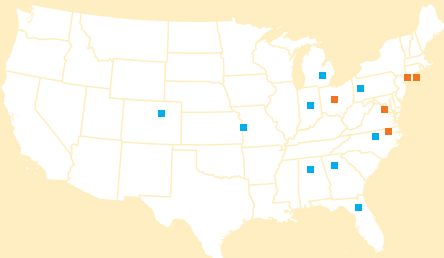
**171**  
FY20 EMR Clinical Data Requests



**75** in FY20      **317** since launch

URIDE De-identified Data Users in FY20

## CTSA TRIAL INNOVATION NETWORK



**25** Trials Queried

**05** Trials Implemented

Ohio State University, Duke University, Johns Hopkins University, NYU Langone Medical Center

## CTSI EDUCATION AND TRAINING



**130** Education and Training Events



**1,690** Total Attendees

**2,300<sup>+</sup>** CTSI Engagement\*

## BIostatistics COLLABORATION AND CONSULTING CORE

Consultations

**1,814** Support Hours

**167** Users

Education Sessions

**36** Sessions

**382** Attendees

## REDCap DATABASE MANAGEMENT

Over **4,500**

Active users



\* Number of instances or people who have used at least one CTSI resource in FY20

## CORONAVIRUS DISEASE (COVID-19) PANDEMIC CTSI'S AGILE RESPONSE (MARCH - MAY 2020)

As COVID-19 emerged as a public health emergency, NCATS and the CTSA Consortium galvanized into action, facilitating scientific and infrastructure projects across the country. The University of Miami CTSI is at the forefront of this effort, leading and supporting several COVID-19 research and education projects.

### CTSI FUNDING FOR DIAGNOSTIC TESTS

FUNDING	\$75,000	\$75,000	\$50,000
TOPIC	Develop rapid point-of-care test for screening of COVID-19.	Develop rapid, inexpensive lab diagnostic assay for SARS-CoV-2.	Determine the prevalence of the SARS-CoV-2 virus infection in UHealth patients and the possible risk factors for these infections.
TEAM	S.Daunert, PharmD, MS, PhD; S.K. Deo, MS, PhD; J-M. Zingg, PhD	M.Sharkey, Ph.D. and M.Stevenson, Ph.D.	(PIs) D.Jayaweera MD, S.Pallikkuth PhD, S.Pahwa MD; (Co-Is) X.Liu MD, PhD, B.Shukla MD, D.Andrews MD, M.Jorda MD, S.Daunert PhD, S.Deo PhD, J.Hare MD.

### COVID-19 EDUCATION RESOURCES

#### TO COMMUNITY STAKEHOLDERS

##### COVID-19 WEBINAR

(for community health workers)

Latest facts and available resources. Led by B.Rodriguez, Program Manager, CTSI Community & Stakeholder Engagement (CASE) Program, and J.Munroe, Epidemiologist, Florida Department of Health.

Participation: **300 CHWs**

#### TO THE SCIENTIFIC COMMUNITY

##### TRANSLATIONAL TUESDAY WEBINAR SERIES

##### Activities from March - May 2020

Webinar and Q&A session every Tuesday sharing ongoing COVID-19 research and innovations at UM.

**7 webinars; total attendance: 1,276**

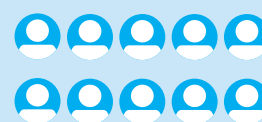
##### CTSI COVID-19 WEB PAGE

Includes webinars, approved and upcoming projects, funding opportunities, important guidelines from UM's research offices and links to innovative COVID-19 research taking place at UM.

##### CTSI NEWSLETTER

Regular dissemination of our COVID-19 related activities, news and collaborations.

**1,100 subscribers**



**347 members**  
of the COVID-19  
Discussion Forum

## INFRASTRUCTURE AND OTHER SUPPORT

**CONDUCTING VIRTUAL CLINICAL RESEARCH** Miami CTSI worked with the University's central research offices to develop guidelines and SOPs to conduct research virtually.

**TECHNOLOGY PLATFORMS** The CTSI invested in technology platforms to facilitate virtual research: **Complion**; **Zoom for Healthcare**; Electronic consent options: **DocuSign**, **REDCap**.

**CONSENT TO CONTACT PROGRAM TO FACILITATE TRIALS** Two Miller School of Medicine investigators are using CTSI's Consent to Contact Program to contact patients for participating in COVID-19 research projects.

**COVID-19 DISCUSSION FORUM** for the UM community to promote collaboration. Specialized discussion threads: pre-clinical, clinical, testing/diagnostics, epidemiological, and social behavioral research.

**HAND SANITIZERS FOR FRONTLINE WORKERS** Miami CTSI used our marketing and promotions vendor to secure and purchase hand sanitizers

**200+**

**Zoom for Healthcare**  
Licenses activated



**1,500** bottles  
of hand sanitizers  
donated

## CTSI LEADERS AND AWARDEES RESPOND TO THE PANDEMIC (MARCH-MAY 2020)

**SPARKC** Surveillance Program Assessing Risk and Knowledge of Coronavirus

**CTSI Team Science & Community Engagement Program Director, Erin Kobetz PhD**, was tapped by Miami-Dade County in March to conduct randomized antibody testing to assess the prevalence of COVID-19 infection in the community. Early results showed over half who tested positive for antibodies report no symptoms in the two weeks prior to testing, and also that the burden of infection was higher among blacks.

**UTRACE** UM Tracking, Resources, and Assessment of COVID-19 Epidemiology

**Erin Kobetz PhD**, also co-leads a project called UTRACE which is a REDCap reporting system designed to track COVID-19 presumptive and confirmed cases among UHealth and Miller School personnel.

**Developing a COVID-19 Early Detection, Tracking and Reporting System**

**CTSI Informatics Director Nicholas Tsinoremas, PhD** and collaborators with the **UM Institute for Data Science and Computing** are developing an interactive geographic visualization alert system using Machine Learning algorithms to provide early warning for COVID-19 surveillance.

**Designing Reusable Masks for Medical Personnel**

**CTSI Participant & Clinical Interactions Program Director Carl Schulman, MD, PhD, MSPH**, is evaluating, new reusable mask designs for use in the health care setting to limit exposure and protect medical personnel treating coronavirus patients.

**Vaccine Research**

**CTSI KL2 Scholar Dr. Natasa Strbo, MD, DSc**, is developing a heat shock protein (HSP) gp96-Ig vaccine against SARS-CoV-2 and other emerging infectious diseases, including HIV, malaria, and ZIKA.

**Stem Cell Therapy Clinical Trial**

**Miami CTSI BERD Program Director Shari Messinger Cayetano, PhD**, is collaborating with Miller School Faculty **Dr. Camilo Ricordi** on a clinical trial testing stem cell therapy to treat COVID-19 patients with life threatening lung inflammation.

**Anti-Inflammatory Drug Aviptadil Clinical Trial**

**Miami CTSI Associate Director and Hub Network Capacity Program Director Dushyantha T. Jayaweera MD**, leads a team of researchers at UM in a clinical trial studying the use of the drug Aviptadil to treat Acute Respiratory Distress Syndrome (ARDS) in patients with COVID-19.

**Link Between Prescription Drugs And COVID-19 Outcomes**

**Former CTSI Internal Funding Awardee Savita Pahwa, PhD**, is examining whether there is a link between drugs that are given to patients with hypertension, coronary artery disease, diabetes, or cardiovascular disease and the outcomes of COVID-19 patients.

*Miami CTSI has supported many other projects, including establishing a COVID-19 feasibility review committee, implementing high profile COVID-19 clinical trials, and more. These will be reported in a special COVID-19 supplement to be published in late fall 2020.*

## CTSI FY20 PILOT AWARDS

CTSI's Pilot Translational and Clinical Studies Program aims to support highly innovative, translational, interdisciplinary, and/or health-disparities-oriented research proposals.



### Luisa Cimmino, PhD \*

Assistant Professor,  
Biochemistry & Molecular Biology

Targeted Vitamin C therapy for the treatment of leukemia



### Yelena Drexler, MD

Assistant Professor,  
Medicine - Nephrology  
and Hypertension

APOM as a Novel Biomarker and Potential Therapeutic  
Target for Glomerular Diseases



### Michael Ivan, MD \*

Assistant Professor,  
Neurosurgery

Prognostic and Predictive Markers to Personalize  
Medicine for Malignant Glioma in Hispanics



### Corinna Levine, MD, MPH

Assistant Professor,  
Otolaryngology

Developing an Integrated Profile of  
Chronic Rhinosinusitis



### Jennifer Manuzak, PhD

Research Assistant Professor,  
Pediatrics

Impact of HIV infection on the gut/liver axis



### Nevis Fregien, PhD +

Associate Professor,  
Cell Biology

Development of a stem-cell based assay to identify  
read-through agents specifically for ciliated airway cells

\* Co-sponsored with Sylvester Comprehensive Cancer Center

+ Co-sponsored with University of North Carolina CTSA

## CTSI FY20 MENTORED TRANSLATIONAL RESEARCH KL2 AND INSTITUTIONAL SCHOLAR AWARDS

Scholars receive 75% salary support for up to two years, \$30,000 for research expenses, and \$2,500 for travel and training-related activities. Scholars work with senior faculty mentors and KL2 Program leaders to create an individual career development plan, and have access to CTSI resources such as biostatistical and regulatory consultations as well as educational programs.

In FY20, in addition to one CTSI KL2 scholar, two institutional scholars were selected with support provided by the CTSI and the scholar's department setting the precedent for collaborative support for junior faculty career development.

### FY20 AWARDED SCHOLARS\*



#### Corinna Levine, MD, MPH

Assistant Professor,  
Otolaryngology,  
CTSI KL2 Scholar

Using an Integrated Profile of Chronic Rhinosinusitis to  
Customize Care and Mitigate Disparities



#### Ayham Alkhachroum, MD

Assistant Professor,  
Neurology,  
CTSI Institutional Scholar

Electrophysiologic Biomarkers of Consciousness Recovery  
after Traumatic Brain Injury: The EBC Recovery Study



#### Jashodeep Datta, MD

Assistant Professor,  
Surgery,  
CTSI Institutional Scholar

Overcoming tumor-intrinsic mechanisms of immune  
exclusion defined by Ras-p53 cooperative signaling in  
pancreatic adenocarcinoma

### FY19 ACTIVE SCHOLARS



#### Lunthita Duthely, EdD

Research Assistant Professor,  
Obstetrics and Gynecology,  
CTSI KL2 Scholar

A Multi-Lingual, Culturally-Competent mobile Health  
Intervention to Reduce Medical Mistrust, Stigma, and Improve  
Treatment Adherence among Women Living with HIV/AIDS



#### Joyce Gomes-Osman, PhD

Assistant Professor,  
Physical Therapy and Neurology,  
CTSI KL2 Scholar

Assessing cognitive improvements, brain neuroplasticity and the  
role of genetic factors after aerobic exercise in sedentary adults

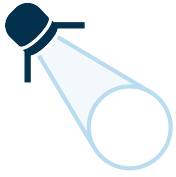


#### Mario da Cunha Saporta, MD, PhD

Assistant Professor, Neurology,  
CTSI KL2 Scholar

Drug development for inherited axonopathies using  
a human cellular platform

\*Selected in FY20. Awards were delayed until FY21 due to the COVID-19 pandemic and began in June 2020



# SPOTLIGHT: FACILITATING CLINICAL RESEARCH

## CTSI FACILITATES PATIENT PARTICIPATION IN RESEARCH

Implemented in 2019 as a resource to the research community, the Consent to Contact for Research initiative allows UHealth patients to learn about clinical studies that may be appropriate for them while increasing UHealth’s ability as an academic medical center to advance research and deliver transformational care to patients. Through the program, UHealth patients can consent to be contacted about clinical study opportunities for which they qualify. Investigators can obtain a patient contact list with their IRB approved protocol.

### CONSENT TO CONTACT

**119,000<sup>+</sup>**

Patient database (consented “yes” to be contacted) by end of FY20

**13%**



Black/African American

**42%**



Hispanic



**27.5k<sup>+</sup>**

Patient list approved

**2,100<sup>+</sup>**

Patients contacted by study teams



**35**

Research studies submitted to use Consent to Contact



**21**

Research studies approved

## UNIVERSITY RESEARCH INFORMATICS DATA ENVIRONMENT

The University Research Informatics Data Environment, also known as URIDE, is a web-based platform that visualizes aggregated de-identified data from the UHealth UChart system. The Google-like search interface allows researchers and their teams to easily explore demographics, diagnoses, procedures, vitals, medications, labs, notes, allergies, comorbidities, locations, physicians, and much more. Applications include study design, feasibility analysis, grant submission or other applications where population assessments need to be conducted.

### URIDE DATABASE

**15m**  
Encounters

**32k**  
Medications

**10k**  
ICD-9 codes

**4.2k**  
Labs

**2.9k**  
Procedures

Over

**1.26m**  
Patients



**55%** Female

**45%** Male

**42%** Hispanic

**13%** Black/African American



Patient population age groups:

**17%** Pediatric

**49%** Young-middle age adults

**34%** Older adults (60+)

### FY20 URIDE UTILIZATION

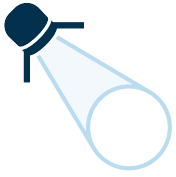
**45**  
Consultations

**75**  
Users

**800<sup>+</sup>**  
Logins

**59**  
Units using URIDE (Departments/Divisions)

**317**  
Lifetime total URIDE users



## SPOTLIGHT: FACILITATING CLINICAL RESEARCH

### CLINICAL DATA REQUESTS

University of Miami investigators can request specific clinical data sets for research by directly submitting requests through a self-service portal or Information Technology helpdesk. Researchers can request data for IRB approved studies or preparatory to research activities.

New in FY20 is the availability of clinical data sets from Hub partner Health Choice Network.

#### IN FY20



# 171

Consultations and clinical data requests processed



# 550,000<sup>+</sup>

Patient records released

### TOOLS TO CONDUCT CLINICAL RESEARCH VIRTUALLY

From March to May 2020, the Miami CTSI in collaboration with institutional research offices implemented several tools to enable investigators to conduct research virtually. Zoom for Healthcare HIPAA-compliant licenses for research will allow study teams to conduct participant visits remotely. The eRegulatory platform Complion will be used to maintain regulatory documentation electronically.

A part-11 compliant electronic-consent option DocuSign is being implemented which will allow study teams to obtain participant consent electronically and can be used by FDA-regulated clinical studies. Additionally, the e-consent module available in REDCap can be used for studies that are not FDA-regulated which makes this option available to a significant number of IRB-approved studies now and in the future.

# 200<sup>+</sup>

Zoom for Healthcare research licenses activated



Studies utilizing licenses

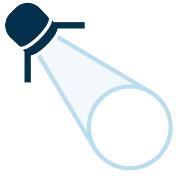
# 2,500

DocuSign envelopes available for e-consent



# 270<sup>+</sup>

Studies interested to use REDCap e-consent



## SPOTLIGHT: EDUCATION AND TRAINING

### MASTER'S OF SCIENCE IN CLINICAL AND TRANSLATIONAL INVESTIGATION

Developed and led by the Miami CTSI, the 30-credit Master's of Science in Clinical and Translational Investigation (MSCTI) graduate program at the University of Miami offers a structured educational program that trains students in the principles and practice of translational science and clinical research. Designed to prepare practitioners and researchers to overcome the perceived bottlenecks that inhibit translational research, the program offers the opportunity for its clinicians, researchers, and students to develop new skills and to remain at the forefront of biomedical science.

MSCTI graduates have demonstrated successful career growth, including leadership positions (NIH) and careers in highly ranked institutions, both at UM and elsewhere.

#### LIFETIME



51

Program enrollment



33

Graduates

#### FY20



24

Enrollment



7

Graduates

**92%** of graduates engaged in clinical and translational research.

#### OVERALL VALUE OF THE PROGRAM



100%

Mentors



86%

Mentees

Rated 'Very Good' or 'Outstanding'

### RESEARCH MENTORING TRAINING

Miami CTSI conducted the inaugural workshop in a series of mentor/mentee training workshops to promote the development of the next generation of clinical and translational scientists. The workshops focus on developing mentoring skills and building successful relationships between both mentors and mentees. The 3-session training program was conducted in partnership with Gregory Austin, M.D., who leads the CO-Mentor Training Program at the Colorado Clinical and Translational Sciences Institute and is a nationally recognized leader in research mentoring training.

The first cohort consisted of 27 mentor-mentee teams from 14 departments and four schools – Miller School of Medicine, Engineering, Nursing, and RSMAS. Through group exercises and discussions, mentor-mentee teams covered a wide range of topics such as scientific goal setting, academic persistence and work-life balance, and effective mentoring partnerships.

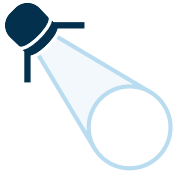
*“It was also great to interact with so many different mentors/mentees in different fields at UM. It was a very enjoyable experience and was very helpful in gathering new information, establish new collaborations and networking.”*

Mentee perspective

*“Sharing mentorship experiences with other mentors and Dr. Austin with a perspective from a different institution, and hearing issues and articulated specific research and career development needs from all mentees.”*

Mentor perspective





# SPOTLIGHT: EDUCATION AND TRAINING

## SEMINAR SERIES HIGHLIGHTS COLLABORATION AND TEAM SCIENCE

The Dean Henri Ford’s Interdisciplinary Research Seminar Series highlights innovative, collaborative, translational research conducted by University of Miami faculty across all its disciplines. The monthly seminar series features successfully funded interdisciplinary teams of scientists, of all ranks and levels, who participate in translational projects. Interdisciplinary teams have presented on topics such as neurology, inflammation, cancer, aging, precision medicine, cardiology, neuroscience and more.

 **9** Seminars in FY20

 **485** Attendees in FY20

## NETWORK OF CLINICAL RESEARCH PROFESSIONALS (NCRP)

CTSI’s bi-monthly seminar series for clinical research professionals is a forum for clinical research personnel to learn about research office functions, clinical research policy and process updates, best practices, and to network with peers. In FY20, the NCRP brought two national level virtual meetings to UM research professionals: the 2019 OHRP Exploratory Workshop: Privacy in a Data-Driven World and the PRIM&R Virtual SBER/AER 2019 Conference, that were attended by 88 participants and provided an opportunity to the attendees to earn continuing education credits.

 **10** Seminars in FY20

 **424** NCRP subscribers

## TRANSLATIONAL TUESDAYS COVID-19 SEMINAR SERIES

CTSI’s new series highlighting the ongoing research and innovations at University of Miami in fighting the COVID-19 public health crisis was created in April 2020. The seminar series, held weekly, is a forum for clinicians, researchers and interdisciplinary teams to present their COVID-19 work in areas such as diagnostic testing, measuring community spread, vaccine research, drug trials, stem cell therapy and COVID-19 symptoms among others.

 **7** Seminars (April – May)

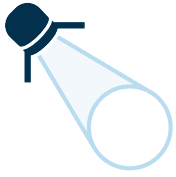
 **1,276** Total attendees

## OTHER EDUCATION AND TRAINING TOPICS

CTSI offers a diverse range of interdisciplinary clinical and translational research education and training opportunities to faculty, staff and students.

### Education & Training events conducted in FY20:

TOPIC	TOTAL ATTENDANCE
Biostatistics Roundtables, Clinics and REDCap trainings	382
Connection Meetings and Other Program Seminars	93
Dean Henri R. Ford’s Interdisciplinary Research Seminar Series	485
Grant Writing Boot Camp and Consultations	56
I-Corps Entrepreneurship Training	40
Network of Clinical Research Professionals Seminar Series	500
Research Regulatory Training	233
Translational Tuesdays Seminar Series	1,276



## SPOTLIGHT: RESOURCES

### BIostatISTICS COLLABORATION AND CONSULTING CORE (BCCC)

The BCCC is a key part of Miami CTSI's Biostatistics, Epidemiology, and Research Design Program. Through CTSI support, the BCCC offers initial consultations to clinical and translational researchers free of charge and offers office hours to address quick questions or give statistical advice. BCCC personnel are available for collaboration at all stages of research, including, but not limited to, preparation of grants and contracts, study design, data analysis, and manuscript preparation. Obtaining biostatistical collaboration as early as possible in development of a research project increases the quality of the research, and the likelihood of success in obtaining extramural funds, and meeting study objectives.

CTSI also supports the educational efforts of the BCCC through seminars, clinics which are presented to the research community and address specific statistical topics, and roundtables which are small-group interactive sessions where researchers can bring their own research design questions for discussion.



# 167

BCCC Consultation Users in FY20



# 36

Roundtables, Clinics & Seminars conducted



# 382

Participants



# 160

Training Center Events in FY20



# 4,600

Total attendees



# 30

Departments/ Offices using Center

### CTSI RESEARCH TRAINING CENTER

The state-of-the-art CTSI Research Training Center serves as the event-hub for the research community at the University of Miami. The training center is dedicated to supporting the UM research community for education and training activities, research seminars, collaborative meetings and networking, and consultations. In FY20, the training center hosted several key events including the Miller School's strategic research retreat, annual external advisory committee meetings for the CTSI and the Center for Aids Research (CFAR), and the Dean Henri Ford's Interdisciplinary Research Seminar Series among numerous other high-profile events.

## YEAR IN REVIEW: SELECTED FY20 EVENTS

### CTSI EXTERNAL ADVISORY COMMITTEE

The Miami CTSI hosted its External Advisory Committee (EAC) Members on March 2 for its annual on-site meeting. Presentations included an overview of CTSI progress and highlighted accomplishments in Translational Workforce and Career Development, Pilot, Hub Research and Network Capacity and Team Science Programs. A lunchtime mini poster session showcased the exciting translational research being done by seven CTSI Pilot Awardees. The EAC meets annually to review progress, discuss plans, and provides recommendations for the future. This year's meeting was chaired by David Nelson\*, MD, Director of the UF Clinical and Translational Science Institute in FY20.



### HIGH-PERFORMANCE TEAMS RETREAT

The Miami CTSI, the Office of the Executive Dean for Research, the Office of Graduate Studies and the Clinical Research Operations & Regulatory Support Office participated in a four-day intensive leadership course titled "Foundation for High-Performance Teams". The course focused on developing a common language, approach, and tools for high performance to improve efficiency and effectiveness for research at UM. The workshop was conducted at the CTSI Training Center and had 38 participants in total.



\*Dr. Nelson transitioned to a new role in 2019. He is now the Senior Vice President for Health Affairs, UF & President, UF Health.

## YEAR IN REVIEW: SELECTED FY20 EVENTS

*...continued*



### RESEARCH MENTORING WORKSHOP

CTSI conducted its first full-scale research mentoring training initiative with a cohort of 14 mentors and 20 mentees selected from 4 schools and over 14 departments. Facilitated by Dr. Greg Austin from the University of Colorado, a nationally recognized leader in research mentoring training, this intensive three-session program spread over several months from December - April. The final session was conducted virtually in response to in-person restrictions due to the COVID-19 pandemic, and featured topics on academic persistence and work-life balance, time management, writing effective letters of support, discussing dilemmas and career mapping.

### CONNECTION AND RSMAS JOIN FORCES TO STRENGTHEN HEALTH-FOCUSED RESEARCH COLLABORATIONS

On November 23, the CTSI initiative, University-wide Connection for Faculty Research Career Enhancement, together with the Rosenstiel School of Marine and Atmospheric Science (RSMAS), held its second retreat of 2019. RSMAS Dean Roni Avissar, Associate Professor of Marine Biology and Ecology Danielle McDonald PhD, and Connection Advisory Board Members welcomed Connection Members to the half-day retreat to learn about RSMAS scientific perspectives and how to strengthen health-focused research; explore interdisciplinary collaborations; and brainstorm possible solutions to research career dilemmas. The event had 34 attendees.



## YEAR IN REVIEW: OTHER HIGHLIGHTS AND ACHIEVEMENTS

### DR. RALPH SACCO NAMED TO CTSA PROGRAM STEERING COMMITTEE

Ralph Sacco, MD, CTSI Director and Principal Investigator was appointed to the Clinical and Translational Science Awards (CTSA) Program steering committee for a three-year term beginning on January 1, 2020. The committee identifies and recommends best practices and policies to advance clinical and translational research as a discipline and facilitates collaboration and sharing among CTSA Program institutions as well as with academic, industry and other partners in clinical and translational research.

### INSIGHTS TO INSPIRE: CTSA WEBINARS

The Miami CTSI was one of four hubs featured in CTSA Program's Insights to Inspire series – a series of blogs and webinars highlighting the innovative strategies implemented by a CTSA Program institution to improve common metrics tracked across all CTSA institutions. The Miami CTSI was featured for increasing the number of scholarly publications resulting from research funded through its Pilots Program.

### ABSTRACTS AND MANUSCRIPTS FROM MIAMI CTSI IN JOURNAL OF CLINICAL AND TRANSLATIONAL SCIENCE

Five conference abstracts submitted by the Miami CTSI were published in the Journal of Clinical and Translational Science (JCTS). The abstracts covered topics in evaluation and the Pilots, KL2, Network and PCI Programs. Two papers were published in JCTS with Brendaly Rodriguez as a co-author on a manuscript focusing on academic-public partnerships in the CTSA network, and Dr. Daniel Armstrong, PhD as a co-author on a paper focusing on lifecourse and lifespan research.

### CTSI PARTNERS WITH CFAR AND NCI-DESIGNATED SCCC

CTSI collaborated with Center for Aids Research (CFAR) and the NCI-designated Sylvester Comprehensive Cancer Center (SCCC) on several initiatives including a joint request for application for pilot funding, co-funded pilot awards, and education and faculty development programs.

### CTSI COLLABORATIVELY FUNDED AWARDS

**U-LINK (UM Laboratory for Integrative Knowledge)** interdisciplinary award on Hazardous Occupational Noise: Hillary Snapp, AuD, PhD, Otolaryngology; Uzma Khan, PhD, Marketing; Barbara Millet, PhD, Interactive Media; Zsuzsanna Nemeth, PhD, Health Informatics; Suhrud Rajguru, PhD, Biomedical Engineering; Natasha Solle, PhD, Medicine.

**Public Voices Fellowship:** National initiative aimed at increasing the public impact of women and minorities in public discourse. Fellows: Roger McIntosh, PhD, Psychology; Teshamae Monteith, MD, Neurology

**Magic Leap:** Build on Magic Leap's mixed reality (MR) technology to move 2D computing into the 3D world. Three CTSI-sponsored projects: Angela Blizzard, MS, Pediatrics; Michael Ivan, MD, Neurological Surgery; Lee Kaplan, MD, Orthopaedic Surgery.

### CTSI KL2 SCHOLAR RECEIVES PRESTIGIOUS AMERICAN COLLEGE OF SURGEONS RESEARCH FELLOWSHIP

The Miami CTSI congratulates KL2 Scholar and Sylvester Comprehensive Cancer Center surgical oncologist Jashodeep Datta, MD, for being selected by the American College of Surgeons Scholarship Committee as the sole recipient of the 2020 Franklin H. Martin Faculty Research Fellowship award. The \$40,000 annual grant was awarded to Dr. Datta for two years.

### CTSI SCHOLAR RECEIVES NIH MENTORED RESEARCH SCIENTIST CAREER DEVELOPMENT AWARD

Miami CTSI KL2 Scholar Tali Elfassy, PhD, was awarded a 4-year, Mentored Research Scientist Career Development (K01) grant from the National Institute on Minority Health and Health Disparities, for her project titled "Understanding drivers of incident hypertension disparities among US Hispanics of diverse backgrounds."

### CTSI PILOT AWARDEE RECEIVES \$3M NIH GRANT FOR INNOVATIVE RESEARCH ON ANEURYSMS

Miami CTSI Pilot Awardee and Miller School neurosurgeon Robert M. Starke, MD, was awarded a \$3 million grant from the NIH for his innovative research on aneurysms.

## A SPECIAL THANK YOU TO:

### CTSI PROGRAM LEADERS

Daniel Armstrong, PhD  
 Olveen Carrasquillo, MD, MPH  
 Shari Messinger Cayetano, ME, PhD  
 Sylvia Daunert, PharmD, PhD, MS  
 Stephen DeGennaro  
 W. Dalton Dietrich, PhD  
 Alessia Fornoni, MD, PhD  
 Dushyantha Jayaweera, MD  
 Norma Kenyon, PhD  
 Erin Kobetz, PhD, MPH  
 David Loewenstein, PhD  
 Suhrud Rajguru, PhD  
 Sunil Rao, PhD  
 Tatjana Rundek, MD, PhD  
 Carl Schulman, MD, PhD, MSPH, FACS  
 Gwendolyn Scott, MD  
 Nick Tsinoremas, PhD  
 Jonelle Wright, PhD

### CTSI OPERATIONS PERSONNEL

Patricia Avissar	Gigi Giobio
Carlos Canales	Enjoli Johnson
Caprice Battle	Chin-Chin Lee
Stellamarina Covelli	Raquel Perez
Rosalina Das	Deepthi Puram
Marisabel Davalos	Daru Ransford
Jessica Diaz	Brendaly Rodriguez
Sheela Dominguez	Peyman Taghioff

## CTSI RESOURCES

### C/T RESEARCH INFRASTRUCTURE

- Biostatistics Consultations
- Consent to Contact Program
- Feasibility Analysis & Cohort ID Tools
- Network Trial Operations
- One Florida Research Consortium
- Pilot Grants
- REDCap Database Support
- Regulatory Consultations
- Research IT & Data Storage Tools
- Research Navigator
- Research Training Center
- Research Writing Support
- COVID-19 Research Facilitation

### TRANSLATIONAL WORKFORCE DEVELOPMENT

- Biostatistics Education
- C/T Research Workshops
- The Connection
- Commercialization Seminar Series
- Grant Writing Support & Consultations
- I-Corps Training Program
- Informatics Training
- KL2 Program
- Master's Program
- Network for Clinical Research Professionals
- Research Mentoring Training Program
- Team Science Seminars

### STAKEHOLDER ENGAGEMENT AND CULTURALIZATION

- Community Engagement
- Community Health Workers Training
- Health Disparities Focus
- Lifespan Study Consultations
- Study Recruitment:
  - Consent to Contact Program
  - ResearchMatch

For a comprehensive list of resources,  
visit [www.miamictsi.org](http://www.miamictsi.org)



Don Soffer Clinical Research Center, home of the CTSI.  
Photo: Jorge Perez



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