The U statue on the Foote University Green.
Photo: University Communications
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 (Chair, Otolaryngology)
Omaida Velazquez (Chair, Surgery)
Roy Weiss (Chair, Pediatrics)
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
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 CTSA, 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

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.

CTSI FY20 TEAM

32 Faculty
37 Staff
11 Students
58 External Collaborators

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
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+ CTSI Engagement*

BIOSTATISTICS COLLABORATION AND CONSULTING CORE

1,814 Support Hours

167 Users

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

<table>
<thead>
<tr>
<th>FUNDING</th>
<th>$75,000</th>
<th>$75,000</th>
<th>$50,000</th>
</tr>
</thead>
<tbody>
<tr>
<td>TOPIC</td>
<td>Develop rapid point-of-care test for screening of COVID-19.</td>
<td>Develop rapid, inexpensive lab diagnostic assay for SARS-CoV-2.</td>
<td>Determine the prevalence of the SARS-CoV-2 virus infection in UHealth patients and the possible risk factors for these infections.</td>
</tr>
<tr>
<td>TEAM</td>
<td>S.Daunert, PharmD, MS, PhD; S.K. Deo, MS, PhD; J-M. Zingg, PhD</td>
<td>M.Sharkey, Ph.D. and M.Stevenson, Ph.D.</td>
<td>(Phs) 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.</td>
</tr>
</tbody>
</table>

COVID-19 EDUCATION RESOURCES

TO COMMUNITY STAKEHOLDERS

COVID-19 WEBINAR
(for community health workers)
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

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-lg 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.

<table>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
<th>Co-sponsored with</th>
<th>Research Proposal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Luisa Cimmino, PhD *</td>
<td>Assistant Professor, Biochemistry &amp; Molecular Biology</td>
<td>Sylvester Comprehensive Cancer Center</td>
<td>Targeted Vitamin C therapy for the treatment of leukemia</td>
</tr>
<tr>
<td>Yelena Drexler, MD</td>
<td>Assistant Professor, Medicine - Nephrology and Hypertension</td>
<td>University of North Carolina CTSA</td>
<td>APOM as a Novel Biomarker and Potential Therapeutic Target for Glomerular Diseases</td>
</tr>
<tr>
<td>Michael Ivan, MD *</td>
<td>Assistant Professor, Neurosurgery</td>
<td></td>
<td>Prognostic and Predictive Markers to Personalize Medicine for Malignant Glioma in Hispanics</td>
</tr>
<tr>
<td>Corinna Levine, MD, MPH</td>
<td>Assistant Professor, Otolaryngology</td>
<td></td>
<td>Developing an Integrated Profile of Chronic Rhinosinusitis</td>
</tr>
<tr>
<td>Jennifer Manuzak, PhD</td>
<td>Research Assistant Professor, Pediatrics</td>
<td></td>
<td>Impact of HIV infection on the gut/liver axis</td>
</tr>
<tr>
<td>Nevis Fregien, PhD +</td>
<td>Associate Professor, Cell Biology</td>
<td></td>
<td>Development of a stem-cell based assay to identify read-through agents specifically for ciliated airway cells</td>
</tr>
</tbody>
</table>

* 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**
  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.

#### 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

<table>
<thead>
<tr>
<th>Category</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients</td>
<td>1.26m</td>
</tr>
<tr>
<td>Female</td>
<td>55%</td>
</tr>
<tr>
<td>Male</td>
<td>45%</td>
</tr>
<tr>
<td>Hispanic</td>
<td>13%</td>
</tr>
<tr>
<td>Black/African American</td>
<td>42%</td>
</tr>
<tr>
<td>Encounters</td>
<td>15m</td>
</tr>
<tr>
<td>Medications</td>
<td>32k</td>
</tr>
<tr>
<td>ICD-9 codes</td>
<td>10k</td>
</tr>
<tr>
<td>Labs</td>
<td>4.2k</td>
</tr>
<tr>
<td>Procedures</td>
<td>2.9k</td>
</tr>
<tr>
<td>Pediatric</td>
<td>17%</td>
</tr>
<tr>
<td>Young-middle age adults</td>
<td>49%</td>
</tr>
<tr>
<td>Older adults (60+)</td>
<td>34%</td>
</tr>
</tbody>
</table>

#### FY20 URIDE UTILIZATION

<table>
<thead>
<tr>
<th>Category</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consultations</td>
<td>45</td>
</tr>
<tr>
<td>Users</td>
<td>75</td>
</tr>
<tr>
<td>Logins</td>
<td>800</td>
</tr>
<tr>
<td>Units using URIDE</td>
<td>59</td>
</tr>
<tr>
<td>(Departments/Divisions)</td>
<td></td>
</tr>
<tr>
<td>Lifetime total URIDE users</td>
<td>317</td>
</tr>
</tbody>
</table>

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**CONSENT TO CONTACT**

<table>
<thead>
<tr>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>119,000+</td>
</tr>
<tr>
<td>Patients database (consented “yes” to be contacted) by end of FY20</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ethnicity</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hispanic</td>
<td>13%</td>
</tr>
<tr>
<td>Black/African American</td>
<td>42%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>27.5k+</td>
</tr>
<tr>
<td>Patients list approved</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>2,100+</td>
</tr>
<tr>
<td>Patients contacted by study teams</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>35</td>
</tr>
<tr>
<td>Research studies submitted to use Consent to Contact</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>21</td>
</tr>
<tr>
<td>Research studies approved</td>
</tr>
</tbody>
</table>
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.

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.

IN FY20

171 Consultations and clinical data requests processed

550,000+ Patient records released

200+ Zoom for Healthcare research licenses activated

2,500 DocuSign envelopes available for e-consent

250 Studies utilizing licenses

270+ Studies interested to use REDCap e-consent
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.

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.

“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

“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

OVERALL VALUE OF THE PROGRAM

100% Mentors

86% Mentees

Rated ‘Very Good’ or ‘Outstanding’

SPOTLIGHT: EDUCATION AND TRAINING

LIFETIME

51 Program enrollment

33 Graduates

FY20

24 Enrollment

7 Graduates

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

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.

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.

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:

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

7 Seminars (April – May)

1,276 Total attendees

485 Attendees in FY20

424 NCRP subscribers
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.

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

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.

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.

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 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.
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
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Erin Kobetz, PhD, MPH
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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 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
Don Soffer Clinical Research Center, home of the CTSI.
Photo: Jorge Perez