



MIAMI CLINICAL &  
TRANSLATIONAL  
SCIENCE  
INSTITUTE

# ANNUAL REPORT

FISCAL YEAR 2022

(June 2021 - May 2022)

UNIVERSITY  
OF MIAMI



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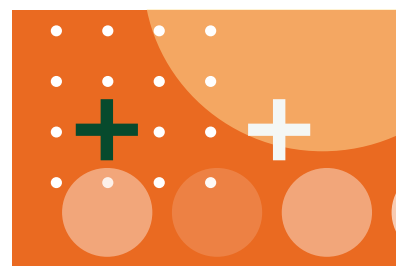
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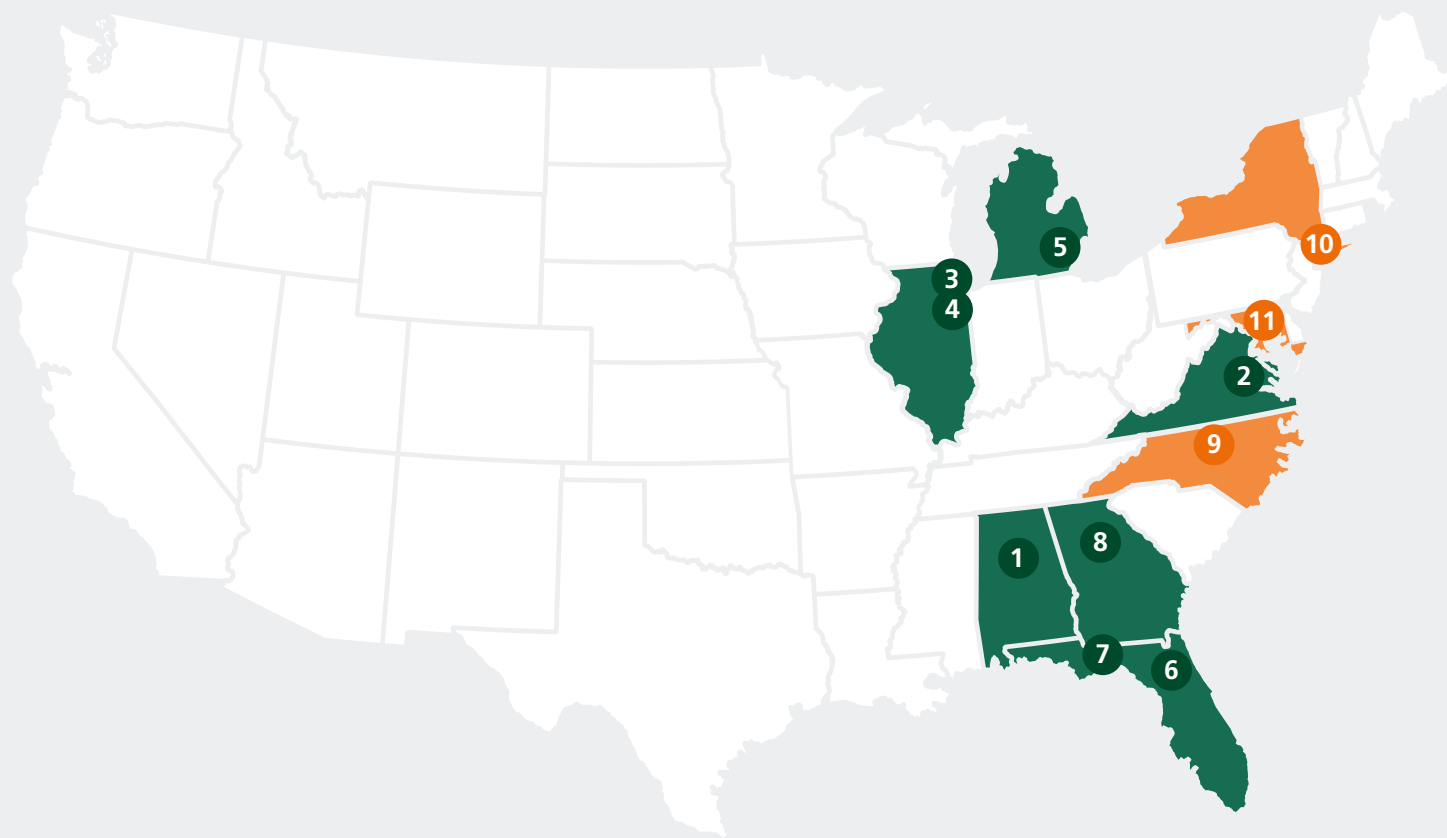


# MISSION STATEMENT

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.

# CTSA FY22 COLLABORATIONS:

Miami CTSI established new collaborations and continued existing collaborations with other CTSA institutions in FY22 and facilitated several NIH-funded COVID-19 clinical trials.



**1-3 UNIVERSITY OF ALABAMA BIRMINGHAM  
UNIVERSITY OF VIRGINIA  
NORTHWESTERN UNIVERSITY**  
Conducted two I-Corps@NCATS courses offering entrepreneurship training for research teams

**4 UNIVERSITY OF ILLINOIS AT CHICAGO**  
CIRTification training program in human research protections tailored to the unique roles of community research partners

**5 UNIVERSITY OF MICHIGAN ANN ARBOR**  
UMiamiHealthResearch.org portal, lay-friendly health research site to improve community participant recruitment, including healthy participants, into clinical trials

**6 UNIVERSITY OF FLORIDA  
FLORIDA STATE UNIVERSITY**  
Network Science pilot program to foster team science and establish new research collaborations

**7 ONEFLORIDA+ CLINICAL RESEARCH NETWORK**  
Clinical research, data consortium, and practice network across Florida, Alabama and Georgia

**8 GEORGIA CTSA**  
2022 Southeast Regional Clinical and Translational Conference

## CLINICAL TRIALS

- 9 DUKE UNIVERSITY**  
**ACTIV-6:** Evaluating repurposed medications for effective, safe treatments for mild-to-moderate COVID-19  
**PREVENTABLE:** Pragmatic Evaluation of Events And Benefits of Lipid-lowering in Older Adults
- 10 NYU LANGONE MEDICAL CENTER**  
**CONTAIN COVID-19 and CONTAIN-Extend:** Convalescent Plasma to Limit COVID-19 Complications in Hospitalized Patients
- 11 JOHNS HOPKINS UNIVERSITY**  
**CSSC-001 and CSSC-002:** Convalescent Plasma to Stem Coronavirus

## CTSI BY THE NUMBERS

### Miami CTSI Funding (ALL SOURCES)

**\$5.9M**  
FY22

**\$60.1M**  
LIFETIME

### CTSI FY22 Team

**45**  
FACULTY



**58**  
STAFF



### FY22 KL2/Career Development Awards

**\$1.24M**

FY22 AWARDED SCHOLAR FUNDING

**4** ACTIVE SCHOLARS

**3** NCATS KL2  
**1** INSTITUTIONAL

### FY22 Pilot Awards

**4** PILOT AWARDS

**\$160,000**

PILOTS  
TOTAL FUNDING

LIFETIME ROI  
ON CTSI PILOT  
AWARDS

**18.7:1**

**53**

EDUCATION &  
TRAINING EVENTS

**635**

CONSULTATIONS &  
SERVICE REQUESTS

### CTSI Publications

**50**

FY22 CTSI-SUPPORTED  
PUBLICATIONS\*

\* Includes publications that cited the CTSI grant, used a CTSI resource, by CTSI career development and pilot programs' awardees



TOP RESEARCH, CONDITION, &  
DISEASE CATEGORIES REPRESENTED  
Source: Research Fields in *Dimensions*

Prevention • Infectious diseases •  
Neurological disorders • Cancer •  
Digestive system disorders

# CTSI PILOT AWARDS PROGRAM

The CTSI pilot awards provide up to \$40,000 to support junior faculty whose proposals are innovative, translational, interdisciplinary, and/or health disparities-oriented. Investigators go on to generate data for publications and external funding.

## MIAMI CTSI PILOTS (LIFETIME):

**43** Pilots and Grant Resubmission awards



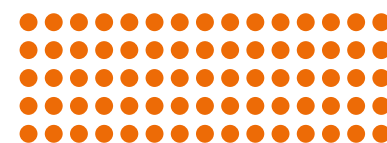
**38%**  
projects addressed health disparities

Of the awardees



## RETURN ON INVESTMENT

**75** Publications



**\$28M+**  
Funding to date  
(18.7 : 1 ROI)

## CTSI FY22 PILOT AWARDS

CTSI awarded four new Pilot Awards for FY22.



**Thomas Masterson, MD**  
Assistant Professor, Urology

Novel Treatment for Microvascular Erectile Dysfunction Combining Shockwave Therapy and Platelet Rich Plasma in Oral Medication Non-Responders



**Jennifer Munoz Pareja, MD**  
Assistant Professor\*, Pediatrics

Utility of a Novel Combined Blood-based Biomarker Panel of Central Nervous System Injury and Inflammation in Pediatric Traumatic Brain Injury

\*Rank at the time of award



**Abhishek Prasad, PhD**  
Associate Professor, Biomedical Engineering

Effects of Iron Accumulation in Intracortical Implants and Protection by Iron Chelation



**Swarup Swaminathan, MD**  
Assistant Professor, Pediatrics

Non-invasive Imaging of Aqueous Humor Outflow Pathways Using Iontophoresis of a Carbon Dot Solution

# MENTORED TRANSLATIONAL RESEARCH KL2 AND INSTITUTIONAL SCHOLAR AWARDS

The award provides a structured research training environment that allows early stage faculty to acquire the skills and experience needed to become outstanding independent clinical and translational investigators. NCATS KL2 scholars are fully funded by the Miami CTSI and Institutional scholars are co-sponsored with the scholar's department.

Awardees receive mentorship, an individualized research and career development plan, experiential training with established faculty, and access to educational programs and resources through CTSI's various programs.

Both CTSI KL2 and institutional scholars have demonstrated significant accomplishments during and after their award period, thereby underscoring the success of expanding the KL2 program to include additional institutional scholars.

## LIFETIME:

**18** NCATS KL2 Scholars  
**3** UM Institutional Scholars

**52%**  
women

**38%**  
underrepresented minorities

**50%**  
Projects on minority health and health disparities



## SCHOLAR RESEARCH PRODUCTIVITY

**546**  
Publications



**\$52M**  
Funding to date

## FY22 SCHOLARS

The Miami CTSI had seven active scholars for FY 2022. They include four NCATS-funded KL2 scholars and three institutional scholars jointly funded by the CTSI and the scholar's department.



**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



# MENTORED TRANSLATIONAL RESEARCH KL2 AND INSTITUTIONAL SCHOLAR AWARDS

## FY22 SCHOLARS CONTINUED



### **Marissa DeFreitas, MD**

Assistant Professor, Clinical Pediatrics

NCATS KL2 Scholar

Soluble klotho as a predictor of reduced nephron endowment and kidney injury in preterm infants



### **Yelena Drexler, MD**

Assistant Professor, Clinical Medicine

NCATS KL2 Scholar

Apolipoprotein M and S1P as Novel Biomarkers of Glomerular Lipotoxicity in Nephrotic Syndrome



### **Corrina Levine, MD, MPH**

Assistant Professor\*, Otolaryngology

NCATS KL2 Scholar

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



### **Nicole Sur, MD**

Assistant Professor, Neurology

NCATS KL2 Scholar

Treatment Disparities in Stroke and Atrial Fibrillation Study (TDS-AF)

\*Rank at the time of award



### **Katlyn Meier, PhD**

Assistant Professor, Chemistry

CTSI Institutional Scholar

Metal-centric approach to medicine: Combining spectroscopy, in vivo imaging, and quantum-chemical calculations to define metal-protein interactions in the progression and treatment of neurodegenerative disease

# SPOTLIGHTS

# SPOTLIGHT



## Tali Elfassy, PhD, MSPH

**Tali Elfassy, PhD, MSPH**, Research Assistant Professor of Epidemiology in the Department of Public Health Sciences at the University of Miami Miller School of Medicine, has been heavily involved with Miami CTSI since she was awarded a KL2 grant in 2018 for her work studying hypertension in Hispanics living in the United States.

As part of the KL2 project, Dr. Elfassy described rates of incident hypertension among US Hispanic/Latino participants of the NHLBI-funded Hispanic Community Health Study/Study of Latinos. “Different populations suffer from different rates of hypertension and cardiovascular disease,” she says. “Identifying the factors that contribute to these differences is critical to developing targeted interventions.”

Dr. Elfassy’s current research is funded by a NIH K01 award, an extension of her KL2 project that examines genetic, social, clinical, and behavioral factors that contribute to observed hypertension disparities across different US Hispanic/Latino groups. “The KL2 was really my springboard. It gave me all the tools and the time to secure longer-term funding,” she says. “It absolutely paved the way for me to do that.”

In March 2021, Dr. Elfassy joined three of her UM colleagues in Siracusa, Italy, for the International Certificate Program in Translational Medicine hosted by the Eureka Institute for Translational Medicine. As a sponsor of the program since 2015, the Miami CTSI has sent 19 junior faculty to the conference.

With a focus on communication, team building, and one-on-one mentorship, the Eureka program is designed to train and mentor new professionals in translational science. Attendees come from a variety of fields, but all share the common interest in the direct impact of their work on patients. “In the continuum of translational science, I fall on the population science end,” says Dr. Elfassy. “It was really a huge introduction to a pipeline and the process by which science occurs and eventually makes a population level impact.”

One of the most valuable aspects of her affiliation with the Miami CTSI is the strength of its networking and mentorship opportunities, says Dr. Elfassy. She is an active member of The Connection, a networking group for junior faculty designed to bring together scientists across disciplines.

Dr. Elfassy has also participated in the CTSI mentor/mentee training program. “I learned both perspectives, what to expect as a mentee, but also what the mentor should expect as well,” she says. “I have really good mentorship that’s helping me succeed, and in turn I am passing that on.”

“CTSI has been a wonderful, warm resource. The staff is so helpful, and they are always there for you. They play an instrumental role in connecting scientists like me with resources to promote and evolve their science.”

**Dr. Elfassy**

# SPOTLIGHT



## Ayham Alkhachroum, MD

Since joining the University of Miami Miller School of Medicine in 2019, **Ayham Alkhachroum, MD**, Assistant Professor of Clinical Neurology Neurocritical Care, has fully embraced all the resources that Miami CTSI offers for researchers seeking new skills, guidance, and connection.

Dr. Alkhachroum provides care for patients with acute brain and spine injury in the Neurocritical Care Units at University of Miami and Jackson Memorial Hospitals. Upon his arrival at UM, he secured the Miami CTSI Institutional Career Development grant, a two-year award supporting his research on the recovery of consciousness after acute brain injury.

Using electroencephalogram (EEG), Dr. Alkhachroum and his team measured response to sound stimuli in ICU patients who had fallen into a coma after suffering head trauma. “We play a standard tone, like 100 hertz, and then interrupt that with deviant tone to see the response of the brain to different tones. The goal of these assessments is to elicit a state called covert consciousness or covert recognition. We can detect things we don’t see clinically,” he says.

Another project led by Dr. Alkhachroum called MUSICA, Music and Speech Induced Cerebral Activation, funded by a NIH K23 award, looks at music and speech processing in patients in comas by playing various sounds including stories and music. A new NIH R21 grant will support Dr. Alkhachroum’s study looking at eye tracking to visual stimuli in patients in comas after brain injuries, both traumatic and non-traumatic.

Dr. Alkhachroum’s work has important implications for patients and families, especially in the early days following an injury when critical healthcare decisions are made. The work could also inform how therapeutics are delivered based on how a patient responds to music, eye tracking or sound stimuli.

All three grants were funded from first submission, which Dr. Alkhachroum attributes to his first encounter with the Miami CTSI, a grant writing course. “What I learned in that course continues to help me get funded,” he says.

Following his positive experience with several individual courses offered by the Miami CTSI, Dr. Alkhachroum went on to complete his MS in Clinical and Translational Investigation, a highly-tailored course of study offered by the CTSI. “In addition to providing advanced understanding of clinical research and statistics, the master’s program also gave me what I needed in terms of communication, collaboration, and connection,” he says.

Dr. Alkhachroum also attributes his success to career mentorship, provided by his mentor and Miami CTSI KL2 Program director and Workforce Development program co-director, Tatjana Rundek, MD, PhD, “Academia has an unspoken language that can be difficult to decode without a mentor to help you navigate it, regardless of how smart or accomplished you are,” he says. “I think to show the way is very important. You need someone to tell you, ‘This can be done.’”

“My work is multidisciplinary. It includes music, speech processing, data science, machine learning, and statistical analysis.

Miami CTSI helps me connect with people in other disciplines. This is how I find collaborators and to this day, it is how I plan to submit future grants.”

**Dr. Alkhachroum**

# FY22 HIGHLIGHTS

# EDUCATION & TRAINING HIGHLIGHTS

## MS IN CLINICAL AND TRANSLATIONAL INVESTIGATION

26

Students enrolled



Faculty



Staff



Postdoctoral trainees/students

10

Departments



### BIostatistics Clinics, Roundtables, and Seminars

31

Sessions conducted



200

Total attendees

### I-CORPS @NCATS Entrepreneurship Training

2

Five-week courses conducted



19

Teams Trained

45

Total Participants

### The Connection for Junior Faculty

7

Networking events and seminars



81

Members

### Dean Henri Ford's Interdisciplinary Research Seminar Series

4

Seminars



250

Total attendees

### Research Mentoring Training

3

Sessions



17

Mentor-Mentee Teams

### Network of Clinical Research Professionals (NCRP)

6

Seminars Conducted



317

Total attendees

**TOPICS COVERED:** *Improving research processes, eliminating roadblocks, conflict of interest policy, research recruitment, external IRB submission, human subjects' research updates and improvements*

# CLINICAL RESEARCH SUPPORT HIGHLIGHTS

## CONSULTATIVE SUPPORT

325

Informatics and Clinical Data  
for Research Consultations

159

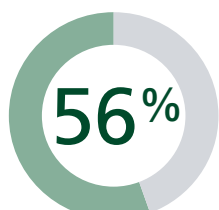
Biostatistics Consultations

## COMMUNITY PARTICIPANT RECRUITMENT FOR RESEARCH

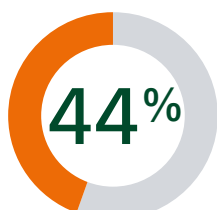
Consent to Contact Program (as of FY22)

123,000+

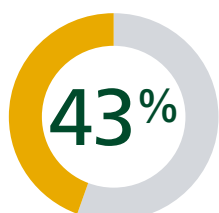
Patients in Consent to  
Contact Database



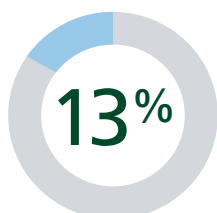
Male



Female



Hispanic



Black/African  
American

*Race/Ethnicity  
under-  
represented in  
research*

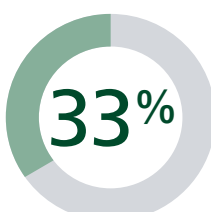
University of Miami Health Research  
Portal (as of FY22)

700+

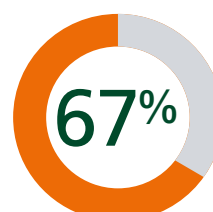
Volunteers registered  
to be contacted for  
potential studies:

134

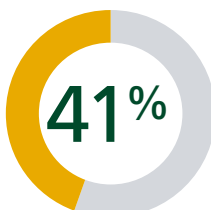
Research studies  
listed



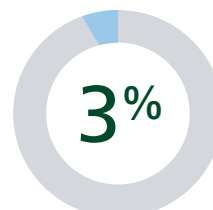
Male



Female



Hispanic



Black/African  
American

*Race/Ethnicity  
under-  
represented in  
research*

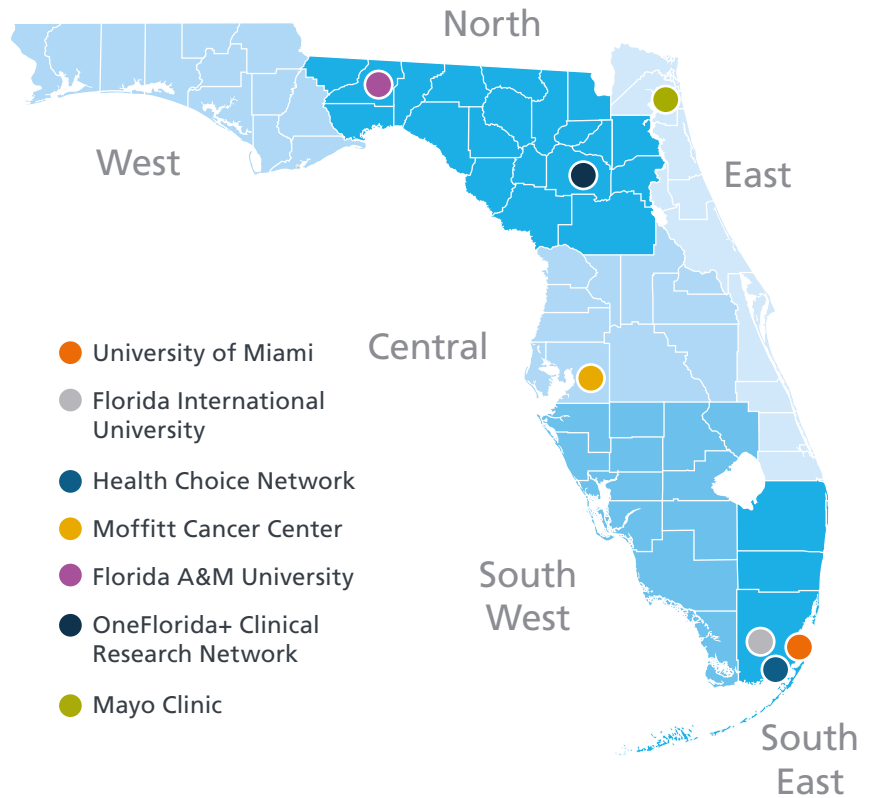
# COMMUNITY ENGAGEMENT HIGHLIGHTS

In FY22, the Florida Community Engagement Alliance (FL-CEAL) Against COVID-19 Disparities continued to disseminate evidence-based health promotion practices and addressed COVID-19 vaccine hesitancy. The program is administered by the Miami CTSI.

## COMMUNITIES ENGAGED

- Latinx communities in Miami-Dade County: rural agricultural, urban low income, sexual/gender minorities
- Underrepresented minority communities in South FL (Black, elderly)
- Rural minority communities in north-central & north-eastern FL, & the FL panhandle
- West-central and western FL vulnerable communities

- University of Miami
- Florida International University
- Health Choice Network
- Moffitt Cancer Center
- Florida A&M University
- OneFlorida+ Clinical Research Network
- Mayo Clinic



## FOCUS AREAS

### COVID-19 Education

**339** outreach activities conducted

**51** CEAL resources on COVID-19 basics, diversity & inclusion

**450,000+** persons reached through traditional/ social media and outreach activities

### Vaccines

**195** outreach and education activities, vaccine drives

**7,800+** individuals reached



# YEAR IN REVIEW

# YEAR IN REVIEW

## I-CORPS@NCATS PROGRAM EXPANSION

The I-Corps@NCATS course conducted by Suhrud Rajguru, PhD, co-director of the CTSI Translational Workforce Development Program, helps entrepreneurial researchers move their new drugs, diagnostics, technologies, and devices forward to the next stage of development. With a recent supplemental grant from NCATS, this program further expanded its reach regionally in South Florida and across the state with teams from Florida International University, Florida Atlantic University and University of Florida participating in the program.

## NEW REDCAP E-CONSENT FRAMEWORK FOR FDA REGULATED STUDIES

In FY22, the 21 CFR Part 11 compliant REDCap e-consent framework was made available to the research community to obtain electronic consent from research participants enrolling in FDA regulated studies. With this new addition, there are now two e-Consent templates available to researchers to use for both non-FDA regulated and FDA-regulated studies.

## NATIONAL COVID COHORT COLLABORATIVE'S (N3C) NEW PUBLIC HEALTH BROWSER

The N3C Data Enclave housing the largest repository of COVID-19 data in the United States, with more than 4.5 million COVID+ patients, launched the Public Health Browser, which provides snapshots of high-value health data for policy makers, investigators, and entrepreneurs to facilitate further research questions for better health outcomes. Miami CTSI contributes deidentified clinical data to the N3C Data Enclave.

## COVID COMMAND CENTER DASHBOARDS AND RESEARCH RECRUITMENT

The CTSI informatics team developed a COVID-19 dashboard for use university-wide, intended to support a data driven approach to clinical care and trends, and to monitor recruitment into studies. These tools supported inpatient and outpatient trials and were used to inform clinical care and University policies and practices. In addition, the CTSI-supported COVID-19 feasibility committee approved 48 clinical/interventional studies and issued 68 expedited/exempted review of non-clinical/non-interventional studies.

## RESEARCH MENTORING TRAINING PROGRAM

In its third year of implementation, the program is aimed at advancing effective mentor-mentee relationships for translational research-focused faculty. In FY22, the program was led by an interdisciplinary team of faculty at the University of Miami, including faculty from the CTSI, Center for AIDS Research, Center for HIV and Research in Mental Health and the Sylvester Comprehensive Cancer Center, with a curriculum that was developed in collaboration with the University of Colorado CTSI. Three virtual sessions were held for a cohort of 17 mentor-mentee pairs from 15 departments/divisions across the University of Miami.

## CTSI AWARDEE ACHIEVEMENTS IN FY22

**Merline Benny, MD, Assistant Professor of Pediatrics** and Miami CTSI KL2 scholar was awarded a Mentored Clinical Scientist Research Career Development Award (K08) from the National Heart, Lung, and Blood Institute to continue to study the protective role of CXCR7 in neonatal hyperoxia induced systemic vascular dysfunction in adulthood.

**Eric A. Mellon, MD, PhD, Associate Professor of Radiation Oncology and Biomedical Engineering** and past CTSI pilot awardee was awarded a \$5 million seven-year grant from the National Cancer Institute to study how advanced imaging during treatment may be used to improve radiation therapy for patients with glioblastoma.

**Swarup Swaminathan, MD, Assistant Professor of Clinical Ophthalmology** and past CTSI pilot awardee was awarded a five-year, \$1 million Mentored Patient-Oriented Research Career Development Award (K23) from the National Eye Institute to improve estimates of glaucoma progression. Dr. Swaminathan was also awarded the Mary Lee and Richard E. Bastin Chair in Ophthalmology at the Bascom Palmer Eye Institute in 2022.

**MSCTI and CTSI KL2 graduate Lunthita Duthely, EdD, MS,** was accepted into the University of California, San Francisco Center for AIDS Prevention Studies Visiting Professor (VP) program. Dr. Duthely is Research Assistant Professor in the departments of Obstetrics, Gynecology & Reproductive Sciences and Public Health Sciences at the Miller School of Medicine.

**MSCTI and CTSI KL2 graduate Alberto Ramos, MD, MSPH, MS** was appointed a member of the National Heart, Lung, and Blood Institute Sleep Disorders Research Advisory Board. Dr. Ramos is also Associate Professor of Neurology and Research Director of the Sleep Disorders Program at the Miller School of Medicine.

**CTSI pilot awardee Ranjith Ramasamy, MD**, was awarded the Young Investigator Award of Excellence from the Sexual Medicine Society of North America Inc. during its annual fall scientific meeting in Scottsdale, Arizona.

## NATIONAL C TSA CONSORTIUM ACTIVITIES

Miami CTSI is serving a three-year term in the CTSA Steering Committee – first with Dr. Ralph Sacco, and now with Dr. Olveen Carrasquillo. The steering committee provides leadership for the sharing of policies, practices & resources, & discussion of issues impeding clinical research.

Miami CTSI presented four posters at the Translational Science 2022 Meeting in Chicago, showcasing its achievements and impact in translational research, workforce education, and training and community engagement.

Miami CTSI Program Directors were elected to leadership roles in national consortium committees and invited to serve on Diversity Committees for the Clinical and Translational Science Awards program.



**Daniel Armstrong, PhD, co-director of Miami CTSI's Program for Integrating Special Populations, joined the**

Lead Team for the Integration Across the Lifespan Enterprise Committee.



**Olveen Carrasquillo, MD, MPH, co-director for the Miami CTSI's Community and Stakeholder**

**Engagement (CASE) and Participant and Clinical Interactions (PCI) programs**, and Miami CTSI MPI, joined the Lead Team for the Collaboration and Engagement Enterprise Committee and the national CTSA Diversity, Equity and Inclusion Task Force.



**Shari Messinger  
Cayetano, PhD,  
Co-Director of the  
CTSI's Biostatistics,  
Epidemiology and**

**Research Design Program,** was invited by the Association for Clinical and Translational Science (ACTS) to serve on its newly formed Diversity Equity and Inclusion (DEI) Committee.