

MIAMI CLINICAL &
TRANSLATIONAL
SCIENCE
INSTITUTE

COVID REPORT

MARCH 2020 - JANUARY 2021



UNIVERSITY
OF MIAMI





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The Miami Clinical and Translational Science Institute facilitated a rapid response at the onset of the COVID-19 pandemic in March 2020 to address the needs of researchers and the broader university community. Working in partnership with the Vice Provost for Research + Scholarship and the Miller School of Medicine Executive Dean for Research, we were able to quickly steer CTSI resources and efforts towards infrastructure to support COVID-19 research and services to enable research program continuity. Some initiatives, such as implementing HIPAA-compliant Zoom for Healthcare and REDCap e-consent, enable researchers to obtain electronic consent and conduct research remotely during the pandemic and beyond. The launch of the public-facing UMiami Health Research website, led by the CTSI, has provided a platform for research volunteers to search for active research studies, including COVID-19 studies, and communicate securely with study teams.

The following report highlights some key achievements of the Miami CTSI since March 2020 in support of COVID-19 research.



CTSI COVID-19 RESEARCH SUMMARY AT-A-GLANCE

COVID-19 FUNDING

\$22m+

Total funding received
by CTSI researchers

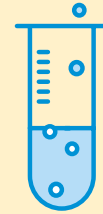
\$6.4m+

Funding received
for projects led by the CTSI

\$200,000

Direct funding awarded by CTSI
for COVID-19 research projects

SCIENTIFIC ACTIVITY



30

COVID-19 clinical studies
by CTSI researchers



54

COVID-19 publications
to date by CTSI researchers

CTSI COVID-19 PUBLICATION ATTENTION* AND IMPACT

1,643

Total number of mentions
for CTSI-affiliated COVID-19
publications *

33

Number of COVID-19 publications
that have Altmetric mentions

7

Number of attention sources
that mention CTSI COVID-19
publications

* as of Jan 15, 2021. Source: Altmetric <https://www.altmetric.com/>

THE NUMBER OF MENTIONS FROM EACH SOURCE THAT ALTMETRIC HAS TRACKED FOR THE PUBLICATIONS *



148
News



9
Blog



2
Policy



1,484
Social media

Policy sources:
National Institute for Health and
Care Excellence, UK;
The Association of the Scientific
Medical Societies in Germany

Social media sources:
Facebook, Twitter, Video and Reddit

CTSI FUNDING ACCELERATES COVID-19 RESEARCH

Through the Emerging Diseases award mechanism as part of its Pilot Translational and Clinical Studies program, the Miami CTSI rapidly funded three high-impact multi-disciplinary projects in April 2020, totaling \$200,000. Due to timely Miami CTSI funding, it was possible to rapidly develop critically needed tools for diverse investigators to detect and quantitate the novel coronavirus.

Develop rapid point-of-care test for screening of COVID-19

Funding

\$75,000

Team

Sylvia Daunert *PharmD, MS, PhD*
Sapna K. Deo *MS, PhD*
Jean-Marc Zingg *PhD*

Outcomes

\$300,000+ subsequent funding to continue the research and business development.

Technology protected by **two patents** and **one invention disclosure**.

The point-of-care test ready for use in Clinical Laboratory Improvement Amendments approved labs.

Clinical pilot studies being conducted with Department of Pathology and additional collaborations ongoing with industry partners.

Research has received positive public attention with **over 40 highlights in radio, television, and print media**.

Develop rapid, inexpensive lab diagnostic assay for SARS-CoV-2

Funding

\$75,000

Team

Mark Sharkey *PhD*
Mario Stevenson *PhD*

Outcomes

The optimized assay is highly specific and sensitive, costs less than \$1 per reaction, and has led to several applications:

Analyze research samples from the UM CRUSH cohort and the HEART cohort.

Measure SARS-CoV-2 RNA levels quantitatively in research samples from an ongoing cohort study (ACTION).

Measure SARS-CoV-2 RNA levels in wastewater weekly at UM campus and hospital sites in a collaboration with Civil Engineering. Data is generated and reported within 24 hours to UM administrators to guide appropriate responses. The methodology is a component of a recently **funded \$5m U01 proposal** from the NIH RADx-rad program focused on SARS-CoV-2 wastewater surveillance.

Determine the prevalence of the SARS-CoV-2 virus infection in UHealth

Funding

\$50,000

Team

Dushyantha Jayaweera *MD*
Suresh Pallikkuth *PhD*
Savita Pahwa *MD*

Outcomes

Established process for immunologic investigations in persons confirmed positive and negative for COVID-19 and for creation of a sample repository for future research in immunology, transcriptomics, genetic, epigenetic and other studies.

Developed a self-reported questionnaire to collect information on risk factors for virus infection including demographics and social determinants of health among patients at University of Miami and Jackson Memorial hospitals.

CTSI PROGRAMS SUPPORT COVID-19 RESEARCH

CTSI Programs have been instrumental in providing clinical and translational research expertise to investigators through support and consultations and facilitating collaborations for COVID-19 clinical research.

COVID-19 CLINICAL TRIAL DESIGN AND FEASIBILITY

BIostatistical DESIGN AND ANALYSIS

Biostatistics, Epidemiology and Research Design program experts have collaborated with study design and statistical analysis for 14 COVID-19 clinical trials and studies funded internally or externally through NIH and NSF, and have provided consultations for several other studies.



31

Approved studies

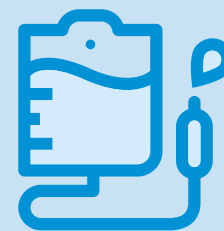
FEASIBILITY ASSESSMENT FOR COVID-19 CLINICAL TRIALS

Through the **Participant and Clinical Interactions** and **Network Capacity** programs and in collaboration with institutional leadership, CTSI facilitated the creation of an eight-member COVID-19 Feasibility Committee. The committee enables fast-tracking of studies with the best chance of benefiting current and future patients and ensures that there are not duplicative studies that recruit from the same participant population. To date, the committee has approved 31 studies.

COVID-19 MULTI-SITE TRIALS

The **Network Capacity** program facilitated the implementation of two NCATS Trial Innovation Network (TIN) multi-site phase 2 clinical trials using convalescent plasma to limit coronavirus associated complications. The TIN connects CTSA Program Hubs nationwide to leverage their expertise and resources to conduct large, multi-site clinical trials.

The **Network Capacity** and **Informatics** programs have supported the CONTAIN COVID-19 clinical trial awarded to Miami CTSI by Operation Warp Speed and NCATS through a \$5.4M CTSA administrative supplement. The collaborative multi-site trial led by New York University Langone Health is a double-blinded randomized controlled trial evaluating the efficacy of convalescent plasma to limit COVID-19 complications in hospitalized patients.



2

Clinical trials using convalescent plasma

\$5.4m

Funding awarded

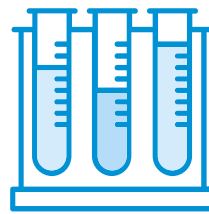
WEBSITE FOR COVID-19 CLINICAL TRIALS

Miami CTSI implemented **UMiamiHealthResearch.org** - a website for University of Miami study teams to feature their health research studies and connect with participants. The site allows potential volunteers to search for health studies across the University of Miami using lay-friendly key words. The website has over 125 active clinical studies listed, including actively recruiting COVID-19 studies. The site enables us to promote individual studies using unique URLs.



125

Recruiting clinical studies



23

Recruiting COVID-19 clinical studies

URIDE AND DATA WAREHOUSE

CTSI's Informatics program has enabled researchers to search and request COVID-19 clinical data for research use through the clinical data warehouse and URIDE. Researchers can search de-identified UHealth System clinical data through URIDE's user-friendly search interface and request COVID-19 clinical data for IRB-approved protocols.

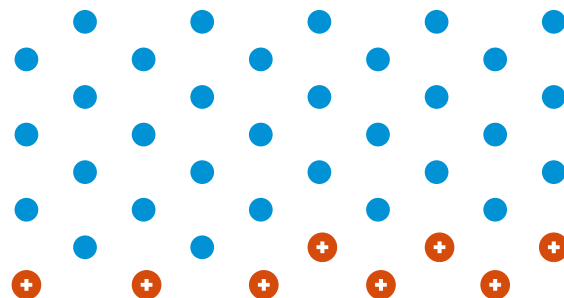
ONEFLORIDA CLINICAL RESEARCH CONSORTIUM

Through CTSI's Informatics program, COVID-19 clinical data for research has also been provided to hub partner OneFlorida Clinical Research Consortium. The Consortium enables UM investigators to access data on more than 15 million patients from across the state for research. Data from partner institutions, including UM, is also being used to facilitate recruitment into COVID-19 therapeutic trials.

NATIONAL COVID COHORT COLLABORATIVE

At the national level, the Informatics program is providing data as a member of the NCATS-funded National COVID Cohort Collaborative (N3C) Data Enclave. The N3C Data Enclave is a centralized national data resource that stores demographic and clinical characteristics of nearly 2.8 million people from 39 participating institutions, including more than 575,000 patients who have been tested for or diagnosed with COVID-19. Through a data use agreement with NCATS, UM researchers can access the expanded dataset by submitting or joining a project.

Having access to a secure, centralized enclave of this magnitude will allow UM research teams to study, probe and answer clinically important questions about COVID-19 that they could not have answered previously.



2.8m

Persons

575,000+

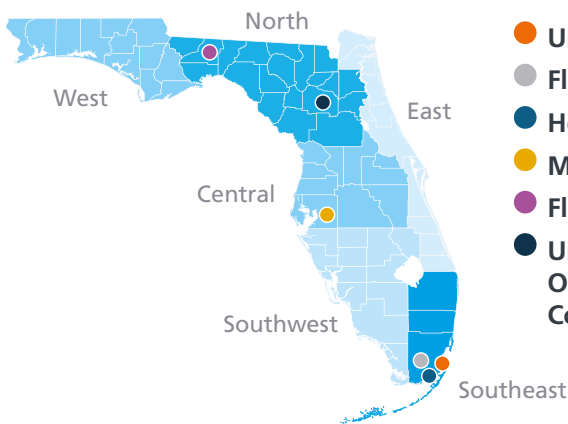
positive COVID cases

Data characteristics:



CTSI FACILITATES COVID-19 COMMUNITY ENGAGED RESEARCH, DISSEMINATION AND OUTREACH

Funded through a \$1M award by NIH’s national CEAL Alliance Program, the Florida Community Engagement Research Alliance Against COVID-19 in Disproportionately Affected Communities (FL-CEAL) is a statewide collaborative outreach program to engage ethnic and racial minority communities affected by the COVID-19 pandemic. This multi-PI statewide initiative is led by **CTSI’s Community and Stakeholder Engagement (CASE)** Program Director, Dr. Olveen Carrasquillo and is managed and evaluated by the Miami CTSI. The UM team also includes Dr. Erin Kobetz, CTSI Team Science and CASE Program Co-Director and UM’s Vice Provost for Research + Scholarship, and Dr. Victoria Behar-Zusman, CTSI Institutional Executive Committee member, and Associate Dean for Research, School of Nursing and Health Studies.



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

FL-CEAL KEY ACTIVITIES:

Advance evidence-based health promotion practices

Promote minority participation in vaccine and therapeutic clinical trials

Develop education and outreach activities to address vaccine hesitancy

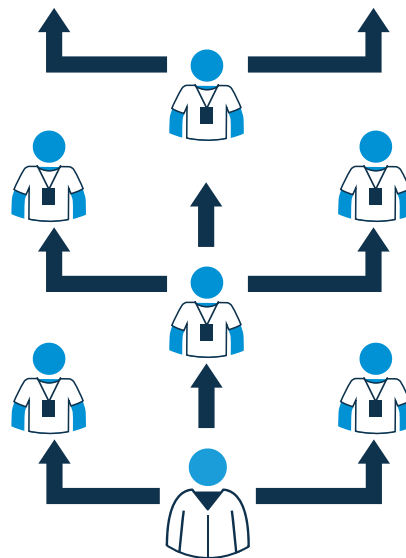
\$1m

Award by NIH’s national CEAL Alliance Program



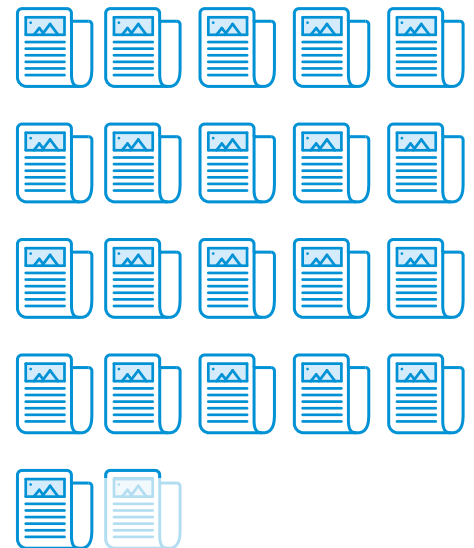
140

Participation in media programs and community forums for FL-CEAL COVID-19 communication and dissemination activities



380

Outreach workers engaged statewide for FL-CEAL activities



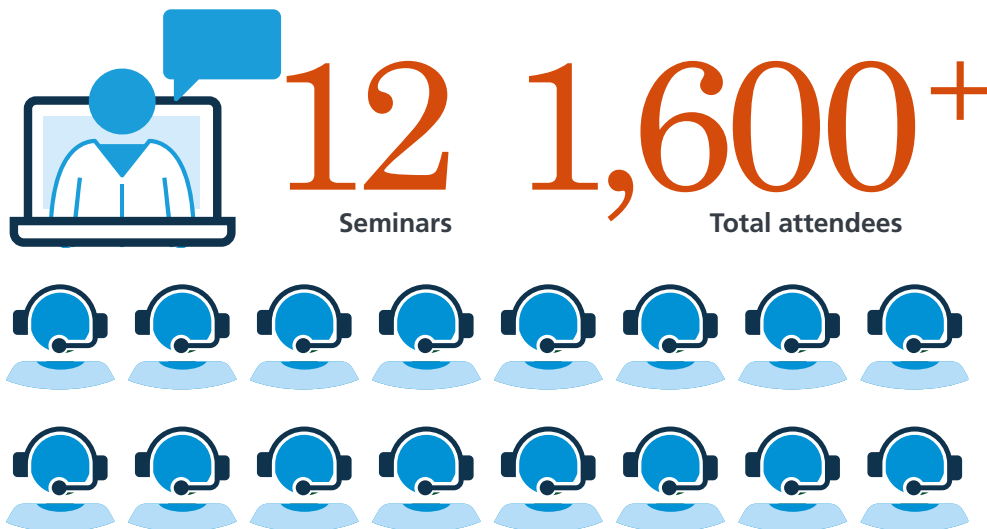
2,618

Community members have received COVID-19 education messages and materials developed by FL-CEAL

CTSI PROMOTES COVID-19 EDUCATION AND DISSEMINATION

TRANSLATIONAL TUESDAYS SEMINAR SERIES

CTSI's seminar series highlighting the ongoing research and innovations at the University of Miami in fighting the COVID-19 public health crisis was created in April 2020. The seminar series, is a forum for clinicians, researchers and interdisciplinary teams to present new and ongoing COVID-19 research.



TOPICS DISCUSSED

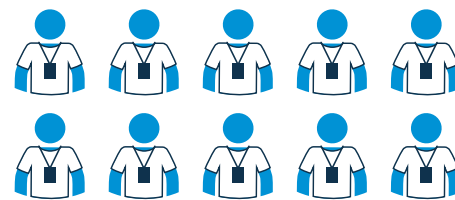
- Surveillance and tracking
- Community spread
- Diagnostics
- Vaccines
- COVID-19 symptoms
- Stem cell therapies
- Convalescent Plasma therapy
- Community engagement strategies to combat COVID-19 misinformation
- Clinical trial diversity

STATE AND NATIONAL COMMUNITY SEMINARS

In partnership with FL-CEAL, 7 events have been held since September 2020 where community health experts and leaders discussed COVID-19 topics relevant to minority populations across the state. Two of the seminars are highlighted here:

CTSI hub partner Health Choice Network and Alliance Chicago conducted a national virtual conference in November 2020, co-sponsored by Miami CTSI, that brought together healthcare providers across the nation to provide critical educational information on COVID-19 and healthcare topics. CTSI's CASE Program co-director Dr. Olveen Carrasquillo presented in the research session *"Community Health Centers Research and COVID-19: Opportunities for health justice and inclusion"* with 169 attendees.

Miami CTSI CASE Program Dr. Olveen Carrasquillo participated in a state-wide virtual seminar in December 2020 as part of FL-CEAL titled *"Addressing the Challenges of COVID-19 in Black and Latino Communities: Get the Answers"*, organized by FL-CEAL's UF project team. Other panel experts included Dr. Kizzmekia Corbett, Scientific Lead – NIH Coronavirus Vaccine Program; Jessica Malaty Rivera, infectious disease epidemiologist and science communications lead, The COVID Tracking Project; and FL-CEAL team members Dr. Cynthia Harris, FAMU and Dr. Folakemi Odedina, UF and moderated by Jessica Otero, Community Health Educator, UF. Over 900 people attended the virtual event.



COLLABORATION AND DISCUSSION FORUM

The COVID-19 Discussion Forum on Microsoft Teams has 365 users collaborating via five active channels in pre-clinical, clinical, epidemiological, social behavioral, and testing and diagnostics research areas.

365

Users collaborating
via Microsoft Teams



5 ACTIVE CHANNELS

Pre-clinical

Clinical

Epidemiological

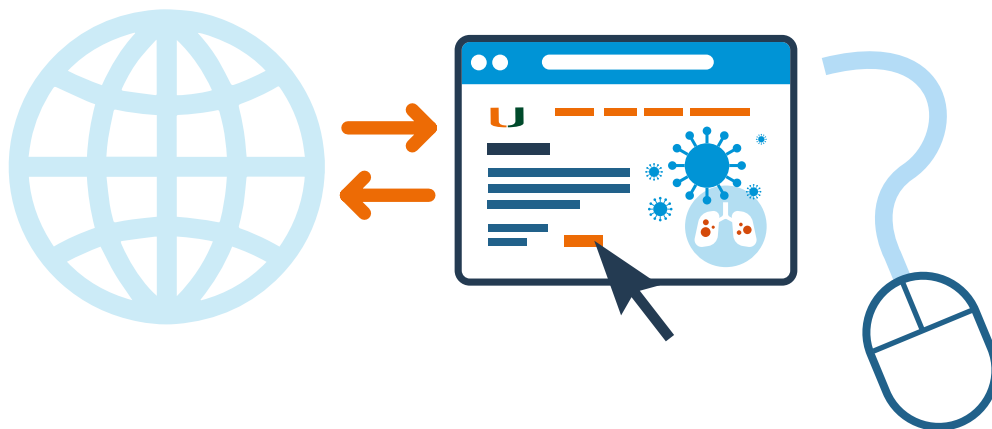
Social behavioral

Diagnostics and testing

CTSI COVID-19 WEBPAGE

The CTSI COVID-19 webpage on our website is a one-stop resource dedicated to all COVID-19 related activities occurring throughout the university. It 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.

<http://www.miamictsi.org/coronavirus>



CTSI LEADERS AND AWARDEES RESPOND TO THE COVID-19 PANDEMIC

CTSA NETWORK INFORMATICS MANUSCRIPT

CTSI Informatics Director **Dr. Nicholas Tsinoremas** and program faculty **Dr. Richard Bookman** are leading the informatics writing group for the CTSA network that is submitting a paper to the Journal of Clinical and Translational Science describing the informatics challenges and successes in the COVID-19 era.

COVID-19 CLINICAL TRIALS

CTSI researchers, including program leaders and awardees are leading and collaborating in over **30** COVID-19 clinical studies that include risk assessment, prevention, vaccine, and therapeutic trials. Selected trials include:

Stem Cell Therapy Clinical Trial

BERD Program Director Dr. Shari Messinger Cayetano, collaborated with Miller School of Medicine faculty **Dr. Camilo Ricordi** on a unique and groundbreaking randomized controlled trial showing umbilical-cord derived mesenchymal stem cell infusions safely reduce risk of death and quicken time to recovery for the severest COVID-19 patients.

Convalescent Plasma Clinical Trial

Miami CTSI Associate Director and Network Capacity Program Director Dr. Dushyantha T. Jayaweera is the lead of the NCATS funded trial investigating the use of convalescent plasma to limit coronavirus associated complications in COVID-19 hospitalized patients.

Janssen Vaccine Trial

Dr. Jayaweera and CASE Program Director Dr. Olveen Carrasquillo participated in the Janssen vaccine trial, a randomized Phase 3 study to assess the efficacy and safety of Ad26.COV2.S for the prevention of Sars-Cov-2-mediated COVID-19 in adults. The trial performed better than the national average in successfully enrolling Hispanic and African-American minority participants.

SURVEILLANCE, TRACKING, AND RISK ASSESSMENT STUDIES

Surveillance Program Assessing Risk and Knowledge of Coronavirus (SPARKC)

CTSI Team Science Program Director, UM's Vice Provost for Research + Scholarship and a public health expert Dr. Erin Kobetz was tapped by Miami-Dade County in March 2020 to conduct randomized antibody testing to assess the prevalence of COVID-19 infection in the community in a project called SPARKC. Early findings showed more than half who tested positive for antibodies report no known symptoms in the two weeks prior to testing, and also that the burden of infection was higher among blacks.

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

Dr. Erin Kobetz also co-leads a project called UTRACE, a REDCap reporting system designed to track the COVID-19 presumptive and confirmed cases among UHealth and Miller School of Medicine personnel.

Developing a COVID-19 Early Detection, Tracking and Re-Porting System

CTSI Informatics Director Dr. Nicholas Tsinoremas and collaborators with the UM Institute for Data Science and Computing developed 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 Dr. Carl Schulman tested, evaluated and created new reusable mask designs for use in the health care setting to limit exposure and protect medical personnel and first responders who treat coronavirus patients.



COVID-19 RESEARCH BY CTSI CAREER SCHOLARS

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

CTSI Institutional Scholar Dr. Ayham Alkhachroum is conducting a clinical study on acute encephalopathy in critically ill patients with SARS-COV-2 infection.

CTSI KL2 Scholar Dr. Corinna Levine is leading a study to identify ENT issues in COVID-19 patients at UM and evaluate new approaches for Healthcare Workers protection.



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