



CTSC External Advisory Committee Meeting December 7, 2021



Zoom Reminders

- Video Camera
 - EAC Members: on during the entire meeting
 - Presenters: on only when your group is presenting
 - Others: off during the entire meeting, on when contributing
- Audio
 - All: remain muted unless speaking
 - If you are using phone audio, mute and unmute is *6
- Chat Feature will be reserved for questions and comments from the EAC members

External Advisory Committee Members



Daniel Cooper, MD
Univ of California-Irvine



Patrick Flume, MD
Medical Univ South
Carolina



Rebecca Jackson, MD
The Ohio State University



Sean Mooney, PhD
Univ of Washington



Philip Payne, PhD
Washington University



Julian Solway, MD
Univ of Chicago



John Yates, PhD
Scripps Research Institute

NCATS CTSA Program Officer



Jamie Doyle, PhD
Program Director



(Day 1)



REC
In Memoriam

Dr. James E. Heubi, MD – 1948-2021

Center for Clinical and Translational Science and Training (CCST) Director

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“As a **clinician**, he treated many children, restored smiles, and helped them grow well into adulthood. As a **scientist**, he developed a treatment that saved the lives and lives of children with bile acid defects. As a **teacher**, he guided many young physicians who now lead successful careers.”

- *Jorge Bezerra, MD, Director, Division of Gastroenterology, Hepatology and Nutrition*



Pending Change in CTSC Leadership



Grace A. McComsey, MD, FIDSA

Associate PI, CTSC

Vice President of Research and
Associate Chief Scientific Officer,
University Hospitals Health System

Director, UH Clinical Research Center
Director, Dahms Clinical Research Unit
Professor of Pediatrics and Medicine



Welcome and Comments from the New Dean



Stan Gerson, MD

Dean, School of Medicine

Senior Vice President for Medical Affairs CWRU

Director, Case Comprehensive Cancer Center (acting)

Director National Center for Regenerative Medicine





2021 CTSC External Advisory Committee

- > Reading Materials
- > Meeting Agenda
- > Slide Presentations

<https://case.edu/medicine/ctsc/2021-external-advisory-committee>

Agenda

GENERAL SESSION (11:00 am – 3:00 pm EST)

- Welcome and Overview of the CTSC
- Overview of Plans for New Suite Submission

10 MIN BREAK

- Element D: Health Informatics, CTS Pilots, Resources and Services
- Element C: WFD for CRPs, Community & Stakeholder Engagement

10 MIN BREAK

- Element E: CTS Research Program
- Training and Education Programs: R25, K12, and T32 Programs

CLOSED SESSIONS (3:00 – 4:00 pm EST)

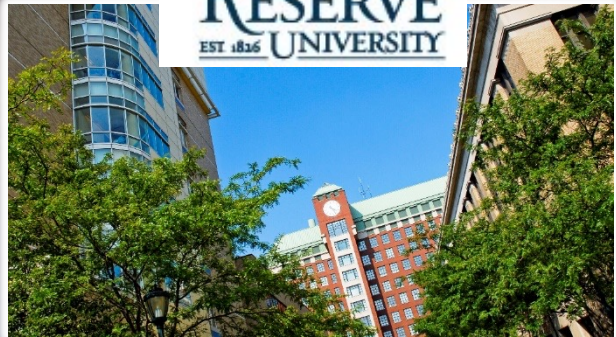
- Executive Session: EAC members only
- EAC Feedback and Recommendations to CTSC leadership





Overview and Year 3-4 Highlights of the CTSC of Cleveland





Clinical and Translational Science Collaborative of Cleveland (CTSC)



Our Mission:

To improve human health by streamlining science, transforming training environments and improving the conduct, quality and dissemination of clinical and translational research

Our Vision:

A healthy Cleveland, Ohio, and America without disparities



Highlights: COVID-19 Research Task Force

- A catalyst for collaborative research city-wide (co-led by Nora Singer, Assoc PI)
- 4 focus areas, 17 workgroups
- Facilitated grant applications and establishment of data and biorepositories



COVID PILOT GRANT DISSEMINATION DAY

FRIDAY OCTOBER 29th
9:00AM-1:30 PM
VIRTUAL EVENT

- C&C managed COVID-19 Rapid Response Pilot Program 7/20-6/21
- 48 submissions, 18 awards (\$500K). 7 funding entities, CTSC funded 5.
- Dissemination Day:
 - 190 city-wide attendees
 - Int'l vaccine keynote speaker



Highlights: COVID-19 Research Task Force

- NEO-CURE. MPI McComsey, Singer, Zidar. \$17M/4 yrs.
- CWRU selected as 1 of 15 awarded sites (289 submissions) for PASC Adult Cohort



- N=1000 (20K total)
- 4 year follow-up
- 4 Visits in year 1
- Blood and other specimens collected
- SDOH, metabolic and endocrine function, cardiac injury
- Deep phenotyping on a subset of patients



[Post-COVID study to enroll more than 900 in Northeast Ohio](#)

NOVEMBER 9, 2021

Case Western Reserve University (CWRU) and its hospital partners, University Hospitals, the MetroHealth System, and the Louis Stokes Cleveland VA Medical Center, have received federal funding....

[HEALTH & WELLNESS RESEARCH](#) 3



Highlights

- **Academic-Community collaborative research support**
 - Partnerships to reduce food insecurity, infant mortality, health disparities (Better Health Partnership, Greater Cleveland Food Bank, First Year Cleveland)
 - Launched CIRTification for our community (from Univ Illinois Chicago CTSA)
- **Expansion of research into the community**
 - UH Mobile Clinical Research Unit to increase recruitment of diverse and underrepresented minorities (aided community recruitment into COVID-19 studies)
 - New clinical trial finder (powered by Vanderbilt CTSA “Trials Today”)
- **HRC invested in study recruitment and start-up support**
 - Developed an online Toolkit to help investigators navigate the study start-up process
 - Launched Project Management CTSC webpage and 4-part “Intro to Clinical Trial Project Management” YouTube video series
 - City-wide “Recruitment of Special Populations” focus group and YouTube video



Highlights: Education and Training

- **Informatics**
 - Biomedical and Health Informatics (Certificate, MS, and PhD)
 - Clinical Informatics Fellowship Program
- **C&C Team Science**
 - Team Science Learning Modules on our YouTube channel
- **TE: Entrepreneurship**
 - Translational Fellows Program second year launch
 - Case Venture Mentoring Program expanded mentor pool
- **Research Methods**
 - BERD: Clinical Trials courses to med and grad students
 - RKS: Launched FDA Regulation in Entrepreneurship and CRM as a joint certificate program between SOM and WSOM
- **TL1 Grant Writing Workshop selected for I2I 2022 Careers Metric**

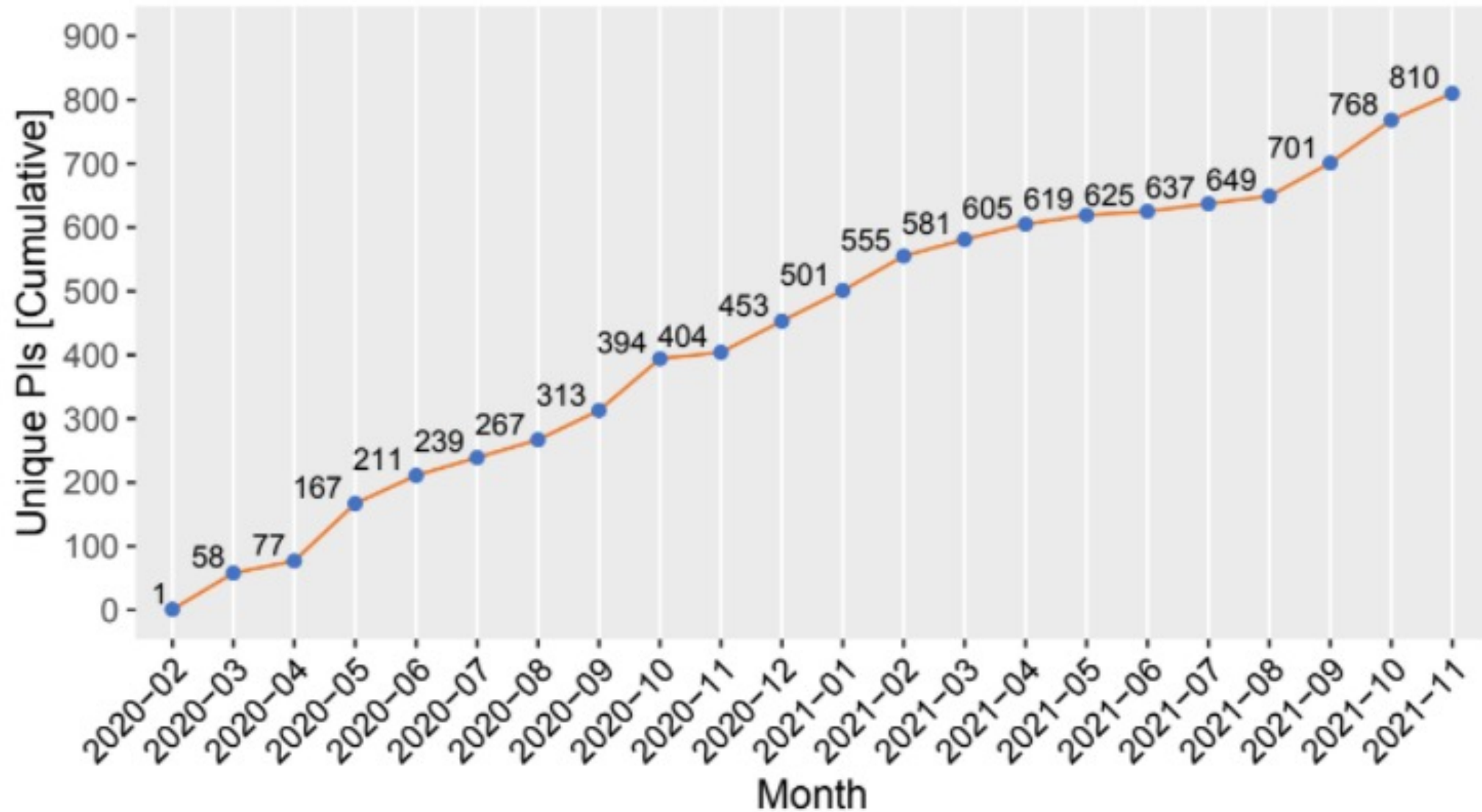
Highlights

- HRC research services to investigators

	Yr01	Yr02	Yr03-COVID	Yr04 –COVID (Annualized)
# Studies Served	772	626	895	689
# Subject Visits	7,924	7,798	5,707	7,693
# Subject Visit Hours	18,911	18,938	16,427	18,401
# Recruitment Consultations	46	31	67	92
# Project Management Support	6	30	35	68

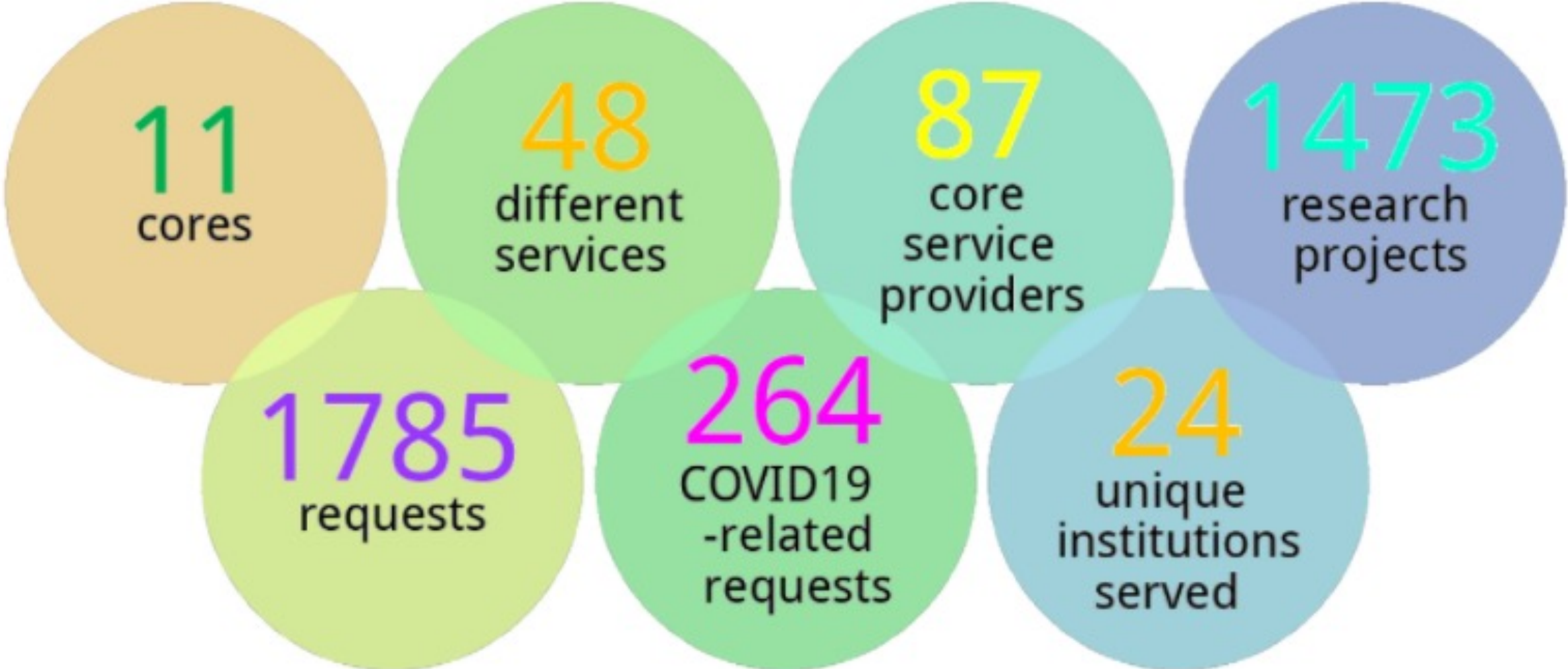
Unique PIs in SPARC

Cumulative since Feb 2020



CTSC SPARC Request consultation activity¹

Since Inception, Feb. 2020



¹ Does not include new REDCap project requests

Highlights - Pilot Grant Program

Annual Pilot Awards: 4 awards; \$50,000, supported by CTSA Award

Community and Collaboration Annual Pilots: 1 award; interdisciplinary team with engaged stakeholders to address public health issues in clinical and translational research. \$30,000, supported by CTSA award

Core Utilization Grant Awards: CTSC Core Facilities; accepted, reviewed, and awarded monthly; e.g. BERD, Informatics, Imaging, cytometry, genomics. 30-35/year; \$10,000, supported by partner institutions

Themed Pilot Awards: Translational research in areas of special need; \$30,000-\$50,000, supported by institutional funds (COVID Pilots recent example)

ROI: Since inception of CTSC: 2007 – Nov 2021*

Invested \$9.6 M / Impact \$121 M

*Includes Annual, Community, Core Utilization, Themed



Highlights - Publications

Productivity

920 publications since 2018
29% ↑ in scholarly productivity compared to Nov 2020

Influence

Weighted Relative Citation Ratio is **> 1.7x** the total number of publications (1537/920)
& Mean RCR = **2.09**
The NIH defines this as **highly influential**.

 National Institutes of Health
Office of Portfolio Analysis

 **CTSC Pubs**
2018-2021

Translation

21% of have been cited by a clinical document

Expected Translation

44% of all CSTC publications are **expected to translate**
(likelihood to be cited in clinical documents)



Collaborations with other Hubs

- **Informatics:**
 - OHDSI Collaborative (multiple CTSA hubs), EMERSE (with U Mich Consortium), LEAF Consortium (with UW and governing group), ACE (with Stanford)
- **Community & Collaboration:**
 - Monthly meetings with Buffalo CTSA re health disparities and health equity
 - HEALing Communities Study: OSU (and Cinci)
- **Translational Endeavors:**
 - iCorps@NCATS: UAB lead with 15 CTSA hubs
 - Developed and refined training for health care entrepreneurs: UAB & Penn State CTSA
- **Evaluation:** Lead on all 3
 - Bibliometrics of Scholarly Success: UNC, Mayo
 - Great CTSA Team Science Contest: Georgetown, VCU
 - Case Study Collaboration: MUSC, Tufts, VCU, IU, U Michigan, Columbia U, U Minnesota, U Wisconsin, Cornell, plus NIH OEPR

Journal of Clinical and Translational Science

A Retrospective Case Study of Successful Translational Research: Gazelle Hb Variant Point-of-Care Diagnostic Device for Sickle Cell Disease

Published online by Cambridge University Press: 25 October 2021

Kelli Qua , Shannon Swiatkowski, Umut Gurkan and Clara M. Pelfrey 

Journal of Clinical and Translational Science, 1-2

DOI: <https://doi.org/10.1017/cts.2021.871>

- Created new manuscript category JCTS - Translational Science Case Study (TSCS)
- Published a TSCS protocol
- First case study published Oct 2021



CLIC Center for Leading Innovation & Collaboration
Amplifying research impact

Cleveland CTSA Team Publishes First Ever Retrospective Case Study in JCTS

News Mike's Blog CLIC News Roundup CTSA Ansible

A group of evaluation researchers at Clinical and Translational Science Award (CTSA) hubs are conducting retrospective case studies to evaluate the translational research process. Earlier this year, Dr. Clara Pelfrey and the CTSA evaluation researchers petitioned the Journal of Clinical and Translational Science to include retrospective case studies as a manuscript category. The objective of these studies is to deepen knowledge of the transitional process and identify contributors to successful translation.

Clinical & Translational Science Collaborative of Cleveland members Dr. Kelli Qua, Shannon Swiatkowski, and Dr. Clara Pelfrey teamed up with Dr. Gurkan to investigate the successful translation of the HemeChip using a protocol for retrospective translational science case studies of health interventions developed by the CTSA evaluation researchers. Their findings have recently been published in the Journal of Clinical and Translational Science: "A Retrospective Case Study of Successful Translational Research: Gazelle Hb Variant Point-of-Care Diagnostic Device for Sickle Cell Disease".

[Read the full article and link to the manuscript here.](#)



Research to Practice: Sickle Cell Diagnostic Milestones

EVIDENCE OF IMPACT ON HUMAN HEALTH

DR. Umut GURKAN

2014
HemeChip laboratory prototype developed
*First proof-of-concept laboratory prototype was developed in Dr. Gurkan's laboratory at CWRU

12/2015
1st international conference presentation of the laboratory prototype and preliminary results
*First public disclosure of the technology at American Society of Hematology Annual Meeting

5/2016
HemeChip was licensed to Hemex
Included all microchip electrophoresis applications

6/2017
HemeChip functional product prototype developed
*Prototypes of HemeChip were injected molded in Ohio and ran on a prototype reader designed by Hemex with a contract engineering company

2017-2018
Seed Funding
Multiple angel groups and small VCs

12/2017
1st clinical study in Africa - Nigeria
*First pilot clinical study in Africa was in Kano, Nigeria for sickle cell disease

3/2018
1st clinical study Thailand
*First study in Thailand for hemoglobin E disease

6/2018
Vodafone Wireless Innovation Project Competition First Place
\$300K for developing data connectivity over mobile networks

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SMART: Sickle cell and Malaria Remote Accurate Testing
For developing data connectivity over mobile networks

8/2018
NIH/NIDDK Phase I STTR: Portable, affordable, quantitative microchip electrophoresis for hemoglobin A1C testing
\$275K to explore additional test capabilities on HemeChip Platform

9/2018
NIH/NHLBI Fast-track SBIR: Affordable, quantitative microchip electrophoresis for sickle cell disease screening
\$1.7M to develop automated single step cartridge and additional clinical studies

12/2018
Business Oregon Matching Grant for Fast-Track HemeChip SBIR: Enhanced Sickle Cell Disease Cartridge Automated Manufacturing Process
\$150,000 to develop automated manufacturing process

2020
2nd clinical study in Africa - Ghana
First clinical study in Africa's first reader and included newborns for sickle cell disease testing

2020
3rd clinical study in Africa - Nigeria
Validation study on large number of subjects and includes digital data transfer to the cloud

3/2020
Cover article in Analyst journal
A comprehensive description of diagnostic accuracy based on clinical validation studies performed in Nigeria, India, Thailand for hemoglobin variants

1/2019
Series A Funding Achieved
Led by strategic partner

5/2019
1st clinical study in India
First study in India was for sickle cell disease and sickle beta thalassemia

9/2019
Manufacturing started in India
Manufacturing is done by two contract manufacturers in India

9/2019
CTIP: Consortium for Tech & Innovation in Pediatrics: Clinical Research for Breakthrough SCD Device
\$45K for additional clinical studies

11/2019
1st peer-reviewed publication (proof of concept)
Presented and published as a conference proceeding of the 2019 IEEE Healthcare Innovators and Point of Care Technologies (IH-POCT) conference at the NIH

2021
Users provide feedback for design and development

4/2020
NHLBI Phase I STTR: Portable, affordable, quantitative microchip electrophoresis system for integrated anemia and Hb variant testing
\$225K for adding anemia testing capability

9/2020
NIH Technical Accelerator: Affordable, Non-Invasive and Minimally Invasive Diagnosis of Anemia, Malaria, and SCD
\$100K for developing a non-invasive testing modality

10/2020
1st sale of units
*First revenue shipments of reader and cartridges

6/2021
Newborn screening test received regulatory approval
*First worldwide remote software update expands patient age range from 6 weeks to all ages

GHANA, AFRICA

REAL WORLD TESTING WAS CRITICAL

INVESTING IN INNOVATION FOR UNDERSERVED POPULATIONS SAVES LIVES

Participation in NCATS/CTSA Program Initiatives

1. Informatics: N3C
2. COVID trials: PASC-RECOVER, ACTIV
3. U01 Submissions:
 - REMOTE: UW, MUSC, CWRU (McComsey)
 - DSMB New Member Education, increasing DSMB diversity:
UTMB, Northwestern, Vanderbilt, OSU, Stanford, Tufts, CWRU (Gassman)
 - APPLE-PIE: CWRU (Remy), Univ Cinci, Florida, Iowa, Minnesota and Wash U
4. KL2 Visiting Professorship Program
 - Exchanges with Stanford, Univ Kansas, UCLA, Univ Pitt
5. Evaluation: Pilot test site for new CM-PRISM Common Metric Data Collection
6. Un-Meetings: Hosted 2021 meeting



Marisa McGinley, DO, MSc
 Neurologist, Mellen Center for Multiple
 Sclerosis, Cleveland Clinic
 CTSC KL2 Scholar
 Un-Meeting Principal Investigator

Tackling the Digital Divide to Improve Telehealth

Friday, March 26, 2021
 11:00 AM - 3:00 PM

Un-Meeting hosted by the
 Clinical and Translational Science
 Collaborative of Cleveland





Shanina Knighton, RN, PhD

Frances Payne Bolton School of
Nursing, CWRU

CTSC KL2 Scholar



<https://youtu.be/B0DNDh-7Ho4>

REC

10 YEARS IN CTS

CELEBRATE. IMPACT. ACCELERATE.

CTSA MVPs (Most Valuable Personnel)

NIH

NIH National Center for Advancing Translational Sciences

