



## CTSC COMPONENT PROGRESS SUMMARIES – YEAR 3 TO PRESENT

December 7, 2021

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### Specific Aims

#### Overall Aims:

**Aim 1: Engage all C/T science stakeholders, the workforce, patients and community members to collaborate locally, regionally, and nationally, to advance human health.**

**Aim 2: Develop and cultivate the current and next generation C/T research workforce, with special focus on preparation for team science and increasing the diversity of the workforce.**

**Aim 3: Promote integration of our translational processes from discovery through clinical trials, of our community throughout the research enterprise, and of special and underserved populations into C/T research across the lifespan.**

**Aim 4: Increase the quality and efficiency of C/T research, particularly multi-site trials, through innovative methods and processes and strong collaboration among CTSC hubs.**

**Aim 5: Provide innovative informatics to support the training and research environment both in the CTSC and nationally.**

## Informatics Component

Lead: Jonathan Haines, PhD

Co Leads: David Kaelber, MD and Lara Jehi, MD

### Accomplishments

The last year continues to see major advancements in the capabilities of the Cleveland CTSC informatics hub along with increased outreach both internally and externally.

- a) We introduced >180 participants consisting of UH clinicians, UH clinical staff and researchers (both at UH and CWRU) to the EMERSE (Electronic Medical Record Search Engine) tool during a pilot phase that ended in October. In early July, EMERSE was updated to the current version from the University of Michigan. In early November, an EMERSE presentation and demo was held for all the University Hospitals clinical chairs and institute/center directors. Among other research studies, EMERSE is currently being used to facilitate PediTrac, a longitudinal multi-center study (with University of Michigan and Eastern Michigan University) that is working with families from different environments to explore infant development related to their social environment. A secondary study of note is the ROSE (Reach Out, Stay Strong, Essentials for New Moms) pilot study at the UH Rainbow Center. ROSE is an evidence-based intervention shown to reduce the risk of developing pre-natal depression in high-risk populations.
- b) TriNetX has substantially increased the number of accepted clinical trial opportunities at MH and UH and is supporting clinical research efforts at both institutions. At MetroHealth, since going live with TriNetX Trial Connect in the summer of 2019 we have seen an order of magnitude increase in external accepted clinical trial opportunities from 2-3 per year before implementing TriNetX Trial Connect to 20-30 per year since implementing TriNetX Trial Connect. Similarly, UH has recently seen over 27 Trial Connect studies presented, with a total of 9 accepted. In addition, UH has supported over 155 Export IDs in the last quarter alone to assist with clinical trials enrollment.
- c) The Biomedical Health Informatics (BHI) academic programs saw increased interest with the addition of 9 MS and 2 PhD students this fall. The Clinical Informatics fellowship program was successfully reaccredited in the fall of 2019 and, since inception, 6 fellows have completed the program. The ACGME Clinical Informatics fellowship program is actively working on expanding. A multi-site block diagram has been approved and for the first time a Clinical Informatics fellow based at MetroHealth is participating in a clinical informatics elective at the Cleveland Clinic. This learner will be the first learner for the new clinical informatics elective at the Cleveland Clinic that will be open to medical students, residents, and fellows, and parallels a similar clinical informatics elective that has been offered through MetroHealth for the last decade. Active discussions are also underway with board certified clinical informaticians and graduate medical education leadership at the Cleveland Clinic and University Hospitals to expand slots in our Clinical Informatics fellowship program. We expect to be recruiting Clinical Informatics fellowship applicants for additional fellowship slots by the end of 2022.
- d) The UH OMOP Data Mart was validated using the EMERSE tool, which contains both the structured and unstructured clinical data, as the gold standard. This completion allows for the installation of the LEAF cohort tool, the ATLAS/OHDSI web interface, and the ACE (Advance Cohort Engine) this winter/spring.
- e) MH continues to pilot and serve in a leadership role for the Epic Cosmos platform that now has EHR data on over 120,000,000 patients in the aggregate data warehouse.

MetroHealth research informatics physicians led the team to publish the first ever manuscript using Cosmos - Yasir Tarabichi, Adam Frees, Steven Honeywell, Courtney Huang, Andrew M. Naidech, Jason H. Moore, David C. Kaelber. The Cosmos Collaborative: A Vendor-Facilitated Electronic Health Record Data Aggregation Platform. *ACI* open 2021; 05(01): e36-e46. The Cosmos data research network has recently moved from quality assurance testing to full production, with all contributing healthcare systems with the Epic electronic health record now able to have 50 Cosmos users. Over 100 healthcare systems with the Epic electronic health record are now contributing data to

Cosmos. Cosmos COVID vaccine data was recently presented to ACIP as part of the evidence to additional COVID-19 vaccine doses.

- f) All of these efforts around tools and infrastructure have resulted in papers and presentations in high quality journals (e.g., Chest, JAMIA, Nature) and conferences (e.g., ID Week, SHEA, American Geriatrics Society).
- g) In the winter of 2021/2022, we will be piloting a limited informatics consult service for researchers at UH and CWRU that utilizes the informatics tools that have been deployed so far. The service will aim to identify the gaps between researcher questions and the data available to answer those questions. Section 3 describes additional details.
- h) Both MetroHealth and CWRU have signed master DUAs with N3C. MetroHealth has executed a DTA and has received final approval to start submitting data to the N3C enclave. They will begin submitting data in partnership with TriNetX by the end of this calendar year.
- i) We are partitioning REDCap databases for research and non-research use cases to better support the Cleveland Clinic REDCap community. Planning continues to develop a support organization and computing platforms to assist users with operating support and quality improvement use cases. REDCap software upgrades continue on a monthly base, operating currently at version 11.1.16 Long Term Support. Additional resources were added to support REDCap research projects. REDCap statistics as of October 2021:

<b>Total projects</b> (excludes 'practice' projects)	<b>14,946</b>
• Project status	
- Production <a href="#">view types</a>	5,153
- Development <a href="#">view types</a>	7,316
- Analysis/Cleanup <a href="#">view types</a>	1,995
- Completed <a href="#">view types</a>	482

• Project purpose		
- Research		9,312
- Basic or bench research		9,312
- Clinical research study or trial		856
- Translational research 1 (applying discoveries to the development of trials and studies in humans)		6785
- Translational research 2 (enhancing adoption of research findings and best practices into the community)		147
- Behavioral or psychosocial research study		143
- Epidemiology		402
- Repository (developing a data or specimen repository for future use by investigators)		264
- Other		604
- [Subcategory not selected]		1045
		62
- Operational Support		1,909
- Quality Improvement		3,245
- Other		449
- e-Consent Framework		
- Projects with surveys utilizing e-Consent Framework	36	
- PDF consent files stored via e-Consent Framework	3,819	

- j) CC rolled-out of Explorys on 11/20/2020. A system for requesting Explorys access was implemented in 2021. The REDCap Explorys Application – Version 2-20201230 was approved by the Cleveland Clinic IRB and managed by a protocol supervised by the PI Dr. Joe Zein. This enables users to search and browse patient populations, analyze relationships, define temporal events, and understand historical trends. Researchers can create populations cohorts based upon numerous demographics as well as clinical factors and can further refine cohorts according to clinically relevant ranges, timeframes, care venues, and temporal associations between events. Explorys is allowing researchers to use it for both preparatory to research and as a basis for research because it aids them in hypothesis generation and initial exploration, protocol feasibility, clinical trial design, outcomes research and comparative analytics

as well as helping define populations of interest for advanced study and analytics. Twenty-six (26) Explorys access request applications were entered from March 2021 through September 2021 for seventeen (17) investigators. This brings the current Explorys roster to twenty-five (25) active research accounts.

- k) Cleveland Clinic’s COVID-19 Registry comprises 265,254 patients who were tested for COVID-19 at a CCF facility, including 113,938 positive patients and a case-control data set of 151,316 negative patients matched on age, sex, race, geographic location, and date of testing. Over 700 data points per positive patient (130 for the matched negatives) were collected from the electronic medical record via a combination of automated discrete data pulls, natural language processing, and manual chart abstraction covering patient demographics, symptoms and comorbidities, COVID immunization and treatments, lab values, and hospital and ICU admission details. The registry helped to streamline 316 research requests into 242 ongoing projects that have added to the compendium of over 900 publications by CCF researchers related to COVID-19. The registry also resulted in a set of COVID-19 risk-calculators already integrated locally in the clinical workflow to support decision-making, to be adopted nationally by 100 million MyChart Epic users. Additionally, MetroHealth worked with CCF to incorporate 300 data fields CCF chose from the COVID-19 registry, which enabled them both to collaborate with the Mayo Clinic registry. There has been a total of 103 publications to date from the COVID Registry.
- l) The development of the data infrastructure for the Cleveland Clinic BioRepository (CC-BioR) is underway in collaboration with Enterprise Analytics (big data management and front-end web development), the Information Technology Division (software and hardware provisioning), Enterprise Data Governance (data lineage and usage protocols), and clinical content experts across various Institutes. Biospecimen details (e.g., type, volume, processing methods, physical location), patient phenotypic details extracted from the electronic medical record and institute-curated registries (e.g., STS), and biospecimen usage permissions obtained through informed consent processes are all assembled in the CC-BioR Data Warehouse to provide a common platform upon which biospecimen research can be performed. An online “query builder” web application, due to go live at the end of October 2021, will allow prospective researchers to browse biospecimens available in the CC-BioR by specific patient characteristics constructed via a fluid Boolean logic interface. The results of these queries are then automatically included in an online biospecimen request form, which serves as a central intake point for all CC-BioR biospecimen requests and ensures all study details are tracked and audited in a central secure location.
- m) DocuSign was rolled out at the CC in August 2020, as a method to obtain electronic consent that is 21 CFR Part 11 compliant, and to assist in obtaining remote consent in the time of COVID-19. There are a total of 255 active users from 17 Institutes and it has additionally been rolled out to Cleveland Clinic Akron and at the Cleveland Clinic Lou Ruvo Center for Brain Health in Las Vegas. The IRB approved consent documents in the system totals 91.
- n) The EPIC Research IT Analysts have worked on numerous projects for Cleveland Clinic investigators to assist with subject recruitment. Projects include recruitment messages, best practice advisories, MyChart recruitment, MyChart surveys, smart lists, smart texts builds, patient information sheets for MyChart recruitment, updating the EPIC modified consent for the CC BioR, and research order sets.

**The table below shows the alignment of our accomplishments to date with the overall aims of the entire Cleveland CTSC:**

<b>Accomplishments</b>	<b>Aim 1</b>	<b>Aim 2</b>	<b>Aim 3</b>	<b>Aim 4</b>	<b>Aim 5</b>
a – EMERSE	<b>x</b>	<b>x</b>	<b>x</b>	<b>x</b>	<b>x</b>
b – TriNetX			<b>x</b>	<b>x</b>	
c – BHI/Fellowship	<b>x</b>	<b>x</b>	<b>x</b>		<b>x</b>
d – UH OMOP			<b>x</b>	<b>x</b>	<b>x</b>
e – Cosmos				<b>x</b>	<b>x</b>

f – Pubs/abstracts	x	x	x	x	x
g – Informatics consult			x	x	x
h – REDCap				x	x
i – Explorays				x	x
j – COVID Registry			x	x	
k – Data Infrastructure for CC BioR					
l – DocuSign	x	x	x		
m – EPIC IT					

### Services Provided to CTSC Investigators

In addition to what we described in 2020, we are not only assisting investigators by utilizing the informatics tools at our collective disposal to assist with either ongoing research studies or by providing preliminary data for grant proposals, but also by vetting and clarifying the research questions that are being asked by those investigators. As an example, an informatics consult desk pilot is being put into place at UH where informatics staff will clarify the question being asked, and then categorize the refined questions as either clinical characterizations/descriptions (e.g., cohort creation), causal analysis/inference, or predictive analysis. Rather than simply deploying informatics tools, we are becoming adept at the utilization of these tools to be able to assist investigators directly on their research projects. In these cases, the BIT informatics personnel are being added to the IRB protocols as warranted.

### Accomplishments/Solutions Scalable for Dissemination to the CTSA Consortium

The lessons learned in bringing up the open-source EMERSE tool will be written up as a brief methods paper and shared with the CTSC consortium. Our method to validate the UH OMOP data mart via random patient selection (comparing to the data within the EMERSE tool, where differences were then used to refine the ETL and data acquisition/cleaning process for OMOP) will be written up and disseminated as a methods paper. Our experience in licensing the ACE tool from Stanford, and the efficiencies it should create in performing temporal/longitudinal queries previously only possible through complex coding, will be written up a disseminating in a methods paper. Finally, our experience in contributing directly to the research projects, by being adept at the tools we have provided, will be written up as a paper and shared with the CTSC consortium.

### Integration with other CTSC Components and CTSA Hubs

We provide support for the BERD by providing help with software and access to large-scale computational resources. We support the Trial Innovation Network by providing organization and performing or providing access to EHR data. We support the research capacity through our management of the REDCap data capture system. We assist investigators with preliminary data for grants applications via utilization of our informatics tools.

We continue our collaborative efforts with the other CSTC hubs utilizing EMERSE (U. of Michigan, U. of North Carolina, Columbia U., U. of Cincinnati, U. of Kentucky, U. of California SD) including facilitating the testing of a networked version of the tool that uses the University of Michigan as an honest broker for queries. We continue to serve on the data governance committee for the LEAF cohort and patient visualization tool with U. of Wash. Med., U. of Chicago Med., Harvard U., Johns Hopkins U., and U. of Oklahoma Health Sciences Center. We have initiated discussions with Stanford University to be able to license the ACE (Advanced Cohort Engine) tool for searching longitudinal records to be used in concert with the UH OMOP data mart. This tool, intended to be used by informatics specialists, will facilitate complex temporal queries across the patient population to directly assist clinical researchers.

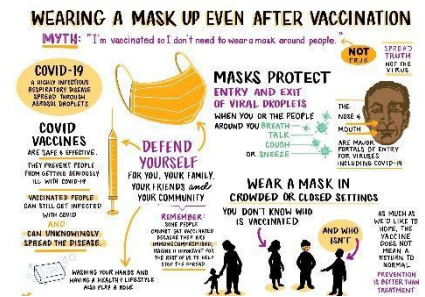
## Community and Collaboration Component (C&C)

Lead: Elaine Borawski, PhD

### Accomplishments

#### COVID-19 response support

- **COVID-19 Rapid Response Pilot Program:** The C&C component continued to oversee the administration of **COVID-19 Rapid Response Pilot Program**, including the 6 month (Dec 2020) and 12 month (July 2021) reporting process and summarizing the 18 reports for respective funders and the COVID-19 Taskforce leadership. Currently, C&C is spearheading the upcoming **COVID-19 Pilot Grant Dissemination Day** (Oct 29, 2021), a virtual conference that will include keynote speaker, Dr. Heidi Larson from the London School of Hygiene and Tropical Medicine, 9 oral presentations and an interactive poster session of key findings and lessons learned from the Pilot Grant awardees with the greater CTSC community and the University at large.
- **University-wide COVID Education Committee with the Provost's Office:** The C&C Supported **CWRU's COVID Education Committee**, which developed a range of educational materials for the university's COVID vaccine Hub. In addition to Drs. Borawski and Freedmanserving on the committee, the C&C (1) supported student engagement on this committee; (2) provided funds to develop, print, translate (English, Spanish) and distribute 5,000 sets of innovative, locally-inspired infographics developed by KL2 scholar, Dr. Shanina Knighton; and (3) distributed 3,000 co-branded (Cleveland Department of Health and the CTSC) bags at clinics and vaccination sites across the city to encourage vaccine adoption where rates were beginning to slow.



#### Academic-Community Collaborative Research Support

- **Nourishing Beginnings:** The C&C team continued to work closely with Better Health Partnership (BHP), First Year Cleveland (FYC) and the Greater Cleveland Food Bank (GCFB) to support the research underlying the novel Nourishing Beginnings (NB) project, **aimed to reduce food insecurity** among low-income pregnant individuals, known to contribute to the significant **health disparities in premature births and infant mortality** across the county. Since Jan, 2021, the team has collectively secured over \$200k in local grants to conduct an implementation pilot with 120 food insecure pregnant women, who will be randomized into one of two intervention arms - direct food delivery from the GCFB or financial support with personalized local food navigation implemented as part of the BHP's Community Health Worker (CHW) Pathways HUB. The study will track dietary behavior, psychosocial health, health care utilization, and health outcomes for the mother and baby, as well as documenting the recruitment, enrollment, coordination of services and data sharing phases of the intervention.
- The team also submitted a **U01 application**, led by Dr. Borawski (PI), in response to RFA-RM-21-021: Transformative Research to Address Health Disparities and Advance Health Equity. Individuals from GCFB, BHP, and FYC were included as co-investigators, as well as a number of CTSC engaged faculty. The application extends the pilot, expands the underlying theoretical model, adds the capacity to study implementation processes for the intervention in order for future scalability of the intervention and includes a significant effort on workforce development for CHWS and development of increased nutrition education training. While not funded, we received positive feedback from reviewers and will submit again in Feb, 2022 with more pilot data in hand.
- **IDEARICH** is a cross-institutional collaboration that brings together hospital, social service and community organizations focused on **reducing disparities in childhood asthma**. This collaboration links critical medical and social service data needed to identify the most important social determinants of health driving not only high rates of asthma and its consequences but also the observed racial and income disparities across the region. The C & C component supported the analytic phase of their pilot, enabling the group to move their collective work to intervention development and testing via R level grants.



## Community Engagement and Team Science Resource Development

- CIRTification: In spring, 2021, C&C launched CIRTification at CWRU, an alternative to deliver human research protection training in a more accessible and digestible manner for community partners involved in research (e.g., community health workers). The program, developed by the University of Illinois Chicago CTSA, as an IRB approved option to fulfill the requirement of human research protection training for community members. C&C is currently working with the CTSC Regulatory Core to offer CIRTification to all CTSC partner institutions.
- Team Science learning modules: The third video of the C&C team science learning modules was filmed in June 2021 and is currently in post-production at UTECH. The completed video and its accompanying toolkit are anticipated to be posted to the website in late 2021. The draft of the script for the 4th and final video is currently being revised.

## Support for large-scale Cross-Institutional Collaborations

- C&C, Case Cancer Center and the CWRU Provost's Office are in the early planning stages to co-support a new, more integrated **Community Engagement (CE) HUB**, a virtual, shared resource that will streamline CE resources across campus, reduce duplication, track community projects, allow for new CE resource development, and increase awareness of community-engaged research across CWRU, our partner institutions and the community at large.
- Dissemination and Implementation Science Inquiry Project: In March-April 2021, the C&C, led by faculty member Dr. Darcy Freedman conducted discovery analysis to explore the breadth and needs of dissemination and implementation (D&I) science investigators across our institution, with goal of increasing cross-institutional collaborations and advancing translational research. Held two virtual meetings with the 32 identified D&I investigators, with representations from across CWRU and all four of our health care partners (UH, Metro, Cleveland Clinic, VA). A report summarizing the meetings was presented to the Steering Committee in July, 2021. Next steps are creating a D&I focused co-design studio and developing the network by supporting 10 investigators (two from each member institution) to attend the Annual National D&I conference (virtual) in Dec 2021, followed by a facilitated retreat in February to develop a collective plan.

## Services Provided to CTSC Investigators

- Drs. Borawski and Goodwin of the C&C serve as co-investigators of a funded NCI grant submitted by the Cancer Center's Community Outreach and Education core to help basic scientists better connect their work with the CCC's catchment areas across the region. *Services provided: Proposal development, development and analyses of stakeholder interviews, development of a CCC-wide survey, and development of expanded education program.*
- Dr. Borawski mentored junior faculty member Dr. Katy McManus (Nutrition) in her ADA new investigator award submission, "Diabetes inspired culinary education (DICE): an innovative approach to type 1 diabetes management for at-risk youth". Participants recruited from clinics; however, intervention conducted at community kitchen. *Services provided: study design consultation, community linkages, budgetary guidance, grant submission support.*
- Working with two junior faculty members at CCF, interested in looking at the role of the food environment on disparities in post-bariatric surgery success. *Services provided: links to the PRCHN's food retail database, help with data use agreements and IRB, study design and measurement.*
- C&C team supporting the establishment of center, headed by Dr. Betul Hatipoglu (UH and CWRU) - the Center for Diabetes, Obesity and Metabolism. *Services: Helping with faculty and community contacts and conceptualization assistance. Currently planning two facilitated meetings with interested faculty for Jan, 2022.*
- Serve as project advisors for CTSC pilot grant awardees with community-focused projects.

## Accomplishments/Solutions Scalable For Dissemination to the CTSA Consortium

- Tailored team retreat packages: pre-work, consult, retreat, feedback, tracking
- Tool for tracking interdisciplinary team progression over time.
- Cross institutional infrastructure to coalesce and administer rapid response to Call for Proposals; used to respond to COVID-19 but framework enables the CTSC respond quickly to any large national

call

- Utilization of the Multi-Track feature on the InfoReady platform.

#### **Integration with other CTSC Components and CTSA Hubs**

- Consultations with the Oregon Health Science University CTSA on Community Engagement HUB development
- Consultations with the Univ of Illinois Chicago CTSA on using CIRTification at CWRU
- Monthly calls with Buffalo CTSA to discuss possible collaborations
- Collaborating with the Cleveland CTSC Regulatory Core on launching the CIRTification across the Cleveland CTSC
- Active participation on the Community and Collaboration Group and two of its working groups.



SELECTED INFOGRAPHICS (FROM A SET OF 10)

DEVELOPED BY KL2 SCHOLAR, DR. SHANINA KNIGHTON (NURSING) FOR COVID RESPONSE

5000 COPIES DISTRIBUTED THROUGHOUT CLEVELAND COMMUNITY

THE COVID-19 VACCINE HELPS PROTECT YOU AND OTHERS

A HIGHLY INFECTIOUS RESPIRATORY DISEASE SPREAD THROUGH AEROSOL DROPLETS

CAN SAVE YOUR LIFE!

HELPS YOUR IMMUNE SYSTEM BUILD A DEFENSE ARMY TO FIGHT AGAINST COVID-19



AFTER YOUR VACCINATION YOU MAY EXPERIENCE A FEVER, HEADACHE, TIREDNESS, CHILLS OR SORENESS AT THE INJECTION SITE  
THIS IS NORMAL

MISINFORMATION IS EVERYWHERE

KNOW THE FACTS

THE COVID-19 VACCINE

- CANNOT GIVE YOU COVID-19
- CANNOT CHANGE YOUR DNA
- CANNOT INCREASE YOUR RISK FOR CONTRACTING COVID

CONTINUE TO WEAR A MASK

IT WILL TAKE ABOUT 2 WEEKS FOR YOUR BODY TO BUILD UP A ROBUST DEFENSE RESPONSE



AND WASH YOUR HANDS FREQUENTLY INCLUDING YOUR 3RD HAND... YOUR PHONE

STAY AWAY FROM CROWDED PLACES

EXERCISE & DO HOBBIES THAT LOWER STRESS

DRINK FLUIDS & EAT HEALTHY FOODS

SOME DISEASES & CONDITIONS PUT YOU AT HIGHER RISK OF SEVERE SYMPTOMS OR DEATH IF YOU GET COVID INCLUDING...

- \*PREGNANCY
- \*ADVANCED AGE
- \*OBESITY

GETTING VACCINATED PROTECTS YOU AND THE PEOPLE AROUND YOU

YOU MAY STILL BECOME INFECTED WITH THE VIRUS BUT BEING VACCINATED CAN LIMIT THE SEVERITY OF THE ILLNESS & PREVENT YOU FROM DYING



AS WELL AS :  
HEART CONDITIONS  
DIABETES  
COPD  
CANCER  
DOWNS SYNDROME  
HIGH BLOOD PRESSURE  
AND MORE  
IT'S ESPECIALLY IMPORTANT TO GET VACCINATED

Shanina Knighton PhD RN \*REMEMBER... PREVENTION IS BETTER THAN TREATMENT

©SHANINA KNIGHTON, PhD RN / SEEYOURWORDS.COM

NAVIGATING DOCTOR VISITS

Shanina Knighton PhD RN

DURING COVID-19

BEFORE YOU GO... CALL THE PRACTICE AND ASK HOW THEY ARE KEEPING PATIENTS SAFE OR ASK IF THEY CAN DO A TELEHEALTH VISIT INSTEAD



AFTER YOU ARE THERE... MINIMIZE CELL PHONE USE TO LIMIT SURFACES IT COMES IN CONTACT WITH. GENTLY WIPE IT DOWN WHEN YOU RETURN HOME

DO NOT SKIP APPOINTMENTS

MANAGING YOUR HEALTH SHOULD BE A PRIORITY

MEDICAL CONDITIONS, LIKE ASTHMA OR OBESITY, CAN INCREASE YOUR RISK OF DEATH FROM COVID-19

NOT CARING FOR EXISTING CONDITIONS SUCH AS HIGH BLOOD PRESSURE & HEART FAILURE ALSO INCREASES YOUR RISK OF ORGAN DAMAGE AND DEATH.

PREVENTION IS BETTER THAN TREATMENT

BE MINDFUL IN PUBLIC SPACES

WEAR A MASK

HEALTHCARE FACILITIES REQUIRE THEM



CLEAN YOUR HANDS

AFTER TOUCHING PENS, TOUCHSCREENS OR DOORKNOBS



WIPE DOWN ARMS OF CHAIRS YOU SIT IN



AND MAKE SURE YOUR PROVIDER CLEANS THEIR HANDS WHEN ENTERING THE ROOM

USE THEIR HAND CLEANING PRODUCTS... ESPECIALLY AS YOU LEAVE THE OFFICE

REMEMBER TO WIPE DOWN ANY MEDICAL DEVICES YOU BROUGHT WITH YOU WHEN YOU GET HOME



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## HELP

### WHEN YOU NEED IT

Better Health Partnership is working with the Greater Cleveland Food Bank, Case Western Reserve University, and First Year Cleveland to bring the Nourishing Beginnings program to Pathways HUB participants.

Nourishing Beginnings is a collaborative study project that investigates the impact of nutritional resources and their effects on expecting parents and their babies during pregnancy and postpartum.



## QUESTIONS

Better Health Partnership  
Pathways HUB Referral Coordinator  
ajenkins1@metrohealth.org  
mvelez@metrohealth.org  
216.778.7525

**Case Western Reserve University**  
Meredith Goodwin  
Meredith.Goodwin@case.edu  
216.368.0337

**Greater Cleveland Food Bank**  
Alissa Glenn  
aglenn@clevelandfoodbank.org  
440.785.0379

For Participant's Rights Questions  
216.368.0838

*This project has been approved by the  
Case Western Reserve University  
Institutional Review Board under protocol  
number: XXXXXXXX.*



*Collaborating for a healthy community*



Greater Cleveland

Food Bank

**First Year  
Cleveland**



CLINICAL AND  
TRANSITIONAL  
SCIENCE COLLABORATIVE



Offering parents extra support  
during and after pregnancy





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**Supporting pregnant people by connecting them to fresh, nutritious food, during pregnancy and postpartum.**

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#### **PARTICIPATION IN THE PROJECT**

The Nourishing Beginnings project's goal is to identify the most effective way to support people during and after their pregnancies. Participants will be asked a series of questions to help researchers understand the impact of the program.

#### **ENROLLMENT & EVALUATION**

Once enrolled in the Better Health Pathways HUB, participants will be randomly placed into one of two program study groups.

Based upon response, the research team will evaluate which group's approach best benefits pregnant people and their babies. Both groups are of equal value and neither group is better than the other.

During enrollment in this project — and throughout the 12–18 months study afterward — participants will be asked questions about the following categories:

[ **HEALTH • DIET • LIFESTYLE  
PREGNANCY & DELIVERY INFO** ]

**GROUP 1** Participants receive boxed food items delivered every other week from the Greater Cleveland Food Bank containing fresh, quality ingredients to make healthy meals at home:

- 🍏 Foods are unprocessed, highly nutritious, and customized to fit the pregnant person's preferences.
  - 🍏 Boxes are sized to feed all members of the household.
  - 🍏 Participants will provide monthly feedback on the food boxes, which can be adjusted.
- 

**GROUP 2** Participants receive:

- 🍏 Cash card for groceries which is reloaded every other week.
  - 🍏 Access to a web-based food resources tool.
  - 🍏 Training from community health workers about how to find healthy and affordable foods near home.
- 

**PARTICIPANTS IN BOTH GROUPS will be offered resources to help them with their food needs, including:**

- 🍏 Financial support to purchase kitchen items for their home.
- 🍏 Access to personalized and easy-to-understand recipes that reflect their dietary needs during pregnancy and after delivery.

**Translational Endeavors Component:  
Workforce Development and Pilot Grants**

Lead: Mark Chance, PhD

Co-Lead: Ofer Reizes, PhD

**Pilot Program**

Co-Leads: Kingman Strohl, MD; Mark Aronica, MD and John Chae, MD

**Accomplishments**

The current year accomplishments include:

- funding a new set of CTSC pilot awards.
- receiving a supplement award for entrepreneurship training with UAB.
- launching a second year of the translational fellows program.
- expanding the mentor and mentee pools of the Case Venture Mentoring Program (CVMP).
- reviewing and funding innovation projects in a collaborative program with Taipei Medical University.
- holding regular OTI meetings.

In fall 2020 we solicited LOIs' through the CTSC RFA and we received 77 responses. After a panel review, we selected 15 projects for full proposal, 12 were completed by the deadline and 6 were funded. Projects managers were assigned each project to help accelerate success. Projects include support for traumatic brain injury, increasing efficacy of treatments in heart disease, therapy for glioblastoma brain tumors, and addressing the connection between food insecurity and tobacco use, among others. In particular, investigators are working to develop an intervention for patients in the clinical setting who are suffering from the additive effects of food insecurity and tobacco addiction. The 2021 RFA is just commencing and the LOIs will be due shortly.

We wrote and received a supplement award (Konstan PI) with UAB to deliver a special iCorps@NCATS customary discovery training to interested community stakeholders. iCorps@NCATS is based on national iCorps programs which are offered around the country to provide training in and time to focus intensely on understanding your technology's market and customer base to develop technologies with high potential to be successful in the commercial space. iCorps@NCATS condenses this traditionally months long program to a basic 5-week program to be offered at the more local level via NCATS funded CTSA's. To refine and optimize the population to receive the training, the instruction was embedded in a yearlong fellowship, where individual students, post-doctoral fellows, or residents applied for 1-day a week paid support for entrepreneurship training (Translational Fellows Program, see below). The goal is for individuals in a laboratory (fellows) to have protected time (1-day per week) to work on developing the technology in their laboratory. The fellows receive programming at least every month and have access to a venture mentoring service (CVMP). Mentors for CVMP are drawn from the business and non-profit community around Cleveland and a team based mentoring style is emphasized.

The Translational Fellows Program completed its Year 1 graduating 12 fellows in 2021. These 12 fellows were diverse in their experience in the field. Career experiences ranged from graduate students to more senior research associates. 3 of the fellows are underrepresented minorities and 6 are female. Technologies they are working on range from therapeutics to medical devices to community-based healthcare. Levels of experience with entrepreneurship prior to starting TFP varied from having little idea of what entrepreneurship really looks like to having some experience starting a company. The career ambitions of the fellows also varied where some were interested in working in startups/entrepreneurship, some wanted to remain in an academic career with a translational focus whereas some were exploring careers. All fellows received a monthly program of events, including an intensive 5-week iCorps@NCATS. Two fellows also completed an advanced iCorps@OHIO training, four started companies as a result of their efforts and three submitted small business grants (SBIR) to fund their work. Several entrepreneurs entered national pitch competitions and were awarded slots. In addition to these accomplishments, all of the fellows increased their understanding of their career ambitions as a result of the work they did in the TFP program and the support of all of those involved with TFP and CVMP (based on survey results). They report that the perspectives they gained while participating in TFP has changed the way they make research decisions. Starting July 2021, 12 new fellows (9 funded and 3 non-funded) were selected for Year

2. Just like the first year's cohort, this second year of fellows is similarly diverse. All of the fellows are currently completing iCorps@NCATS training and 11 of these fellows have begun their mentoring in CVMP

With the creation of TFP came the rapid growth of CVMP. To accommodate the increase in mentees, we have expanded our CVMP mentor pool by adding 11 new members from the community. Efforts to add more mentors to the program are underway as we hope to have 3 mentors for each CVMP mentee for an optimum experience. Efforts put into our new CVMP website have focused on the people who have made CVMP a success, attracting budding entrepreneurs who have reached out to us about mentorship provided in CVMP.

We identified 5 possible projects as collaborations between TMU and CWRU and after review settled on 3 translational projects for funding. The year 6 projects continue to develop important clinical treatments for sleep apnea, head and neck cancers, and diabetes. Past year awardees were recommended to apply to the CTSC pilot program. The electrical biosensor for diagnosing diabetic nephropathy is being led by Dr. Umut Gurkan.

### **Accomplishments As They Link To The Overarching Aims/Goals Of Our CTSA Hub**

Of these accomplishments, list those accomplishments that link specifically to the overarching aims/goals of our CTSA hub.

Aim 1: Our activities engage all of the stakeholders with potential opportunities for them to receive pilot funds or be trained as entrepreneurs, with the goals of advancing human health.

Aim 2: The Translational fellows program develops scientific teams and entrepreneurial skills for trainees in the workforce.

Aim 3,4,5: NA

### **Services Provided to CTSC Investigators**

Translational Fellows are provided a defined curriculum (see above). Pilot grant investigators receive project management services to complete their projects and stay on time and on budget.

### **Accomplishments/Solutions Scalable for Dissemination To The CTSA Consortium**

The Translational fellows program is scalable and can be exported to other CTSA sites. It fits well as a "wrapper" for the i-Corps@NCATS program we have utilized.

### **Integration with Other CTSC Components and CTSA Hubs**

Partnering with UAB and Penn State CTSA's we have developed and refined training for health care entrepreneurs.

**CTSC Research Methods Hub: Biostatistics and Epidemiology Research Design (BERD) and Regulatory Knowledge and Support (RKS)**

**BERD**

Lead: Jennifer Gassman, PhD

Co-Leads: Curtis Tatsuoka, PhD and Doug Gunzler, PhD

**RKS**

Co-Leads: Phillip Cola, PhD; Joan Schenkel, MS; Joan Booth, RN

**Accomplishments**

**BERD:** Our BERD team site leads Drs. Gassman (CCF), Tatsuoka (CWRU), and Gunzler (Metro) have worked with biostatisticians and epidemiologists at their cores to educate and assist Cleveland investigators as they develop their grant proposals. Over Years 1 to 3, the Cleveland BERD has provided support for more than 616 grant submissions developed by 518 investigators at our CTSC institutions. A total of 378 grants have been funded with BERD investigators as co-investigators. The majority of these protocols required help with study design and led to grant applications. Some protocols included assistance with observational studies, the use of mixed methods (quantitative and qualitative) designs, health services and outcomes research in public health, medical decision-making, behavioral health, structural equation modeling, and electronic health records-based clinical research. Of the protocols that BERD supported members have assisted on in previous years, at least 378 have received funding. Not all funded grants are known as this metric is difficult to track.

Representative awards (>\$1.5 Million, chronological order) include:

DRL 1561716 (Tatsuoka, PI), 8/01/16 - 7/31/21

NSF (Brain Initiative) Cognitive and Neural Correlates of Mathematics Problem Solving Using Diagnostic Modeling and Dynamic Real-Time MRI, Total award \$1,500,000, Role: Principal Investigator

NIH/NINDS R01NS073717 (Alberts, PI) 05/15/2019 – 04/30/2024

Cyclical Lower Extremity Exercise for Parkinson's Trial (Cycle Trial), Total award \$3,016,817, Co-investigator: Imrey

NIH/NIAMSD R01AR075422 (Li and Spindler, PIs) 07/16/2019 – 06/30/2024

Imaging post-traumatic osteoarthritis 10-years after ACL reconstruction: a multicenter cohort study with quantitative MRI, Total award \$3,167,370, Co-investigator: Obuchowski

NINDS 1R01NS118760-01 (Chen, PI) 7/1/20-6/30/25

Peripheral Tissue Biomarker for Premortem Diagnosis of Lewy Body Dementia, Goal: Using novel skin-based assay to diagnose Lewy Body dementia, Total award \$5,481,760, Co-investigator: Tatsuoka

1R01AA028190-01A1, 09/25/2020 - 07/31/2025, Cleveland Clinic, Co PIs Srinivasan Dasarathy, MD & Laura Nagy, PhD, NIH, Novel mechanism-based treatment to improve tissue injury in alcoholic hepatitis, \$2,781,167 Co-investigator: Gassman

Pediatric Populations Focus:

Cleveland Clinic Co-PIs Amit Anand, MD & Tatiana Falcone, MD, NIH, 1R01MH125214-01, 09/15/2020 - 08/31/2024, Ketamine Treatment of Youth Suicide Attempters for Fast Reduction of Severe Suicide Risk and Facilitation of Long-term Collaborative Clinical Engagement, statistician Bo Hu, \$2,493,320

COVID-19 Focus:

#1 NCI 1 U01 CA260539-01 (King, PI) 9/30/20-9/30/25

Early Drivers of Humoral Immunity to SARS-CoV-2 Infections

Total award \$4,006,843, Co-investigator: Tatsuoka

U01 CA260513 (Zidar, PI) 9/30/20- 8/31/25. Pre-exposure Immunologic Health and Linkages to SARS-COV2 Serologic Responses, Endothelial Cell Resilience, and Cardiovascular Complications: Defining the mechanistic basis of high risk endotypes, Total award \$3,982,535, Tatsuoka Role: Statistician

NCI 1 U01 CA260513-01 (Frank and Zidar, PIs) 4/1/21-3/31/26. Pre-exposure Immunologic Health and Linkages to SARS-COV2 Serologic Responses, Endothelial Cell Resilience, and Cardiovascular Complications: Defining the mechanistic basis of high risk, Total award \$4,007,423, Co-investigator: Tatsuoka

Protective role of naturally acquired and vaccine-induced sIgA antibodies in COVID-19. Joint supplement for grants U01 CA260539 (PI: King, CWRU) and U54 CA260582 (PI Oltz, Ohio State) was funded. Start date: 9/19/21. Amount unknown

Additionally, BERD statisticians have worked on major center grants:

- Systolic Blood Pressure Intervention Trial (SPRINT) Study, NHLBI, HHSN 260200900049C (Jackson Wright, PI) 9/1/2009-3/31/2020 Tatsuoka and Chen Roles, Statisticians (\$23,040,298)
- Cleveland Alzheimer's Disease Research Center, NIA, PI: Jim Leverenz, CCF. Tatsuoka Role: Statistician. \$15,400,000. 8/1/21-7/30/26.
- Center of Excellence P30: Impact of Substance Use on HIV, NIDA, PI- Alan Levine, Tatsuoka Role: Statistician \$16,000,000 12/1/21-11/30/26

Key COVID Publications

- Dalton JE Gunzler DD Jain V Perzynski AT Dawson NV Einstadter D Tarabichi Y Imrey P Lewis M Kattan MW Yao J Taksler G Berg KA Krieger NI Kaelber D Jehi L Kalra A. Mechanisms of Socioeconomic Differences in COVID-19 Screening and Hospitalizations. *PLOS ONE*. 2021. Accepted for Publication.
- Thornton DJ Dixon-Williams S Huml A Perzynski A Gunzler D Einstadter D. A Cross-Sectional Study of SARS-CoV-2 Vaccination Among Employees of an Urban Safety-Net Health Care System. *Annals of Internal Medicine*. 2021. Brief report available at <https://www.acpjournals.org/doi/10.7326/M21-1513#>.
- Tarabichi Y Watts B Collins T Margolius D Avery A Gunzler D Perzynski A. SARS-CoV-2 Infection among Serially Tested Emergency Medical Services Workers. Prehospital emergency care: official journal of the National Association of EMS Physicians and the National Association of State EMS Directors. 2020 Oct 30:1-7. doi: 10.1080/10903127.2020.1831668. Online ahead of print. PMID: 33026286. BERD Statistician Doug Gunzler.
- Margolius D Hennekes M Yao J Einstadter D Gunzler D Chehade N Sehgal AR Tarabichi Y Perzynski AT. On the Front (Phone) Lines: Results of a COVID-19 Hotline in Northeast Ohio. *Journal of the American Board of Family Medicine*. 2020 (Online ahead of print: [https://www.jabfm.org/sites/default/files/COVID\\_20-0237.pdf](https://www.jabfm.org/sites/default/files/COVID_20-0237.pdf)). PMID pending. BERD Statistician Doug Gunzler.

**RKS:** (A) A certificate program was launched entitled FDA Regulation in Entrepreneurship and Clinical Research Management as a joint program at the CWRU School of Medicine and the Weatherhead School of Management at CWRU. The initial cohort enrolled 42 students for a 10-week course. The goal of this course is to provide foundational knowledge in and understanding of moving technology through the FDA approval process. The course includes a series of instructors, including both local experts as well as nationally renowned experts in FDA regulation, law and management. (B) An online Healthcare Master's in Business Administration (MBA) was launched in Fall 2021 at the Weatherhead School of Management at CWRU with scholarships available for individuals located at all CTSC institutions. The program targeted 25 enrollees in Fall 2021 and 27 students were enrolled. A Spring 2022 cohort is expected to enroll another 25 students. (C) At UH they revised their COVID-19 change forms/bio-repository request forms and developed a COVID leadership committee to review COVID submissions for appropriateness and utilization. (D) The citywide CTSC Regulatory Steering Group and held two meetings over last year, engaging 25 clinical research professionals across our partner institutions. (E) Throughout the CTSC a comprehensive review of Clinical Trial.gov requirements and responsibilities were held internally over the last year. (F) The Institutional Review Board Advisory Committee (IAC) meets quarterly and includes all CTSC partner institutions. This group is dedicated to harmonizing IRB processes to advance translational research more effectively and efficiently.

## Accomplishments that link to the overarching aims/goals of our CTSA hub

**BERD:** The BERD's activity of assisting research investigators on research proposals is directly part of the CTSA's Aim 1: Engage all C/T science stakeholders, the workforce, patients and community members to collaborate locally, regionally, and nationally, to advance human health. The BERD's teaching and mentoring efforts are linked to the CTSA's Aim 2: Develop and cultivate the current and next generation C/T research workforce, with special focus on preparation for team science and increasing the diversity of the workforce. As noted, over Years 1 to 3, the Cleveland BERD has provided support for more than 616 research protocols developed by 518 investigators at our CTSC institutions. A total of 378 grants have been funded with BERD investigators as co-investigators. BERD members have continued to train clinical investigators at both the pre- and post-doctoral level. At the Cleveland Clinic, training for medical students attending the Cleveland Clinic Lerner College of Medicine of CWRU has included a semester long course in Clinical Trials (CMED 450) directed by Dr. Beck and co-taught by Drs. Beck and Gassman and others. Additionally, Drs. Gunzler and Tatsuoka have served on Thesis committees for multiple Ph.D. and Master's level students. Curtis Tatsuoka is doctoral advisor to 3 students, one in the Department of Population and Quantitative Health Sciences, one in the Department of Computer and Data Sciences, and one in the Clinical Translation Science program. Dr. Tatsuoka also teaches PQHS 450, Clinical Trials and Intervention Studies, Spring 2021 (with Loretta Szczotka-Flynn). Dr. Gunzler taught Introduction to Structural Equation Modeling with Health-related Outcome Measures with Drs. Adam Perzynski and Adam Carle) as a half day course. American Statistical Association Council of Chapters Traveling Course, Course given to seven different local chapters (Central Arkansas, Northeastern Illinois, Nebraska, Montana, Kansas, Kentucky and Cincinnati) between May and November 2021. Approximately 45 attendees attended each lecture. The following were published:

*Structural Equation Modeling for Health and Medicine* (Chapman & Hall/CRC Biostatistics Series) by Douglas D. Gunzler, Adam T. Perzynski, et al. | Apr 12, 2021 ISBN 978-1138574250.

*Administration of Study Treatments and Participant Follow up in Principles and Practice of Clinical Trials*, Jennifer Gassman, Steven Piantadosi and Curtis Meinert, ISBN 978-3319526355, 2021

**RKS:** The launching of enrollment and courses for the FDA Regulation and Entrepreneurship class (A) and the Online Healthcare MBA (B) link to **Aim 2: Develop and cultivate the current and next generation clinical translational research workforce**; Optimization and prioritization of the review of COVID-related biorepository utilization and IRB review (C) and ClinicalTrials.gov continuous quality improvement for compliance (E) link to **Aim 4: Increase the quality and efficiency of clinical translational research, particularly multi-site trials, through innovative methods and processes and strong collaboration among CTSC hubs**; and CTSC Regulatory Steering Group (D) and the work of the IAC (F) link to **Aim 1: Engage all clinical translational science stakeholders, the workforce, patients and community members to collaborate locally, regionally, and nationally, to advance human health.**

## Services Provided to CTSC Investigators

**BERD:** As noted above, BERD collaborates with CTSC investigators to ensure use of optimal study designs and appropriate development of statistical analysis plans. After a study is funded, BERD members that are supported by the grant are actively involved to ensure the success of the study and help in the analyses and preparation of study results for publication. In the past year, 41 papers were published with BERD supported authors from studies previously assisted upon. BERD also assists investigators by giving many courses and seminars on statistical/epidemiological methods and research methods. Also, BERD members help mentor students and researchers, including KL2 scholars.

**RKS:** At UH, CC and Metro there have been restructuring of the Human Research Protection Programs to concentrate on adding additional staff specifically trained in reliant review mechanisms and working with Smart IRB. Each CTSC organization has also added new quality assurance and/or investigator support specialist positions to assist investigators with research compliance and related educational activities. At UH they revised and streamlined clinical trial participant recruitment forms to assist with subject recruitment into clinical trials. UH has also added transportation options throughout the community for participants making clinical trial visits to the academic medical center. At CC they have provided IND/IDE training specifically for sponsor



investigators and over 40 investigators in the past year have been trained. Additionally, CC developed a monitoring training program for FDA regulated trials and developed an enterprise clinical and translational quality assurance-training program. CC is in the beginning stages of developing a certificate program for research administrators.

Additionally, extensive on-line and interactive courses are offered to investigators each quarter across all institutions. See table below for just Year 3 – Quarter 4 data covering the period February 1, 2021 through April 30, 2021 relative to participants in the CTSC’s innovative investigator and research staff training programs.

<b>Expand delivery to on-line and interactive courses (Metric: # of participants trained, # courses offered)</b>	<b>CC Courses</b>	<b>Participants</b>
	Investigator Research Education	262
	Quality Assurance Training Program (Series of 9 classes)	442
	Workshops <ul style="list-style-type: none"> <li>• Clinical Research Billing Compliance</li> <li>• Creating a Budget for Competitive Funding</li> <li>• Data Safety and Monitoring Board</li> <li>• How to Start a Research Device Study</li> <li>• Informed Consent Document and Process</li> <li>• Investigational New Drug Regulations</li> <li>• Investigator Held IND Application and Reporting Requirements</li> <li>• Navigating Your Way into Clinical Research (2)</li> <li>• Required Training on NIH COI</li> <li>• Regulatory Document Essentials (2)</li> <li>• REDCap-Intro- Research Electronic Data Capture</li> <li>• REDCap-Intro-eLearning</li> <li>• Serious Adverse Event and Adverse Events</li> <li>• Source Documentation in Clinical Research Using EMR Data in Research</li> </ul>	251
	<b>CWRU/Metro/UH Courses</b>	<b>Participants</b>
	Eliciting the Patient's Experience of Illness through Narrative & Reflection	19
	Research Involving Vulnerable Populations	9
	Reshaping Research Module 1: What is Cultural Competency?	13
	Reshaping Research Module 2: Engaging the Community	22
	Reshaping Research Module 3: Cultural Considerations in the Informed Consent Process	3
Reshaping Research Module 4: Recruitment & Retention	0	

## Accomplishments/Solutions Scalable for Dissemination to the CTSA Consortium

**BERD:** Members train clinical investigators at both the pre- and post-doctoral level as well as medical students at CWRU and the Cleveland Clinic Lerner College of Medicine of CWRU. Courses and seminars are no doubt similar to those given at other CTSA hubs. Also, approaches to reaching out to and assisting investigators can be shared with other BERDs.

### Publications Citing UL1/KL2/TL1 in NIH's *iCite* Indicating "Translation"

- Variations in 24-Hour BP Profiles in Cohorts of Patients with Kidney Disease around the World: The I-DARE Study., Paul E Drawz, Roland Brown, Luca De Nicola, Naohiko Fujii, Francis B Gabbai, Jennifer Gassman, Jiang He, Satoshi Iimuro, James Lash, Roberto Minutolo, Robert A Phillips, Kyle Rudser, Luis Ruilope, Susan Steigerwalt, Raymond R Townsend, Dawei Xie, Mahboob Rahman, Clin J Am Soc Nephrol, 2018
- Implementation and Patient Experience of Outpatient Teleneurology., Lindsay Ross, James Bena, Robert Bermel, Lauren McCarter, Zubair Ahmed, Harold Goforth, Neil Cherian, Jennifer Kriegler, Emad Estemalik, Matthew Stanton, Peter Rasmussen, Hubert H Fernandez, Imad Najm, Marisa McGinley, Telemed J E Health, 2021

**RKS:** RKS members are collaborating with Regulatory Science Special Interest Groups for scalable projects, papers, policy and procedural revisions in collaboration with the CTSA hubs located at the Weill Cornell Medicine (specifically at Memorial Sloan Kettering Cancer Hospital), University of Utah, University of Rochester, University of Pennsylvania, University of North Carolina, University of Pittsburgh, Boston University, University of Cincinnati, University of Florida and Florida State University, University of Wisconsin on broad projects that include: 1) Emerging Technologies and their Application to Regulatory Science; 2) Regulatory Science and Precision Medicine Group; 3) Gathering Data Directly from Participants – Digital Health; 4) Knowledge Translation and Translational Science Impact; 5) Career Opportunities in Team Science; 6) IRB Policies for Efficiencies; 7) Drug Repurposing and Regulatory Methods; and 8) Educational Training for Regulatory Sciences.

## Integration with other CTSC Components and CTSA Hubs

**BERD:** BERD Co-leads are members of the ACTS BERD SIG which has monthly calls that discuss common issues and share best practices and organizes sessions at the annual Association for Clinical and Translational Science meetings. Gerald Beck, Jennifer Gassman, Douglas Gunzler, Stephen Ganocy and Curtis Tatsouka are members of ACTS BERD SIG and attend monthly conference calls as able; Dr. Gassman routinely participates in these calls. Dr. Gassman will continue to attend the Tuesday N3C calls as able. Douglas Gunzler will continue to provide innovative input as our representative on the national CTSA Methods and Processes Domain Task Force, as he has done since 2018. BERD members reach out to other CTSC components as necessary and are always open to them collaborating with us. In particular, Dr. Tatsouka has talked with Bioinformatics about common data elements and -omics data, and Douglas Gunzler has monthly meetings among CTSC leaders at MetroHealth to encourage collaboration within CTSC components and disseminate on CTSC activities. The BERD Lead and two Co-Leads participate in the Association of Clinical Translational Statisticians (ACTS) BERD SIG group to foster the goals of BERD components across the CTSA hubs. BERD Lead Gassman is working on a CTSC Supplemental U01 with investigators from five other BERD Cores. We also participate in the national CTSA Methods and Processes Enterprise Committee. DSMB Education CTSC Grant Application We have submitted a grant with six CTSA sites, co-PIs Heidi Spratt and Jody Ciolino and co-investigator Jennifer Gassman, to develop an infrastructure to educate potential DSMB members and create a core of available DSMB members, with a particular focus on biostatisticians who have never before served on a DSMB. DSMBs are not diverse. This project will increase diversity in DSMBs, enabling an increase of young female and minority members on DSMBs, which currently include more males than females and relatively few minority members. This will enhance inclusiveness in clinical research processes and help with future clinical trials. BERD Member Jennifer Gassman PhD. Cleveland Clinic. This Scored a 25 on its first submission. We have not yet received notification of funding, and a resubmission is planned so it will be ready to resubmit if it is not funded.

**RKS:** Both educational programs referenced in Section 1 above (i.e., the FDA Regulation in Entrepreneurship and Clinical Research Management and the online MBA) are recruiting student participants nationally. For example, the FDA certificate course was listed in the August 2021 CLIC Newsletter found at the link below: <https://mailchi.mp/05af33e3752f/clic-news-roundup-july2021-5673171?e=7f7e35ae47>. MBA information will be shared in the CTSA network also.

Additionally, CTSC RKS members present at national conferences on topics that are scalable and disseminated nationally to members of CTSA consortium sites. Representative presentations include:

Goff-Albritton, R., & **Cola, P.A.** (2021, April). Systematic Literature Review of Faculty Views on the Barriers and Facilitators to Grants Writing. National Organization of Research Development Professionals (NORDP). (Partnership with University of Florida and Florida State University Hub)

Campbell, C.A., **Cola, P.A.**, & Lyytinen, K. (2021, January). Factors Impacting the Influence of Analytics Capabilities on Organizational Performance in Higher Education Institutions. Hawaii International Conference on System Sciences (HICSS-54). Kauai, HI. (Partnership with Indiana University Hub – First author has moved from University of Indiana to Indiana State University)

**Pelfrey, C.M.**, Khatri, S.B., **Cola, P.A.**, Edgar B., & Gerlick, J.A. (2020, October). *Evaluation of a Leadership Development Program for Women Faculty*. American Evaluation Association (AEA) (Cleveland CTSC Hub)

**Cola, P.A.**, & Knapp Jack, K. (2021, August). Workforce Development: Research Job Families. *Research Administration in Healthcare Systems and Hospitals. Summer Intensive Training Workshop*. Society of Research Administrators International (Partnership with Weill Cornell Medicine Hub)

**Cola, P.A.**, Williams, M., Sikalis, A.J. (2021, July). The Research Enterprise in Hospitals and Healthcare Systems/Research Engagement. *Research Administration in Healthcare Systems and Hospitals. Summer Intensive Training Workshop*. Society of Research Administrators International (Partnership with University of Utah Hub).

**Cola, P.A.**, Titus, K., McHugh, V. & Lemke, T. (2021, May). What is COVID Changing in Clinical Research? Society for Research Administrators International (SRAI) Webinar (Partnership with University of Cincinnati Hub and University of Wisconsin Hub).

**Cola, P.A.**, & Knapp Jack, K. (2021, April). Beyond Collection and Storage: Considerations for Utilization of Bio specimens and Data. Society for Research Administrators International Webinar, Joint Section Meeting (Partnership with Weill Cornell Medicine Hub).

## Hub Research Capacity (HRC) Component

Lead: Wilson Tang, MD

Co-Leads: Grace McComsey, MD and Nora Singer, MD

### Accomplishments

HRC major accomplishments in Yr4 include:

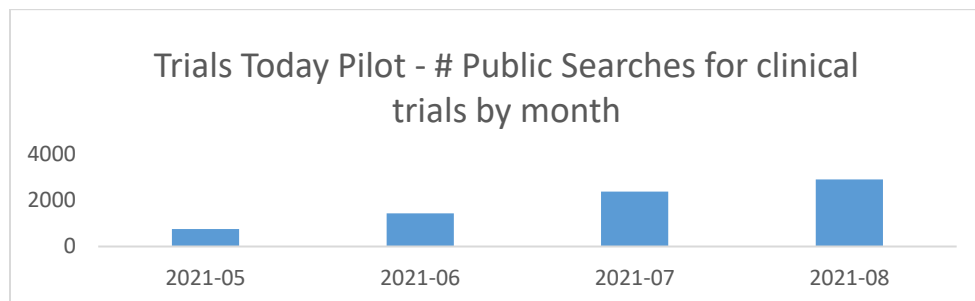
- Facilitated a city-wide “Recruitment of Special Populations” focus group with 25 attendees including ISP point persons (representing 13 different special population categories from all three hospitals) and CTSA staff. The 1.5 hour lively and engaged discussion was recorded and transcribed. The meeting’s video is hosted on the CWRU CTSC YouTube channel and promoted on the CTSC website.
- Redesigned and promoted the [CTSC website Clinical Resource section](#) to showcase new toolkits and tutorials for investigators and to support the navigation, start-up and project management of multi-center projects across the clinical research units. In this new CTSC Clinical Resource Section we:
  - Launched a new [Project Management CTSC webpage](#) with a new, 4-part “Intro to Clinical Trial Project Management” tutorial on the CTSC website and partner hospital’s websites to reinforce the study start-up process goal of “getting more studies to more patients more quickly”. Part 4 of the tutorial promotes both local Hub and national CTSA resources available to investigators.
  - Developed a shared CTSC website page with a [Multi-Site Study Start up Toolkit](#), including research roadmaps --a step-wise approach to study implementation -- to help navigate investigators more efficiently through the study start-up process.
- Formalized access to an expanded team of inter-institutional point persons for recruitment of special populations.

### Participant Recruitment Services (PRS)

- **92** requests for PRS recruitment services included: rare disease pediatric study, women's health study/rare disease, minority/pediatric healthy control, underserved population, IND children, minority/women healthy control. During the COVID-19 pandemic, PRS efforts have been largely focused on recruitment to COVID studies and the COVID biorepository.
- **2,145** subjects are now in the site-specific research subject registries that were developed and continue to grow (even during COVID). PRS matches subjects with difficult to recruit trials.

### Expansion of research into the community

- A new mobile clinical research unit bus has been launched to take research capabilities into community sites; the mobile unit has 2 exam rooms, bio-specimen processing and refrigerated storage capability.
- Clinical Research Nurses, Study Coordinators and lab personnel were scheduled into community sites and successfully enhanced recruitment into COVID-19 studies, trial conduct and community access.
- A new clinical trial finder (powered by the Vanderbilt CTSA’s “Trials Today” open-source CTSC search engine) was piloted to support physician and patient ease-of-access. The Number of searches performed by the public through this pilot has increased significantly since the beginning of Yr4 (May 1, 2021). See table, below:



## Accomplishments As They Link to the Overarching Aims/Goals of our CTSA Hub

Of these accomplishments, list those accomplishments that link specifically to the overarching aims/goals of our CTSA hub.

- The CTSC Hub Research Capacity supports the overarching Aims and Goals of our CTSA hub by ensuring quality oversight of clinical research and supporting investigators and study teams through the development and integration of collaborative and innovative education, methods, and processes throughout the discovery process.

### Services Provided to CTSC Investigators

HRC supports our organizations' ability to provide excellent clinical research facilities and expand the reach of the quality research environments beyond the clinical research unit by supporting investigators with recruitment services and by the ability to expand studies into the community. This allows more trials to reach more participants more quickly.

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

### Accomplishments/Solutions Scalable for Dissemination to the CTSA Consortium

Creation of a 4-part "Intro to Clinical Trial Project Management" tutorial – recorded PowerPoint presentation on CTSC website – available for dissemination and posted on the CTSC and hospital websites.

### Integration With Other CTSC Components and CTSA Hubs

HRC members attend a variety CTSA consortium webinars, forums, networks and working groups (i.e., Methods and Processes DTF webinars, DCRI NIH collaborative webinars, SC-CTSI forums, and TIN Network Liaison Team/Open Forum meetings). Internally, HRC attends quarterly Regulatory Knowledge and Support Core component meetings.

## Network Capacity Component

Lead: Kristie Ross, MD

### Accomplishments

**Network Capacity/Trial Innovation Network (TIN) continues to adapt to support the National TIN's processes and procedures, especially throughout the COVID-19 pandemic**, including rapid study evaluation, feasibility and PI identification. We prioritized operational efficiencies of TIN and NIH studies, including COVID-19 studies and other diseases.

As the COVID-19 pandemic has continued, the procedural and logistical structure of the TIN provided a solid infrastructure to help rapidly disseminate information, evaluate study feasibility and engage in unprecedented rapid startup of studies across the CTSC. The studies proposed by the TIN in Yr4 were primarily COVID-related, requiring rapid turnaround and a nimble infrastructure.

**Table 1** indicates the number of studies evaluated by Cleveland's CTSC from the Trial Innovation Network. Due to the ongoing COVID-19 pandemic in Yr4, there were fewer investigator-initiated studies proposed to the national TIN than in prior years. The national TIN organization focused on the unprecedented rapid onboarding of sites into NIH COVID-19 studies in Years 3 and 4 and created needed enhancements to the [trialinnovationnetwork.org](http://trialinnovationnetwork.org) dashboard and website.

<b>Table 1. Studies Evaluated from the Trial Innovation Network:</b>	<b>Y1</b>	<b>Y2</b>	<b>Y3</b>	<b>Y4 *to date (May 1-Oct 18-2021)</b>	<b>Total</b>
<b># of TIN/HEAL Studies Evaluated</b>	<b>15</b>	<b>20</b>	<b>12</b>	<b>4</b>	<b>51</b>
<b># of Responses to the TIN (breakdown below)</b>	<b>52</b>	<b>73</b>	<b>24</b>	<b>7</b>	<b>156</b>
# PIs Identified as interested	19	22	13	3	57
Electronic Cohort Responses	8	34	4	0	46
Budget Reviews	2	3	2	0	7
Feasibility Questionnaires	8	2	2	0	12
Protocol Reviews	15	12	2	0	29
<b># TIN studies started</b>	<b>3</b>	<b>2</b>	<b>2</b>	<b>4</b>	<b>11</b>
<b># TIN Studies Submitted</b>	<b>1</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>1</b>
# services received from the TIN	2	0	0	0	2

With the support of Network Capacity project managers, 2 CTSC partner institutions collaborated to apply for and were recently awarded a COVID [RECOVER grant](#) from NHLBI. RECOVER is a 5-year combined retrospective and prospective, longitudinal observational meta-cohort study to better understand, prevent, and treat persons with post-acute sequelae of SARS-CoV-2 infection (PASC).

All CTSC partner institutions continue COVID committees for the evaluation of scientific value, patient availability, operational feasibility and prioritization of COVID-19 studies. In addition, CTSC partner institutions have ever expanding COVID registries that can be utilized for future COVID studies.

### **New recruitment tools were developed and advertised to provide an innovative platform for recruitment:**

We successfully published, advertised and educated over 150 faculty and research staff on a) a pilot [‘Trials Today’ search engine](#) and b) a new, externally-facing [clinical trials web page](#). This has led to 7,694 clinical trial searches and 550 unique page views on the clinical trials web page since its inception. Trials Today offers a user-friendly, interface over ClinicalTrials.gov, allowing the community and visitors to search active and enrolling clinical trials in a seamless, institutionally-branded, website environment. This interface was selected primarily because does not require personnel time to maintain.

### **Accomplishments as They Link to the Overarching Aims/Goals of our CTSA Hub**

Of these accomplishments, list those accomplishments that link specifically to the overarching aims/goals of our CTSA hub.

Network Capacity supports the aims of our CTSA Hub, to facilitate the engagement of our workforce to collaborate, locally, regionally and nationally to advance human health and to increase the quality and efficiency of our research, especially through multi-site trials with innovative methods and processes.

### **Services Provided To CTSC Investigators**

Network Capacity provides support for multi-site and TIN studies for COVID-19 and others and linking investigators with support services of the local TIN Hub Liaison Team for streamlined contracting and study start-up. **For example**, the TIN POC served as a liaison to connect the physician-director of the MetroHealth School Health program with the NIH [ABC Science Collaborative project](#) via a TIN Expression of Interest. The TIN POC successfully assisted in contract negotiations by facilitating several meetings with the study team of the DCRI ABC Science Collaborative study and the local PI. As a result, school and community leaders in the **Cleveland Metropolitan School District** and **2 other Northeastern Ohio school districts (with >10,000 students)** have been with the most current and relevant information about COVID-19 using data from their own school districts and communities. This ongoing collaboration between the ABC Science Collaboration and the school systems, with the support of the local PI, prepares school and community leaders to make informed decisions regarding return-to-school policies based on scientific local data and supports school systems to enact policies to safely navigate the school year and keep their teachers, children and local communities safe.

### **Accomplishments/Solutions Scalable for Dissemination to the CTSA Consortium**

The **custom CTSC TIN REDCap Database**, is a modifiable and scalable tool with potential for consortium-wide dissemination. In Yr 4 we have added an “instrument” to the database that supports Project Management reporting of multi-site studies and introduced the CTSC Project Managers to this tool.

### **Integration with Other CTSC Components and CTSA Hubs**

**Collaborating with other CTSA Hubs:** The CTSC TIN POCs participate in monthly National TIN meeting webinars, TIN Open Forum webinars and surveys from the National TIN. PRS and PMs regularly engage with the national RIC online discussions and RIC/TIN webinars. The TIN POCs also attend Peer-to-Peer Point of Contact (POC) meetings led by the Medical University of South Carolina, involving POC representatives from 8 other CTSAs to discuss TIN processes, update and clarify information from the national TIN and share ideas for managing multi-site trials.

**Collaborating with other CTSC Components:** The TIN continues to regularly interact with the CTSC **Informatics Core** to coordinate data pulls for intra-institutional feasibility, provides CTSC-wide updates and meets quarterly with **Hub Research Capacity Core** and **Regulatory Knowledge and Support Cores**.

## Institutional Career Development – KL2 Program

Principal Investigator: Raed Dweik, MD

### KL2 Accomplishments/Solutions Scalable for Dissemination to the CTSA Consortium

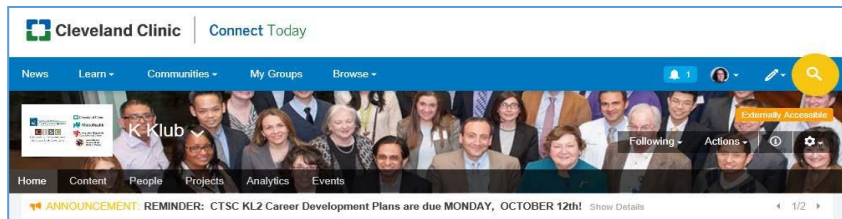
**K Klub** The K Klub was designed to provide a regular forum for exchange and to help compensate for the reduced number of scholars (from 16 to nine). The K-Club sustains the cohesiveness of the scholars' experience at the CTSC institutions and to provide a sense of participation in a diverse, multidisciplinary, scientific environment. The K-Club provides different levels of involvement, including:

- Individuals seeking to apply for a K or already enrolled in a post-doctoral TL1 program (pre-K).
- Individuals who have already received individual K awards (K23, K08, K99, etc.),
- Individual who has recently successfully transitioned from a mentored (K, award) to independence (post-K)

#### Current K Klub Participants:

Amy Attaway, MD:	K12 Pulmonary Medicine, COPD and muscle health
Rebecca Anderson, PhD:	TL1 Post-Doctoral Fellowship (CTSC TL1): Cancer Biology
Luke Bury, PhD:	TL1 Post-Doctoral Fellowship (CTSC TL1): Neuroscience
Ignazio Cali, PhD:	K99/R00 Research Scientist: Alzheimer's disease
Katie Heinzinger, DO:	T32 Supporting Multidisciplinary Achievement in Respiratory Research Training
Erica Orsini, MD:	T32 Supporting Multidisciplinary Achievement in Respiratory Research Training
Animesh Tandon, MD:	K23 Pediatric Cardiology
Wayne Tsuang, MD:	K23 Improving Access to Lung Transplant
Agustin Vicente-Gonzalez, PhD:	T32 Kidney Genomics
Andrea Waksmunski, PhD:	TL1 Post-Doctoral Fellowship (CTSC TL1): Genetics & Genome Sciences

**Connect Today** is a virtual platform, set up as a private group, established for K Klub members to connect, comment, ask questions, share materials / information, and start / participate in conversations.



**RCR:** July 2021 Kurt Stange, MD PhD: Transdisciplinary Collaboration with a Research Group and Community Practices  
September 2021 John Sedor, MD: Peer Review  
November 2021 Janice Crow, Council: Data Use Agreements

**Scholar Seminar Series:** Semi-Monthly ➡ Scholar Presentations ➡ Guest Speakers ➡ Networking Elevator Speeches ➡ Leadership Interaction ➡ Collaboration

- expanded # of K Klub participants
- enhanced diversity of participants and their research areas
- increased leadership & Alumni presence

#### Writer's Accountability Group

Scholars meet at a designated time; indicate their goal for the next hour, stay connected virtually but silently work towards their goal. They come back together after the first hour to report back and report for a second hour. They hold each other accountable for their goals.



## Collaboration:

Leaders within the CTSA community and Elizabeth Pfoh, PhD (Scholar) wrote a paper: "Innovation in the time of the COVID-19 Pandemic: Focusing on the futures of post-graduate trainees." We believe that findings from the paper, particularly taking a hybrid approach to meetings and mentorship is scalable to the CTSA community.

## COVID-19

Elizabeth Pfoh, PhD (2020): "COVID-19 Is Associated with an Increase in Visits for Anxiety but Not Depression" Cureus: <https://pubmed.ncbi.nlm.nih.gov/34660000/>

## Awards, KL2 Alumni & Current Scholars (Year Matriculated)

Kavita Arora, MD (ALUM): named National Academy of Medicine Fellow

Jeffrey Claridge, MD (ALUM): President, The Eastern Association for the Surgery of Trauma

Mary Dolansky, RN, PhD (ALUM): Midwest Nursing Research Society (MNRS) Award: Outstanding Partnership for her work with The John A. Hartford Foundation and CVS MinuteClinic

Ruth Farrell, MD (ALUM): The impact of the emergence of COVID-19 on women's prenatal genetic testing decisions, *Prenatal Diagnosis* <https://doi.org/10.1002/pd.5902>

Heidi Gullett, MD (2020):

- 2021 Women of Note – Crain's Cleveland Business
- Family Medicine *Boundary Breaker*, by the American Academy of Family Physicians

Douglas Gunzler, PhD (ALUM):

- American Statistical Association Structural Equation Modeling workshops/tour re book *Structural Equation Modeling for Health and Medicine*

Vanessa Ho, MD (2019):

- Early Career Reviewer (ECR) for Surgery, Anesthesiology and Trauma Study Section

Chris Hubert, PhD (2019): Pediatric Relevant

- 3 Primary Author Manuscripts (3 last author): *Acta Neuropath.* *Comm*, *Translational Oncology* & *bioRxiv* (one of the published papers includes pediatric brain cancer research)
- CTSC Pilot Award: Therapeutic Targeting of Glioblastoma through WDR5 Inhibition

Robin Jump, MD, PhD (ALUM) (media): <https://www.mcknightsseniorliving.com/home/news/educating-or-taking-a-stand-associations-differ-on-approach-to-long-term-care-worker-covid-vaccination/>

Shanina Knighton, RN, PhD (2019) (media):

- <https://www.news5cleveland.com/news/continuing-coverage/coronavirus/local-coronavirus-news/changing-behaviors-not-vaccine-alone-will-help-put-pandemic-behind-us-doctor-says>
- <https://thedaily.case.edu/meet-the-faculty-and-staff-members-named-covid-19-champion-honorees/>
- [NCATS Council meeting presentation of research by Dr. Michael Kurilla](#)
- October 2021 Young Alumni Award, Frances Payne Bolton, Case Western Reserve University
- July 2021 (Notified) National Institute on Aging Loan Repayment Program Awardee, National Institutes of Health
- July 2021 National Consultant on a CDC Grant: The National Network to Innovate for COVID-19 and Adult Vaccine Equity NNICE
- October 2021 Funding: New Venture Fund 2021 PIT-UN Challenge: Integrating Community Knowledge and Core Resources in a Graduate Certificate Program in Data Science for Social Impact (DSSI) at Case Western Reserve University. PI- Francisca Richter Role: Co-Investigator
- October 2021 Submission Pending Funding: National Institute on Aging Application ID: 1 R01 AG078273-01 Grant application titled 'Clean Hands Accessible and Manageable for Patients (CHAMPs): A technology-based self-management intervention to improve patient hand hygiene and reduce hand contamination among older adults.'
- October 2021 CTSA recognized as Most Valuable Personnel
- September 2021- MedPage Today's The Lab (new collaborative advisory board and help advise us on the most pressing issues impacting health and healthcare.)

Marisa McGinley, DO (2019):

- Collaboration with KL2 Elizabeth Pfoh, PhD (2020) to submit an abstract to the ACTRIMS Forum
- R01 submission with a UCSF collaborator and a CTSI statistician (Dr. Lazar)

Elizabeth Pfoh, PhD (2020):

- “Excellence in Research” Award from Cleveland Clinic Lerner College of Medicine
- Collaboration with KL2 Marisa McGinley, DO (2019) to submit an abstract to the ACTRIMS Forum
- Podium Presentation: Abstract: “Implementing Behavioral Health Social Workers Increased Mental Health Care

Among Older Adults” (Gerontological Society of America)

- CTSA: Integration Across the Lifespan Enterprise Committee

Grant Pignatiello, RN, PhD (2019):

- The Ohio Nurses Foundation Awards \$100,000 to Conduct Nurses Moral Injury Research: *A Study of the Well-Being of Ohio Nurses Who Have Cared for Patients During COVID-19*
- MNRS Award: Early Career Investigator

Melissa Pinto, PhD, RN (ALUM): (media) *Many ‘Long Covid’ Patients had no Symptoms from their Initial Infection*, NY Times

Andrew Reimer, RN, PhD (ALUM): MNRS Award Mid-Career Investigator

Daniel Rotroff, PhD (ALUM): New analysis of previous trial results offers insights into personalized care for Type 2 Diabetes, Diabetes Care

Seth Rotz, MD (2019): Pediatric Relevant

- 7 Publications (2 first author): J Thromb Thrombolysis, Pediatr Hematol Oncol, J Am Coll Cardiol CardioOnc, Pediatr Blood Cancer, Pediatric Blood and Cancer, Cancer Medicine, Blood Adv
- Kilic S, Guo B, Zavala J, Cherian S, Murphy E, Halima A, Magnelli A, Kolar M, Hanna R, Rotz S, Majhail N, Lu L, Cho Y, Xia P. Image-Guided Volumetric Modulated Arc Therapy for Total Body Irradiation: A Single Institution Experience. American Society for Radiation Oncology Annual Meeting, Chicago, IL, October 2021.

**Research Concierge Service:** This service is designed to connect researchers from all partner Institution’s with the resources necessary to conduct their research more effectively.

The types of services offered include: CTSC Resources, Research Process, Collaborator & Core Resources, Data and Safety Monitoring, Data Transfer and Data Use Agreements, Research Education

### **Integration with other CTSC components and CTSA Hubs**

The Cleveland CTSC hosted 3 KL2 Scholars, one each from University of Kansas, University of California, Los Angeles and Stanford University, through the CTSA Visiting Scholars Program. We also had one Scholar from our site who matched with the University of Pittsburgh. This program provided KL2 scholars the opportunity to serve as “virtual” Visiting Professors and give “CTSA Grand Rounds” at a host institution. The host institution was responsible for scheduling and hosting the scholar and the CTSA Grand Rounds and for scheduling meetings with faculty and the Scholars.

### **Un-Meeting March 2021**

In response to an RFA from the CTSA coordinating center, CLIC, to organize an Un-Meeting, our CTSA Hub was selected among several applicants to host “Tackling the Digital Divide to Improve Telehealth” on March 26, 2021. KL2 Scholar Marisa McGinley, DO was the PI for this well received program. The goal of the un-meeting was to identify the barriers and limitations of the current system to improve care delivery for patients. Over 100 participants, including 32 CTSA Hubs, interacted to further this field of research. Breakout sessions included *Telehealth in routine care and chronic conditions*, *Remote monitoring and objective testing*, *Payor and policy considerations*, *Telehealth and underserved areas*, *Aging, urban and minority populations*, *patient experience*.

## Clinical and Translational Scientist Training Program (CTSTP) – TL1 Program

Principal Investigator: Clifford Harding, MD, PhD

**Goal:** Our goal is to provide cutting edge clinical and translational research training for predoctoral and postdoctoral trainees to provide them with skills necessary for successful careers in clinical and translational research. We also aim to train a diverse set of researchers who will cumulatively possess broad skills to bring to the future clinical and translational research workforce.

**Curriculum:** The CTSTP provides predoctoral training to combined degree medical students in MD-PhD and nursing students in DNP-PhD programs. Two years ago, we added a new postdoctoral program. Postdoctoral training in clinical and translational research is now offered to trainees from three different applicant pools:

1. Research track residents/fellows who will obtain clinical/translational research training in the course of their research track residency/fellowship training.
2. Postdoctoral trainees who are seeking to add a PhD in Clinical Translational Research to their prior training (e.g., those with an MD degree who enter this PhD program).
3. Other clinical and translational research fellows who will be trained in clinical/translational research.

In addition to their individualized plans for research training and career development activities, the postdoctoral TL1 trainees participate in a subset of the KL2 career development activities offered by our KL2 program, linking these two CTSA programs and creating synergy. The predoctoral trainees will participate in research training and professional development activities of relevant graduate programs and those offered by the CWRU MSTP, as well as their individualized plans and CTSTP and CTSA-specific events. All trainees continue to receive training in responsible conduct of research and research rigor and reproducibility.

### **Progress:**

This grant currently has 8 predoctoral slots and 2 postdoctoral slots. There are two postdoctoral appointees in their first year of support on this grant, Andrea Wakmunski and Rebecca Anderson. Dr. Wakmunski is a clinical/translational research postdoctoral fellow in the Department of Population and Quantitative Health Sciences at CWRU School of Medicine (research mentor, Dr. Jessica Cooke Bailey, PhD). Dr. Anderson is a postdoctoral fellow at the Cleveland Clinic Foundation doing her research under the mentorship of Dr. Seth Corey, MD, MPH. Dr. Luke Bury is finishing his second year of support, under the direction of Dr. Anthony Wynshaw-Boris in the Department of Genetics and Genome Sciences. There are 8 predoctoral appointees in the current year, all of whom are in their first or second year of the program. These students are listed with their prospective PhD program of interest, but they have not fully committed to the particular PhD program. Biomedical Engineering: Christina MacAskill, Prerna Singh; Systems Biology & Bioinformatics: Paulameena Shultes; Neurosciences: Thomas Lavin, Benjamin Mittman, Hannah Zamore; Biochemistry: Henock Befekadu (URM); Molecular Virology: Olubukola Abiona (URM).

Trainees who are still in the program, either on the TL1 grant or still in their predoctoral program but having transitioned to another support source: There are 8 currently appointed MD-PhD trainees and 2 postdoctoral trainees, as listed above. We do not currently have a DNP-PhD student appointed to the grant, but that is a goal for the next budget period. COVID-19 has continued to disrupt our recruitment plans for that program, but we are planning recruitment with the new DNP-PhD Director, Dr. Joachim Voss, who started in that position in 2019. Trainees who are still in the CTSTP but supported by other sources: There are 23 MD-PhD students and 1 DNP-PhD student who are still in predoctoral training but have transitioned from TL1 support to another support source. An MD-PhD student is on leave pursuing an MBA, and a DNP-PhD student withdrew from the program.

Total trainees supported by this grant since inception: Since its inception in 2007, this program has supported a total of 87 trainees (81 predocs and 6 postdocs). In addition to the current trainees indicated above, the CTSTP has graduated from the program 42 students, 39 MD-PhD students and 3 DNP-PhD students; 6 students have withdrawn from the program (through October 2021). There are 4 postdoctoral graduates of the program.

Leadership Structure: The TL1 grant remains closely coordinated with the KL2 program (Dr. Harding serves as

Associate Director of the KL2 and Dr. Raed Dweik, PI of the KL2 grant, is an Associate Director of the TL1). Dr. James Spilsbury, Director of the Clinical Translational Science PhD program, Dr. Catherine Stein (Population and Quantitative Health Sciences), and Drs. Harding and Dweik constitute the executive leadership group for the TL1. Dr. Joachim Voss of the School of Nursing is the Director of the DNP-PhD program and our liaison to that program (starting in 2019); he is on the TL1 Steering Committee.

CTSTP Executive Committee:

- Clifford V. Harding, MD, PhD (CTSTP Director, CWRU SOM/UHCMC)
- Raed Dweik, MD (KL2 Director, CTSTP Associate Director, CC)
- James Spilsbury, PhD (CTSTP Associate Director, Co-Director, C/T Science PhD Program, CWRU SOM)
- Catherine Stein, PhD (CTSTP Associate Director, CWRU SOM)

Current TL1 appointees:

Predoctoral:

<b>Student</b>	<b>Undergraduate Institution</b>	<b>Area of interest</b>
Olubukola Abiona	University of Maryland - Baltimore County	Molecular Virology
Henock Befekadu	Carleton College	Biochemistry
Thomas Lavin	University of Maine	Neurosciences
Christina MacAskill	Case Western Reserve University	Biomedical Engineering
Benjamin Mittman	Hamilton College	Neurosciences
Paulameena Shultes	University of California - Berkeley	Systems Biology and Bioinformatics
Prerna Singh	Johns Hopkins University	Biomedical Engineering
Hannah Zamore	Bryn Mawr College	Neurosciences

Postdoctoral:

<b>Trainee</b>	<b>PhD or MD institution</b>	<b>Research Topic</b>
Rebecca Anderson	Northwestern University	Discovering New Treatment Options for Ewing Sarcoma
Andrea Waksmunski	Case Western Reserve University	From Community to the Clinic: Elucidating and Communicating Glaucoma Risk using Multidisciplinary Approaches

Student Progress

CTSTP trainees supported by our TL1 in the current budget year or a previous budget year who completed a PhD in 2020-2021 are listed below.

<b>Student</b>	<b>MD-PhD or DNP-PhD</b>	<b>PhD Program</b>	<b>PhD Mentor</b>
Uriel Kim	MD-PhD	Clinical Translational Science	Kurt Stange, MD PhD
Michael McHenry	MD-PhD	Epidemiology & Biostatistics	Catherine Stein, PhD
Peter Qiao	MD-PhD	Biomedical Engineering	Zheng-Rong, Lu, PhD

Students who completed the program in 2021 are listed below. These students completed the MD and PhD and entered residency training in strong programs that fit their clinical and research career goals. The mean time to completion of the program is 8.9 years for MD-PhD students graduating in 2021.

<b>Student</b>	<b>PhD Program</b>	<b>PhD Mentor</b>	<b>Residency Field</b>	<b>Institution</b>
Awuri Asuru	Systems Biology and Bioinformatics	Mark Chance, PhD	Psychiatry	Washington University - Barnes Jewish
Stevephen Hung	Genetics and Genome Sciences	Peter Scacheri, PhD	Pathology	George Washington University
Gloria Tavera	Clinical Translational Science	Scott Williams, PhD	Internal Medicine	University of California San Francisco

Minority student recruitment and progression: Trainees who are currently supported on the TL1 include 2 TGE URM students among 8 current predoctoral trainees and zero URM trainees among the two postdoctoral trainees. In 2021-2022 we have 10 TGE URM students out of a total of 32 current CTSTP students (those who are currently supported on the TL1 grant plus those who have been supported on our prior TL1 grant and are currently supported by other sources and still in training; not including one student on leave of absence; all CTSTP students are TGE). Thus, 2/10 (20%) of trainees currently on TL1 slots are URM (predoctoral and postdoctoral combined), and (10/32) 31% of trainees who are still in training are URM (trainees who are either currently supported on the grant or predoctoral trainees who have been supported on the grant and are still completing the program while supported from a different source).