WEST VIRGINIA UNIVERSITY PROGRAM EVALUATION AND RESEARCH CENTER

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The West Virginia Clinical and Translational Science Institute contracts the WVU Program Evaluation and Research Center to staff the WVCTSI Tracking and Evaluation Core and provide external formative and summative evaluation services pursuant to National Institutes of Health Award No. U54GM104942.

West Virginia Clinical and Translational Science Institute (WVCTSI) Tracking and Evaluation Quarterly Report

2nd Quarter of Fiscal Year 2019-2020 (Y8)

Reporting Period: October 1, 2019 - December 31, 2019

Statewide Distribution of WVCTSI Partner Organizations and Practice-Based Research Network Sites



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West Virginia Clinical Translational Science Institute Tracking and Evaluation Quarterly Report

(October 1, 2019 – December 31, 2019)

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WVCTSI Year 8 Dashboard

Metric		Year 8						
Period of Performance	7/01/2019 to 6/30/2020							
		Y8 Q1		Y8 Q2	Total	I	TARGET	
CTR-Linked Publications		24(8)		17(3)	41(11)		300	
Proposals Submitted (#)		54		75	129		225	
Subcategory: Proposals Submitted by ESIs		19		8	27			
Subcategory: Proposals Submitted by Clinicians		14		20	34			
Proposals Funded (#)		48		24	72		160	
Subcategory: ESIs-Proposals Funded		7		5	12			
Active		7		5	12			
New		3		4	7			
Subcategory: Clinician-Proposals Funded		20		13	33			
Active		20		13	33			
New		7		5	12			
Total External Funding Received (\$)		\$13.60		\$19.60	\$	33.20	\$40M	
Subcategory: Federal	\$	10.2	\$	1.9	12.1			
Subcategory: State	\$	1.6	\$	5.8	7.4			
Subcategory: Industry	\$	274,103.00	\$	11.7	11.9			
Subcategory: Other*	\$	1.6	\$	233,972	1.8			
Disclosures Submitted:	_						10	
Patent Applications								
Patents Awarded								
WVCTSI Membership		2,327		2,409	2409)	2,600	
Non-Morgantown		683		709	709		800	
Community Membership		229		219	219			
Investigators accessing WVCTSI services or resources	_							
(unique # per quarter)		240		227			800	

Executive Summary and Key Recommendations

This is the quarterly tracking and evaluation report of the WV Clinical and Translational Science Institute (WVCTSI) for the 2nd quarter (Q2) of fiscal year 2019/2020 (Y8), which covers a reporting period from October 1st, 2019 through December 31st, 2019. The WVCTSI received Y8 renewal notice of award dated August 28, 2019 with an annual award of \$4,000,000 for the budget period from July 1, 2019 through June 30, 2020 and a total project period from August 15, 2012 through June 30, 2022.

This report prepared by WVCTSI Tracking and Evaluation Core personnel is organized by specific aim within each key component area/core plus information from partner institutions as available. This report does not describe every tracking and evaluation metric in each core, rather key elements and recommendations are summarized and readers are referred to the Quarterly Data Sheet (Excel) distributed with this report for information on all metrics as reported by all cores and partners.

Considering top-line metrics for productivity and return on investment, there were 17 peer-reviewed

publications officially linked¹ to WVCTSI funding, 75 external funding proposals (\$88.4 million), and 24 funded awards (\$19.7 million) this quarter. The amount of external funding was up for a fourth consecutive quarter. While linking of publications lags real-time, the number of linked publications (41 year-to-date) is not on track for annual target and is a primary concern that must be addressed.

Overall recommendations from Tracking and Evaluation Core

- Increase number of publications linked to the WVCTSI NIH funding award;
- Implement a system leading to all WVCTSI members who generate scholarly publications having an active ORCID as part of their WVCTSI membership profile;
- Ensure transparent and consistent utilization of iLab across cores and partners with particular emphasis on action items agreed upon at May 29, 2019 WVCTSI Steering Committee meeting
- Continue to increase partner engagement outside of Morgantown; and
- Maintain focus on priority health areas when allocating resources and effort.

Key Recommendations to Administrative Core

- Increase number of publications linked to the WVCTSI NIH funding award.
- Implement a system leading to all WVCTSI members who generate scholarly publications having an active ORCID as part of their WVCTSI membership profile.
- Identify Year 8 annual targets for all appropriate metrics.
- Identify barriers to partner participation and engagement; work to increase membership and service utilization across partner sites.
- Make needed adjustments to allow timely provision to TEC of all quarterly evaluation information, including core contributions to publications, proposals, and funded awards. Key Recommendations to Clinical Research Design, Epidemiology & Biostatistics Core
- Identify barriers and work to increase service utilization across partner sites.
- Implement and report activity related to the Appalachian Research Consortium (ARC).

Key Recommendations to Clinical Research Resources & Facilities Core

- Review TriNetX study activation rates and drivers of current quarter increase compared to past performance on this metric. Determine whether additional action is warranted.
- Identify appropriate metrics for Specific Aim 2 and report data on those metrics in upcoming quarterly report cycles.

Key Recommendations to Community Engagement & Outreach Core

- Continue and expand efforts to disseminate research results through publication in high-quality journals and other outlets.
- Review progress toward annual targets for all metrics and consider necessary actions to accelerate those less than 50% accomplished at this time.

¹ Publications are officially linked if they appear in NCBI as published (excluding Epub ahead of print) and are associated with quarterly reporting periods based on their official NCBI publication date (not ahead of print date).

Key Recommendations to Pilot Projects Core

- Identify barriers and work to increase submissions of pilot project applications from partner institutions outside of WVU.
- Specific Aim 1 includes mentored support to bring projects to completion. Consider how this mentored support and project completion could be tracked.

Key Recommendations to Professional Development Core

- Identify year 8 annual targets for all appropriate metrics.
- Identify barriers and work to increase engagement with partner institutions outside of WVU Morgantown.

Key Recommendations to Technology and Resources for Core Laboratories Core

- Consider whether the number of open projects reported for Q2 is accurate, and if so whether action should be taken to increase that number in future evaluation periods.
- Consider opportunities to facilitate patentable projects.
- Continue to facilitate excellent collaborative relationships between CAMC, Marshall, and WVU

Key Recommendations to Tracking and Evaluation Core

- Support continued refinement of the publication reporting process, including identification of publications that should be linked to the grant
- Support continued refinement of partner dashboards and/or more integrative inclusion of partner evaluation data within appropriate core reports.
- Implement next steps for WVPBRN and ECHO evaluations.

Key Recommendations to Marshall University, National Institute for Occupational Safety and Health, Veterans Affairs Medical Centers, and West Virginia School of Osteopathic Medicine

- Identify year 8 annual targets for all appropriate metrics.
- Work to implement and/or increase utilization of iLab.
- Continue efforts to increase WVCTSI membership.
- Work toward increasing awareness and utilization of WVCTSI core services.
- Work with relevant cores to refine evaluation metrics and reporting within each core related to activity at specific partner institutions.

Quarterly Reporting Annual Timeline Targets

1st quarter Reporting Period = July 1 – Sept 30

Sept 18 1st quarter report task assigned to each KCA/Partner via email to key contacts

Oct 1 TEC begins data acquisition from repositories (e.g., iLab)
Oct 7 Quarterly data submission due from key contacts to TEC

Sept-Oct Pre/post submission meetings (TEC and key contacts)

Oct 28 1st quarter formative evaluation report and metric data distributed by TEC

Nov-Dec Steering Committee discusses 1st quarter formative evaluation

2nd quarter Reporting Period = Oct 1 – Dec 31

Dec 18 2nd quarter report task assigned to each KCA/Partner via email to key contacts

Jan 1 TEC begins data acquisition from repositories (e.g., iLab)

Jan 7 Quarterly data submission due from key contacts to TEC

Dec-Jan Pre/post submission meetings (TEC and key contacts)

Jan 28 2nd quarter formative evaluation report and metric data distributed by TEC

Feb-Mar Steering Committee discusses 2nd quarter formative evaluation

3rd quarter Reporting Period = Jan 1 - Mar 31

Mar 18 3rd quarter report task assigned to each KCA/Partner via email to key contacts

Apr 1 TEC begins data acquisition from repositories (e.g., iLab)

Apr 7 Quarterly data submission due from key contacts to TEC

Mar-Apr Pre/post submission meetings (TEC and key contacts)

Apr 28 3rd quarter formative evaluation report and metric data distributed by TEC

May-June Steering Committee discusses 3rd quarter formative evaluation

4th quarter Reporting Period = Apr 1 – June 30

June 18 4th quarter report task assigned to each KCA/Partner via email to key contacts

July 1 TEC begins data acquisition from repositories (e.g., iLab)

July 8 Quarterly report data due to TEC from each core

June-July Pre/post submission meetings (TEC and key contacts)

July 29 4th quarter formative evaluation report and metric data distributed by TEC

Aug-Sept Steering Committee discusses 4th quarter formative evaluation

Organizational Structura

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Administrative Core

Specific Aim 1. Implement an effective operational structure that facilitates attainment of all proposed WVCTSI Specific Aims and projects.

There were 75 external funding proposals (\$88.4 million) and 24 funded awards (\$19.7 million) during Y8 Q2 (see Figures 2 and 3). Four new staff were added to the ADMIN core, totaling 48 WVCTSI staff members.

Tracking and Evaluation Core pulled linked publications from NCBI utilizing all appropriate grant numbers to accurately identify which

publications should be considered linked to the grant in this and all previous quarters (see Table 1). Table 1 displays officially linked publications associated with each quarterly reporting period. Numbers in parentheses are additional publications with a current status of "ahead of print" that are expected to be linked to the grant at some point.

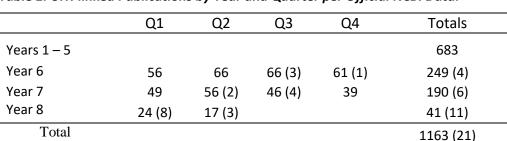


Table 1. CTR-linked Publications by Year and Quarter per Official NCBI Data.

Note: Numbers in parentheses are additional linked publications with a status of "ahead of print".

There were 17 publications officially linked to the grant (with an additional 3 ahead of print) in Quarter 2. Cores and partners contributed to the following number of linked publications each: 9 ADMIN, 5 TECH, 2 CRRF, 2 CEO, 2 CRDEB, 2 PD, 1 WVSOM, and 1 MU. These numbers do not sum to 17 because four publications included multiple contributing cores/partners (see Figure 1).

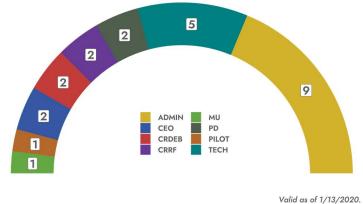


Figure 1. Contributions per core to WVCTSI linked publications during Quarter 2 (Year 8).

Year-to-date number of linked publications was 41 (with an additional 11 ahead of print). This remains a primary area of concern, especially given that the number of linked publications across the same time period in year 6 and 7 were 122 and 105, respectively; both more than double the number of linked publications for the current year-to-date.

In order to address the concern that WVCTSI may be supporting publications that are not being appropriately identified and linked to the grant, TEC pulled publications from appropriate library databases (e.g., PubMed) utilizing all names on the WVCTSI member list and limiting the search to

publications during the grant funding period. The resulting list (over 30k publications) was reduced by including only those publications with first author institutional affiliations in West Virginia. While the resulting list of 452 publications that may need to be linked is not likely exhaustive, ADMIN is contacting all first authors regarding whether their publication should be linked to the grant. TEC suggests that including an active ORCID as part of WVCTSI membership profiles will allow future pulls of publications by member list to be much more efficient and accurate.

External Funding Proposal Amounts by Core

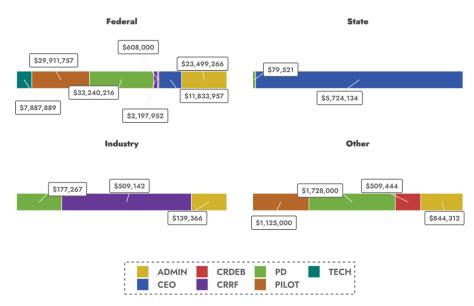


Figure 2. External funding proposals dollar amount requested and category per core.

External Funding Award Amounts by Core

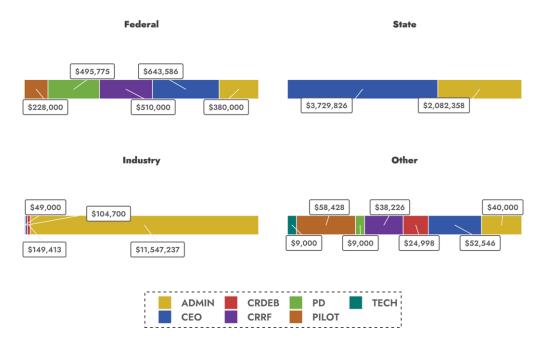


Figure 3. External funding awards dollar amount per core.

Specific Aim 2. Create policies and procedures to drive performance, transparency, constructive communication and collaboration among multiple, diverse stakeholders (i.e., investigators, rural providers, community members).

WVCTSI website traffic was unable to be tracked throughout the quarter due to an error with the servers, because of that the data only represents October through Dec. 6. WVCTSI's social media engagement continues to steadily increase: Facebook (+11 Likes and +353 follows), Twitter (+5 Followers), and Listserv (+112).

Specific Aim 3. Provide sound fiscal and resource management, ensuring appropriate resourcing of cores, flexibility to meet changing needs and environments, and sustainability of services.

As noted above, WVCTSI supported 75 external funding proposals and 24 external awards this quarter. Percentage of NIH award expended per core ranged from 16% to 46%, with two cost transfers/corrections reported this quarter.

Specific Aim 4. Recruit talented, committed investigators addressing research questions relevant to the WVCTSI priority health areas.

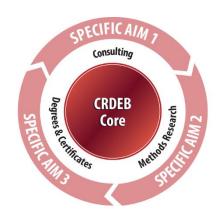
No Clinical Translational investigators were reported to be hired this quarter.

Key Recommendations to Administrative Core

- Increase number of publications linked to the WVCTSI NIH funding award.
- Implement a system leading to all WVCTSI members who generate scholarly publications having an active ORCID as part of their WVCTSI membership profile.
- Identify Year 8 annual targets for all appropriate metrics.
- Identify barriers to partner participation and engagement; work to increase membership and service utilization across partner sites.
- Make needed adjustments to allow timely provision to TEC of all quarterly evaluation information, including core contributions to publications, proposals, and funded awards.

Clinical Research Design, Epidemiology & Biostatistics Core Specific Aim 1. Effectively engage investigators throughout WV by providing traditional services in biostatistics and epidemiology.

Investigators engage through the CRDEB core utilizing available resources including the Integrated Data Repository (IDR), REDCap, and TriNetX. There were 61 new REDCap users in Q2 with a total of 1,782 REDCap users to date. Of the 1,782 REDCap users, 1,337 were from WVU (317 active), 16 from CAMC (5 active), 11 from WVSOM (4 active), and 418 not affiliated with the above entities (69 active).



Additionally, 30 minutes was spent updating existing REDCap projects and providing project follow-up meetings in Q2. 1 REDCap project was made for WVCTSI- funded investigators (annual target = 15) and 2 REDCap projects were made for non-WVCTSI investigators, 37.5 hours were spent building new REDCap projects for investigators, and 6 hours of REDCap consultations were reported in Q2. There were 98 new REDCap projects/data instruments (with a total of 2,204 projects/data instruments), and 69 new REDCap service inquiries. The total number of current TriNetX users was 312 in Q2 and there were 1811 new TriNetX inquiries, with 32 new TriNetX logins and no data set requests (annual target = 25). CRDEB reported no professional development events (annual target = 5) or practice/policy changes in Q2.

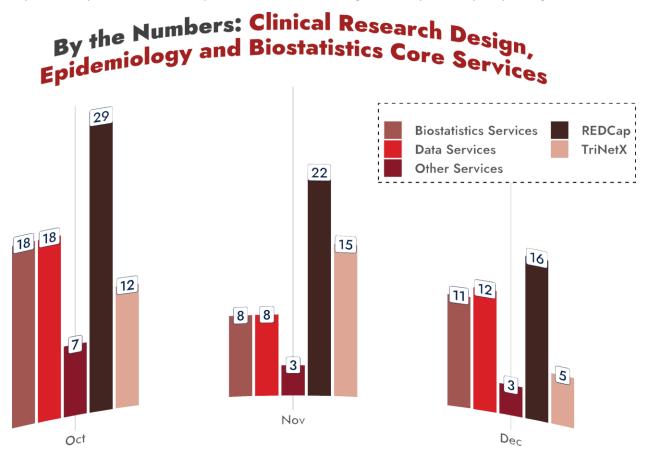


Figure 4. CRDEB iLab Core Management System services logged by month and service type.

Specific Aim 2. Implement cutting-edge tools and methods in biostatistics and epidemiology, with a particular focus on the needs of WV researchers.

CRDEB reported 64 BMIR-related inquiries, 28 new CRDEB consultations, 11 sample size/power consultations, 15 new statistical analysis consultations, and 16 new clinical study design consultations in Q2. Additionally, 369.25 hours were dedicated to biostatistics consultations. 2 GIS analysis consultations were reported for Q2.

Specific Aim 3. Disseminate current and classical information in biostatistics and epidemiology.

CRDEB had 4 supported external funding proposals in Q2 (totaling over \$1.1M and 2 externally funded awards (totaling \$174,411). CRDEB reported no presentations supported by WVCTSI and contributions to 2 linked publications.

Specific Aim 4². Leverage the newly enhanced Integrated Data Repository (IDR2) and partnership through the Appalachian Research Consortium (ARC) to facilitate outcomes research, predictive modeling, and geospatial analysis.

There were 23 new custom IDR dataset requests, 8 requests for updates to previous IDR datasets, and 20 IDR projects reported as completed in Q2. There were 418 hours spent on new data requests, 32 hours on updates to previous data sets, and 81.75 hours on data request consultation. CRDEB did not report any activity related to the Appalachian Research Consortium (ARC).

Key Recommendations to Clinical Research Design, Epidemiology & Biostatistics Core

- Identify barriers and work to increase service utilization across partner sites.
- Implement and report activity related to the Appalachian Research Consortium (ARC).

² CRDEB Specific Aim 4 was previously CRRF Specific Aim 2. This revision was specified by letter to NIH dated November 27, 2017 and subsequently approved.

Clinical Research Resources & Facilities Core

CRRF contributed to 4 external funding proposals (totaling over \$2.4 M) in Q2 including collaborations with ADMIN and CEO. CRRF received 5 external funding awards (over \$650,000) including collaborations with ADMIN, CEO, and PD. CRRF contributed 2 linked publications and reported no presentations. See Figure 5 for number of CRRF iLab service requests monthly across the reporting period by category.



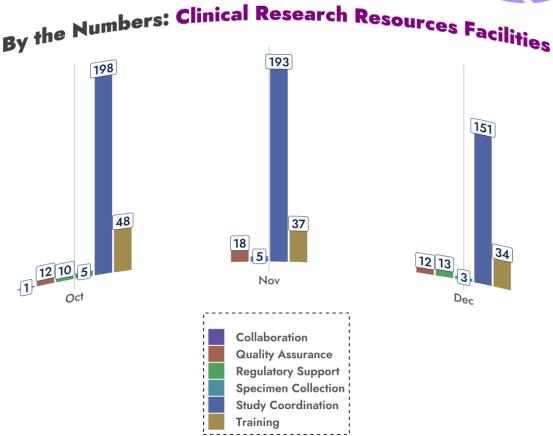


Figure 5. CRRF iLab Core Management System services logged by month and service type.

Specific Aim 1. Create a Clinical Trials Center of Excellence (CTCOE) with connection to rural communities and practitioners, thereby providing access to cutting-edge trials addressing health disparities affecting West Virginians.

CTCOE provided 99 unique instances of support to non-WVCTSI studies in the form of regulatory assistance (31), study coordination (21), accounting (45), or quality assurance audits (2) in Q2. Further, CRRF expanded their activities within the CTCOE to include Registration, a Risk Assessment Committee, and an Appeals Committee. Within those services, 15 trials were registered, and 5 trials were reviewed

and approved by the risk assessment committee. Additionally, CRRF supported 2 new Early Stage PI's with industry or WVCTSI-initiated funding in Q2. A total of 126 participants were recruited, with 50 completing a study. CRRF had 24 TriNetX study offers and 10 accepted offers, 8 studies (four times as many this quarter than in any other quarter) were activated this quarter.

Specific Aim 2. Establish the Environmental Exposures Unit to stimulate environmental health research in collaboration with the National Institute for Occupational Safety and Health (NIOSH).

While there has been some activity with NIOSH personnel, there have been no data reported on the Environmental Exposures Unit since the beginning of this funding cycle (2016).

Key Recommendations to Clinical Research Resources & Facilities Core

- Review TriNetX study activation rates and drivers of current quarter increase compared to past performance on this metric. Determine whether additional action is warranted.
- Identify appropriate metrics for Specific Aim 2 and report data on those metrics in upcoming quarterly report cycles.

Community Engagement & Outreach Core

Specific Aim 1. Actively engage patients and other community stakeholders as research partners.

There were 107 WVPBRN and 112 ECHO sites reported in Q2. This included 5 new ECHO sites: WVU Medicine Population Health, Bluefield Regional Medical Center, WV Prevention Research Center, Williamson Health and Wellness Center, and Community Liver Alliance. There was 1 new partner organization reported: South Texas Ambulatory Research Network (STARNet) and 1 CEO (non-ECHO) site reported.



During Q2, there were 2 networking opportunities: A Design Studio on 11/18/2019 about metabolic study/evaluation development and the Appalachian Addiction Conference. Additionally, there was 1 Community Advisory Board meeting on Colorectal Cancer Screening and Cervical Cancer Prevention, and 1 mentored investigator reported in Q2.

By the Numbers: Community Engagement Core

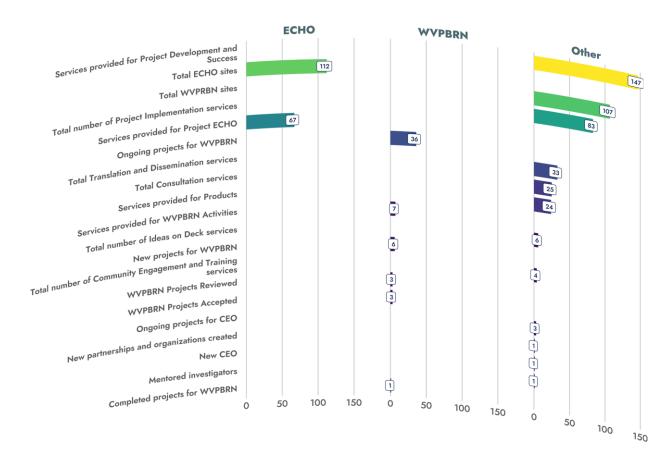


Figure 6. CEO core services logged by service type.

Specific Aim 2. Transform community-identified research questions into externally-funded projects that improve health outcomes in WVCTSI health priority areas.

There were 6 new, 36 ongoing, and 1 completed WVPBRN projects in Q2. There were 147 Project Development and Success services, 83 Project Implementation services, 4 Community Engagement and Training services, 6 Ideas on Deck services, 67 ECHO services, 25 Consultation services, 7 services for WVPBRN Activities, and 24 services for products reported during Q2.

CEO identified 3 funding opportunities and reviewed 3 WVPBRN projects, all of which were accepted. CEO also contributed to 13 external funding proposals (totaling over \$17.5M), 3 of which were in collaboration with other cores (Admin, CRRF, and both Admin & CRRF), and 6 externally funded projects (totaling over \$4.4 M, one of which was in collaboration with CRRF) in Q2. CEO contributed to 1 linked publication and no presentations were reported in Q2.

Specific Aim 3. Translate and disseminate research results to inform West Virginia health policy and practice.

In Q1 there were 33 Research Translation and Dissemination services provided. No CEO Project Policy Briefs were reported.

Key Recommendations to Community Engagement & Outreach Core

- Continue and expand efforts to disseminate research results through publication in high-quality journals and other outlets.
- Review progress toward annual targets for all metrics and consider necessary actions to accelerate those less than 50% accomplished at this time.

Pilot Projects Core

Specific Aim 1. Provide infrastructure supporting competitive pilot funding opportunities for early stage (ESI) and new investigators (NI) with subsequent mentored progression to project completion, publication, and external funding application.

Total number of pilot grant applications received in Y8 Q2 was 37 (28 Open, 3 Launch, 6 Small), 19 with ESIs. Thirty-three applications came from WVU, four came from MU, and there were none from any other institutional partner. No Pilot grants were awarded this quarter. The Pilot core provided 1 workshop and 27 consultations.



The Pilot core contributed to 1 publication this quarter and no presentations were reported.

Specific Aim 2. Advance collaborative research endeavors to address WVCTSI priority health areas within WV as well as throughout the Appalachian region.

Because no pilots were awarded this quarter, no projects addressing critical health issues received funding in Y8 Q2. However, the Pilot Core contributed to over \$33 million in external grant proposals and over \$280k in external grants awarded.

Specific Aim 3. Implement the Launch Pad Pilot Program to maximize opportunities for commercialization of novel science.

Pilots received 3 Launch grant applications in Y8 Q2 from 3 PIs from WVU, 2 of which were ESIs.

Key Recommendations to Pilot Projects Core

- Identify barriers and work to increase submissions of pilot project applications from partner institutions outside of WVU.
- Specific Aim 1 includes mentored support to bring projects to completion. Consider how this mentored support and project completion could be tracked.

Professional Development Core

Specific Aim 1. Create the Scientific and Career Success (SACS) program to provide access to formal mentoring for C/T researchers of all career stages.

A total of 227 users requested 403 services through iLab constituting 4,673 hours of service in Q2. There were 67 new investigator development service requests through iLab. There were 8 orientations or consultations provided to investigators new to WVCTSI. Additionally, there were 12 external active members in the



SACS program in Q2, as well as 5 female clinician scientists being mentored. There was 1 special event/program for women in science in Q2 entitled "FACTS: Conflict and Managing Difficult Conversations."

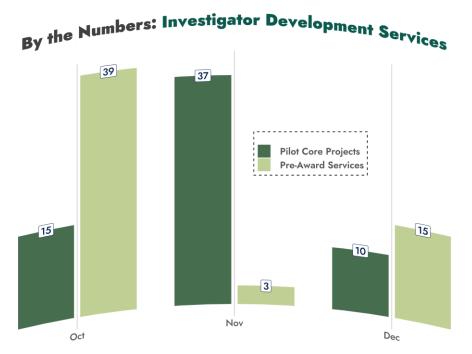


Figure 7. Investigator development services per service category as logged in iLab.

Specific Aim 2. Develop formal programs that serve as "on-ramps" to introduce C/T research to early or new investigators and trainees at different career stages.

The PD core reported mentoring 6 unique fellows/residents, 3 graduate students, 3 undergraduate students, and 1 full team meeting, as well as 4 professional development activities: 3 Works-in-Progress and a presentation of Gallup's Strength Assessment Training. Additionally, PD reported 5 other professional development activities related to Research Scholars. These included: (1) a presentation to Radiology Department on TriNetX, (2) a presentation to a P1 class on INTRO program, (3) An overview presentation of WVCTSI to Peds Department, (4) a presentation to MS1 & 2 on NIH Medical Research Scholars Program, and (5) a presentation to the Department of Family Medicine on WVCTSI.

There was 1 CTS Certificate application received and 8 CTS PhD students enrolled at WVU in Q2 (MU enrollment was not reported). Education programming reported no new academic courses or workshops and 2 C/T research seminars: (1) Conflict and Managing Difficult Conversations, and (2) Developing a Personal Statement for Your NIH Biosketch- Avoiding Gender Bias. These research seminars had a total of 22 unique participants, 19 of which were from WVU, 2 from MU, and 1 from WVSOM.

Specific Aim 3. Develop educational opportunities to support and retain externally funded C/T researchers statewide.

The Professional Development core contributed to 27 external funding proposals (over \$35 M total; 9 of which were collaborative with Pilots, Admin, and/or TECH cores) and 5 externally funded awards totaling more than \$500K, 4 of which were in collaboration with other cores (Pilots, TECH, CEO, Admin and/or CRRF). The Professional Development core reported 0 presentations supported by CTR Award and 2 linked publications.

Key Recommendations to Professional Development Core

- Identify year 8 annual targets for all appropriate metrics.
- Identify barriers and work to increase engagement with partner institutions outside of WVU Morgantown.

Technology and Resources for Core Laboratories Core

The Technology and Resources for Core Laboratories core contributed to external funding proposals totaling over \$7.8 million, and externally awarded funds of \$9,000 during Y8 Q2. TRCL contributed 5 publications during Q2, 2 of which were in collaboration with the ADMIN core.

Specific Aim 1. To establish a statewide biospecimen repository that collects patient and study participant samples in WVCTSI priority health areas (addiction and resultant emerging epidemics, cancer, cardiovascular disease, and chronic lung disease).



TRCL reported 1 WVCTSI-supported projects, with 0 new projects, and 1 open project this quarter. The number of open projects is considerably lower than typical. This marks the second quarter in which Biospecimen sample collection and utilization is fully collaborative. Biospecimen samples and utilization were reported for each affiliate institution: WVU, MU, and CAMC.

Specific Aim 2. To establish a statewide West Virginia University (WVU) - Marshall University (MU) genomics shared research facility for the efficient generation of genomic and related data for C/T studies that address WVCTSI priority health areas.

There were 3 total genomics studies (WVU and MU), 7 Illumina projects (MU), and 14 Illumina runs (MU) reported this quarter.

Specific Aim 3. To establish a statewide WVU-MU shared Bioinformatics and Data Management (BDM) Facility for C/T studies that address WVCTSI priority health areas.

Two educational sessions with 32 total attendees were provided.

Specific Aim 4. To establish state-of-the-art imaging in support of biologically relevant modeling of disease.

Good progress toward meeting annual targets for Imaging continued this quarter. At this rate, nearly all annual targets are expected to be met. However, two targets may require special attention, specifically, numbers of patents (0) and disclosures (0).

Key Recommendations to Technology and Resources for Core Laboratories Core

- Consider whether the number of open projects reported for Q2 is accurate, and if so whether action should be taken to increase that number in future evaluation periods.
- Consider opportunities to facilitate patentable projects.
- Continue to facilitate excellent collaborative relationships between CAMC, Marshall, and WVU

Tracking and Evaluation Core

Specific Aim 1. Develop Investigator Tracking and Support System (ITSS) utilizing quantitative and qualitative approaches to identify factors contributing to success or providing barriers to productivity.

TEC continued its efforts in communicating with key contacts to refine metrics for increased accuracy in reporting, with CRRF having the most significant updates. TEC was successful in identifying all publications linked to the WVCTSI grant number directly from NCBI.



TEC supported identifying publications potentially associated with the WVCTSI grant number. A list of potential publications was created this quarter and is currently being reviewed by other cores. This process will continue to be refined and expanded over future quarters. TEC continues to refine Social Network Analysis visualizations to show collaboration among authors on linked publications as well as geographic location. TEC distributed the Awareness Survey to over 20,000 individuals, both WVCTSI members and nonmembers, during Q2. This survey will close during Q3 with a full report to follow.

Specific Aim 2. Create and implement systematic set of tools and measurements to drive continuous quality improvement and demonstrate impact of community stakeholder participation and engagement.

TEC continued to work with CEO and ECHO on the ECHO "SuperHub" evaluation plan. During this quarter an interview protocol and instruments were developed and the IRB Protocol was approved. TEC helped in developing and disseminating several surveys for the Professional Development Core. The INTRO survey and Alumni survey were sent to the participants of those programs and reports were completed. TEC agreed to continue helping the PD core facilitate the completion of 6 surveys with corresponding reports. TEC continued to work with CEO related to WVPBRN network evaluation.

Specific Aim 3. Build focused research and evaluation demonstrating WVCTSI impacts on health outcomes in West Virginia.

The Tracking and Evaluation Report for the 1st Quarter of Y8 was disseminated in Q2 of Y8. Additionally, a TEC core member contributed to an NIH supplement designed with the following two specific aims: 1) describe community attitudes toward opioid use disorder and harm reduction services including syringe exchange, and 2) understand the multilevel syndemic factors that may contribute to development of opioid use disorder among young women for the purposes of informing future intervention studies. TEC's qualitative specialist continued to refine and analyze interview data. The ECHO research evaluation plan when completed will demonstrate impact on health outcomes.

Key Recommendations to Tracking and Evaluation Core

- Support continued refinement of the publication reporting process, including identification of publications that should be linked to the grant
- Support continued refinement and more integrative inclusion of partner evaluation data within appropriate core reports.
- Implement next steps for WVPBRN and ECHO evaluations.

Marshall University (MU)

MU, located in Huntington, WV in Cabell County, partners with the WVCTSI and is engaged in activities primarily related to



research and investigator development. The Joan C. Edwards School of Medicine at MU is a community-based, Veterans Affairs-affiliated medical school dedicated to providing high quality medical education and postgraduate training programs to foster a skilled physician workforce to meet the unique healthcare needs of West Virginia and Central Appalachia. The Joan C. Edwards School of Medicine focuses on developing centers of excellence in clinical care, including primary care in rural underserved areas, focused and responsive programs of biomedical science graduate study, biomedical and clinical science research, academic scholarship, and public service outreach. MU houses WVCTSI Associate Director, Dr. Gary Rankin.

For Q2, MU reported 1 peer-reviewed publication. MU submitted 28 external funding proposals and had 10 funded awards. MU worked collaboratively with many WVCTSI cores in Q2. Marshall PI's submitted 4 open grant applications, 2 Pilot Kick-off meetings, and 2 active pilot projects this quarter. The PD core provided 2 services for proposal development. TRCL core reported 6 biospecimen samples used by MU, as well as 172 biospecimen samples collected. MU reported 2 genomic studies, 7 Illumina projects, and 14 runs (Illumina sequencing lanes). MU currently has 45 (5 new) WVCTSI members.

West Virginia School of Osteopathic Medicine (WVSOM)

WVSOM, located in Lewisburg, WV in Greenbrier County, partners with the WVCTSI in activities related to research and community engagement. WVSOM focuses on educating students as lifelong learners in osteopathic medicine and complementary health related programs, supporting graduate medical education training, advancing scientific knowledge through academic, clinical, and basic science research, and promoting patient-centered, evidence-based medicine.



In Q2, WVSOM reported 1 peer-reviewed publication and 4 presentations, 3 of which were at the WV Rural Health Association annual conference. They submitted 4 funding proposals and received 2 awards this quarter. WVSOM recruited 2 investigators and has 2 WVCTSI funded pilot projects. No ESI's at WVSOM accessed WVCTSI services this quarter. In relation to the PD Core, WVSOM attended 11 workshops/courses/seminars/retreats and 6 posters/exhibits/promotional events in Q2. WVSOM provided 3 student opportunities for C/T research and had 1 student participate in summer research projects during Q2. WVSOM had 14 trainees in community-engaged research curriculum and 4 open collaborative CTS projects outside the WVPBRN. WVSOM housed 11 REDCap users (4 active). WVSOM membership increased by 8 members to a total of 79.

National Institute for Occupational Safety and Health (NIOSH)

NIOSH consists of a network of research facilities across the nation, including the Health Effects Laboratory Division (HELD)



located on the WVU campus in Morgantown, WV. NIOSH/HELD is a world-wide leader in the study of occupational lung diseases and actively collaborates with WVU. Several NIOSH researchers maintain joint appointments in departments at the Health Sciences Center, creating numerous research

partnerships in the area of occupational health, biostatistics, and epidemiology.

NIOSH contributed to a proposal for a trial of antifibrotic therapy for treatment of coal miners with PMF submitted to pharmaceutical company through WVCTSI. This proposal received positive reception and is currently awaiting final decision. In collaboration with the CRDEB core, NIOSH staff have become familiar with available WVCTSI resources such as the Integrated Data Repository and TriNetX allowing them to access these tools for their research. The PD core held a meeting at NIOSH to familiarize staff with WVCTSI. This created strong interest and resulted in at least one group meeting regularly in anticipation of developing a grant proposal. NIOSH membership remained at 10 members.

As reported previously, Dr. Erdely (NIOSH) and Dr. Hussain (WVU), who received WVCTSI funding to stimulate interactive research between NIOSH and WVU, submitted a NIH grant proposal and although they are within the funding range they are still awaiting final notification.

Veteran Affairs Medical Centers (VAMC)

Addition of the Veterans Health Administration (VHA) in WV as a partner in the WVCTSI is critical to improving health outcomes throughout the state. VHA



operated medical centers (Clarksburg, Huntington, and Martinsburg) participate in the WVCTSI. WV has one of the highest per capita percentages of veterans with over 9% of residents having served in the US Armed Forces, making this partnership even more significant.

The West Virginia Veterans Medical Centers continue to disseminate information related to WVCTSI to increase engagement and collaboration between Veteran Affair Medical Centers (VAMC) and WVCTSI. Email communication with local VAMC personnel continues to be used to increase awareness. To date, VAMC has 6 WVCTSI members, adding no new members during this quarter.

The VA continues engaging with WVCTSI via participation on the Advisory Board and the ESI Advisory Board and by providing educational information to key VAMC staff regarding WVCTSI services, as well as educational, and collaborative opportunities.

Charleston Area Medical Center (CAMC)

Charleston Area Medical Center (CAMC) did not report any quarterly evaluation data this cycle.

Key Recommendations to Marshall University, National Institute for Occupational Safety and Health, Veterans Affairs Medical Centers, and West Virginia School of Osteopathic Medicine

- Identify year 8 annual targets for all appropriate metrics.
- Work to implement and/or increase utilization of iLab.
- Continue efforts to increase WVCTSI membership.
- Work toward increasing awareness and utilization of WVCTSI core services.
- Work with relevant cores to refine evaluation metrics and reporting within each core related to activity at specific partner institutions.