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

4th Quarter of Fiscal Year 2018-2019 (Y7)

Reporting Period: April 1, 2019 – June 30, 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

(April 1, 2019 – June 30, 2019)

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Executive Summary

This is the quarterly tracking and evaluation report of the WV Clinical and Translational Science Institute (WVCTSI) for the 4th quarter (Q4) of fiscal year 2018/2019 (Y7), which covers a reporting period from April 1st, 2019 through June 30th, 2019. The WVCTSI received verbal approval for Y7 renewal funding dated July 23, 2018 with an annual award of \$4,000,000 for the budget period from July 1, 2018 through June 30, 2019 and a total project period from August 15, 2012 through June 30, 2022.

This report prepared by WVCTSI Tracking and Evaluation Core staff 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 for all cores and partners included.

There were 18 peer-reviewed publications officially linked¹ to WVCTSI funding, 46 external funding proposals (\$40.9 million), and 23 funded awards (\$9.2 million) this quarter. These numbers demonstrate productivity and return on investment. The amount of external funding was up for a third consecutive quarter. The number of linked publications (155+16 epubs ahead of print) did not reach the Annual Target of 300, but official linking of publications lags real time so these numbers are not final.

Overall recommendations from Tracking and Evaluation Core

- Identify Year 8 annual targets for all appropriate metrics;
- Work to revise core metrics such that partner activity is communicated clearly within each core;
- Ensure transparent and consistent utilization of iLab across cores and partners;
- 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

- 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.
- Continue to work with Tracking and Evaluation to clarify and streamline reporting of linked publications utilizing NCBI as official data source.

Key Recommendations to Clinical Research Design, Epidemiology & Biostatistics Core

- Identify Year 8 targets for all appropriate metrics
- 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

- Identify Year 8 targets for all appropriate metrics
- Review TriNetX study activation rates and determine whether action is warranted to facilitate accepted studies being activated in a timely fashion.
- Identify appropriate metrics for Specific Aim 2 and report data on those metrics in upcoming quarterly report cycles.

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 Community Engagement & Outreach Core

- Identify Year 8 annual targets for all appropriate metrics.
- Require iLab account creation and use of iLab for all service requests.
- Continue and expand efforts to disseminate research results through publication in high-quality journals and other outlets.

Key Recommendations to Pilot Projects Core

- Identify Year 8 annual targets for all appropriate metrics.
- Identify barriers and work to increase submissions of pilot project applications from partner institutions outside of WVU.
- Consider tracking proposals with ESIs separately from proposals without ESIs so that ESIs per institutional partner are specified.
- 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

- Identify year 8 annual targets for all appropriate metrics
- Continue to work with CAMC to initiate their participation in the Biospecimen program.
- Consider opportunities to facilitate patentable projects.

Key Recommendations to Tracking and Evaluation Core

- Support continued refinement of the publication reporting process
- Support continued refinement of partner dashboards and/or more integrative inclusion of partner evaluation data within appropriate core reports.
- Complete and implement system for reporting linked publications directly from NCBI.
- 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 guarter 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

Administrative Core (Admin)

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

There were 155 publications (18 in Q4) officially linked to the grant (with an additional 16 epubs ahead of print), 230 external funding proposals, 34 funded awards (\$33.11 million), and 3 provisional patents for Y7. The number of WVCTSI staff increased from 33 (Q1) to 43 (Q4). Y7 ended with a total of 618 iLab users. Of the 18 linked publications in Q4, Admin provided support for three.



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. Figure 1 displays an author network for Y7 linked publications where colors on nodes indicate the quarterly reporting period and colors on links denote which core contributed to each publication. Figure 2 displays geographic location of author institutional affiliations where darker colors indicate more publications in a particular locale. Figures 3 and 4 display core contributions to external funding proposals and awards, respectively.

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 began a membership audit during Y7 Q4 that will be completed Y8 Q1 so accurate membership numbers are not currently available. WVCTSI website traffic decreased by 38 average hits per day, and WVCTSI's social media engagement steadily increased across quarters in Y7: Facebook (Q4 +6 likes, Y7 +20), Twitter (Q4 +6 followers, Y7 +26), and Listserv (Q4 +105, Y7 +211).

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.

WVCTSI supported an average of 57 external funding proposals and 17 external awards per quarter. (see Figures 3 and 4). Percentage of NIH award expended per core for Y7 was reported as 100% in every core by Q4.

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

Two new investigators were recruited at WVSOM in Q4.

Key Recommendations to Administrative Core

- 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.
- Continue to work with Tracking and Evaluation to clarify and streamline reporting of linked publications utilizing NCBI as official data source.

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

	Q1	Q2	Q3	Q4	Totals	
Years 1 – 5					682	
Year 6	54	64	65 (4)*	59 (1)	242 (5)	
Year 7	48 (1)	51 (5)	38 (10)	18	155 (16)	
	102 (1)	115 (5)	103 (14)	77 (1)	1079 (21)	

Note: Numbers in parentheses refer to linked publications with a status of "epub ahead of print".

Year 7 WVCTSI Publication Network

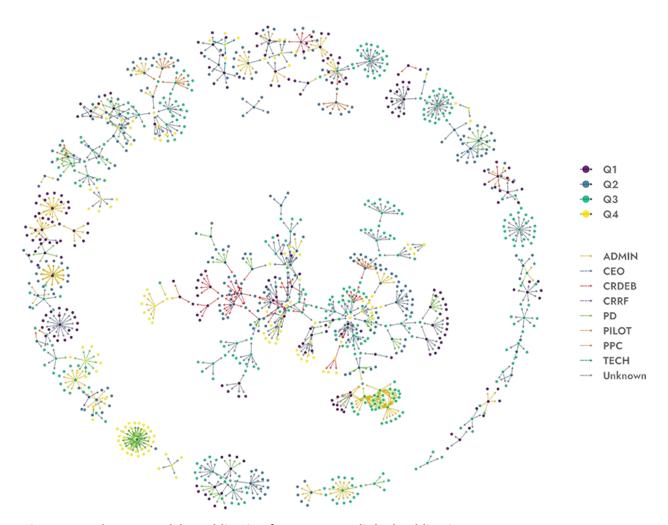


Figure 1. Author network by publication for Y7 WVCTSI linked publications.

WYCTSI Year 7 Author Affiliation

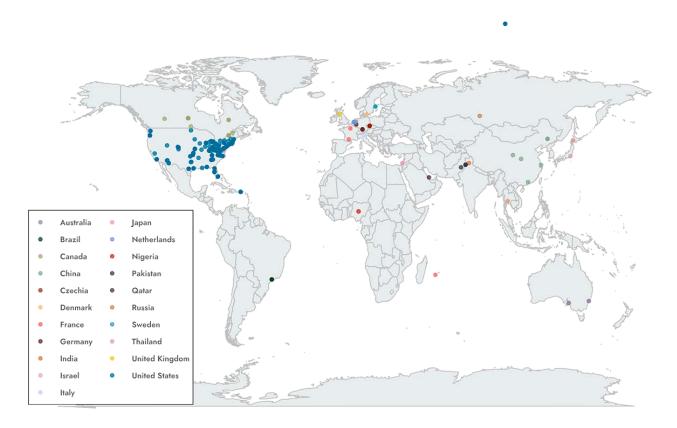


Figure 2. Geographic location of author institutional affiliations for Y7 WVCTSI linked publications.

External Funding Proposal Amounts by Core

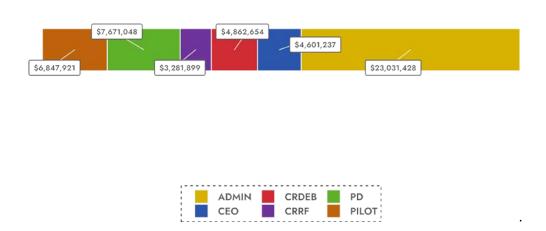


Figure 3. External funding proposals dollar amount requested and category per core.

External Funding Award Amounts by Core

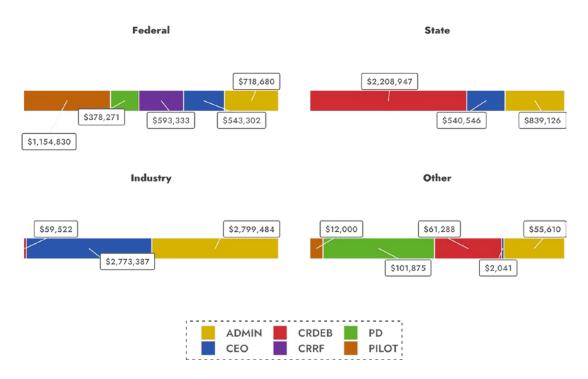
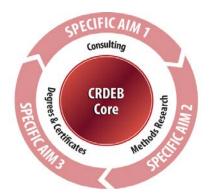


Figure 4. External funding awards dollar amount per core.

Clinical Research Design, Epidemiology & Biostatistics Core (CRDEB)

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 52 new REDCap users in Q4 bringing the total of new user number for Y7 to 235, just 5 short of the 240 annual goal; with a total of 1,635 RECap users for Y7. Of the 1,635



REDCap users, 1,232 are from WVU (surpassing the 1100 annual goal), 15 from CAMC, 12 from WVSOM, and 376 not affiliated with the above entities.

Additionally, 22.75 hours were spent updating existing REDCap projects and providing project follow-up meetings in Q4, more than doubling the Y7 annual goal of 15 hours. During Q4, 15.75 hours were spent building new REDCap projects for investigators, 129 new REDCap projects/data instruments, and 67 new REDCap service inquiries. The total number of current TriNetX users was 301 in Q4 (exceeding the annual goal of 300), and there were 883 new TriNetX inquiries (totaling 3,570 inquiries for Y7, almost double the annual goal of 2000), with 28 new TriNetX logins and 3 data set requests. There were 18 new unique CRDEB consultations in Q4, totaling 90 for Y7 surpassing the goal of 75. CRDEB reported 5 professional development events in Q4, which consisted of TriNetX demonstrations to Pharmacy, Anesthesiology, 2 to IRB, and one TriNetX-hosted webinar; totaling 14 events for Y7. CRDEB reported no practice/policy changes. Of the 18 linked publications in Q4, CRDEB provided support for four.

By the Numbers: Clinical Research Design, Epidemiology and Biostatistics Core Services

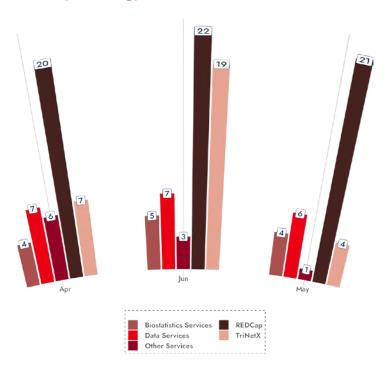


Figure 5. CRDEB iLab Core Management System services logged by month and service type.

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 47 BMIR-related inquiries, 9 sample size/power consultations, 9 new statistical analysis consultations, and 15 new clinical study design consultations in Q4. Additionally 192.25 hours were dedicated to biostatistics consultations. No GIS analysis consultations were reported for Q4.

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

CRDEB contributed to 4 of the 18 Q4 publications officially linked to the grant. CRDEB supported 5 external funding proposals in Q4 (\$4.9M), one of which was a joint effort with ADMIN (\$2.5M). Additionally, there was 4 externally funded awards (over 2.3M). During Y7 CRDEB contributed to 36 external funding proposals (\$121M) and 14 externally funded awards (\$1M).

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.

In Q4 there were 14 new custom IDR set requests, 4 requests for updates to previous IDR datasets, and 10 IDR projects reported as complete (bringing the total of completed IDR projects for Y7 to 54, surpassing the annual goal of 50). Hours spent on new data requests increased significantly with every quarter, adding 516 hours in Q4 alone (totaling 890 hours in Y7). 21 hours were spent on updates to previous data sets and 14.5 hours spent on data request consultations, both of which surpassed Y7 annual targets. CRDEB did not report any activity related to the Appalachian Research Consortium (ARC).

Key Recommendations to Clinical Research Design, Epidemiology & Biostatistics Core

- Identify Year 8 targets for all appropriate metrics.
- 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)

CRRF contributed to over \$113 million in external funding proposals, and \$2.56 million in externally funded awards for Y7. Of the 18 linked publications in Q4, CRRF provided support for one.

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.



CRRF made steady progress each quarter on nearly all metrics related to Specific Aim 1, resulting in meeting or exceeding all Y7 targets including several targets that were increased multiple times throughout the year. CTCOE provided 287 unique instances of support to non-CTSI studies in the form of regulatory, study coordination, accounting, or quality assurance assistance in Y7. Additionally, CRRF completed 7 quality audits and supported 13 new Early Stage PI's with industry or CTSI-initiated funding in Y7. A total of 1599 participants were recruited, with 607 completing a study. Although TriNetX offers and acceptance occurred throughout the year (76 and 32, respectively), only 2 of those studies were activated (both in Q1 of Y7).

By the Numbers: Clinical Research Resources Facilities

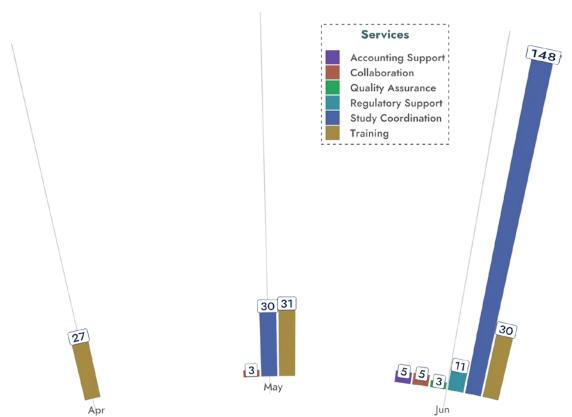


Figure 6. CRRF iLab Core Management System services logged by month and service type.

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

- Identify Year 8 targets for all appropriate metrics
- Review TriNetX study activation rates and determine whether action is warranted to facilitate accepted studies being activated in a timely fashion.
- Identify appropriate metrics for Specific Aim 2 and report data on those metrics in upcoming quarterly report cycles.

Community Engagement & Outreach Core (CEO)

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

The Community Engagement & Outreach Core ended Y7 with 95 WVPBRN sites, exceeding their annual target by 5, and 96 ECHO sites, exceeding that annual target by 16. During Q4, there were 5 networking opportunities, which included the WVCTSI Annual meeting, annual WVPBRN Retreat, WV Project ECHO Workshop, ECHO Policy Day in DC, and 3 people attending the North American



Primary Care Research Group WVPBRN Conference. Additionally, there was 1 Community Advisory Board meeting in Q4 bring the Y7 total to 3 with an annual target of 4.

While CEO core service tracking data was present in iLab, CEO indicated those numbers were not accurate because some services were provided to individuals who did not have iLab accounts. Tracking and Evaluation utilized metric data reported from CEO outside of iLab for this report, but strongly encourages more consistent and accurate service tracking in iLab for future reporting.

By the Numbers: Community Engagement Core

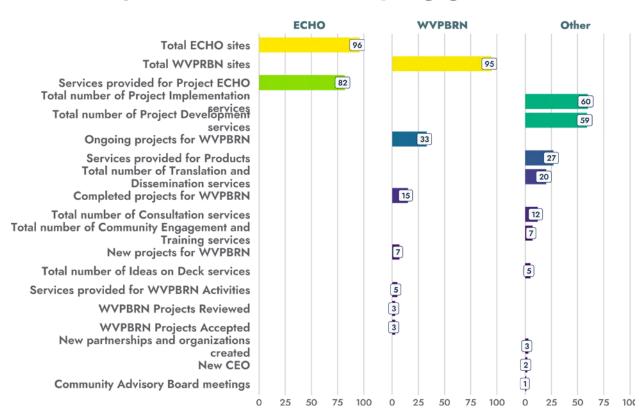


Figure 7. CEO core services logged by service type.

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

There were 7 new, 33 ongoing, and 15 completed WVPBRN projects in Q4, bringing the annual totals to 38 new and 33 completed. There were 59 Project Development services, 60 Project Implementation services, 7 Community Engagement and Training services, 12 Consultation services, 5 Ideas services (4 "on deck", 1 "to action"), 82 ECHO services, and 27 services for products were reported during Q4, each category surpassing their annual target with the exception of Ideas on Deck. CEO contributed to 6 external funding proposals (totaling \$4.4M), 4 of which were in collaboration with Admin and 1 in collaboration with PD, and 6 externally funded projects (totaling over \$3.8 M), five of which were in collaboration with Admin in Q4. During Y7, CEO contributed to 21 external funding proposals (totaling \$123M) and 10 externally funded awards (totaling \$4.7M).

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

In Q4 there were 20 Research Translation and Dissemination services provided in Q4. No CEO contributions to publications and no Community/Project Policy Briefs were reported in Q4.

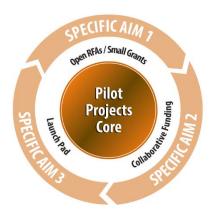
Key Recommendations to Community Engagement & Outreach Core

- Identify Year 8 annual targets for all appropriate metrics.
- Require iLab account creation and use of iLab for all service requests.
- Continue and expand efforts to disseminate research results through publication in high-quality journals and other outlets.

Pilot Projects Core (Pilot)

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 Open pilot applications received and awarded increased in Y7 (94 and 35, respectively) compared to Y6 (69 and 19). ESIs were PIs on fewer Open pilot applications this year (35) compared to Y6 (39), but received more awards (11 during Y7, compared to 6 for Y6). The total number of Pilot grants awarded



increased to 35 from 19 in Y6. Pilot grant applications and awards remain skewed toward PIs from WVU (See Table 2). The number of workshops provided remained the same across both years (7 total), with an increase in participants in Y7 (44 compared to 32 in Y6). Consultations also increased in Y7 (56 total) compared to Y6 (32). Of the 18 linked publications in Q4, Pilots provided support for one.

Table 2. Distribution of Y7 Pilot Awardees and Applicants by PI WVCTSI Partner Institution

	WVU	MU	WVSOM	NIOSH	CAMC	VA	Total
# (%)PIs awarded	29 (80)	4 (11)	2 (6)	1 (3)	0 (0)	0 (0)	36 (100)
# (%) PIs applying	77 (74)	17 (17)	5 (5)	0 (0)	4 (4)	0 (0)	103 (100)

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

The Pilot Projects Core reported funding 20 projects in Y7 that addressed critical health issues within WV including Addiction, Cancer, Cardiovascular Lung Disease, and Neuroscience. In Q4 the Pilot Core contributed to over \$37.6 million in external grant proposals, and over \$9.2 million (28% of all external funds awarded to WVCTSI) in external grants awarded for Y7.

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

Pilots reported providing funding for 2 Launch Pad projects in Y7; both PIs were from WVU.

Key Recommendations to Pilot Projects Core

- Identify Year 8 annual targets for all appropriate metrics.
- Identify barriers and work to increase submissions of pilot project applications from partner institutions outside of WVU.
- Consider tracking proposals with ESIs separately from proposals without ESIs so that ESIs per institutional partner are specified.
- 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 (PD)

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.

Of the 18 linked publications in Q4, PD provided support for nine. The Y7 ended with a total of 618 iLab users and a total of 2,337 services requested in iLab (572 in Q4). Of the 2,337 requests, 658 were investigator development service requests. A total of 140 new investigator development services were requested in Q4.



Additionally, there were 23 internal and 8 external active members in the SACS program in Q4, all of whom initially were reported in Q1. There were 2 special events/programs for women in science in Q4, which included "Invited Speaker: Understanding Hidden Codes" and the FACTS Breakfast at Annual Meeting, bringing the Y7 total to 11 (annual target = 10).

By the Numbers: Investigator Development Services

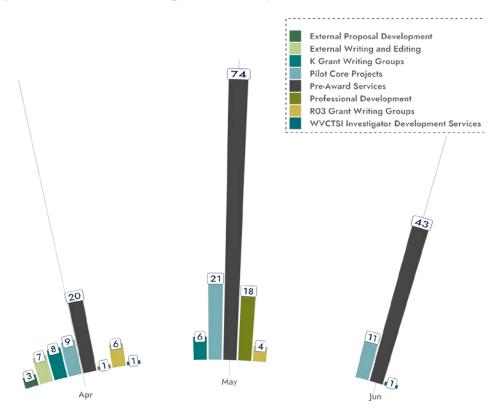


Figure 8. Investigator development services per service category as logged in iLab.

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.

There was 1 CTS Certificate program student, 15 WVU MS in CTS students, and 7 CTS PhD students enrolled in Q4. Education programming included 1 new academic course (titled, "Scientific Integrity"), 2 workshops/short courses with 19 unique participants originating from MU, and 1 reviewer training at the WVCTSI Annual Meeting (collaborative with Pilot Core).

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

The Professional Development core contributed to 11 external funding proposals (over \$7.6M total; 5 in collaboration with other cores) and 3 externally funded awards (\$480k total) in Q4. They contributed to 47 external funding proposals (\$22.5M) and 16 funded proposals (\$3.5M) throughout Y7.

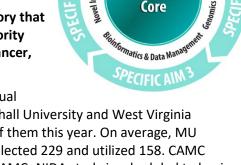
Key Recommendations to Professional Development Core

- 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 (TRCL)

The Technology and Resources for Core Laboratories core contributed to external funding proposals totaling over \$7.7 million, and externally awarded funds totaling over \$1.3 million during Y7. Of the 18 linked publications in Q4, TRCL provided support for one.

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).



cyate-wide Biospecimen Repository

Technology

Biospecimen sample collection began Y6 Q4. Nearly all Y7 annual targets for biospecimen projects were met or exceeded. Marshall University and West Virginia University collected a total of 1253 samples and utilized 765 of them this year. On average, MU collected 85 samples and utilized 32 per quarter, and WVU collected 229 and utilized 158. CAMC reported no sample activity throughout the year, however a CAMC -NIDA study is scheduled to begin next quarter (Y8 Q1). There were 54 projects initiated utilizing Biospecimens this year. 3 internal practice changes and 1 policy change were made Y7.

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 21 total genomics studies, 57 total Illumina projects, and 79 total Illumina runs reported by WVU and MU this year. All annual targets were met for MU, and targets for WVU ranged from 67% (i.e., Illumina runs) to exceeded (i.e., number of WVU WVCTSI genomics studies).

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.

A total of 319 participants attended 14 educational Bioinformatics workshops, exceeding this year's current annual target.

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

Nearly all Y7 annual targets related to Imaging were met, with the only exceptions being numbers of patents (0) and disclosures (0). A total of 40 WVCTSI investigators received imaging-related services. 55 educational sessions related to imaging were provided to 35 unique attendees. 16 MRI, 20 MicroCT, and 4 clinical research projects were reported for the entire year.

Key Recommendations to Technology and Resources for Core Laboratories Core

- Identify year 8 annual targets for all appropriate metrics
- Continue to work with CAMC to initiate their participation in the Biospecimens program.
- Consider opportunities to facilitate patentable projects.

Tracking and Evaluation Core (TEC)

Of the 18 linked publications in Q4, TEC contributed one and had 5 proposals accepted for presentation at the 2019 American Evaluation Association annual conference.

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 completed an iLab utilization study, and WVCTSI leadership agreed on action steps from their report following discussion of findings at the quarterly evaluation meeting. TEC continued its efforts in communicating with key contacts to refine metrics for increased accuracy in reporting, with CEO having the most significant updates. TEC's qualitative research methodologist consulted with an investigator on his K23 proposal. TEC continues to refine processes to identify and pull publications that are or should be associated with WVCTSI grant numbers directly from NCBI. TEC continues to refine Social Network Analysis visualizations to show collaboration among authors on linked publications (e.g., Figure 2). TEC in coordination with the Administration Core began development of a WVCTSI-wide Awareness Survey.

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.

During Q4, TEC and CEO met to discuss the ECHO "SuperHub" evaluation plan. 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 3rd Quarter of Y7 was disseminated in Q4. 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. In Q4, TEC's qualitative specialist collected 46 interviews and began the process of developing a scheme for qualitative data analysis.

Key Recommendations to Tracking and Evaluation Core

- Support continued refinement of the publication reporting process
- Support continued refinement of partner dashboards and/or more integrative inclusion of partner evaluation data within appropriate core reports.
- Complete and implement system for reporting linked publications directly from NCBI.
- 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 Q4, MU reported 1 peer-reviewed publication, totaling 3 for Y7. MU submitted 10 external funding proposals and had 5 funded, reaching a total of 30 submitted proposals with 15 funded (annual targets 10 and 5, respectively). MU worked collaboratively with many WVCTSI cores in Q4. Dr. Julie Lockman, Director, Investigator & Professional Development, offered an afternoon workshop dedicated to mentoring at MU. TRCL core reported 31 biospecimen samples used by MU, as well as 100 biospecimen samples collected. MU reported 2 genomics studies, 9 Illumina projects, and 11 runs (Illumina sequencing lanes). MU exceeded their annual target in biospecimen sample collections, genomics studies, and Illumina projects. They nearly reached their annual target for genomic runs of 60, reaching 59. MU exceeded their goal of 1 disclosure, with 2 for Y7.

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 Q4, WVSOM reported 10 external proposals and 1 funded award, reaching 19 proposals and 8 funded awards for Y7. 2 ESI's accessed WVCTSI services. By attending 9 workshops/courses/seminars/retreats and 8 posters/exhibits/promotional events in Q4, WVSOM totaled 21 workshops/courses/seminars/retreats and 15 posters/exhibits/promotional events for Y7. WVSOM provided 7 student opportunities for C/T research and had 5 students participate in summer research projects during Y7. At the end of Y7 WVSOM housed 12 REDCap users.

Charleston Area Medical Center (CAMC)

CAMC is a nonprofit, 908-bed, regional referral and academic medical center of four hospitals and home to one of the largest cardiac programs in the US, the only kidney transplant center in WV, and a level I trauma center. The



CAMC Health Education and Research Institute (CHERI) provides continuing medical education and research support to physicians and allied medical professionals. CHERI operates a nurse anesthesia school with MU as well as 13 graduate medical education residency/fellowship programs. CAMC sponsors pharmacy residency programs and psychology internships.

In Q4, CAMC attended 6 workshops/courses/seminars/retreats, reporting 13 workshops/courses/seminars/retreats for Y7. CAMC received 5 biostatistics consults, totaling 17 for Y7. CAMC received 5 Biostatistics consults, attended 5 journal clubs and 6 workshops/courses/seminars/retreats. CAMC had 66 residents participate in Research Day. CAMC ended the year with 16 clinicians and staff participating in WVCTSI sponsored research training programs and 16 students in summer research projects. At the end of Y7 CAMC had 15 REDCap users and 2 iLab users.

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 had 5 affiliates registered as WVCTSI principal investigators, one of which requested services during Q4. Dr. Erdely (NIOSH) and Dr. Hussain (WVU) received CTSI funding to stimulate interactive research between NIOSH and WVU. Goals of this proposal have been fully met and results have stimulated a NIH grant submission that received a score, which appears to be in the funding range. NIOSH and WVU are engaged in a collaborative pilot project "Occupational and Environmental Co-Exposures: Prospects of novel lung pathologies and drivers of chronic lung disease susceptibility" focusing on chronic lung disease. This project has an expected end date in Y8 Q1. NIOSH is currently collaborating with WVCTSI staff for a potential study with more details to follow in the coming quarters.

Veteran Affairs Medical Centers (VAMC)

Veteran Affairs Medical Centers (VAMC) 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.