

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 2019-2020 (Y8)

Reporting Period: April 1, 2020 – June 30, 2020

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



CAMC / WVU Charleston



Marshall University



West Virginia School of
Osteopathic Medicine



WV Veterans Affairs



National Institute for
Occupational Safety and
Health



West Virginia
University



WVU Medicine



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West Virginia Clinical Translational Science Institute

Tracking and Evaluation Quarterly Report

(April 1, 2020 – June 30, 2020)

Table of Contents

WVCTSI Year 8 Dashboard	3
Executive Summary and Key Recommendations.....	4
Quarterly Reporting Annual Timeline Targets	7
Administrative Core	8
<i>Table 1. CTR-linked Publications by Year and Quarter per Official NCBI Data.</i>	8
<i>Figure 1. External funding proposals dollar amount requested and category per core.</i>	9
<i>Figure 2. External funding awards dollar amount per core.</i>	9
<i>Figure 3. Contributions per core to WVCTSI linked publications during Quarter 4 (Year 8).</i>	9
<i>Figure 4. Author network by publication for Y8 WVCTSI linked publications.</i>	10
<i>Figure 5. Geographic location of author institutional affiliations for Y8 WVCTSI linked publications.</i> ...	11
Clinical Research Design, Epidemiology & Biostatistics Core	13
<i>Figure 6. CRDEB iLab Core Management System services logged by month and service type.</i>	13
Clinical Research Resources & Facilities Core	15
<i>Figure 7. CRRF iLab Core Management System services logged by month and service type.</i>	15
Community Engagement & Outreach Core	17
<i>Figure 8. CEO core services logged by service type.</i>	18
Pilot Projects Core.....	19
Professional Development Core	20
<i>Figure 9. Investigator development services per service category as logged in iLab.</i>	21
Technology and Resources for Core Laboratories Core.....	22
<i>Figure 10. Cumulative samples collected and utilized across collaborative sites. Dashed line indicates annual target for each site.</i>	22
Tracking and Evaluation Core	24
Marshall University (MU).....	25
West Virginia School of Osteopathic Medicine (WVSOM)	25
National Institute for Occupational Safety and Health (NIOSH)	25
Charleston Area Medical Center (CAMC).....	26
Veteran Affairs Medical Centers (VAMC)	26

WVCTSI Year 8 Dashboard

Metric	Year 8					
Period of Performance	7/01/2019 to 6/30/2020					
	Y8 Q1	Y8 Q2	Y8 Q3	Y8 Q4	Total	TARGET
CTR-Linked Publications	24 (8)	17 (3)	10 (3)	17 (1)	120 (8)	300
Proposals Submitted (#)	54	75	56	56	466	225
Subcategory: Proposals Submitted by ESIs	19	8	16	14	57	
Subcategory: Proposals Submitted by Clinicians	14	20	20	23	77	
Proposals Funded (#)	48	24	25	30	127	160
Subcategory: ESIs-Proposals Funded	7	5	2	2	16	
Active	7	5	0	2	14	
New	3	4	2	0	9	
Subcategory: Clinician-Proposals Funded	20	13	10	7	50	
Active	20	13	8	7	48	
New	7	5	2	5	19	
Total External Funding Received (\$)	\$13.60	\$19.60	\$5.6	\$9.5	\$ 48.3	\$40M
Subcategory: Federal	\$ 10.2	\$ 1.9	\$1.4	\$5.8	\$ 19.3	
Subcategory: State	\$ 1.6	\$ 5.8	\$3.4	\$3.0	\$ 13.8	
Subcategory: Industry	\$ 274,103	\$ 11.7	\$338,020	\$112,668	\$ 12.3	
Subcategory: Other	\$ 1.6	\$ 233,972	\$399,880	\$515,563	\$ 2.6	
Disclosures Submitted:	0	0	4	5	9	10
Patent Applications	0	0	4	5	9	
Patents Awarded	0	0	0	0	0	
WVCTSI Membership	2,327	2,409	2518	2669	2669	2,600
Non-Morgantown	683	707	739	772	772	800
Community Membership	229	184	191	198	198	
Investigators accessing CTSI services or resources (unique # per quarter)	240	227	221	195		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 4th quarter (Q4) of fiscal year 2019/2020 (Y8), which covers a reporting period from April 1st, 2020 through June 30th, 2020. 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 across all four quarters this year, there were 120 peer-reviewed publications officially linked¹ to WVCTSI funding, 466 external funding proposals (57 and 77 by early stage investigators and clinicians, respectively), and 127 funded awards (48.3 million). While linking of publications lags real-time, the number of linked publications (120 in year 8) continues to be a primary concern, especially in the context of 261 and 218 publications linked in years 6 and 7, respectively.

Overall recommendations from Tracking and Evaluation Core

- Identify Year 9 annual targets for all appropriate metrics in all cores.
- Continue and accelerate efforts to increase number of publications linked to the WVCTSI NIH funding award. This should include all WVCTSI members who generate scholarly publications having an ORCID ID 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.
- Maintain focus on priority health areas when allocating resources and effort.

Key Recommendations to Administrative Core

- Use Year 8 metric data in all metrics spreadsheet (Excel) distributed with this report to identify Year 9 annual targets for all appropriate metrics.
- Facilitate core and partner discussions and collaborative efforts to innovatively facilitate additional publications supported by and linked to WVCTSI NIH funding award.
- Implement and support participation in a system where all WVCTSI members who generate scholarly publications have an ORCID ID as part of their WVCTSI membership profile.
- Identify barriers to partner participation and engagement; work to increase membership and service utilization across partner sites.

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 Clinical Research Design, Epidemiology & Biostatistics Core

- Use Year 8 metric data in all metrics spreadsheet (Excel) distributed with this report to identify Year 9 annual 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

- Use Year 8 metric data in all metrics spreadsheet (Excel) distributed with this report to identify Year 9 annual targets for all appropriate metrics.
- Continue to work to align core personnel practices with WVCTSI SOPs for iLab data entry.
- 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

- Use Year 8 metric data in all metrics spreadsheet (Excel) distributed with this report to identify Year 9 annual targets for all appropriate metrics.
- Continue to work to align core personnel practices with WVCTSI SOPs for iLab data entry.
- Continue and expand efforts to disseminate research results through publication in high-quality journals and other outlets.

Key Recommendations to Pilot Projects Core

- Use Year 8 metric data in all metrics spreadsheet (Excel) distributed with this report to identify Year 9 annual targets for all appropriate metrics.
- 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 should be distinguished from that done in the Professional Development core, as well as how it should be tracked and evaluated.

Key Recommendations to Professional Development Core

- Use Year 8 metric data in all metrics spreadsheet (Excel) distributed with this report to identify Year 9 annual targets for all appropriate metrics.
- Consider whether demand by service type varies month-to-month and shift either iLab data entry protocols if it does not or consider whether resources need shifting to most efficiently meet demand across time if it does.
- Identify barriers and work to increase engagement with partner institutions outside of WVU Morgantown.

Key Recommendations to Technology and Resources for Core Laboratories Core

- Use Year 8 metric data in all metrics spreadsheet (Excel) distributed with this report to identify Year 9 annual targets for all appropriate metrics.
- 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 and supporting roll-out of ORCID ID utilization.
- Support continued refinement and 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

- Use Year 8 metric data in all metrics spreadsheet (Excel) distributed with this report to identify Year 9 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	1 st 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	1 st quarter formative evaluation report and metric data distributed by TEC
Nov-Dec	Steering Committee discusses 1 st quarter formative evaluation

2nd quarter Reporting Period = Oct 1 – Dec 31

Dec 18	2 nd 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	2 nd quarter formative evaluation report and metric data distributed by TEC
Feb-Mar	Steering Committee discusses 2 nd quarter formative evaluation

3rd quarter Reporting Period = Jan 1 - Mar 31

Mar 18	3 rd 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	3 rd quarter formative evaluation report and metric data distributed by TEC
May-June	Steering Committee discusses 3 rd quarter formative evaluation

4th quarter Reporting Period = Apr 1 – June 30

June 18	4 th 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	4 th quarter formative evaluation report and metric data distributed by TEC
Aug-Sept	Steering Committee discusses 4 th quarter formative evaluation

Administrative Core

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

There were 55 external funding proposals (\$53.8 million) and 30 funded awards (\$9.5 million) during Y8 Q4. Figures 1 and 2 show types of external funding proposed and awarded per cores contributing. WVCTSI Staff numbers dropped by two this quarter, to 46.



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.

	Q1	Q2	Q3	Q4	Totals
Years 1 – 5					691
Year 6	56	67	74 (5)	64 (1)	261 (6)
Year 7	51	59 (1)	57 (3)	51	218 (4)
Year 8	39 (5)	39 (1)	25 (1)	17 (1)	120 (8)
Total					1290 (18)

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

External Funding Proposal Amounts by Core

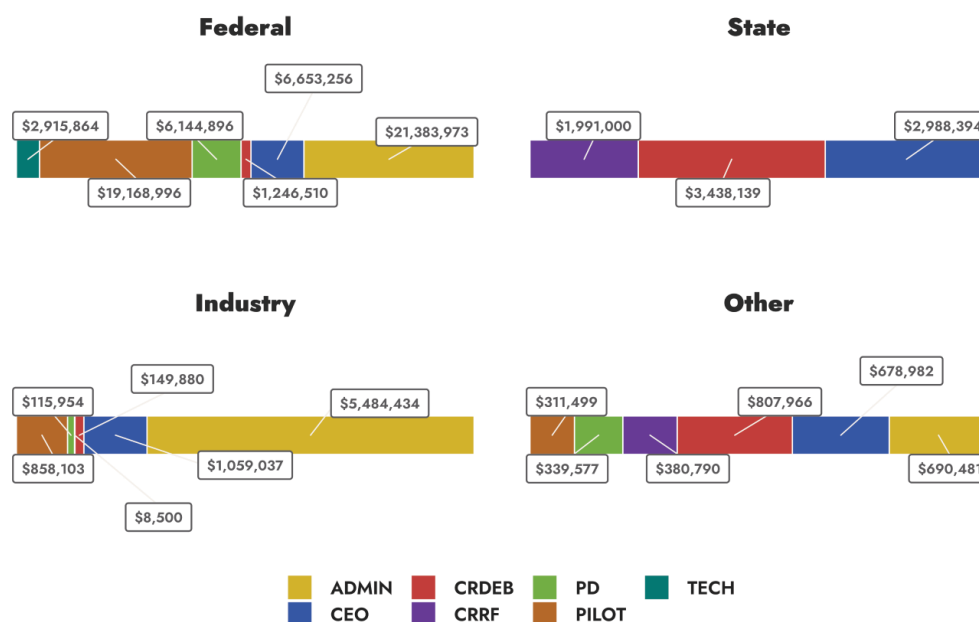
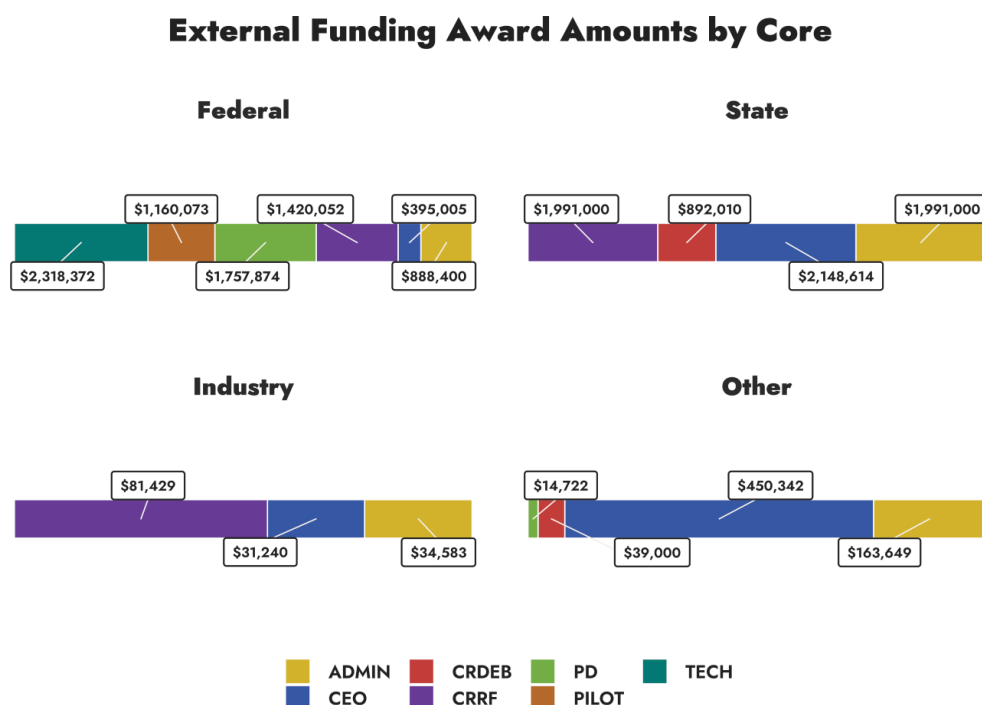
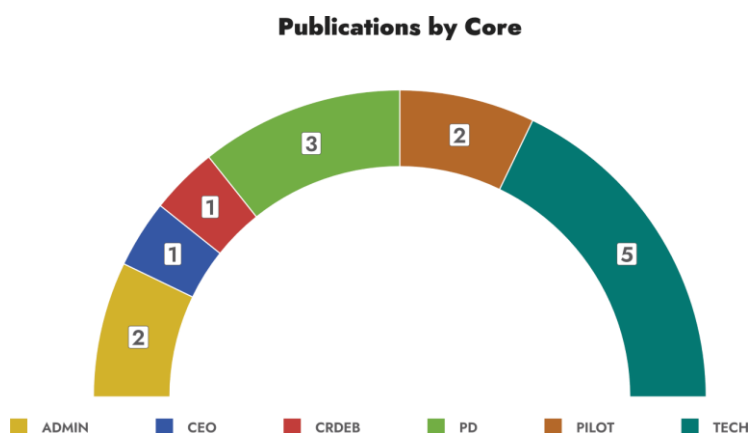


Figure 1. External funding proposals dollar amount requested and category per core.**Figure 2. External funding awards dollar amount per core.**

There were 17 publications officially linked to the grant (with an additional 1 ahead of print) in Quarter 4. Cores and partners contributed to the following number of linked publications each: 2 ADMIN, 1 CEO, 1 CRDEB, 3 PD, 2 Pilot, 5 TECH, 2 WVSOM, and 2 MU. These numbers do not sum to 17 because three publications included multiple contributing cores/partners and several publications were not attributed to a core. (See Figure 3).

**Figure 3. Contributions per core to WVCTSI linked publications during Quarter 4 (Year 8).**

Year-to-date number of linked publications was 120 (with an additional 8 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 261 and 218, respectively. 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 Y8 Q4 funding period. The resulting list was reduced by including only those publications with author institutional affiliations in West Virginia. Core leadership is reviewing the list and contacting all first authors regarding whether their publication should be linked to the grant.

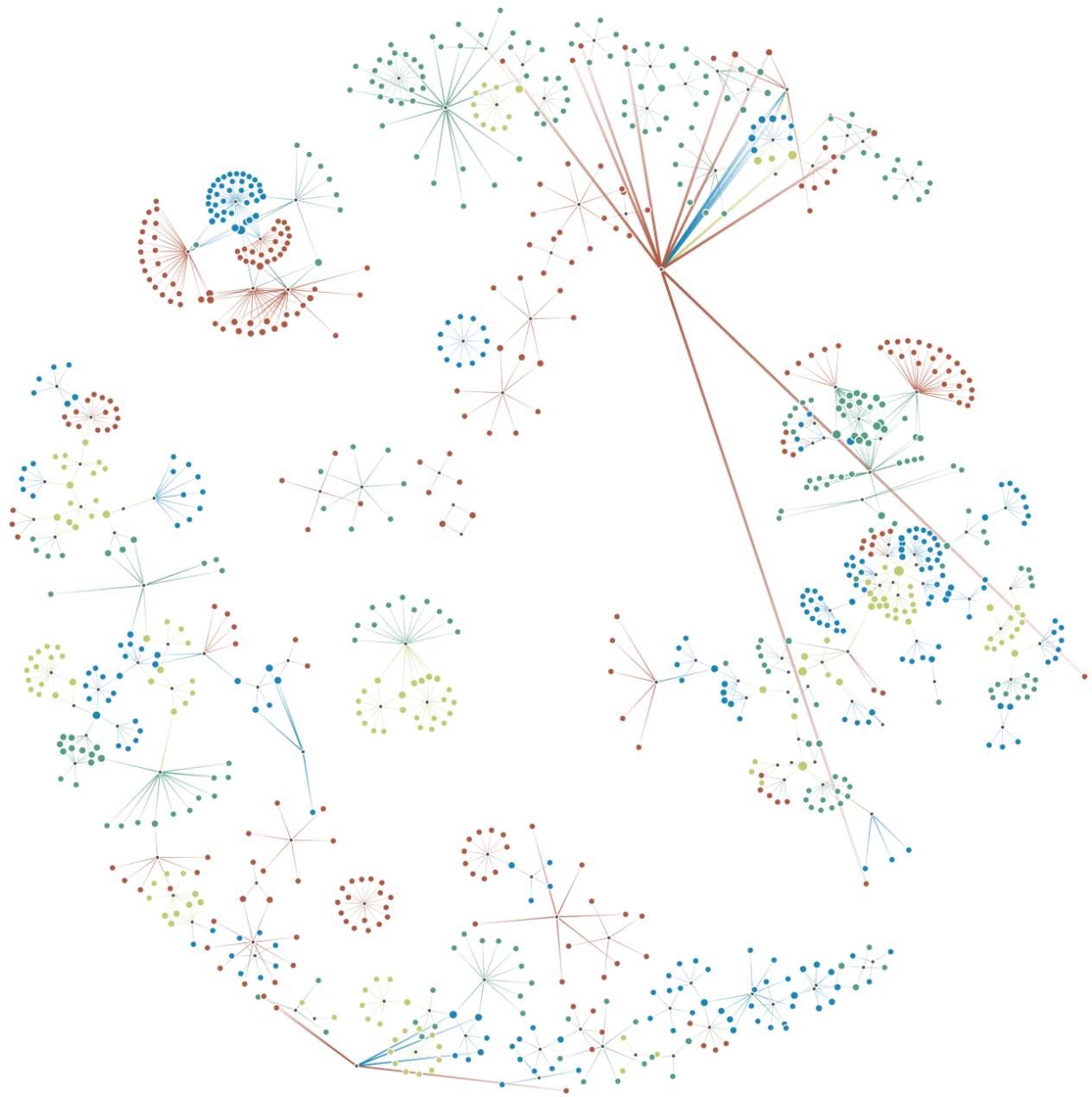


Figure 4. Author network by publication for Y8 WVCTSI linked publications.

Figure 4 displays the author network for year 8 publications linked to WVCTSI, excluding one publication with over 1000 authors listed. In this graphic, black dots are publications, color dots are authors with colors representing which WVCTSI core contributed to each publication. This graphic makes it clear that many publications have contributions from multiple cores, and that while most authors contributed to a single publication, there are several authors who “bridge” multiple publication groups. These “bridging” authors might usefully inform increased efforts to grow connectivity and collaboration across research groups. Figure 5 displays the geographic location author institutional affiliations for year 8 WVCTSI linked publications. While these are understandably concentrated in the eastern half of the United States, there also is substantial international collaboration including authors on every continent except Antarctica with the largest cluster outside of the US in the European Union.

WVCTSI Grant Related Publication Map for 2019 Q1 - 2020 Q4

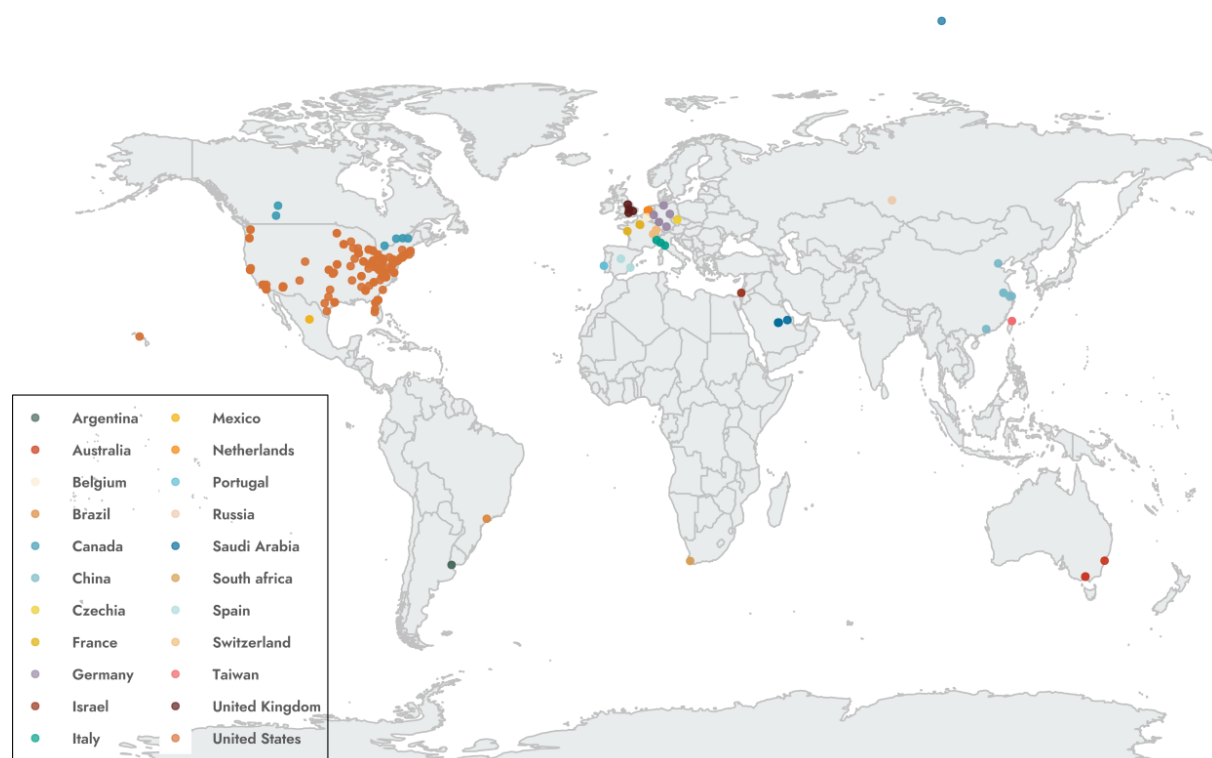


Figure 5. Geographic location of author institutional affiliations for Y8 WVCTSI linked publications.

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 data was unable to be tracked throughout Y8Q3 due to an error with the servers, so data for Y8Q4 were compared to Y8Q2. WVCTSI website traffic decreased on average, with 7 fewer visitors per day, but total visits increased by 2.4k hits. WVCTSI's social media engagement continues to steadily increase: Facebook (+9 Likes and +12 follows), Twitter (+45 Followers), and Listserv (+123). Year 8 saw an increase of 34 Facebook likes, 62 Twitter follows, and 451 Listserv subscribers.

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 55 external funding proposals and 30 external awards this quarter. Percentage of NIH award expended for all cores was 100%, with five 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.

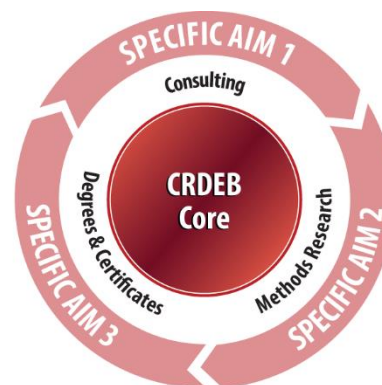
Key Recommendations to Administrative Core

- Use Year 8 metric data in all metrics spreadsheet (Excel) distributed with this report to identify Year 9 annual targets for all appropriate metrics.
- Facilitate core and partner discussions and collaborative efforts to innovatively facilitate additional publications supported by and linked to WVCTSI NIH funding award.
- Implement and support participation in a system where all WVCTSI members who generate scholarly publications have an ORCID ID as part of their WVCTSI membership profile.
- Identify barriers to partner participation and engagement; work to increase membership and service utilization across partner sites.

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 67 new REDCap users in Q4 with a total of 1,927 REDCap users to date (445 of which are active users). Of the 1,927 REDCap users, 1,467 were from WVU (374 active), 16 from CAMC (4 active), 11 from WVSOM (4 active), and 433 not affiliated with the above entities (63 active).



Additionally, 9 hours were spent updating existing REDCap projects and providing project follow-up meetings in Q4, a 5.5 hour increase from Q3. One REDCap project was made for WVCTSI- funded investigators (totaling 6 of the annual target of 15), 3 REDCap projects were made for non-WVCTSI investigators, 56.5 hours were spent building new REDCap projects for investigators, and 5 hours of REDCap consultations were reported in Q4. There were 94 new REDCap projects/data instruments (with a total of 2,418 projects/data instruments), and 77 new REDCap service inquiries. The total number of current TriNetX users was 365 in Q4 and there were 7269 new TriNetX inquiries, with 39 new TriNetX logins and 12 data set requests (totaling 28, hence surpassing the annual target of 25). CRDEB reported no practice/policy changes in Q4 and reported no professional development events (annual target = 5) for year 8.

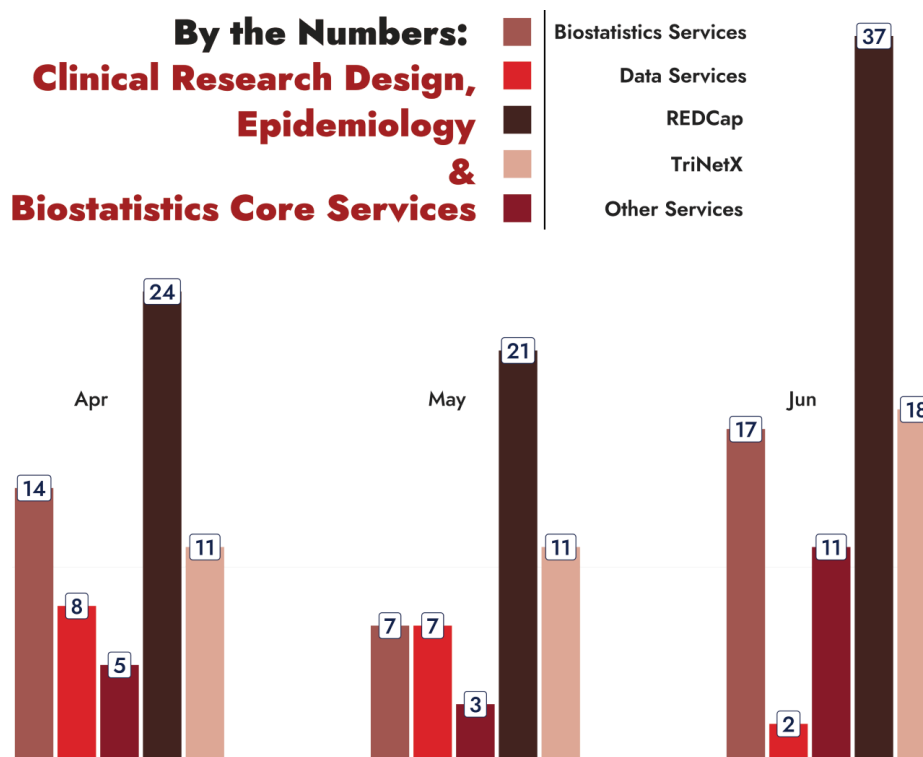


Figure 6. CRDEB iLab Core Management System services logged by month and service type.

iLab services visualized in Figure 6 show that REDCap continues to be the most utilized service followed by Biostatistics and TriNetX.

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 61 BMIR-related inquiries, 25 new CRDEB consultations, 2 sample size/power consultations, 15 new statistical analysis consultations, and 11 new clinical study design consultations in Q4. Additionally, 415.75 hours were dedicated to biostatistics consultations. 4 GIS analysis consultations were reported for Q4, exceeding the annual target of 5 with a yearly total of 11.

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

CRDEB had 10 supported external funding proposals, 6 of which were in collaboration with other cores in Q4 (totaling over \$5.6 M) and 3 externally funded awards (totaling \$931,010). CRDEB reported 6 presentations supported by WVCTSI and contributions to 1 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 16 new custom IDR dataset requests, and 7 requests for updates to previous IDR datasets. 8 IDR projects reported as completed in Q4, totaling 50 for the year with an annual target of 75. There were 200.25 hours spent on new data requests, 54.25 hours on updates to previous data sets, and 0 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

- Use Year 8 metric data in all metrics spreadsheet (Excel) distributed with this report to identify Year 9 annual 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 contributed to 3 external funding proposals (totaling over \$2.3 M) in Y8Q4 including collaborations with ADMIN, CEO, and CRDEB. CRRF received 6 external funding awards (over \$3.3 M) including collaborations with ADMIN, CEO, and TECH. CRRF did not contribute linked publications and reported one presentation. Figure 7 shows the number of CRRF iLab services requested monthly across the current reporting period by category with Study Coordination and Training the most utilized services.

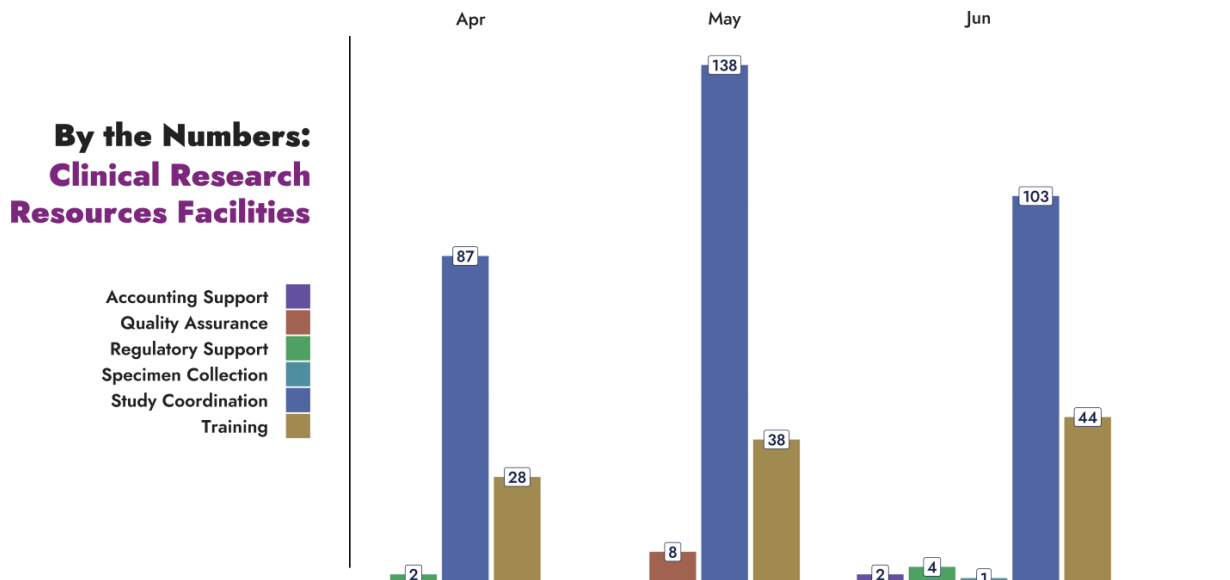
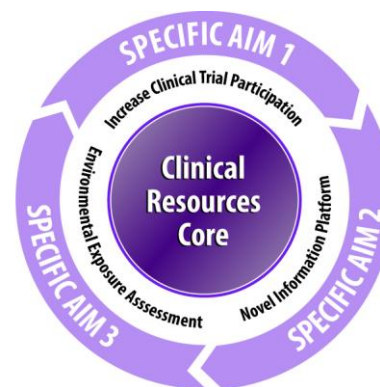


Figure 7. CRRF iLab Core Management System services logged by month and service type.

Note that Figure 7 visualizes services precisely as logged in iLab at the time of evaluation data collection. CRRF continues to fine-tune their utilization of iLab to conform with WVCTSI SOPs and numbers reported in the narrative here are based on core personnel data reports rather than iLab only data.

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 116 unique instances of support to non-WVCTSI studies in the form of regulatory assistance (44), study coordination (31), accounting (41), or quality assurance audits (0) in Q4. Within the recently expanded activities by CTCOE (Q2Y8) which included Registration, a Risk Assessment Committee, and an Appeals Committee; there were 23 trials were registered, and 15 trials were reviewed, 12 of which were approved by the risk assessment committee. Additionally, CRRF supported 3 new Early Stage PI's with industry or WVCTSI-initiated funding in Q4. A total of 19 participants were recruited, with 24 more completing a study. CRRF had 14 TriNetX study offers and 8 accepted offers, and 1 study was 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

- Use Year 8 metric data in all metrics spreadsheet (Excel) distributed with this report to identify Year 9 annual targets for all appropriate metrics.
- Continue to work to align core personnel practices with WVCTSI SOPs for iLab data entry.
- 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 108 WVPBRN and 150 ECHO sites reported in Q4. This included the following 33 new ECHO sites: AccessHealth, MOV Health, United Summit Center, Piney Valley, Berkeley Springs Center, Meadowbrook Acres Nursing Center, Elkins Rehabilitation and Care Center, Positive Health Clinic Morgantown, Weirton Medical Center, Nella's Nursing Home, Inc., Meadowview Manor, Medical Laboratory Science, Speranza Therapeutics, WVU Occupational Medicine, WV Medical Professionals Health Program, WVU Medicine - Center for Quality Outcomes, WVU - Shared Research Facilities, WVU School of Public Health, WVU Cancer Institute, John J Gerlach Center Senior Health, Saint Joseph Hospital, WVU Medicine, WV Bureau of Public Health, Family Crisis Intervention Center of Region V Inc, Maxim Health Care, Raleigh General Hospital, WVU Health Sciences Center, Aetna, TriState Community Health Center Inc, Blue Marble Rehab Inc, WV Medical Group Management Association (MGMA), Monongahela Valley Hospital, and MedMark Treatment Center.

No new partner organizations were reported in Q4, however the annual target of 5 was met.

During Q4, there were 3 new CEO (non-ECHO) projects: WV Community Perceptions of COVID19 and Mitigation Factors, ATRN: COVID19: The Path Forward in Appalachia, and FORE Grant: Enhancing and Expanding MAT in Southern Appalachian Communities. Additionally, Q4 reported 3 networking opportunities: COVID-19 Echo (used for polling and a remote environment collaboration), Design Studio (used for PBRN members to network and collaborate online), and Pilot/ECHO Collaboration (inviting PI's from previous pilots to come disseminate results/research at ECHO sessions). Additionally, there was 1 Community Advisory Board meeting on 5/8: Project Updates: Special COVID19 Project: Wearable Monitoring Devices: Impacts of the Crisis on Communities Statewide, and 3 mentored investigator reported in Q4.

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, 44 ongoing, 3 completed WVPBRN projects, and of the 6 projects that were reviewed 6 were accepted in Q4. There were 223 Project Development and Success services, 125 Project Implementation services, 8 Community Engagement and Training services, 15 new Ideas on Deck services (9 WVSOM), 144 hours of ECHO services, 31 Consultation services, 23 hours of services for WVPBRN Activities, 1 funding opportunities were identified, 4 ongoing CEO projects, 1 new ECHO Project, and 25 services for products reported during Q4.

CEO also contributed to 10 external funding proposals (totaling over \$11.3 M), 9 of which were in collaboration with other cores (Admin, PD, CRDEB, CRRF, and Pilot), and 8 externally funded projects (totaling over \$3 M) in Q4. CEO contributed to 1 linked publication and no presentations were reported in Q4.



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

In Q4 there were 107 Research Translation and Dissemination services provided. 1 CEO Project Policy Brief and 1 internal policy change.

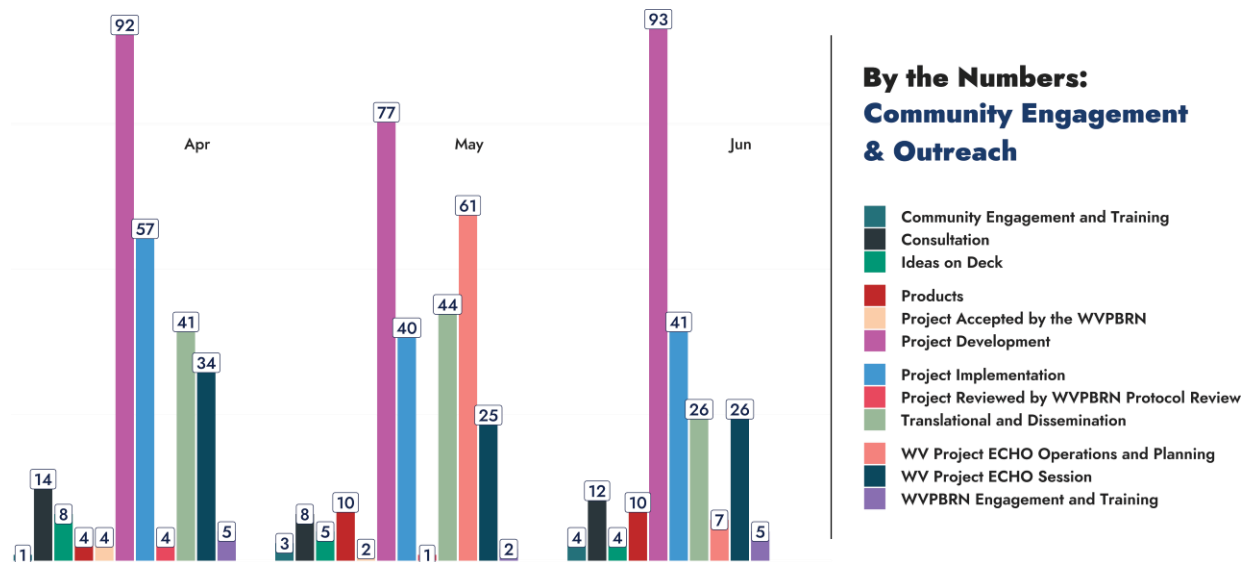


Figure 8. CEO core services logged by service type.

Note that Figure 8 visualizes services precisely as logged in iLab at the time of evaluation data collection. CEO continues to fine-tune their utilization of iLab to conform with WVCTSI SOPs and numbers reported in the narrative here are based on core personnel data reports rather than iLab only data.

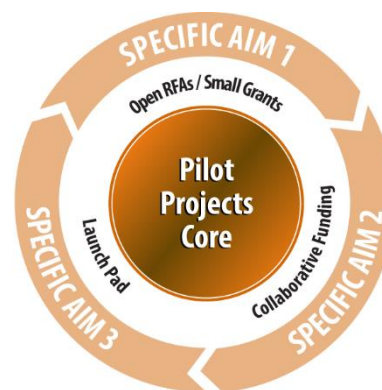
Key Recommendations to Community Engagement & Outreach Core

- Use Year 8 metric data in all metrics spreadsheet (Excel) distributed with this report to identify Year 9 annual targets for all appropriate metrics.
- Continue to work to align core personnel practices with WVCTSI SOPs for iLab data entry.
- Continue and expand efforts to disseminate research results through publication in high-quality journals and other outlets.

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.

Three new pilot grant funding categories were used this quarter: Biostart, Pop-Up COVID 19, and A1Competition. In total, Pilot received 36 applications, including 22 from ESIs. Pilot granted 16 awards, to 12 ESI recipients. The Pilot core provided at least one workshop and 8 consultations. The Pilot core contributed to 2 publications and 1 presentation this quarter.



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

There were 39 active Pilot projects addressing critical health issues in Q4. Additionally, the Pilot Core contributed to over \$19 M in external grant proposals and over \$1.1 M in external grants awarded.

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

There was no launch award activity (letter of intent, applications, or awards) reported during quarter 4 however 5 active launch projects were reported this quarter.

Key Recommendations to Pilot Projects Core

- Use Year 8 metric data in all metrics spreadsheet (Excel) distributed with this report to identify Year 9 annual targets for all appropriate metrics.
- 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 should be distinguished from that done in the Professional Development core, as well as how it should be tracked and evaluated.

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 195 users requested 815 services through iLab in Q4, totaling 1148 iLab users. There were 26 new investigator development service requests through iLab. There were 2 reported orientations or consultations provided to investigators new to WVCTSI. Additionally, there were 12 external active members in the SACS program in Q4, as well as 5 female clinician scientists being mentored. There was 1 special event/program for women in science in Q4 titled FACTS: Balancing Act: Walking the Tightrope Amidst COVID-19.



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 3 undergraduate students, and no full team meeting, as well as 4 professional development activities: (1) PI Academy Idea Lab June 3- Presenter: Ankit Sakhuja, (2) PI Academy Idea Lab April 1- Presenter: Kyle Ritchie, (3) PI Academy Idea Lab May 6 - Presenter: James Bardes, and (4) Webinar- Clinicaltrials.gov- Presenter: Dr. Ford, Johns Hopkins.

There was 2 CTS Certificate enrolled and CTS MS had 1 new student enrolled (with 5 applications received and 3 offers made) at WVU in Q4 (MU enrollment was not reported). CTS PhD program had one degree conferred during Quarter 4. Education programming reported did not have any new academic courses, workshops, or C/T research seminars. There were 39 unique participants in educational programming, 31 originating from WVU, 2 from MU, 0 from CAMC, and 6 from SOM.

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

The Professional Development core contributed to 14 external funding proposals (over \$6.6 M); 5 of which were collaborative with singular cores: ADMIN (1), CEO (2), Pilots (3), and TECH (1) and 7 externally funded awards totaling more than \$1.7 M. The Professional Development core reported 4 presentations supported by CTR Award and 3 linked publications.

By the Numbers: Investigator Development Services

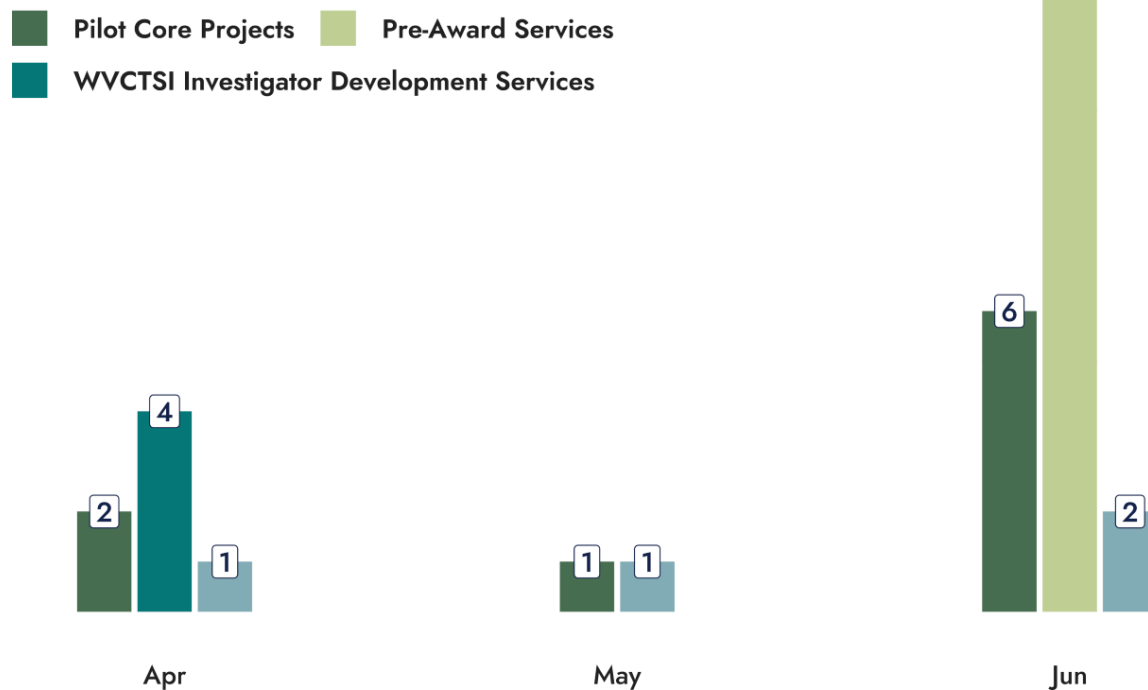


Figure 9. Investigator development services per service category as logged in iLab.

Figure 9 displays Investigator Development Services as logged in iLab by month and service type. Demand for Pre-Award services appears to vary dramatically month-to-month, but it is unclear whether this might be an artifact of iLab data entry not conforming to WVCTSI SOPs.

Key Recommendations to Professional Development Core

- Use Year 8 metric data in all metrics spreadsheet (Excel) distributed with this report to identify Year 9 annual targets for all appropriate metrics.
- Consider whether demand by service type varies month-to-month and shift either iLab data entry protocols if it does not or consider whether resources need shifting to most efficiently meet demand across time if it does.
- 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 (TRCL) core contributed to 5 external funding proposal totaling over \$2.9 M, and 5 external awards totaling over \$2.31 M. TRCL contributed 5 publications during Q4.

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 project and 1 open project this quarter, with no new projects. Biospecimen sample collection and utilization was fully collaborative for all of Year 8. Annual targets for samples collected and utilized were met across all collaboration sites (see Figure 10).

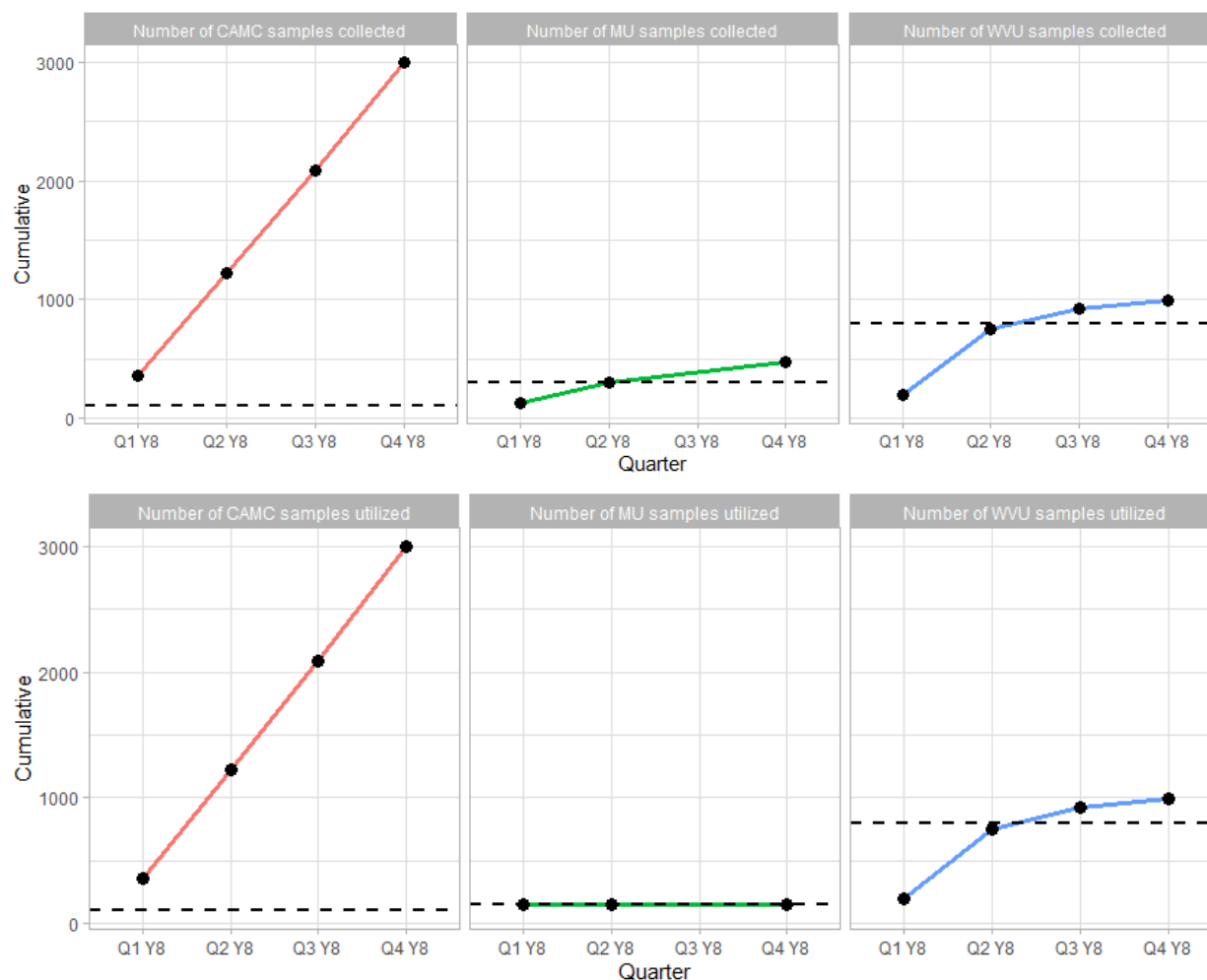
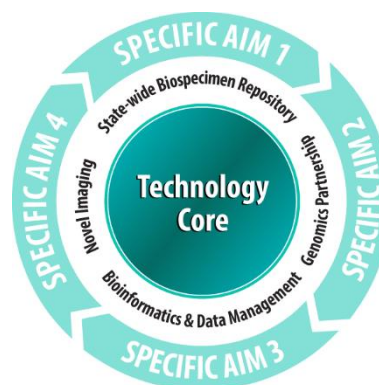


Figure 10. Cumulative samples collected and utilized across collaborative sites. Dashed line indicates annual target for each site.

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 0 genomics studies, 6 Illumina projects (2 WVU, 4 MU), and 9 Illumina runs (1 WVU, 8 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.

One educational session with 23 total attendees was provided.

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

Nearly all annual targets were met for Imaging. However, two targets may require special attention, specifically, total annual numbers of patents (0 out of 2) and disclosures (1 out of 4).

Key Recommendations to Technology and Resources for Core Laboratories Core

- Use Year 8 metric data in all metrics spreadsheet (Excel) distributed with this report to identify Year 9 annual targets for all appropriate metrics.
- 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 communicating with key contacts to refine metrics for increased reporting accuracy, with CRRF having the most significant updates. TEC identified all publications linked to WVCTSI grant numbers directly from NCBI. TEC provided an updated list of publications that potentially should be linked, which list is currently being reviewed by other cores. TEC continues to refine Social Network Analysis visualizations to show collaboration among authors on linked publications as well as geographic location. TEC continues to analyze Awareness Survey data with a full report of findings to be completed next quarter.



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 two interviews were completed. Potential publications for the ECHO project are currently being conceptualized. TEC completed and shared the Alumni survey report with the PD Core, which was the first survey to be shared in an electronic format with interactive data visualizations. TEC completed and disseminated the first version of the progress report for the PD Core to collect quarterly reporting data. TEC will continue to work with the PD Core to make improvements and increase efficiency in analyzing the data. TEC began building a password protected website to house all WVCTSI TEC reports over time. 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 Y8 was disseminated in Q4 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 and supporting roll-out of ORCID ID utilization.
- 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 Q4, MU reported 2 peer-reviewed publications, meeting their target of 12 for Year 8. MU submitted 23 external funding proposals and had 7 funded awards. MU collaborated with many WVCTSI cores in Q4: MU was awarded one Pilot Core Biostart and one COVID-19 pop-up award, had 6 active pilot award projects (one in collaborations with WVU) and had one participant in the Pilot Grant Proposal Workshop. The PD core provided 4 services for proposal development. MU reported 0 genomic studies, 4 Illumina projects, and 8 runs (Illumina sequencing lanes). MU collected 181 biospecimen samples and utilized 2. MU currently has 47 WVCTSI members, with no additional members this quarter.

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 2 peer-reviewed publication and 1 presentation at the National ACP2020 conference. They submitted 1 funding proposal and received 5 funded awards. WVSOM was awarded a WVCTSI COVID-19 Pilot funding award. WVSOM did not recruit investigators or report student opportunities for C/T research during Q4. WVSOM had 14 trainees in community-engaged research curriculum and 3 open collaborative CTS projects outside the WVPBRN. WVSOM housed 11 REDCap users (4 active). WVSOM contributed to COVID-19 related projects and initiatives during Q4. With the assistance of the CEO core, the Boots on the Ground was transitioned from in-person to virtual training. WVSOM also participated in the 3D printing of N95 masks, opened the Clingman Center for feeding programs, and served as part of the Greenbrier County COVID task force. WVSOM membership was 78.

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.

A team consisting of members from WVCTSI, WVU, NIOSH, and a pharmaceutical company (Boehringer-Ingelheim) received approval for funding for a randomized controlled trial of antifibrotic therapy in coal miners with progressive massive fibrosis (PMF). During quarter 4, the contract for this study was finalized and conversations of collaboration are ongoing with University of Kentucky and University of Virginia as potential partners. NIOSH also is working with the CEO core to recruit 3 primary care sites and 2 hospitals to participate in a Fentanyl guideline interview pilot study.

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. 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 and 13 graduate medical education residency/fellowship programs. CAMC sponsors pharmacy residency programs and psychology internships.

In Q4, CAMC did not have publications or presentations. CAMC submitted one grant proposal and an application for WVCTSI COVID-19 pop-funding. CAMC received 4 Biostatistics consults, attended 2 journal clubs, and delivered 2 workshops/courses/seminars/retreats. CAMC had 8 clinicians and staff participating in WVCTSI sponsored research training programs. CAMC had 16 REDCap users and 4 iLab users at the end of Q4. CAMC has 45 members.

Veteran Affairs Medical Centers (VAMC)

Veteran Affairs Medical Center (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

- Use Year 8 metric data in all metrics spreadsheet (Excel) distributed with this report to identify Year 9 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.