

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 2020-2021 (Y9)

Reporting Period: April 1, 2021 – June 30, 2021

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



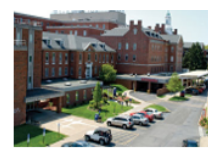
CAMC / WVU Charleston



Marshall University



West Virginia School of
Osteopathic Medicine



WV Veterans Affairs



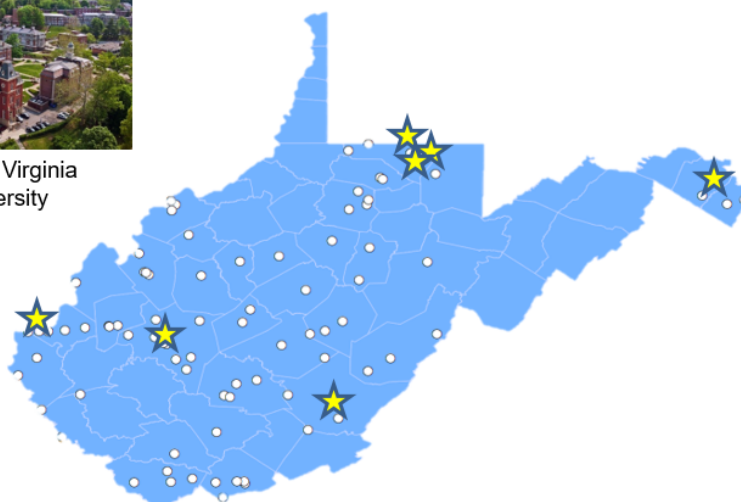
National Institute for
Occupational Safety and
Health



West Virginia
University



WVU Medicine



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West Virginia Clinical Translational Science Institute

Tracking and Evaluation Quarterly Report

(April 1, 2021 – June 30, 2021)

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WVCTSI Year 9 Dashboard

Category	Y9 Q1	Y9 Q2	Y9 Q3	Y9 Q4	Total	TARGET
CTR-Linked Publications	58 (4)	87 (7)	26 (1)	24 (5)	195 (17)	375
Proposals Submitted (#)	48	69	67	74	258	250
Subcategory: Proposals Submitted by ESIs	6	8	14	8	36	
Subcategory: Proposals Submitted by Clinicians	16	32	45	15	108	
Proposals Funded (#)	64	45	50	42	201	175
Subcategory: ESIs-Proposals Funded Totals	5	11	10	3	29	
Subcategory: ESIs-Proposals Funded Active	5	0	10	3	18	
Subcategory: ESIs-Proposals Funded New	1	3	5	1	10	
Subcategory: Clinician-Proposals Funded	44	34	32	10	120	
Subcategory: Clinician-Proposals Active	44	0	32	10	86	
Subcategory: Clinician-Proposals New	6	0	11	3	20	
Total External Funding Received (\$)	\$ 17,034,441.54	\$ 6,601,808.25	\$ 8,232,861.82	\$ 10,737,376.43	\$ 42,606,488.04	\$50M
Subcategory: Federal	\$ 14,781,669.00	\$ 3,954,498.00	\$ 2,907,269.00	\$ 373,609.00	\$ 22,017,045.00	
Subcategory: State	\$ 497,394.00	\$ 1,985,795.00	\$ 2,751,878.96	\$ 154,845.96	\$ 5,389,913.92	
Subcategory: Industry	\$ 860,136.00	\$ 325,250.00	\$ 605,618.29	\$ 28,689.63	\$ 1,819,693.92	
Subcategory: Other*	\$ 895,242.00	\$ 337,266.00	\$ 1,968,095.57	\$ 829,821.59	\$ 4,030,425.16	
Disclosures Submitted:	6	8	2		16	15
Patent Applications	2	5	4		11	10
Patents Awarded	1	0	0		1	2
WVCTSI Membership	2,837	3,079	3258	3520	3,437	3,400
Non-Morgantown	819	972	1089	1234	1089	850
Community Membership	196	206	406	488	406	230
Investigators accessing CTSI services or resources (unique # per quarter)	244	189	273	232	727	750

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 2020/2021 (Y9), which covers a reporting period from April 1st, 2021 through June 30th, 2021. The WVCTSI received Y9 renewal notice of award dated July 9, 2020 with an annual award of \$4,000,000 for the budget period from July 1, 2020 through June 30, 2021 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. At the close of the reporting period, there were 24 peer-reviewed publications officially linked¹ to WVCTSI funding with 5 additional pending, 19 presentations, 74 external funding proposals totaling over \$124 million, and 42 funded awards (\$10.7 million) for quarter 4 of year 9.

Annual targets were exceeded for number of external funding proposals submitted and funded, disclosures submitted, patent applications, and membership (including non-Morgantown and community members). Annual targets have not been met for external funding amount awarded or number of linked publications, patents awarded, or investigators accessing WVCTSI services. The number of linked publications lags real time and will continue to rise, especially for quarters 3 and 4.

Overall recommendations from Tracking and Evaluation Core

- Prepare for conclusion of this 5-year funding period including analysis of all specific aims to ensure appropriate activities are completed and prepare a competitive application for renewal.
- While good progress has been made and 495 investigators have registered ORCID ID's, continue efforts to ensure all WVCTSI members who generate scholarly publications have an ORCID ID as part of their WVCTSI membership profile and that those ORCID ID's are utilized for efficient identification and linking of all WVCTSI related publications and funding awards.
- Ensure transparent and consistent utilization of iLab across cores and partners including core and partner assessment of alignment with action items agreed upon at May 29, 2019 WVCTSI Steering Committee meeting.
- Develop evidence of alignment between resource/effort allocations and priority health areas.

Key Recommendations to Administrative Core

- Shift focus toward closing out this 5-year funding period, such as supporting efficient wrapping up of pilot award funding opportunities and piloting/evaluating recent new endeavors in support of a competitive renewal application.

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). We report all linked publications including any embargoed that do not yet appear on the public facing NCBI list. The number of linked publications for each quarter continues to rise following the end of the reporting period.

- Continue to facilitate core and partner discussions and collaborative efforts to innovatively facilitate additional publications supported by and linked to WVCTSI NIH funding award, including continued effort to get all WVCTSI members who generate scholarly publications to 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.

Key Recommendations to Clinical Research Design, Epidemiology & Biostatistics Core

- Identify barriers and work to increase service utilization across partner sites. Consider whether professional development events targeted at increasing service utilization should be planned.
- Implement and report activity related to the Appalachian Research Consortium (ARC). Consider how to position such activity in a competitive renewal application.

Key Recommendations to Clinical Research Resources & Facilities Core

- Plan and deliver PI Academy events.
- Consider innovative ways to support or contribute to linked publications.
- Identify appropriate metrics for Specific Aim 2 and consider how to position activity related to this aim in a competitive renewal application.

Key Recommendations to Community Engagement & Outreach Core

- Consider whether frequency of Community Advisory Board meetings is appropriate.
- Focus on completing WVPBRN and CEO projects as this funding cycle comes to a close.
- Consider innovative ways to support or contribute to linked publications.
- Consider how to increase utilization of Community Engagement and Training services.

Key Recommendations to Pilot Projects Core

- Consider planning and delivering workshops, mentoring, or other types of support targeted at supporting funded pilot awardees completing their scope of work by June 30, 2022.

Key Recommendations to Professional Development Core

- Consider the viability of the CTS Certificate program considering there are no students reported as enrolled, applying, or accepted.
- Increase engagement and utilization of services by individuals at partner institutions outside of WVU Morgantown.
- Continue working to roll out and evaluate new editorial services supportive of publication and grant proposal preparation. Consider how to position such activity in competitive renewal application.

Key Recommendations to Technology and Resources for Core Laboratories Core

- Consider additional opportunities to facilitate patentable projects, collecting and utilizing biospecimen samples at WVU, and genomics studies at 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.

- Continue to refine the progress report and related data portal for use by PD, Pilot, and Admin cores to collect quarterly report information from individuals receiving WVCTSI services, protected time, or other support.
- Implement next steps for WVPBRN and ECHO evaluations. Consider how to position that activity in a competitive renewal application.
- Continue to refine and enhance data collection and visualization tools available online at <https://percwv.com/> for use by all stakeholders.

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

- Work to implement and/or increase utilization of iLab.
- Continue efforts to increase WVCTSI membership, awareness, and utilization of WVCTSI core services at each partner institution.

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.

WVCTSI had 74 external funding proposals (\$124+ million) and 42 funded awards (\$10.7 million) during Y9 Q4. Of these Admin was directly linked to 24 external funding proposals (\$98.6 million) and 7 external awards (\$1.7 million) this quarter. Figures 1 and 2 show types of external funding proposed and awarded per cores contributing. WVCTSI Staff numbers in Q4 are 71 (up 3 from last quarter).



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.

WVCTSI Linked Publications Hub

	Q1	Q2	Q3	Q4	Totals
Years 1 – 5	141	177	184	195	697
Year 6	58	68	81(2)	68(1)	275(3)
Year 7	56	65(1)	77	92	290(1)
Year 8	69(1)	93	73(1)	107(5)	342(7)
Year 9	58(4)	87(7)	26(1)	24(5)	195(17)
Total					1799 (28)

It should be noted that linking publications requires substantial effort and lags real time. While the total number of linked publications has not reached the annual target at this time, it is on-track based on trends observed in past years where the number of publications continues to rise after a reporting period has ended. Accordingly, the number of linked publications at the time the reporting period closed and for which core contributions are reported here will be fewer than those reported in the table above because additional publications continue to be linked daily.

External Funding **Proposal** Amounts by Core

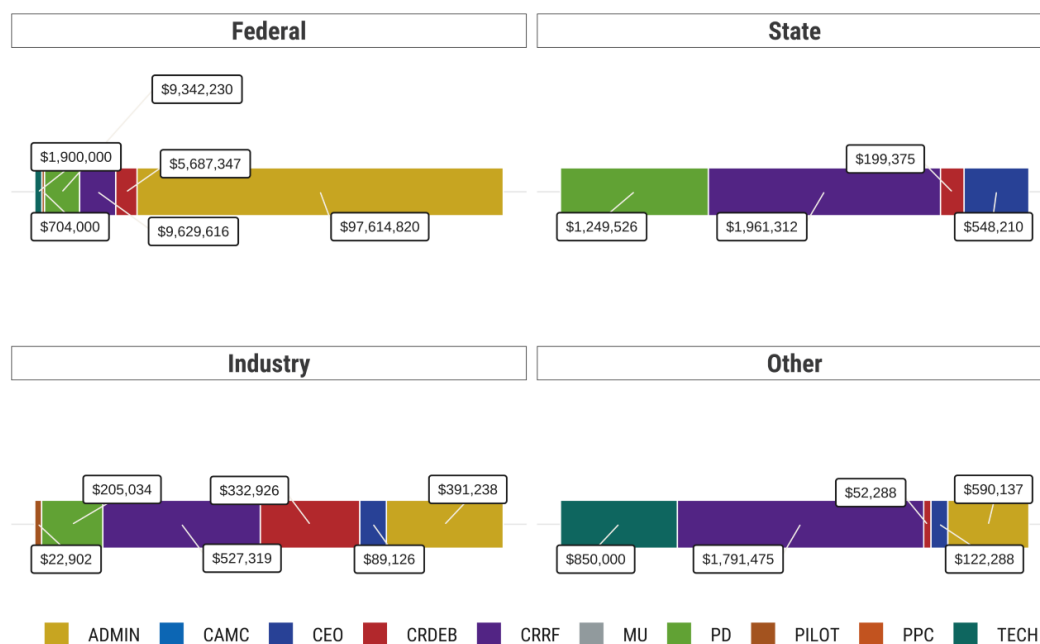


Figure 1. External funding proposals dollar amount requested and category per core

External Funding **Award** Amounts by Core

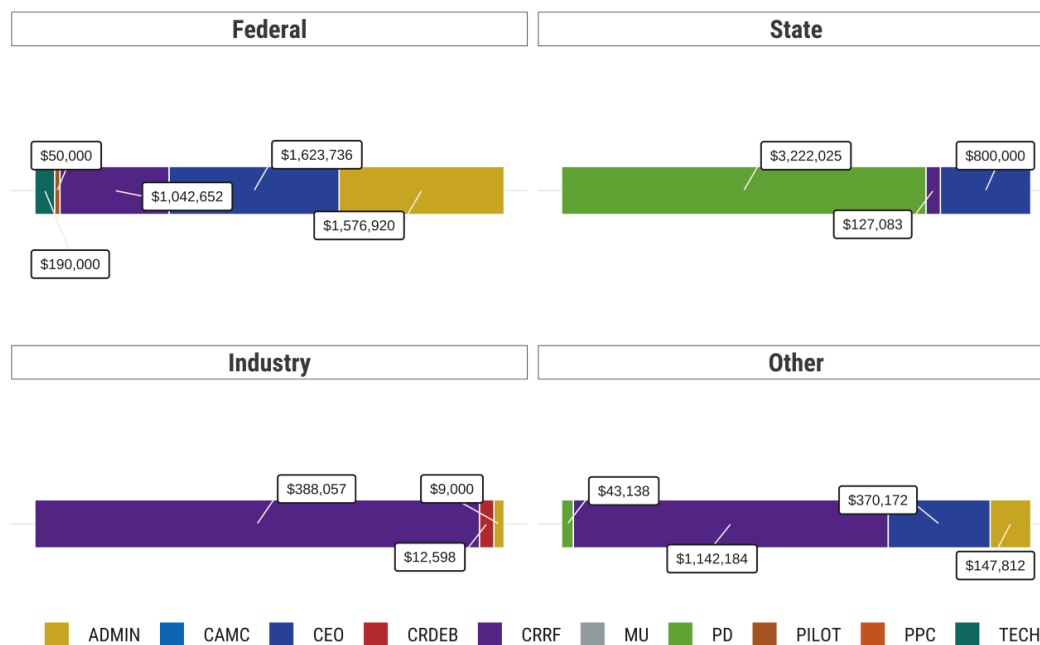
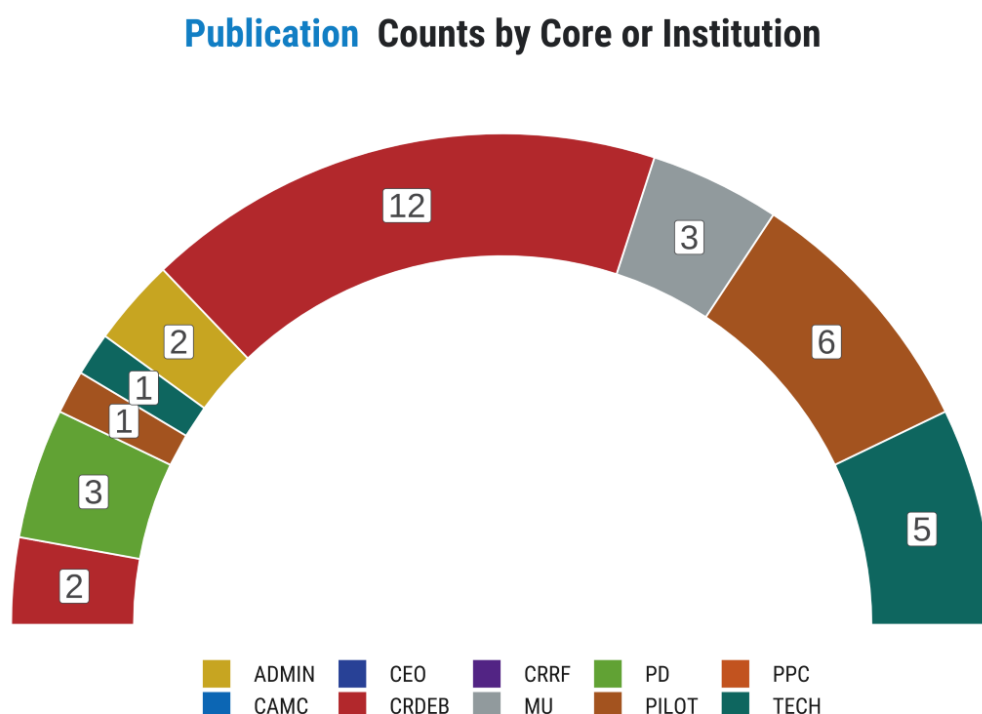


Figure 2. External funding awards dollar amount per core.

There were 24 publications linked to the grant in Quarter 4. Cores and partners contributed to the following number of linked publications each: 2 ADMIN, 14 CRDEB, 3 PD, 6 TECH, 7 Pilot, and 4 MU. These numbers do not sum to 25 because 10 publications included multiple contributing cores/partners. Core contributions to linked publications are displayed in Figure 3.

Figure 3. Contributions per core to Y9Q1 WVCTSI linked publications.



In order to address the concern that WVCTSI may be supporting publications that are not being appropriately identified and linked to the grant, TEC pulls publications from appropriate library databases (e.g., PubMed) utilizing ORCID ID's when available and full names on the WVCTSI member list when ORCID ID's are not available and limiting the search to publications during the Y9 Q4 funding period. The list from the name-based search is reduced by including only those publications with author institutional affiliations in West Virginia. Core leadership review the list and contact all first authors regarding whether their publication should be linked to the grant. TEC continues to use the quarterly progress report through which publications, among several other types of information, are requested from all individuals who receive WVCTSI services or support.

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).

Administration Core reported having 121,211 website visitor hits (up from 102k last quarter), with an average of 407.3 website visitors per day during Q4. WVCTSI's social media engagement reported in Q4

includes: Facebook New Likes and Followers are down (from the +37 Likes and +115 Followers in Q3, to +12 Likes and +15 Followers in Q4), new Listserv subscribers increased from 200 in Q3 to 218 in Q4 (bringing total to 3379), new Twitter followers decreased from 56 to 14 in Q4 (bringing total to 694 followers), Instagram is down from 39 new followers to 13 new followers (bringing the total to 120), and YouTube Subscribers have increased from 953 (Y9Q3) to 1,060 followers (Y9Q4) with a total of +132k views.

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 74 external funding proposals and 42 external awards this quarter. Percentage of NIH award expended was at 100% in Q4. There were 25 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 as hired this quarter.

Key Recommendations to Administrative Core

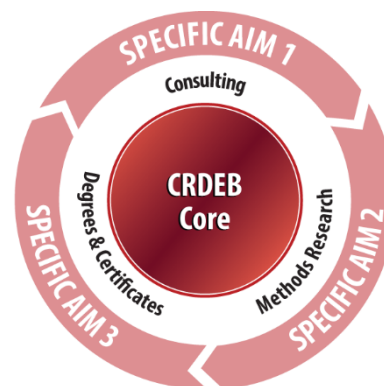
- Shift focus toward closing out this 5-year funding period, such as supporting efficient wrapping up of pilot award funding opportunities and piloting/evaluating recent new endeavors in support of a competitive renewal application.
- Continue to facilitate core and partner discussions and collaborative efforts to innovatively facilitate additional publications supported by and linked to WVCTSI NIH funding award, including continued effort to get all WVCTSI members who generate scholarly publications to 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 140 new REDCap users in Q4 with a total of 2,493 REDCap users to date (775 of which are active users). Of the 2,793 REDCap users, 1,863 were from WVU (575 active), 19 from CAMC (5 active), 15 from WVSOM (6 active), and 596 not affiliated with the above entities (189 active).

There were 8.5 hours reported in the category of updating existing REDCap projects and providing project follow-up meetings in Q4. 3 REDCap projects were made for WVCTSI- funded investigators and 2 REDCap projects were made for non-WVCTSI investigators. There was a total of 3,062 REDCap projects and 8,045 data instruments, 152 new REDCap service inquiries, and 12.5 hours of REDCap consultations reported in Q4. The total number of current TriNetX users was 456 in Q4 and there were 5,162 new



TriNetX inquiries, with 26 new TriNetX logins and 3 data set requests. CRDEB reported 1 practice/policy changes in Q4 and no professional development events.

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

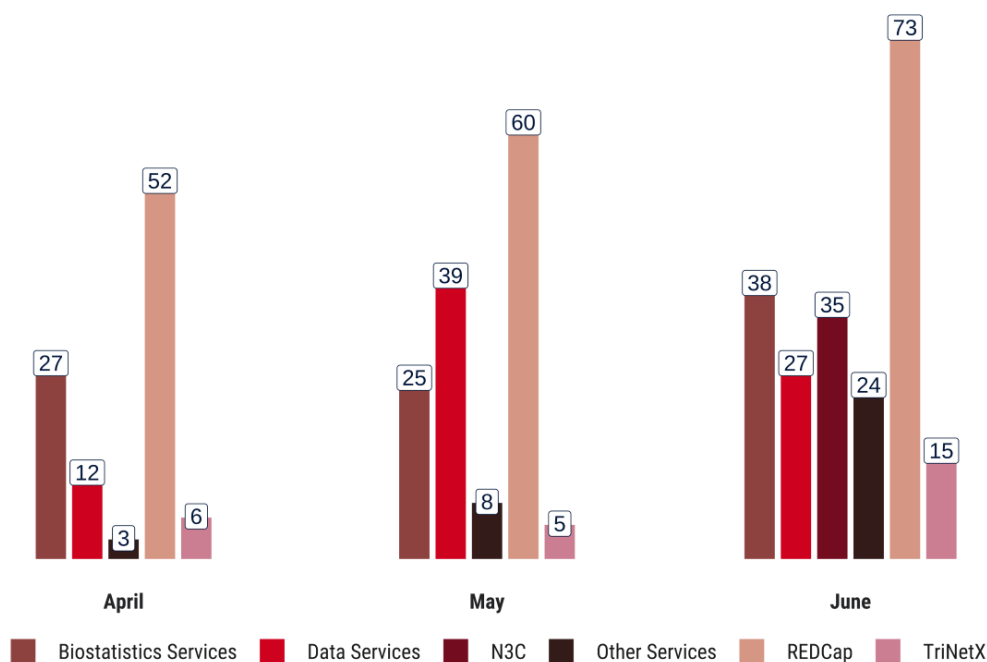


Figure 4. CRDEB iLab Core Management System services logged by month and service type.

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 34 BMIR-related inquiries, 15 new CRDEB consultations, 2 sample size/power consultations, 27 new statistical analysis consultations, and 8 new clinical study design consultations in Q4. Additionally, 694.25 hours were dedicated to biostatistics consultations. Zero GIS analysis consultations were reported for Q4.

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

CRDEB contributed to 11 external funding proposals (totaling over \$6.3 M) in Q4. Of these external funding proposals, 5 were standalone proposals (\$2.5 M), 6 were in collaboration with other cores (\$3.8 M); which included 2 with Admin/CRRF, 1 with Admin/CEO/CRRF, 1 with PD, and 1 with CRRF.

CRDEB supported 2 external funding awards (totaling over \$12K) in Q4. Of these 2 external funding awards, 1 was in collaboration with CRRF. There were 14 linked publications supported by CRDEB, where 3 of those publications were supported in collaboration with other cores; TECH, CRDEB, and PD.

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.

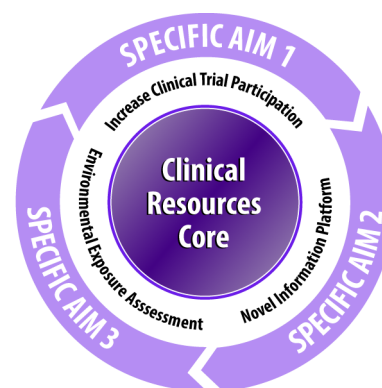
There were 6 new custom IDR dataset requests, 2 requests for updates to previous IDR datasets, and 17 IDR projects reported as completed in Q4. There were 329.5 hours spent on new data requests, 0 hours on updates to previous data sets, and 35.5 hours on data request consultation. CRDEB did not report 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. Consider whether professional development events targeted at increasing service utilization should be planned.
- Implement and report activity related to the Appalachian Research Consortium (ARC). Consider how to position such activity in a competitive renewal application.

Clinical Research Resources & Facilities Core

CRRF contributed to 27 external funding proposals (totaling over \$13M) in Q4, of which 21 were standalone and 6 collaborations with other cores. CRRF received 21 external funding awards (\$2.7M), 19 standalone and 2 collaborations. CRRF did not contribute linked publication in Q4. Figure 5 shows number of CRRF services monthly across Q4 by category and Figure 6 shows the number of OnCore studies by month.



Registration Counts for Clinical Research Resource Facilities

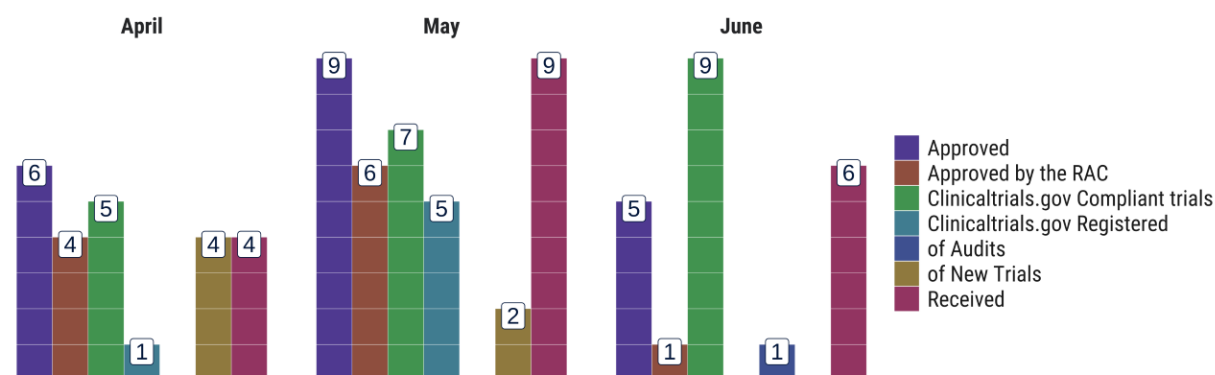


Figure 5. CRRF services by month and service type.

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.

Study Counts for Clinical Research Resource Facilities



Figure 6. CRRF OnCore studies by month.

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.

In Q4, CTCOE provided 126 unique instances of support to non-WVCTSI studies in the form of regulatory assistance (40), study coordination (30), accounting (55), and quality assurance audits (1). Within the expanded activities by CTCOE (established Q2Y8) which included Registration, a Risk Assessment Committee, and an Appeals Committee; there were 20 trials registered, 14 trials reviewed, and 11 approved by the risk assessment committee. Additionally, CRRF supported 4 new Early Stage PI's with industry or WVCTSI-initiated funding and 3 trials in new research areas. 219 participants were recruited, with 48 more completing a study. CRRF had 27 TriNetX study offers and 12 accepted at WVU, and 1 study was activated in Q4. CRRF reported 0 PI Academy events and 4 new PI Academy members.

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

- Plan and deliver PI Academy events.
- Consider innovative ways to support or contribute to linked publications.

- Identify appropriate metrics for Specific Aim 2 and consider how to position activity related to this aim in a competitive renewal application.

Community Engagement & Outreach Core

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

There were 108 WVPBRN and 159 ECHO sites reported in Q4. This included 10 new ECHO sites: (1) American Academy of Pediatrics (Morgantown, WV), (2) Home Sweet Home In Home Medical (Pensboro, WV), (3) Balance Living and Well-Being for Healthcare Providers (Pittsburgh, PA), (4) Invigor (North Chesterfield, VA), (5) Elkview Health LLC (Elkview, WV), (6) Texas Recovery Network Solutions (Houston, TX), (7) St. Joseph's Hospital (Buckhannon, WV), (8) Gilead (Foster City, CA), (9) River Valley Family Care (Ravenswood, WV), and (10) St. George Medical Clinic (Parsons, WV). There were 10 new partner organizations in Q4: (1) Calhoun BOE, and (2) 9 Health Departments (Clay, Greenbrier Mineral, Ritchie, Boone, Marshall, Raleigh, Grant, and Wood CO HD/Mid-Ohio Valley).

During Q4, there was 1 new CEO (non-ECHO) project: FORE Grant: Electronic Cigarette Withdrawal and the Effects of Nicotine Replacement in Electronic Cigarette Users, M. Blank (WVU). Additionally, CEO reported 2 networking opportunities: WVPBRN presentation at North American Primary Care Research Group (NAPCRG) Conference June 24-25 with Virtual Symposium Opportunity disseminated to Network and "Health Inequities Exposed & Exacerbated by the COVID-19 Pandemic" on June 30, 2021. There were 0 Community Advisory Board meeting and 5 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 7 new, 39 ongoing, and 0 completed WVPBRN projects as well as 1 new, 2 ongoing, and 0 completed CEO projects. All 4 of the perspective new projects reviewed in Q4 were accepted. There were 111 Project Development and Success services, 404 Project Implementation services, 0 Community Engagement and Training services, 0 new Ideas on Deck service, 142 hours of ECHO services, 12 Consultation services, 21 WVPBRN Activities, 1 funding opportunity identified, and 12 services for products reported during Q4. CEO had 7 supported external funding proposals (totaling over \$759K) in Q4. Of these, 5 were standalone (totaling \$694 K) and 2 were in collaboration: Admin (1) and Admin/CRRF/CRDEB (1). CEO supported 8 standalone external funding awards totaling \$2.8M in Q4. CEO did not report contributing to any linked publications.

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

In Q4, there were 17 Research Translation and Dissemination services, 5 practice changes, (4 external, 1 internal), and no policy changes or policy project briefs reported.



By the Numbers: Community Engagement & Outreach Services

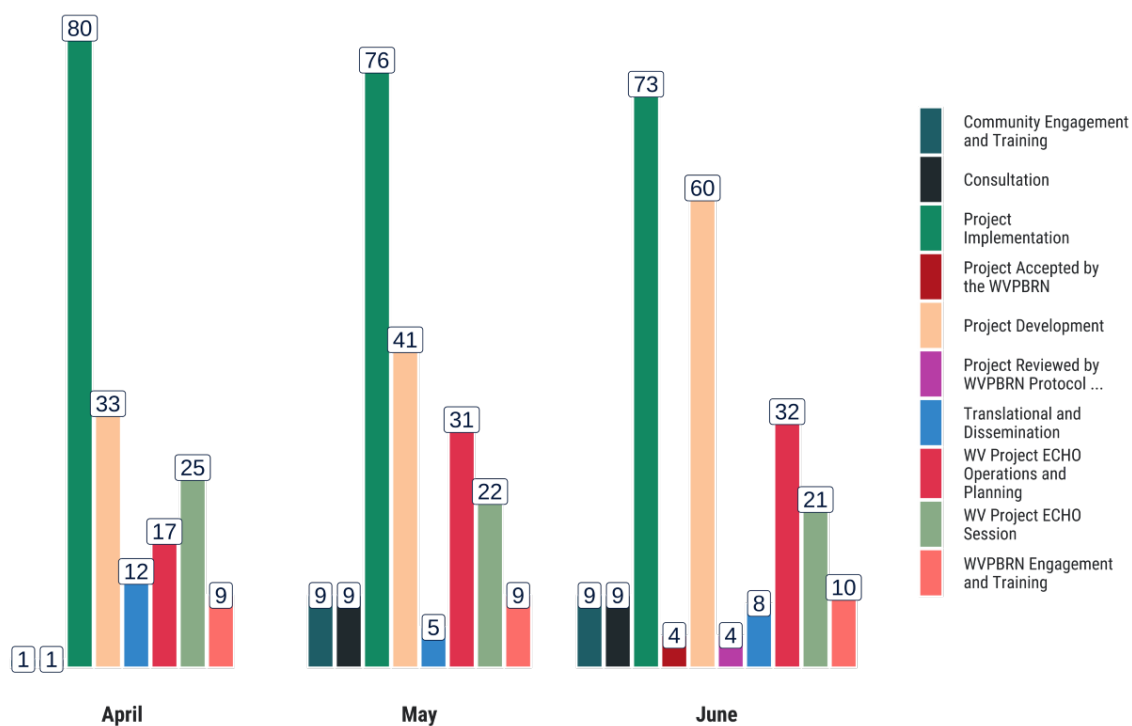


Figure 7. CEO core services logged by service type.

By the Numbers: Community Engagement & Outreach Products

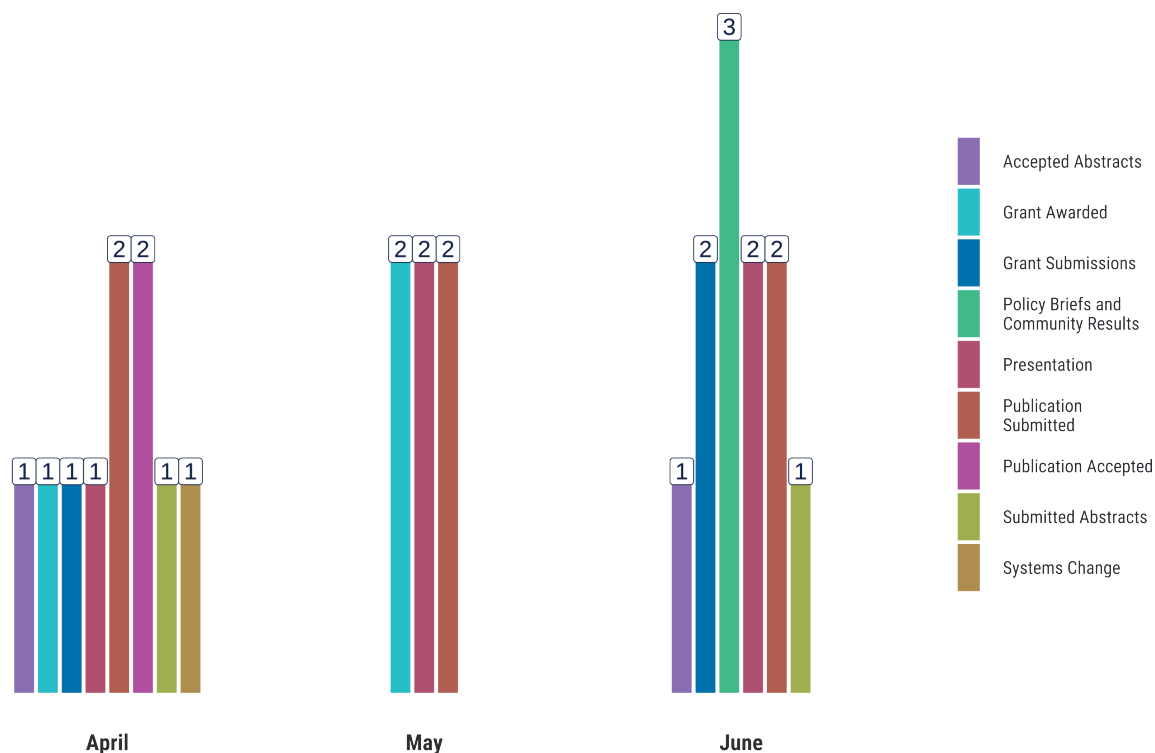


Figure 7. CEO core services for products.

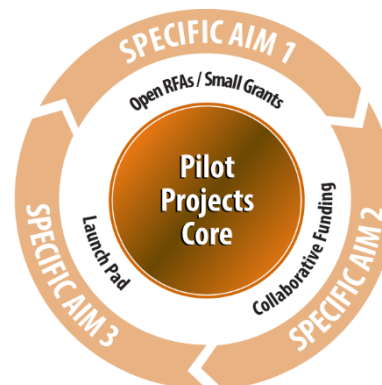
Key Recommendations to Community Engagement & Outreach Core

- Consider whether frequency of Community Advisory Board meetings is appropriate.
- Focus on completing WVPBRN and CEO projects as this funding cycle comes to a close.
- Consider innovative ways to support or contribute to linked publications.
- Consider how to increase utilization of Community Engagement and Training services.

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.

Pilot core received 14 small grant applications and awarded 6 small pilot projects. There will not be any new pilot funding opportunities this cycle to facilitate completion of all funded pilots. Pilot core provided 0 workshops, had 9 requested services, and contributed to 7 linked publications, 3 of which in collaboration: Admin (1), TECH (1), CRDEB/MU (1).



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

There were 34 active Pilot projects in Q4 addressing critical health issues. Additionally, the Pilot Core contributed to 3 standalone external grant proposals (totaling over \$726K) and 1 standalone external funding award (\$50K).

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

No additional Launch Pad Pilot projects will start the remainder of this funding cycle.

Key Recommendations to Pilot Projects Core

- Consider planning and delivering workshops, mentoring, or other types of support targeted at funded pilot awardees completing their scope of work by June 30, 2022.

Professional Development Core

The Professional Development Core is piloting Editorial Services. During Q4, 2 publication consultations, 1 copy editing, and 1 one-on-one manuscript coaching service were related to 2 publications submitted.

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.

There were 232 individuals who requested 511 services in Q4. There were 24 new investigator development service requests logged through iLab. There was 1 reported orientation or consultation provided to investigators new to WVCTSI. Additionally, there were 38 active mentors in the SACS program, as well as 3 female clinician scientists being mentored in Q4. There were 3 special events/programs for women in science: (1) FACTS "Suggestions for Becoming a More Productive Academic Writer-Follow Up Discussion", (2) FACTS "More Effective & Efficient Email Management", and (3) FACTS Follow Up Discussion "More Effective & Efficient Email Management".

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 8 scholars with 7 professional development activities: (1) Midhun Malla, Conflict management, (2) Samantha Minc, Virginias Vascular Study Group Regional Meeting, (3) Samantha Minc, PI Academy, (4) Samantha Minc, Research Scholars meetings and lectures, (5) Samantha Minc, Opioid CME, (6) Amanda Gaulke, R03 Grant Writing Workshop and (7) Toni Rudisill, American College of University Educators Advanced Teaching Course.

There were 0 CTS Certificate students enrolled, 0 new students, and 0 application received. WVU MS in CTS had a total enrollment of 30, with 7 applications received (6 accepted/offer extended) and had 5 students completed the program in Q4. MU MS in CTS did not report data this quarter. CTS PhD program had 7 current enrollments, 0 applications received or reviewed, 1 accepted, and 2 degrees conferred during Q4. Education programming reported no new academic courses, 0 research workshops/short



courses, 9 C/T research seminars, 167 unique participants in educational programming from WVU (153), MU (5), CAMC (3), and SOM (4).

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 \$10.77 M): 11 of which were standalone (totaling over \$8.28 M) and 3 of which were collaborative (totaling over \$2.48 M): ADMIN (2), and CRDEB (1). The Professional Development core supported 4 standalone external funding awards (totaling over \$3.26 M), and 3 collaborative linked publications with CRDEB (1), Admin (1), and Pilots (1).

By the Numbers: Investigator Development Services

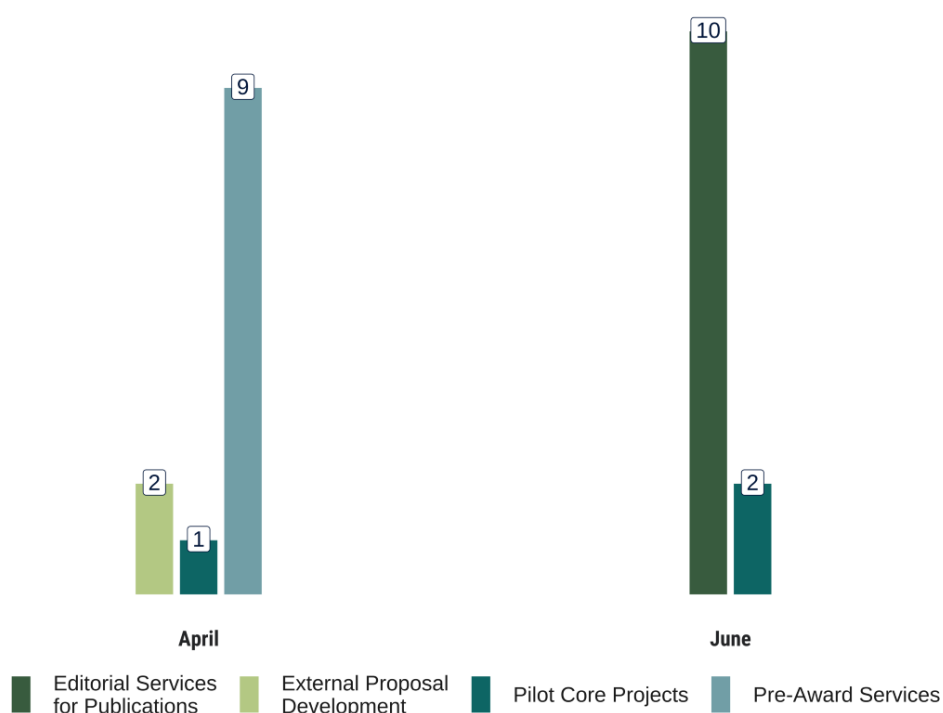


Figure 9. Investigator development services per service category as logged in iLab.

Key Recommendations to Professional Development Core

- Consider the viability of the CTS Certificate program considering there are no students reported as enrolled, applying, or accepted.
- Increase engagement and utilization of services by individuals at partner institutions outside of WVU Morgantown.

- Continue working to roll out and evaluate new editorial services supportive of publication and grant proposal preparation. Consider how to position such activity in competitive renewal application.

Technology and Resources for Core Laboratories Core

The Technology and Resources for Core Laboratories (TRCL) core contributed to 2 standalone external funding proposals totaling \$2.75M. TRCL contributed to 1 standalone external funding award totaling \$190K and 6 publications: 2 standalone and 4 collaborative with MU (2), Pilot (1), and CRDEB/MU (1) in 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 2 WVCTSI-supported projects, 2 open projects, and no new projects in Q4. Biospecimen data shows WVU collecting and utilizing 0 samples, MU collecting 263 samples and utilizing 15 samples, and CAMC collecting and utilizing 105 samples.

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 was 1 genomics studies (0 WVU and 1 MU), 16 Illumina projects (3 WVU, 13 MU), and 15 Illumina runs (3 WVU, 12 MU) reported in Q4. There were 7 total attendees for educational sessions including Bioinformatics at WVU and MU.

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.

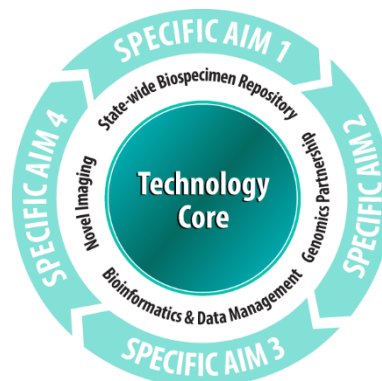
TRCL provided 7 training sessions to 2 unique individuals.

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

19 investigators were served with 208 hours for MicroCT across 5 projects, and 48 hours of MRI across 3 projects. No disclosures or patents were reported.

Key Recommendations to Technology and Resources for Core Laboratories Core

- Consider additional opportunities to facilitate patentable projects, collecting and utilizing biospecimen samples at WVU, and genomics studies at 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.

The Tracking and Evaluation Core (TEC) identified all publications linked to WVCTSI grant numbers directly from NCBI and created a [web-based table](#) displaying this information publicly, as well as [Social Network Analysis visualizations](#) to show collaboration among authors on linked publications. TEC completed and disseminated the Awareness Survey report in Q4.

TEC continues to refine the quarterly progress report through which all individuals who receive support/ services from WVCTSI are requested to report information on activity and products generated. TEC rolled out a user-friendly data portal through which stakeholders can utilize progress report data. TEC utilizes an ORCID ID survey to gather WVCTSI member ORCID ID's to be added to membership list, which currently includes ORCID ID for 495 members (14% of 3,437). This allows more accurate searches for publications by members that should be linked to the grant. TEC met with the Professional Development Core to develop an evaluation plan for the Fellows Research Academy pilot project including implementation of a service utilization survey and is currently working on a post-participation 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.

TEC continued to work with CEO, WVPBRN, and ECHO on the ECHO “SuperHub” and WVPBRN evaluation plans. Potential publications for the ECHO project are currently being conceptualized. TEC met with CEO to discuss collecting collaboration among WVPBRN sites. TEC will develop and present a collaboration survey at the WVPBRN retreat to collect this data. In collecting information through the quarterly progress report mentioned above, we were able to identify additional publications that should be linked to the WVCTSI grant numbers. TEC will continue to work with PD and Admin to make improvements and increase efficiency in analyzing such data. TEC continues to make updates to the [new website](#) that houses a) all tracking and evaluation reports years 6 through current (password protected), b) an automated linked publications hub with counts, full references, and abstracts (publicly available), c) social network visualizations of linked publication author networks (publicly available), and d) the quarterly progress report data portal (password protected).

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 Y9 was disseminated in Q4 and discussed at a WVCTSI Steering Committee meeting. The ECHO and WVPBRN research evaluation plans when completed will demonstrate impact on health outcomes. Additionally, TEC core member Malayna Bernstein served as qualitative methodology consultant designing qualitative instrumentation and mentoring research associates conducting interviews and data analysis for the recently awarded supplement: “Developing Novel Strategies to Increase COVID-19 Testing among Underserved and



Vulnerable Populations in West Virginia through Community and State Partnerships.” NIH Award No. 3U54GM104942-05S3 (Total Awarded: \$4,999,989).

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.
- Continue to refine the progress report and related data portal for use by PD, Pilot, and Admin cores to collect quarterly report information from individuals receiving WVCTSI services, protected time, or other support.
- Implement next steps for WVPBRN and ECHO evaluations. Consider how to position that activity in a competitive renewal application.
- Continue to refine and enhance data collection and visualization tools available online at <https://percwv.com/> for use by all stakeholders.

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 4 collaborative linked publications with Pilot (1), TECH (2), and TECH/CREDEB (1), 21 external funding proposals, and 5 externally funded awards. MU had 4 ESIs accessing WVCTSI services or resources in Q4 and 74 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 Q4, WVSOM reported 2 external funding proposals, 5 workshop/course/seminar/retreat, and 4 poster/exhibits/promotional events. WVSOM had 3 community participatory research projects, 4 open collaborative CTS projects outside the WVPBRN, 1 trainee in community-engaged research curriculum, and 1 current alliance CTS collaboration. WVSOM had 6 new REDCap users (15 total) and 103 WVCTSI members in Q4.

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 supported 0 linked publications, presentations, or funding proposals connected to WVCTSI. CAMC personnel attended 3 journal clubs and there were 19 REDCap users (5 active users), 4 iLab users, and 57 WVCTSI members at CAMC in Q4.

National Institute for Occupational Safety and Health (NIOSH)

NIOSH had 14 WVCTSI members in Q4, and reported 2 substantive accomplishments: (1) NIH T32 training grant ES032920 entitled “Pre-doctoral Training in Systems Toxicology” (syTOX) submitted by WVU with NIOSH collaborators. This training grant proposes to support up to 35 graduate student trainees over five years in diverse inhalation exposures performed in preceptor research programs at HELD and the WVU Center for Inhalation Toxicology (iTOX), and (2) a manuscript describing collaborative work to evaluate source control by cloth masks accepted for publication. The manuscript is reported as being published in scientific literature, and preliminary results were distributed in earlier reporting periods through WVU press releases. Additionally, NIOSH reported training and professional development through (1) a collaborative research effort to evaluate cloth masks, and (2) a collaborative research effort to establish a clinical trial for coal workers' pneumoconiosis.

**Veteran Affairs Medical Centers (VAMC)**

Veteran Affairs Medical Center (VAMC) reported two significant accomplishments in Q4: (1) Initiation of WVU-Eastern Division VA-WVCTSI local collaboration team, and (2) Monthly briefings held began in April 2021. Additionally, VAMC provided opportunities for training and professional development in Q4 in 2 ways: (1) providing announcements for training and education opportunities are provided to local VA Medical Center clinical staff with targeted communications based on specialty areas, and (2) providing meetings held with the whole health team member and chair to discuss future partnership opportunities with CTSI and HSC East division. VAMC had 6 WVCTSI members in Q4.

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

- Work to implement and/or increase utilization of iLab.
- Continue efforts to increase WVCTSI membership, awareness, and utilization of WVCTSI core services at each partner institution.