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

3rd Quarter of Fiscal Year 2019-2020 (Y8)

Reporting Period: January 1, 2020 – March 31, 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

(January 1, 2020 – March 31, 2020)

Contents

WVCTSI Year 8 Dashboard

Metric	Year 8				
Period of Performance	**7/01/2019 to 6/30/2020**				
	Y8 Q1	**Y8 Q2**	**Y8 Q3**	**Total**	**TARGET**
CTR-Linked Publications	24 (8)	17 (3)	10 (3)	60(15)	300
Proposals Submitted (#)	54	75	56	185	225
Subcategory: Proposals Submitted by ESIs	19	8	16	43	
Subcategory: Proposals Submitted by Clinicians	14	20	20	54	
Proposals Funded (#)	48	24	25	97	160
Subcategory: ESIs-Proposals Funded	7	5	2	14	
Active	7	5	0	12	
New	3	4	2	9	
Subcategory: Clinician-Proposals Funded	20	13	10	43	
Active	20	13	8	41	
New	7	5	2	14	
Total External Funding Received ($ Millions)	$ 13.6	$ 19.6	$ 5.6	$ 38.8	$40M
Subcategory: Federal	$ 10.2	$ 1.9	$ 1.40	$ 13.5	
Subcategory: State	$ 1.6	$ 5.8	$ 3.40	$ 10.8	
Subcategory: Industry	$ 0.27	$ 11.7	$ 0.34	$ 12.2	
Subcategory: Other*	$ 1.6	$ 0.23	$ 0.40	$ 2.2	
nonprofits includes: foundations, professional societies, etc.					
Disclosures Submitted:	0	0	4	4	10
Patent Applications	0	0	4	4	
Patents Awarded	0	0	0	0	
WVCTSI Membership	2,327	2,409	2518	2518	2,600
Non-Morgantown	683	707	739	739	800
Community Membership	229	184	191	191	
Investigators accessing CTSI services or resources (unique # per quarter)	240	227	221		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 3rd quarter (Q3) of fiscal year 2019/2020 (Y8), which covers a reporting period from January 1st, 2020 through March 31st, 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, there were 13 peer-reviewed publications officially linked[1] to WVCTSI funding, 14 presentations, 56 external funding proposals ($57.8 million), and 25 funded awards ($5.6 million) this quarter. While linking of publications lags real-time, the number of linked publications (60 year-to-date) continues to be a primary concern.

Overall recommendations from Tracking and Evaluation Core

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

Key Recommendations to Administrative Core

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

Key Recommendations to Clinical Research Design, Epidemiology & Biostatistics Core

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

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[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 Resources & Facilities Core

- Identify appropriate metrics for Specific Aim 2 and report data on those metrics in upcoming quarterly report cycles.

Key Recommendations to Community Engagement & Outreach Core

- Continue and expand efforts to disseminate research results through publication in high-quality journals and other outlets.
- Review progress toward annual targets for all metrics and consider necessary actions to accelerate those less than 75% accomplished at this time.

Key Recommendations to Pilot Projects Core

- Identify barriers and work to increase submissions of pilot project applications from partner institutions outside of WVU.

Key Recommendations to Professional Development Core

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

Key Recommendations to Technology and Resources for Core Laboratories Core

- Consider opportunities to facilitate patentable projects.
- Continue to facilitate excellent collaborative relationships between CAMC, Marshall, and WVU.

Key Recommendations to Tracking and Evaluation Core

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

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

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

Quarterly Reporting Annual Timeline Targets

1st quarter Reporting Period = July 1 – Sept 30

Sept 18	1st quarter report task assigned to each KCA/Partner via email to key contacts
Oct 1	TEC begins data acquisition from repositories (e.g., iLab)
Oct 7	Quarterly data submission due from key contacts to TEC
Sept-Oct	Pre/post submission meetings (TEC and key contacts)
Oct 28	1st quarter formative evaluation report and metric data distributed by TEC
Nov-Dec	Steering Committee discusses 1st quarter formative evaluation

2nd quarter Reporting Period = Oct 1 – Dec 31

Dec 18	2nd quarter report task assigned to each KCA/Partner via email to key contacts
Jan 1	TEC begins data acquisition from repositories (e.g., iLab)
Jan 7	Quarterly data submission due from key contacts to TEC
Dec-Jan	Pre/post submission meetings (TEC and key contacts)
Jan 28	2nd quarter formative evaluation report and metric data distributed by TEC
Feb-Mar	Steering Committee discusses 2nd quarter formative evaluation

3rd quarter Reporting Period = Jan 1 - Mar 31

Mar 18	3rd quarter report task assigned to each KCA/Partner via email to key contacts
Apr 1	TEC begins data acquisition from repositories (e.g., iLab)
Apr 7	Quarterly data submission due from key contacts to TEC
Mar-Apr	Pre/post submission meetings (TEC and key contacts)
Apr 28	3rd quarter formative evaluation report and metric data distributed by TEC
May-June	Steering Committee discusses 3rd quarter formative evaluation

4th quarter Reporting Period = Apr 1 – June 30

June 18	4th quarter report task assigned to each KCA/Partner via email to key contacts
July 1	TEC begins data acquisition from repositories (e.g., iLab)
July 8	Quarterly report data due to TEC from each core
June-July	Pre/post submission meetings (TEC and key contacts)
July 29	4th quarter formative evaluation report and metric data distributed by TEC
Aug-Sept	Steering Committee discusses 4th quarter formative evaluation

Administrative Core

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

There were 56 external funding proposals ($57.9 million) and 25 funded awards ($5.6 million) during Y8 Q3 (see Figures 2 and 3). Four new staff were added to the ADMIN core, totaling 48 WVCTSI staff members.

Tracking and Evaluation Core pulled linked publications from NCBI utilizing all appropriate grant numbers to accurately identify which publications should be considered linked to the grant in this and all previous quarters (see Table 1). Table 1 displays officially linked publications associated with each quarterly reporting period. Numbers in parentheses are additional publications with a current status of "ahead of print" that are expected to be linked to the grant at some point.

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

	Q1	Q2	Q3	Q4	Totals
Years 1 – 5					688
Year 6	56	67	69 (4)	62 (1)	254 (5)
Year 7	51	58 (1)	52 (3)	41	202 (4)
Year 8	26 (6)	24 (6)	10 (3)		60 (15)
Total					1204 (24)

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

There were 10 publications officially linked to the grant (with an additional 3 ahead of print) in Quarter 3. Cores and partners contributed to the following number of linked publications each: 8 ADMIN, 1 TECH, 1 CRRF, 1, CRDEB, 3 PD, 6 Pilot, 1 WVSOM, 1 CAMC, and 9 MU. These numbers do not sum to 13 because five publications included multiple contributing cores/partners (see Figure 1).

Publications by Core or Institution
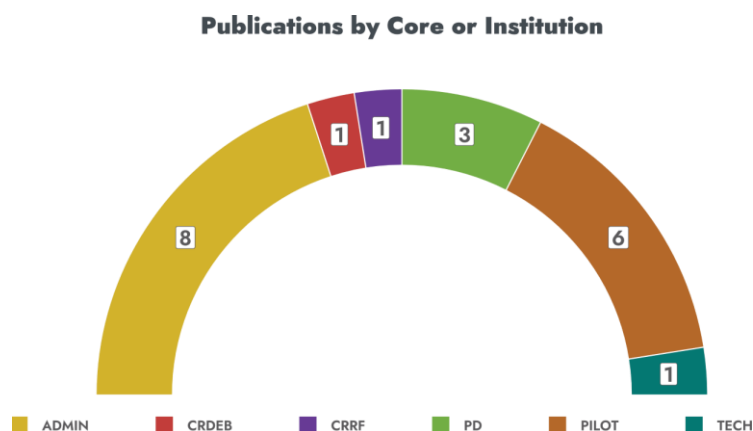
Figure 1. Contributions per core to WVCTSI linked publications during Quarter 3 (Year 8).

Year-to-date number of linked publications was 60 (with an additional 15 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 192 and 161, respectively; both more than double the number of linked publications for the current year-to-date. In order to address the concern that WVCTSI may be supporting publications that are not being appropriately identified and linked to the grant, TEC pulled publications from appropriate library databases (e.g., PubMed) utilizing all names on the WVCTSI member list and limiting the search to publications during the Y8 funding period. The resulting list was

reduced by including only those publications with author institutional affiliations in West Virginia. ADMIN is contacting all first authors regarding whether their publication should be linked to the grant. ADMIN added a field to the membership application to include active ORCID this quarter, this will allow future pulls of publications by member list to be much more efficient and accurate.
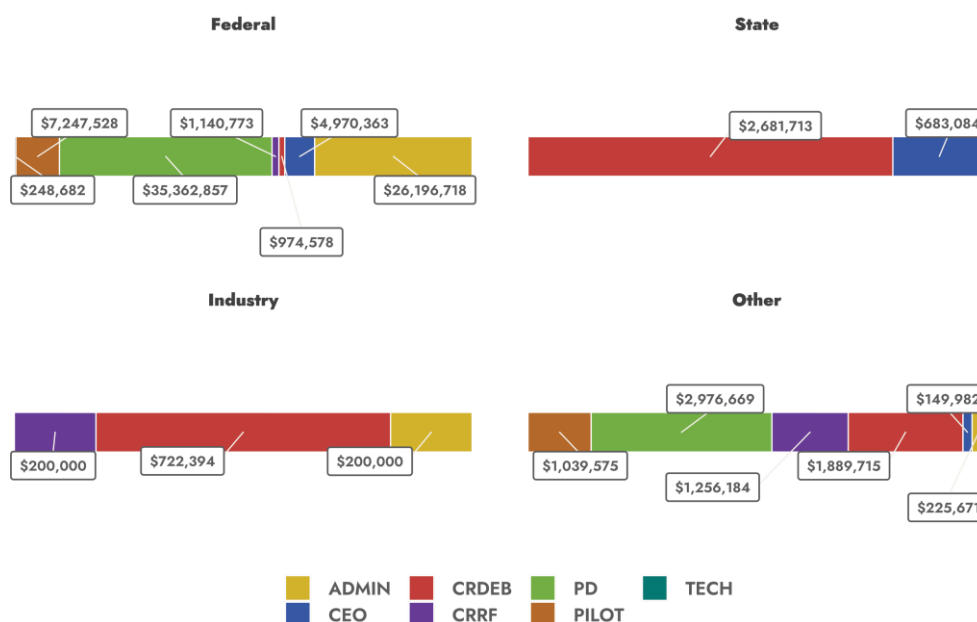
External Funding Proposal Amounts by Core

Federal

$7,247,528 $1,140,773 $4,970,363

$248,682 $35,362,857 $26,196,718

$974,578

State

$2,681,713 $683,084

Industry

$200,000 $722,394 $200,000

Other

$2,976,669 $149,982

$1,039,575 $1,889,715

$1,256,184

$225,671

Legend: ADMIN | CRDEB | PD | TECH
CEO | CRRF | PILOT

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

External Funding Award Amounts by Core

Federal

$343,125 $592,210

$1,117,187

State

$704,521 $2,935,674

$416,272

Industry

$30,909 $31,109 $210,790

$264,915 $31,405

Other

$105,332 $204,763

$245,060 $89,785
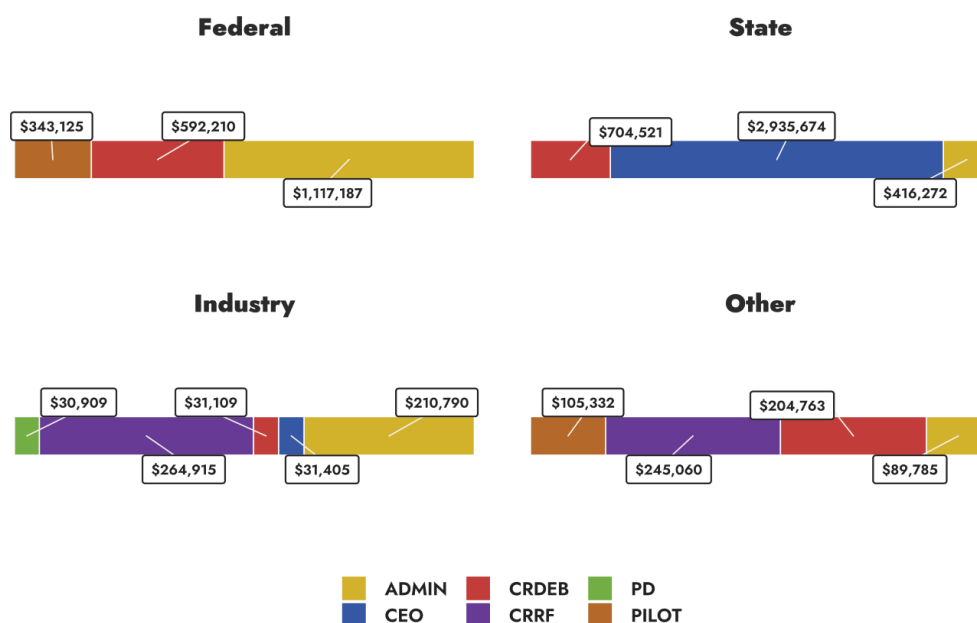
Legend: ADMIN | CRDEB | PD
CEO | CRRF | PILOT

Figure 3. External funding awards dollar amount per core.

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

WVCTSI website traffic was unable to be tracked throughout the quarter due to an error with the servers, because of that the data does not include the month of January. WVCTSI's social media engagement continues to steadily increase: Facebook (+8 Likes and +11 follows), Twitter (+25 Followers), and Listserv (+90).

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 56 external funding proposals and 25 external awards this quarter. Percentage of NIH award expended per core ranged from 42% to 66%, with two cost transfers/corrections reported this quarter.

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

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

Key Recommendations to Administrative Core

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

Clinical Research Design, Epidemiology & Biostatistics Core

Specific Aim 1. Effectively engage investigators throughout WV by providing traditional services in biostatistics and epidemiology.

Investigators engage through the CRDEB core utilizing available resources including the Integrated Data Repository (IDR), REDCap, and TriNetX. There were 78 new REDCap users in Q3 with a total of 1,860 REDCap users to date (423 of which are active users). Of the 1,860 REDCap users, 1,406 were from WVU (350 active), 16 from CAMC (4 active), 11 from WVSOM (4 active), and 427 not affiliated with the above entities (65 active).
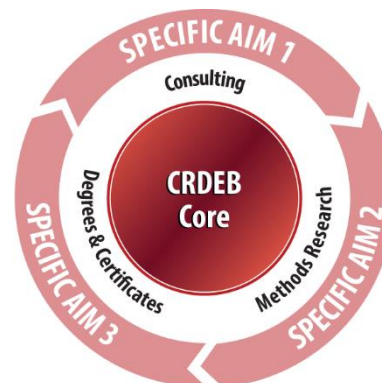
Additionally, 3.5 hours were spent updating existing REDCap projects and providing project follow-up meetings in Q3, a 3 hour increase from Q2. 4 REDCap projects was made for WVCTSI- funded investigators (annual target = 16) and 0 REDCap projects were made for non-WVCTSI investigators, 42.25 hours were spent building new REDCap projects for investigators, and 7.5 hours of REDCap consultations were reported in Q3. There were 120 new REDCap projects/data instruments (with a total of 2,234 projects/data instruments), and 84 new REDCap service inquiries. The total number of current TriNetX users was 345 in Q3 and there were 2393 new TriNetX inquiries, with 33 new TriNetX logins and 1 data set requests (annual target = 25). CRDEB reported no professional development events (annual target = 5) or practice/policy changes in Q3.
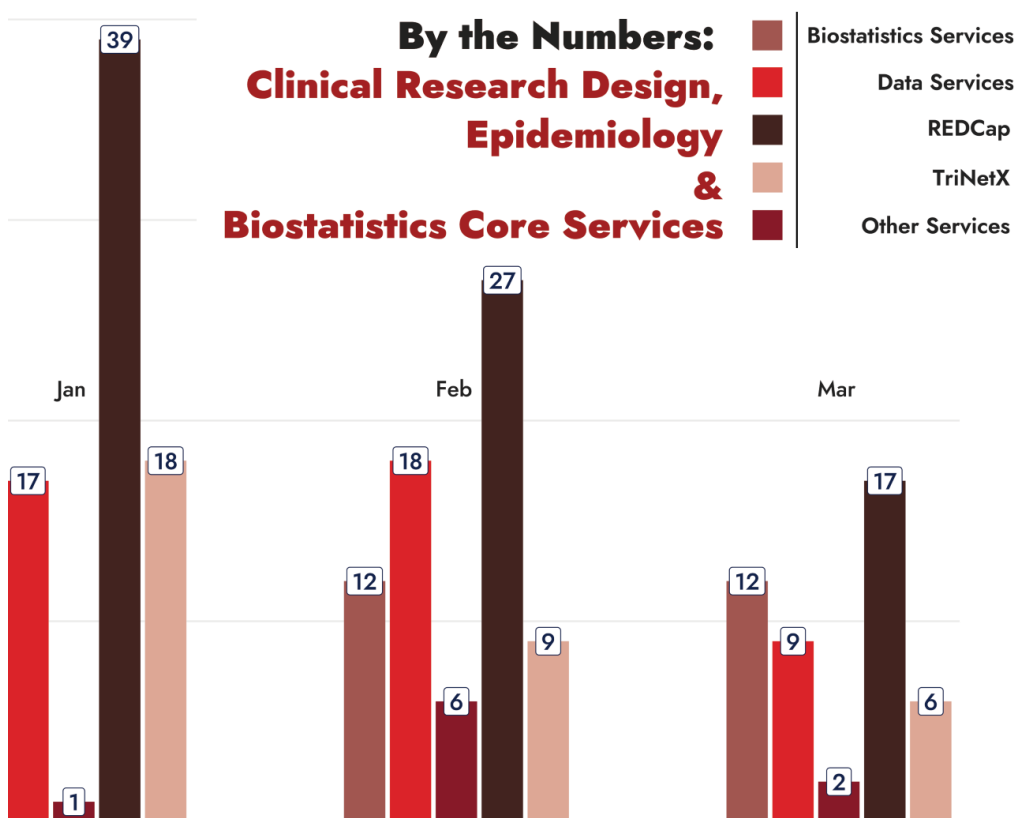

Figure 4. CRDEB iLab Core Management System services logged by month and service type.

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 67 BMIR-related inquiries, 30 new CRDEB consultations, 6 sample size/power consultations, 18 new statistical analysis consultations, and 15 new clinical study design consultations in Q3. Additionally, 447.5 hours were dedicated to biostatistics consultations. 4 GIS analysis consultations were reported for Q3.

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

CRDEB had 12 supported external funding proposals, 8 of which were in collaboration with other cores in Q3 (totaling over $6.1 M) and 7 externally funded awards, 6 of which were in collaboration with other cores (totaling $1.5 M). CRDEB reported 6 presentations supported by WVCTSI and contributions to 1 linked publications.

Specific Aim 4[2]. 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 27 new custom IDR dataset requests, 19 requests for updates to previous IDR datasets, and 7 IDR projects reported as completed in Q3. There were 651.5 hours spent on new data requests, 44.75 hours on updates to previous data sets, and 50.5 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.
- Implement and report activity related to the Appalachian Research Consortium (ARC).

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[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 8 external funding proposals (totaling over $2.59 M) in Q3 including collaborations with ADMIN, PD, CRDEB, and CEO. CRRF received 9 external funding awards (over $509,000) including collaborations with ADMIN, and CRDEB. CRRF contributed 1 linked publications and reported no presentations. See Figure 5 for number of CRRF iLab service requests monthly across the reporting period by category.
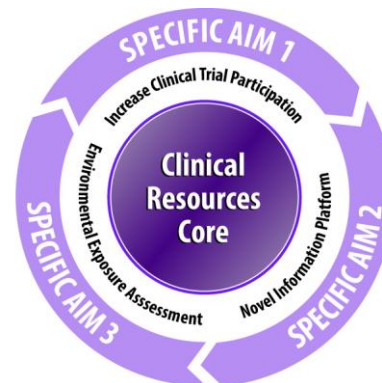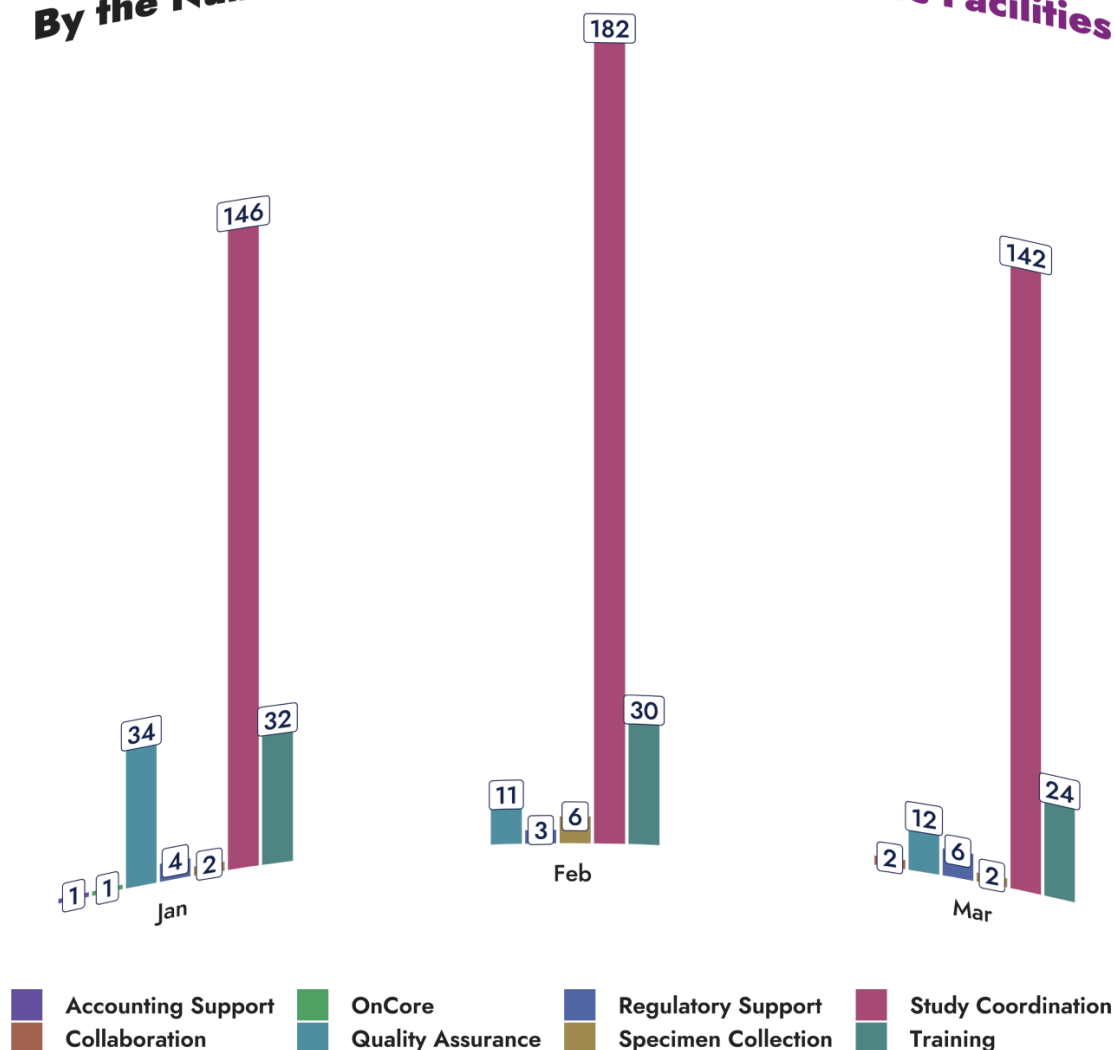
Figure 5. CRRF iLab Core Management System services logged by month and service type.

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

CTCOE provided 100 unique instances of support to non-WVCTSI studies in the form of regulatory assistance (32), study coordination (25), accounting (42), or quality assurance audits (1) in Q3. Within the recently expanded activities by CTCOE (last quarter) which included Registration, a Risk Assessment Committee, and an Appeals Committee; there were 30 trials were registered, and 9 trials were reviewed, 6 of which were approved by the risk assessment committee. Additionally, CRRF supported 1 new Early Stage PI's with industry or WVCTSI-initiated funding in Q3. A total of 60 participants were recruited, with 55 completing a study. CRRF had 14 TriNetX study offers and 6 accepted offers, and 0 studies were activated this quarter.

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

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

**Key Recommendations to Clinical Research Resources & Facilities Core**

- Identify appropriate metrics for Specific Aim 2 and report data on those metrics in upcoming quarterly report cycles.

Community Engagement & Outreach Core

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

There were 107 WVPBRN and 117 ECHO sites reported in Q3. This included 5 new ECHO sites: Central Virginia Health Services, STEPS Wellness Center (OH), MedMark Treatment Centers of WV, Potomac Highlands Guild, and Alleghany Health Network. There was 3 new partner organization reported: WVU Cancer Institute/College of Physical Activity and Sport Science, University of NC Chapel Hill, and Ohio State University.

During Q3, there were 3 networking opportunities: COAT Conference, FACTS, and International Workshop on HIV and Women Conference. Additionally, there was 1 Community Advisory Board meeting done as a virtual call titles AMHI PCORI Funded Depression Project, and 4 mentored investigator reported in Q3.
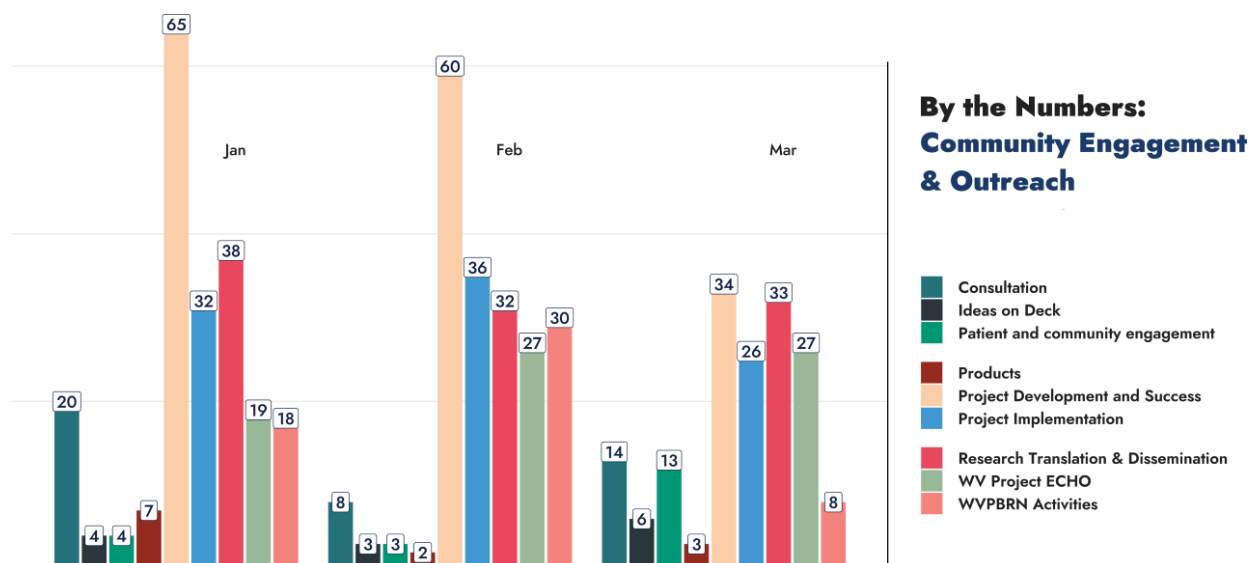
Figure 6. CEO core services logged by service type.

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

There were 13 new, 27 ongoing, 10 completed WVPBRN projects, and of the 9 projects that were reviewed 3 were accepted in Q3. There were 158.5 Project Development and Success services, 93 Project Implementation services, 20 Community Engagement and Training services, 7 new Ideas on Deck services (13 in total) , 73.25 hours of ECHO services, 42 Consultation services, 56.5 hours of services for WVPBRN Activities, 2 funding opportunities were identified, 3 ongoing CEO projects, and 12 services for products reported during Q3.

CEO also contributed to 7 external funding proposals (totaling over $5.8M), 3 of which were in collaboration with other cores (Admin, PD, ad CRDEB &CRRF), and 4 externally funded projects (totaling over $2.9 M, one of which was in collaboration with CRDEB) in Q3. CEO contributed to no linked publication and no presentations were reported in Q3.

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

In Q3 there were 103 Research Translation and Dissemination services provided. 1 CEO Project Policy Brief was reported but not submitted to TEC and 3 practice/policy changes were reported: (1) Practice change- MedManage, (2) Policy Change: Network Infrastructure- Design Studio updates to Tutorial Format, and (3) Internal Policy Change: CAB Project Approval Process.

Key Recommendations to Community Engagement & Outreach Core

- Continue and expand efforts to disseminate research results through publication in high-quality journals and other outlets.
- Review progress toward annual targets for all metrics and consider necessary actions to accelerate those less than 75% accomplished at this time.

Pilot Projects Core

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

There were no pilot grant applications received in Y8 Q3. 3 Pilot grants were awarded in Q3 (1- open, 1-launch, and 1-small). The Pilot core provided 4 workshop and 15 consultations. The Pilot core contributed to 6 publication this quarter and no presentations were reported.
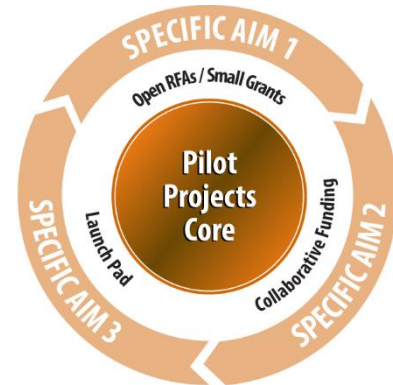
Specific Aim 2. Advance collaborative research endeavors to address WVCTSI priority health areas within WV as well as throughout the Appalachian region.

There were 14 pilot project awards (9- open, 1- launch, and 4-small), allowing for 28 active Pilot projects addressing critical health issues received funding in Y8 Q3. Additionally, the Pilot Core contributed to over $8 million in external grant proposals and over $380k in external grants awarded.

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

Pilots received 1 Launch award in Y8 Q3. Pilots listed 4 awardees on launch; 3 from WVU and 1 from Marshall

Key Recommendations to Pilot Projects Core

- Identify barriers and work to increase submissions of pilot project applications from partner institutions outside of WVU.
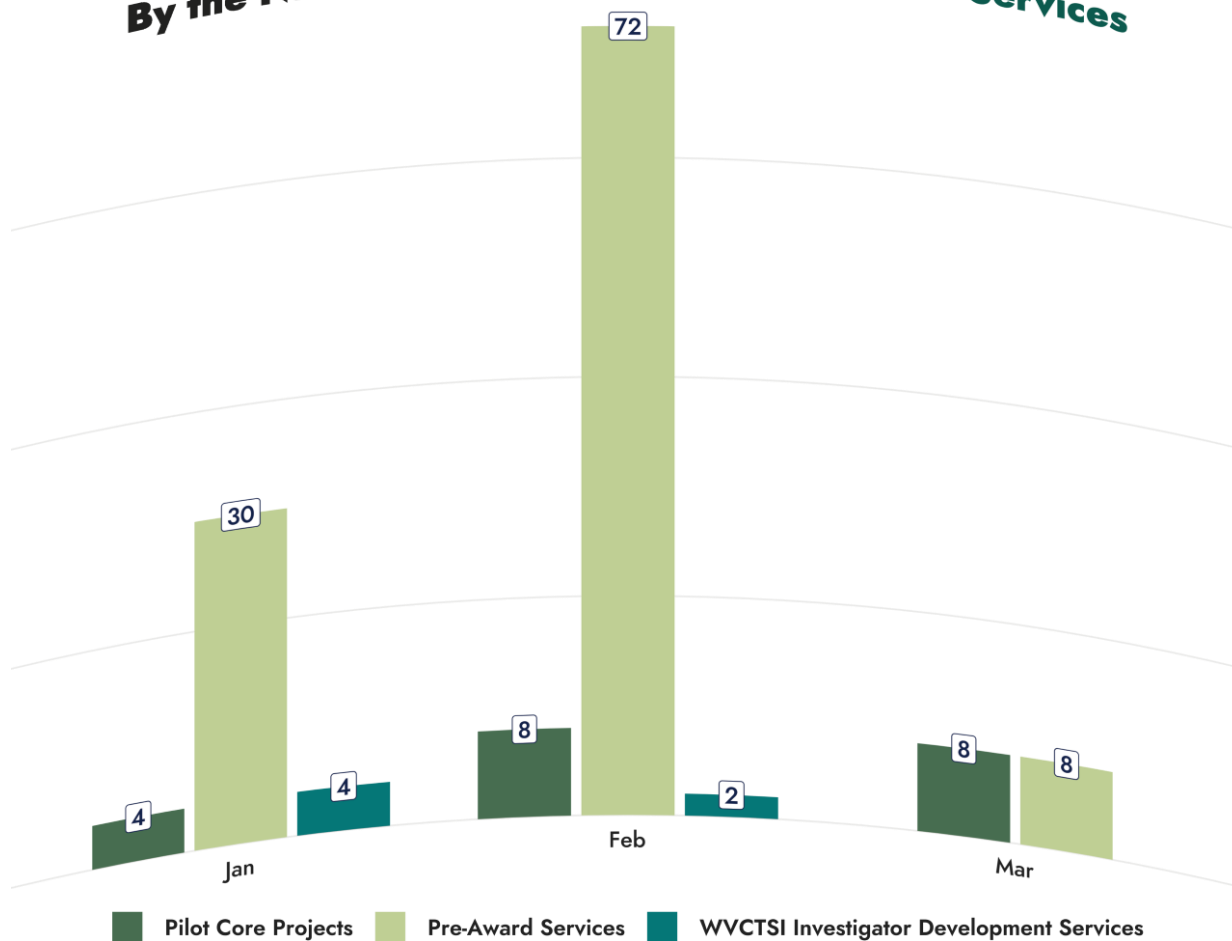
Professional Development Core

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 221 users requested 841 services through iLab in Q3. There were 93 new investigator development service requests through iLab. There were no reported orientations or consultations provided to investigators new to WVCTSI. Additionally, there were 12 external active members in the SACS program in Q3, as well as 5 female clinician scientists being mentored. There was 1 special event/program for women in science in Q3, although 3 were listed in the narrative. There include 1) FACTS: Outreach, where bowls were painted at the WOW Factory for the Empty Bowls of Mon County Campaign, 2) FACTS: Converting an Abstract to a Publication, and 3) FACTS: Navigating Academic Life by Leveraging Your Strengths.

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

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

The PD core reported mentoring 0 unique fellows/residents, 3 graduate students, 2 undergraduate students, and 1 full team meeting, as well as 4 professional development activities.

There was 1 CTS Certificate enrolled and CTS PhD had 8 students enrolled (with 5 applications received, but none accepted) at WVU in Q3 (MU enrollment was not reported). Education programming reported 3 new academic courses (CTS 600- Foundations of Scientific Integrity, CTS 610- Clinical Research- Ethics and Regulatory Aspects, and CTS 620 Scientific Manuscript Writing and Publishing), 1 workshops (Pilot Grant Proposal Workshop), and 2 C/T research seminars (FACTS seminars reported above relative to Specific Aim 1). These research seminars had a total of 47 unique participants, 43 of which were from WVU, 3 from MU, and 1 from WVSOM.

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

The Professional Development core contributed to 31 external funding proposals (over $38.3 M total; 10 of which were collaborative with singular cores: Pilots (3), Admin (4), CRDEB (4), CRRF (1); and 1 collaboration with both Pilot & CEO) and 1 externally funded awards totaling more than $30,909. The Professional Development core reported 1 presentations supported by CTR Award and 3 linked publications.

Key Recommendations to Professional Development Core

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

Technology and Resources for Core Laboratories Core

The Technology and Resources for Core Laboratories core contributed to 1 external funding proposal totaling $248,682.00, and with no externally awarded funds in Q3. TRCL contributed 1 publications during Q3.

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

TRCL reported 1 WVCTSI-supported projects, with 4 new projects, and 71 open project this quarter. This marks the third quarter in which Biospecimen sample collection and utilization is fully collaborative. Biospecimen samples and utilization were reported for both WVU and CAMC, however due to the disruption of the COVID-19 pandemic MU did not report their numbers.

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, 12 Illumina projects (8 WVU, 4 MU), and 28 Illumina runs (4 WVU, 24 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.

Eight educational sessions with 19 total attendees were provided.

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

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

Key Recommendations to Technology and Resources for Core Laboratories Core

- Consider opportunities to facilitate patentable projects.
- Continue to facilitate excellent collaborative relationships between CAMC, Marshall, and WVU
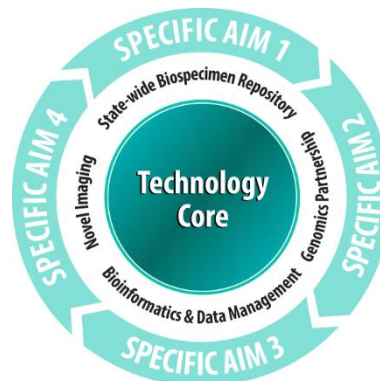
Tracking and Evaluation Core

TEC core members submitted 4 presentation proposals for the American Evaluation Association Annual Conference, one of which was an invited collaboration.

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

TEC continued its efforts in communicating with key contacts to refine metrics for increased accuracy in reporting, with CRRF having the most significant updates. TEC was successful in identifying all publications linked to the WVCTSI grant number directly from NCBI. TEC supported identifying publications potentially associated with the WVCTSI grant number. An updated list of potential publications was created this quarter for Y8 and is currently being reviewed by other cores. ORCID has been added to the membership form to help better facilitate this list of potential publications. TEC is currently creating an ORCID survey to collect this information from current members. This process will continue to be refined and expanded over future quarters. TEC continues to refine Social Network Analysis visualizations to show collaboration among authors on linked publications as well as geographic location. The Awareness Survey distributed during Q2 was closed during Q3 and the data is currently being analyzed, with a report to be completed during Q4.

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 interviews and focus groups were completed. Potential publications for the ECHO project are currently being conceptualized. TEC began working on the Alumni survey data and expect a report completed in Q4. TEC continues to work with the PD core in creating and disseminating surveys, including the progress report for quarterly data collection. 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 2nd Quarter of Y8 was disseminated in Q3 of Y8. Additionally, a TEC core member contributed to an NIH supplement designed with the following two specific aims: 1) describe community attitudes toward opioid use disorder and harm reduction services including syringe exchange, and 2) understand the multilevel syndemic factors that may contribute to development of opioid use disorder among young women for the purposes of informing future intervention studies. TEC's qualitative specialist continued to refine and analyze interview data. The ECHO research evaluation plan when completed will demonstrate impact on health outcomes.

Key Recommendations to Tracking and Evaluation Core

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

Marshall University (MU)

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

For Q3, MU reported 9 peer-reviewed publication. MU submitted 27 external funding proposals and had 4 funded awards. MU worked collaboratively with many WVCTSI cores in Q3. Marshall was awarded one Open Pilot Grant, 4 PI's attended the Pilot Grant Writing Workshop, submitted 4 open grant applications, and 3 active pilot projects (one in collaboration with WVU) this quarter. The PD core provided 5 services for proposal development. MU reported 0 genomic studies, 4 Illumina projects, and 24 runs (Illumina sequencing lanes). MU currently has 47 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 Q3, WVSOM reported 1 peer-reviewed publication and 5 presentations, 4 of which were at the MID-WINTER OSTEOPATHIC SEMINAR. They submitted 6 funding proposals and received 2 awards this quarter. WVSOM had 6 PI's attended Pilot Funding Opportunities ad WVCTSI Services, one Pilot Core Consultation, and one active pilot project. WVSOM did not recruited investigators this quarter. WVSOM provided 5 student opportunities for C/T research during Q3. WVSOM had 12 trainees in community-engaged research curriculum and 3 open collaborative CTS projects outside the WVPBRN. WVSOM housed 16 REDCap users (4 active). WVSOM membership remained at 79.

National Institute for Occupational Safety and Health (NIOSH)

NIOSH consists of a network of research facilities across the nation, including the Health Effects Laboratory Division (HELD) located on the WVU campus in Morgantown, WV. NIOSH/HELD is a world-wide leader in the study of occupational lung diseases and actively collaborates with WVU. Several NIOSH researchers maintain joint appointments in departments at the Health Sciences Center, creating numerous research partnerships in the area of occupational health, biostatistics, and epidemiology.

A team consisting of members from WVCTSI, WVU, NIOSH, and a pharmaceutical company (Boehringer-Ingelheim) continued to work to develop a protocol for a randomized controlled trial of antifibrotic therapy in coal miners with progressive massive fibrosis (PMF).As reported previously, Dr. Erdely (NIOSH) and Dr. Hussain (WVU), who received WVCTSI funding to stimulate interactive research between NIOSH and WVU, submitted a NIH grant proposal and although they are within the funding range they are still awaiting final notification.

The WVCTSI spring announcement for project proposals was disseminated to NIOSH investigators. Dr. Weissman participated regularly in WVCTSI's Chronic Lung Disease ECHO webinars and provided a presentation on respiratory hazards associated with unconventional natural gas production. He has also been involved in the COVID-19 ECHO sessions.

Charleston Area Medical Center (CAMC)

AMC is a nonprofit, 908-bed, regional referral and academic medical center of four hospitals and home to one of the largest cardiac programs in the US, the only kidney transplant center in WV, and a level I trauma center. The CAMC Health Education and Research Institute (CHERI) provides continuing medical education and research support to physicians and allied medical professionals. CHERI operates a nurse anesthesia school with MU as well as 13 graduate medical education residency/fellowship programs. CAMC sponsors pharmacy residency programs and psychology internships.

In Q3, CAMC submitted one publication and 2 presentations. CAMC received 1 Biostatistics consults, attended 6 journal clubs and delivered 3 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 Q3. CAMC membership remains at 50.

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

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