

**West Virginia Clinical Translational Science Institute:  
Tracking and Evaluation Quarterly Report**

3<sup>rd</sup> Quarter of Fiscal Year 2017-2018

Reporting Period: January 1, 2018 – March 31, 2018

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**West Virginia Clinical Translational Science Institute**  
**Tracking and Evaluation Quarterly Report**  
(January 1, 2018 – March 31, 2018)

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### Executive Summary

This is the quarterly tracking and evaluation report of the WV Clinical and Translational Science Institute (WVCTSI) for the 3<sup>rd</sup> quarter (Q3) of fiscal year 2017/2018, which covers a reporting period from January 1, 2018 through March 31, 2018. The WVCTSI received notice of award for renewal funding dated June 20, 2017 with an initial award of \$4,000,000 for an initial budget period from July 1, 2017 through June 30, 2018 and a project period from August 15, 2012 through June 30, 2022.

This report was prepared by the Tracking and Evaluation Core and is organized by specific aim within each key component area/core plus information from the WV School of Osteopathic Medicine partner institution. 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 comprehensive information on all metrics for all cores.

The Quarterly Data Sheet (Excel) includes two tabs for each core: one with quantitative metrics and one with narrative metrics, with the exception of Technology and Resources for Core Laboratories because that core submits only quantitative data. The Quarterly Data Sheet includes columns and tabs for each quarter of the current annual funding cycle as well as for annual targets where those have been specified so that a view of change over time and progress toward targets is available.

This report constitutes the second quarterly tracking and evaluation report for the renewal funding cycle. There is increasing momentum and productivity carrying through from the initial funding cycle as evidenced by 91 publications, 118 external funding proposals, and 104 funded awards this quarter, all considerably more than during Q1 or Q2. Other notable indications of processes scaling up include:

- 153 members requested 678 services through iLab Core Management System, more than doubling users and requests from Q2 with some requests from outside WVU for the first time (see Figure in Administrative Core displaying types of service requests per month per core);
- 26 new custom IDR datasets and 47 ongoing IDR projects plus substantial increases in REDCap users (147 Q3 vs 64 Q2) and TriNetX queries (492 Q3 vs 186 Q2) at WVU and partner sites;
- 38 TriNetX studies offered to date: 19 accepted with the first activated in Q3;
- 26 new ECHO project sites Q1 through Q3 (56 total sites) and 7 new WVPBRN projects Q3;
- 6 new pilot projects funded Q3 with 4 of those led by early stage investigators;
- First 2 biospecimen projects reported in Q3, and there have been 32 Illumina genomics (10 WVU, 22 Marshall) and 16 MicroCT imaging projects Q1 through Q3; and
- WV School of Osteopathic Medicine with 51 WVCTSI members in Q3 contributed 2 publications, had 2 pilots funded, 7 opportunities for students to participate in clinical translational research, and 7 faculty participating in research training programs.

Overall recommendations from tracking and evaluation based on examination of Q1-3 data and our interactions with core and partner personnel include the following:

- Improve alignment between tracking and evaluation metrics and core specific aims because in some instances no data were reported for some specific aims;
- Improve efforts to ensure relevant partner activity is appropriately reported and credited because only two partners reported this quarter;
- Identify targets for all appropriate metrics on individual core reports and dashboards because relatively few annual targets have yet been identified;
- Ensure transparent and consistent utilization of iLab across cores and partners;
- Continue to increase partner engagement outside of Morgantown; and
- Maintain focus on priority health areas when allocating resources and effort.

### Quarterly Reporting Annual Timeline

#### 1<sup>st</sup> quarter Reporting Period = July 1 – Sept 30

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

#### 2<sup>nd</sup> quarter Reporting Period = Oct 1 – Dec 31

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

#### 3<sup>rd</sup> quarter Reporting Period = Jan 1 - Mar 31

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

#### 4<sup>th</sup> quarter Reporting Period = Apr 1 – June 30

June 18	4 <sup>th</sup> quarter report task assigned to each KCA/Partner via email to key contacts
July 1	TEC begins data acquisition from repositories (e.g., iLab, OnCore)
July 7	Quarterly report data due to TEC from each core
June-July	Pre/post submission meetings (TEC and key contacts)
July 28	4 <sup>th</sup> quarter formative evaluation report and metric data distributed by TEC
Aug-Sept	Steering Committee discusses 4 <sup>th</sup> quarter formative evaluation

## Administrative Core

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

Indicators for effective operational structures include publications, conference presentations, and external grant applications and awards. Researchers linked to CTR are continuing to contribute through peer-reviewed publications (91), external funding proposals (118), externally funded awards (104), and provisional patents filed (1). The WVCTSI continues to build an effective operational structure and added 2 new staff members (31 total staff members).

A new service request tool, iLab Core Management System, launched during Q2 and is intended to streamline service delivery across WVCTSI. In Q3, 153 (an increase from 66 in Q2) members utilized the iLab platform to request 678 (an increase from 301) services and 305 (an increase from 97) of those were investigator development services. While there were 9 requests from Marshall University, no services were requested through iLab by any other partner institution (see Figure next page).

### 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 continues to grow in membership with 109 new members added in Q3 bringing the total to 1,754 members. With 1,493, WVU Morgantown has the largest proportion of WVCTSI members. There is room for improvement with membership totals among other partners: WVU Charleston/CAMC (51, a decrease of 8 from Q2), Marshall University (21, an increase of 1 from Q2), WVSOM (52, an increase of 3 from Q2), VA (5, a decrease of 1 from Q2) and NIOSH (4, an increase of 1 from Q2).

Public outreach and communications are tracked through website hits and social media followers. In Q3, the WVCTSI website averaged 307 hits per day with 2.61 page views per visitor. Users engaging with WVCTSI on Facebook (309 likes), Twitter (491 followers), and Listserv (1,692 subscribers) is increasing.

### 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.

Securing external funding is vital to demonstrating fiscal management of the WVCTSI resources. In Q3, a total of 118 applications were submitted and 104 previous applications were awarded. The percentage of NIH award expended varied by core: Admin (93.29%), TECH (55.64%), CRDEB (100%), CRRF (77.81%), CEO (68.43%), Pilots (61%), PD (100%), and TEC (78.58%). There were 5 cost transfers/corrections to ensure accounting standards were followed.

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

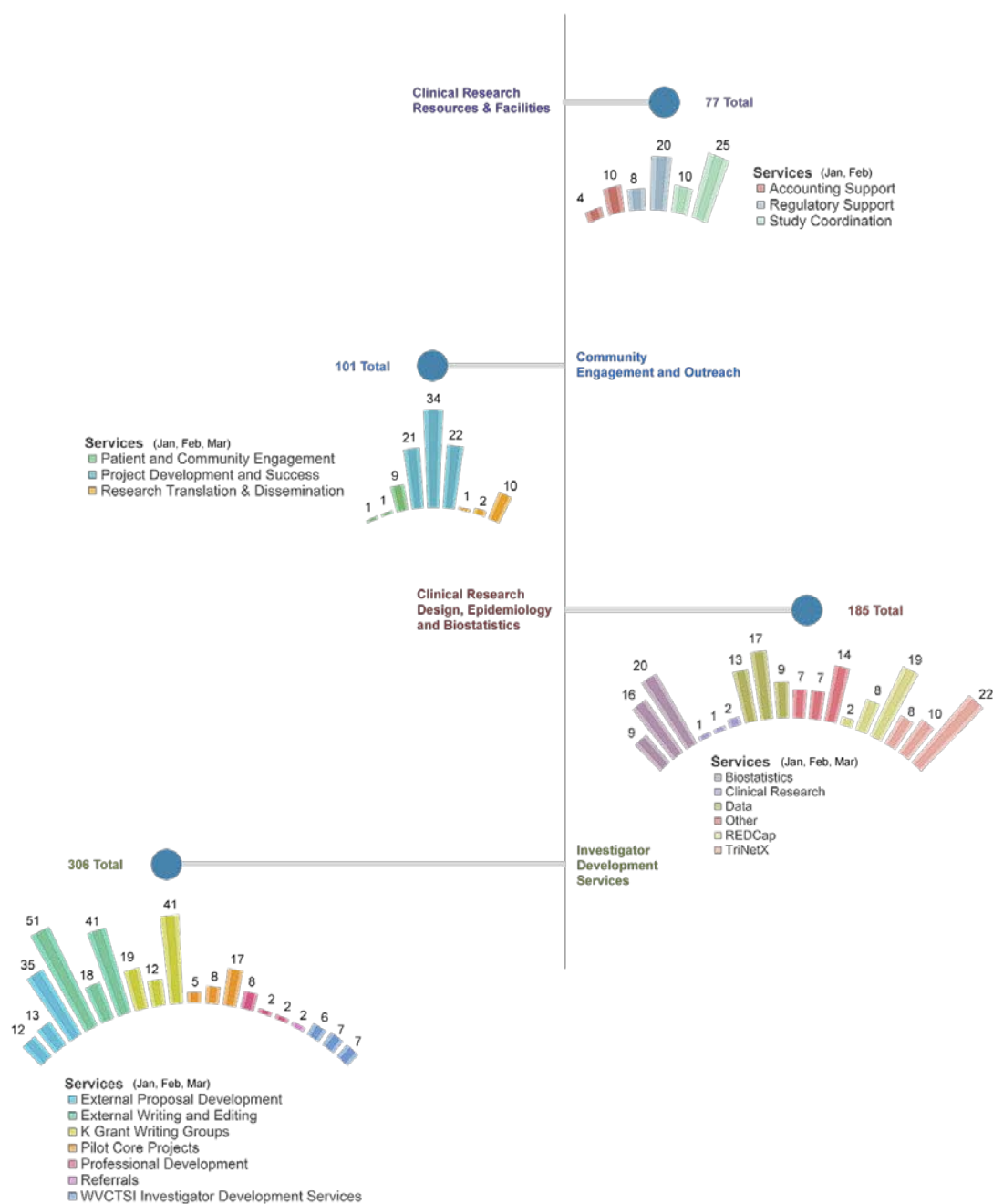
Two new investigators with expertise in neurology, hematology, and oncology were recruited in Q3.



## Administrative Core

### Key Recommendations

- Facilitate parity across cores and adherence to target percentage of NIH award expended
- Provide timely publications data including core contributions to each publication
- Clarify consensus definition of policy/practice changes given that some reported “changes” may fall outside that definition
- Provide proposal services across partners
- Address recommendations from Q2 report

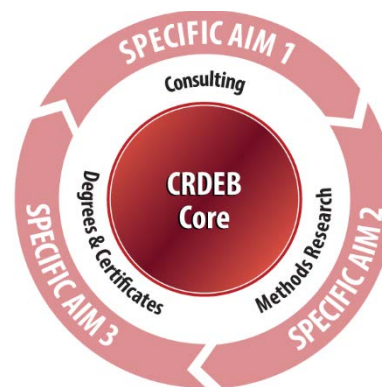


**Figure: Number of Q3 service requests utilizing iLab Core Management System disaggregated per core, service type, and month.**

## Clinical Research Design, Epidemiology & Biostatistics Core

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

Investigators are actively engaged through the CRDEB core utilizing resources including the Integrated Data Repository (IDR), REDCap, and TriNetX. In Q3, there were 26 new custom IDR data set requests and 47 ongoing IDR projects, both of which increased from Q2. There were 147 new users utilizing REDCap in Q3, a substantial increase from 64 users in Q2. The number of REDCap users increased at WVU as well as at WVCTSI partner sites, CAMC and WVSOM. The number of TriNetX queries increased from 186 in Q2 to 492 in Q3. The following were completed in Q3: new statistical analysis consultations (21), sample size/power consultations (15), and BMIR-related inquiries (121).



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

The CRDEB core reported 9 new study design consultations and 6 other consultations. No information was reported for the number of new clinical design project consultations, predictive modeling consultations, and epidemiology consultations. These metrics do not seem to reflect what is specifically tracked in iLab and should be revised accordingly.

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

There were no data provided that reflects any current dissemination information. While the Administration Core did provide publication information, core contributions to specific publications were omitted.

### Specific Aim 4<sup>1</sup>. 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 no data provided related to IDR2 or ARC.

#### Clinical Research Design, Epidemiology, & Biostatistics

##### Key Recommendations

- Continue to work toward increasing utilization at partner sites
- Clarify tracking and evaluation information needs relative to Specific Aims 2 through 4
- Identify targets for all appropriate metrics

<sup>1</sup> 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.

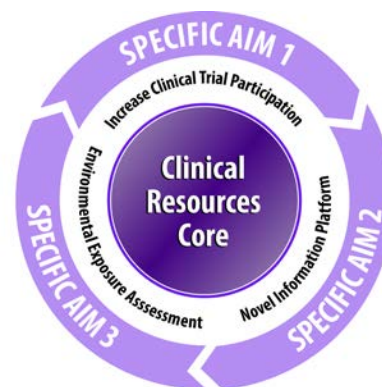
## Clinical Research Resources & Facilities Core

**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.**

The CTCOE is assisting communities and practitioners by providing regulatory, study coordination, and accounting assistance for up to 92 non-WVCTSI clinical studies. TriNetX has offered 8 studies to WVU this quarter, 5 of which were accepted by WVU researchers. No TriNetX studies have begun enrolling subjects. Two CTSI-funded studies received Quality Assurance Audits from the CTCOE. Total program income from service provision is being tracked and will be reported in the future.

**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).**

WVCTSI hosted 17 investigators from NIOSH in Q3 to foster collaboration opportunities between investigators at WVU and NIOSH. NIOSH investigators toured the new inhalation lab and networked with WVU Pulmonary researchers.



### Clinical Research Resources & Facilities

#### Key Recommendations

- Clarify tracking and evaluation information needs relative to Specific Aim 2
- Identify targets for all appropriate metrics



## Community Engagement & Outreach Core

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

Growth was evident in CEO's engagement of community stakeholders. WVPBRN increased from 74 to 86 sites in Q3. 11 new ECHO sites came on board for a total of 26 sites this year. New in-state sites include Beckley VA Medical Center, Roane General Hospital, Coplin Health Systems, WVU School of Medicine-Digestive, WV Department of Health and Human Services, Charleston Area Medical Center (CAMC), Callahan Counseling Services, Davis Health Systems, and Berkeley Medical Center. Out of state sites include M.C. Townsend Associates, LLC (PA) and Florida State University (FL). Two additional partner organizations came on board including Webster County Cancer Education Project and WV Breast and Cervical Cancer Screening Program. In Q3, 11 researchers were connected with providers and lay partners. Eight investigators received mentoring services. Thirty-two Patient and Community Engagement Services were tracked in iLab. During the third quarter, there were 7 networking opportunities, which exceeds the annual target of 4. However, there were no Advisory Board meetings, BOTG training sessions, Focus Group sessions, Community Concept Maps sessions, Community Policy Brief sessions, or networking opportunities reported. While there were no policy changes reported in Q3, there were 2 practice changes related to the IRIS project.



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

There were no new ECHO projects in Q3 but there was 1 (non-ECHO) CEO project and 7 new WVPBRN projects. The WVPBRN projects include: 1) Clinic-Community Linkage to Address Arthritis, 2) CORE: Attitudes and Practice regarding Hepatitis C in WV, 3) CORE: Quality Measures and provider-patient relation, 4) CORE: Weight Management Guideline-Based Project, 5) mHealth Patient Portal, 6) Side effects of proton pump inhibitors, and 7) Healthcare accessibility for people with disabilities. Two Network projects were reviewed and accepted for a 100% approval rate. Services provided for Project Development and Success increased from 48 in Q2 to 84 in Q3 and appear on-track toward the annual target of 120. There were 23 completed and 25 ongoing PBRN projects reported in Q3, as well as 2 completed and 3 ongoing CEO projects.

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

In Q3, there were 11 services provided for Research Translation and Dissemination, up from 5 in Q2. The Pilot Core RFA was disseminated. Evidence related to CEO publication and presentation was not provided from the Administrative Core. However, the CEO Core was affiliated with two external funding proposals and six externally funded awards reported in Q3.

#### Community Engagement & Outreach

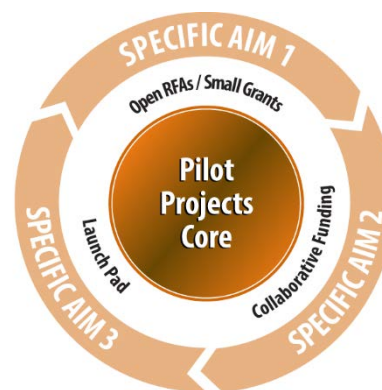
##### Key Recommendations

- Initiate activity on Specific Aim 1 metrics not yet actively engaged
- Disseminate funding opportunities
- Identify targets for all appropriate metrics

## 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.**

A total of 20 pilot project applications (9 Launch, 11 Collaborative) were submitted with early stage investigators submitting 7 of these. All potential collaborative sites submitted an application except for VA and WVPBRN. Pilot Projects funded 5 Open and 1 Launch project with 4 of these led by ESIs. Three Pilot RFA information sessions were provided including one broadcast to WVSOM. Seventeen services or consultations were provided to potential applicants. Mentoring of ESIs was not reported. In addition, new investigators were not reported as a separate category of those funded.



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

The Pilot Projects Core reported 5 ongoing projects that address critical health issues within WV including respiratory disease, response training for first responders, safety education of, and treatment for opioid abuse.

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

Nine letters of intent were submitted for Launch Pad Pilots. Two PIs were ESIs, and all were at WVU.

Pilot Projects Key Recommendations
<ul style="list-style-type: none"> <li>• Consider whether existing metrics adequately capture mentoring activity by the Pilot Core</li> <li>• Address recommendations from Q2 report</li> </ul>

## 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.**

In Q3, 10 research scholar program applications were received. One study section service was provided where a Research Scholar serves as a pilot grant reviewer during the January study section meeting. WVCTSI-supported scientists mentored 7 students in the Initiation to Research Opportunities (INTRO) program and 23 former INTRO students engaged in research within the past 12 months. There were 16 active members in the SACS program but no newly trained mentors, new mentoring teams, or female clinician scientists being mentored were reported.



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

There are 23 medical students participating in the INTRO program. Enrollment in the MS in CTS programs at WVU and Marshall University is 13 and 7, respectively. The MU MS in CTS received 4 applications in Q3. The WVU CTS Ph.D. currently has 8 students enrolled, 1 application received, and no new degrees conferred. No new Educational Programming academic courses were offered in Q3.

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

Two research seminars were offered in Q3: 1) Females Advancing Clinical and Translational Science (FACTS) Tips for Public Speaking and 2) FACTS Time Management for Grant Writing. Additionally, one research workshop was offered: Essential Time Management & Organization Skills Workshop. One Research Scholar received approval for a patent/license agreement.

Professional Development
Key Recommendation
<ul style="list-style-type: none"> <li>● Include only activity during the current reporting period in quarterly evaluation data submissions.</li> <li>● Address recommendations from Q2 report</li> </ul>

## Technology and Resources for Core Laboratories

**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).**

Two WVUCTSI-supported projects were reported for biospecimen. No samples were collected or utilized across all partner sites including WVU, MU, and CAMC.

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

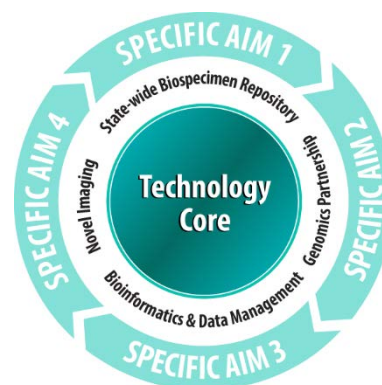
No WVU nor MU WVCTSI studies were reported. There were 32 Illumina projects across Q1-Q3 from WVU (10) and MU (22) with 70 runs across Q1-Q3 from WVU (22) and MU (38).

**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.**

There were no data provided that reflect activity related to this specific aim during the current reporting period. No educational sessions were reported.

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

One clinical research project was reported for each quarter Q1 to Q3. Sixteen MicroCT projects were reported across Q1(5), Q2(4), and Q3(7). One educational session was provided each quarter, with 20, 20, and 18 attendees, respectively.



### Technology & Resources for Core Labs

#### Key Recommendations

- Identify targets for all appropriate metrics
- Work with tracking and evaluation to develop metrics capturing progress on Bioinformatics and Data Management

## Tracking and Evaluation Core

In Q3, the TEC Core continued to collaborate with all core key contacts to refine quarterly reporting metrics, processes, and procedures with a focus this quarter on TEC collecting data directly from iLab, OnCore, and other systems where possible. In addition to the Quarter 2 tracking and evaluation report, TEC developed a survey and associated evaluation report entitled, “WVCTSI Mini-Retreat 2018 Survey: An Assessment of Staff Feedback.” TEC also submitted three WVCTSI-related conference proposals for the 2018 American Evaluation Association annual meeting. Other TEC activities included qualitative expertise supporting an opioid epidemic related research project, evaluation expertise to an external funding proposal to NIH, and evaluation expertise for developing focus groups for community members.



### **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 personnel worked across cores and the iLab vendor to understand processes related to data entry, data structure, data integrity, data retrieval, and reporting procedures and possibilities. This work is critical to understanding current capacity and possibilities for iLab as the system through which investigator service tracking data is collected for analysis. This work also is critical to quality assurance for quarterly reporting processes and programmatic assessment more broadly. TEC personnel analyzed iLab data to generate recommendations for additional proposal development metrics to capture that component of the administrative core’s activity.

### **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 collaborated with CEO to a) develop and deploy a baseline survey of WVPBRN members and sites, b) to develop a collaboration survey for social network analyses of WVPBRN member and site connectivity, and c) to develop a protocol for focus groups with community members.

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

TEC personnel reviewed the 2017 State of American Well-Being report to support maintaining WVCTSI focus on health outcomes. TEC personnel worked with financial leadership in the Administrative core to develop metrics capturing financial accountability and resource allocation. TEC personnel supported refinement of overall dashboard and drove development and refinement of partner dashboards for inclusion in future quarterly reports.

Tracking & Evaluation Key Recommendations
<ul style="list-style-type: none"> <li>• Continue to streamline quarterly reporting data collection from iLab and OnCore systems</li> <li>• Develop and implement training for setting annual targets on evaluation metrics</li> <li>• Support development and refinement of partner dashboards</li> </ul>

### Marshall University

Marshall University, 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 Marshall University 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. Marshall University houses the WVCTSI's Associate Director, Dr. Gary Rankin.

In the first three quarters of this funding cycle, Marshall reported 5 publications and 3 proposals submitted by early stage investigators (ESIs). Among the total 1,754 WVCTSI members, 21 are affiliated with Marshall University. There are 2 ESIs accessing WVCTSI services.

Ten external grant proposals associated with WVCTSI were submitted by investigators at Marshall University. Of those, 4 were federal, 4 were for state, and 2 were submitted to other funding sources (e.g., foundations, professional societies). There were 9 proposal development service requests from Marshall University using the iLab tracking system to access WVCTSI services.

Marshall University
Key Recommendations
<ul style="list-style-type: none"> <li>• Work to increase utilization of iLab</li> <li>• Continue efforts to increase WVCTSI membership</li> </ul>



**West Virginia School of Osteopathic Medicine (WVSOM)**

The WVSOM, located in Lewisburg, WV in Greenbrier County, partners with the WVCTSI and is engaged in activities related to research and community engagement. The 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 the first three quarters of this year, the WVSOM contributed 2 publications and had 2 collaborative pilot projects funded. Among the total 1,754 WVCTSI members, 51 are affiliated with WVSOM.

Although there are no members from WVSOM using the iLab tracking system yet to access WVCTSI services, partner directors had the opportunity to learn more about the system at the recent partner directors meeting in February.

Related to professional development opportunities, there were 7 opportunities for students to participate in clinical and translational research and 2 students are enrolled to participate in summer research projects. Seven WVSOM faculty participated in WVCTSI sponsored research training programs. There were 3 events related to WVCTSI activities.

WVSOM staff are also involved in the CEO Core's WVPBRN project to empower communities to participate in community engagement activities including community participatory research.

**WV School of Osteopathic Medicine****Key Recommendations**

- Identify targets for all appropriate metrics
- Work toward integration and utilization of iLab
- Continue efforts to increase WVCTSI membership