

**West Virginia Clinical Translational Science Institute:**

**Tracking and Evaluation Quarterly Report**

2<sup>nd</sup> Quarter of Fiscal Year 2017-2018

Reporting Period: October 1, 2017 – December 31, 2017

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**West Virginia Clinical Translational Science Institute**

**Tracking and Evaluation Quarterly Report**

(October 1, 2017 – December 31, 2017)

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### **Executive Summary**

This is the quarterly tracking and evaluation report of the WV Clinical and Translational Science Institute for the 2<sup>nd</sup> quarter (Q2) of fiscal year 2017/2018, which covers a reporting period from October 1, 2017 through December 31, 2017. This report was prepared by the Tracking and Evaluation Core and is organized by specific aim within each key component area/core. This report does not describe every element or metric of tracking and evaluation data in each core section; rather key elements and recommendations are summarized and the reader is referred to the Quarterly Tracking and Evaluation 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 did not submit any narrative information. The Quarterly Data Sheet will be updated with additional columns and tabs each quarter so that a view of change over time will be available with future iterations of this report.

The WV Clinical Translational Science Institute received a 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. Tracking and evaluation, in consultation with the administrative core, agreed to utilize the first quarter of fiscal year 2017/2018 (Q1) to restructure quarterly reporting metrics and processes so that they align with the renewal proposal rather than the previous funding cycle (August 15, 2012 through July 1, 2017).

This report constitutes the first quarterly tracking and evaluation report for the renewal funding cycle. There continues to be strong momentum and productivity carrying through from the initial funding cycle as evidenced by 100 publications, 108 external funding proposals, and 134 funded awards to date during the initial budget period. However, it is important to note that the renewal proposal included substantial reorganization and transformative efforts so that some processes and activities in various cores are developing rather than fully formed and functioning at this point in time. There were indications of these new efforts scaling up (e.g., 97 investigator development services through iLab Core Management System, 11 new TriNetX users, 11 new ECHO project sites, 14 new TriNetX studies accepted, 22 early stage investigators submitting pilot project applications, and 11 letters of intent submitted by potential new Research Scholars).

Overall recommendations from tracking and evaluation based on examination of Q2 data and our interactions with core and partner personnel include the following:

- Improve alignment between tracking and evaluation metrics and core specific aims;
- Identify reporting lines and processes to ensure relevant partner activity is appropriately reported and credited within core reports;
- Identify targets for all appropriate metrics on individual core reports and dashboards;
- Ensure consistent utilization of iLab across cores and partners;
- Increase partner engagement and participation 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 publications (57 in Q1; 43 in Q2), presentations (5 in Q1; 15 in Q2), external funding proposals (45 in Q1; 63 in Q2), and external funded awards (76 in Q1; 58 in Q2). The WVCTSI continues to build an effective operational structure and added 7 new staff members during Q2 bringing the total number of staff members to 31.



### **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 77 new members added in Q2 for a total of 1,710 members. With a total of 1,336, WVU Morgantown has the greatest representation of WVCTSI members. There is room for improvement with membership totals among other partners: WVU Charleston/CAMC (59), Marshall University (20), WVSOM (49), VA (6) and NIOSH (3).

A new service request tool, iLab Core Management System, launched during Q2 and is intended to streamline service delivery across all WVCTSI programs. In Q2, 66 members utilized the iLab platform to request 301 services and 97 of those were investigator development services.

Public outreach and communications are tracked through website hits and social media followers. The WVCTSI website averaged 311 hits per day in Q2 with an average of 2.46 page views per visitor. Users engaging with WVCTSI on platforms such as Facebook (299 likes), Twitter (478 followers), and Listserv (111 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 Q1 and Q2, a total of 108 applications were submitted and 134 previous applications were awarded. Financial accountability is not captured through current reported metrics.

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

No new C/T investigators were recruited, however, a total of 10 new WVCTSI staff were recruited to fill vital roles supporting ongoing efforts across multiple cores, including program coordinators and clinical research specialists.

#### **Administrative**

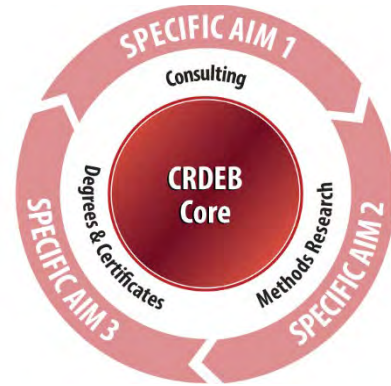
#### **Key Recommendations**

- Evaluate Steering Committee, EAC, and IAC contributions to Specific Aim 1
- Increase WVCTSI membership statewide
- Facilitate consistent implementation across cores of iLab Core Management System
- Identify appropriate fiscal accountability metrics
- Identify targets for all appropriate metrics

## 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 available resources including the Integrated Data Repository (IDR), REDCap, and TriNetX. In Q2 there were 16 new custom IDR data set requests and 9 completed IDR projects, both of which increased from Q1. There were 64 new members utilizing REDCap in Q2. While the number of REDCap users at WVU increased in Q2, there were no new users through WVCTSI partner sites. The total number of TriNetX users increased (11 new in Q2) to 186, who made 337 inquiries in Q2. The following were completed in Q2: new data analysis consultations (22), sample size/power consultations (18), grant preparation service requests (7), manuscript preparation requests (4), and requests for abstract submission services (1).



### 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 14 data analysis consultations, 16 new study design consultations, and 3 referrals from Investigator Development Core. No information was reported for the number of new clinical design project consultations, predictive modeling consultations, and epidemiology consultations. These metrics do not appear to be tracked in iLabs.

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

There were no data provided that reflects any current dissemination information.

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

##### Key Recommendations

- Increase utilization at partner sites
- Clarify tracking and evaluation information needs relative to Specific Aims 2 and 3
- Identify targets for all appropriate metrics

## 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 assistance, study coordination assistance, and accounting assistance for up to 60 non-WVCTSI clinical studies. TriNetX has offered 30 studies to WVU, with 14 (12 in Q1; 2 in Q2) being accepted by WVU researchers. No TriNetX studies have begun enrolling subjects. No non-WVCTSI studies have 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: 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 the IDR2 or ARC.

**Specific Aim 3: Establish the Environmental Exposures Unit to stimulate environmental health research in collaboration with the National Institute for Occupational Safety and Health (NIOSH).**

There were no data provided related to the Environmental Exposures Unit.



### Clinical Research Resources & Facilities

#### Key Recommendations

- Clarify tracking and evaluation information needs relative to Specific Aims 2 and 3
- 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 engagement of community stakeholders. Q2 PBRN membership was 133 including 74 sites, which was an increase of 29 members from Q1. Eleven new ECHO sites joined in the second quarter. In-state sites include Bluestone Health Association, FMRS Health Systems Inc., Martinsburg Institute, Med-Surg Physician Group, Inc., Polaris Emergency Specialists, LLC, Southern WV Health Systems, and Wetzel County Schools. Out of state sites added include Big Sandy Health Care Inc. (KY), Indiana University Health Arnett (IN), UPMC Altoona (PA), and West Caldwell Health Council, Inc. (NC). Three additional partner organizations came on board including Harvard Medical School, WVU Department of Anesthesiology, and Mountains of Hope. In Q2, researchers (7) and mentored investigators (7) were connected with providers and lay partners. There were 22 services provided for Patient and Community Engagement.

During the second quarter, there were 3 Advisory Board meetings. However, there were no BOTG training sessions, Focus Group sessions, Community Concept Maps sessions, Community Policy Brief sessions, or networking opportunities reported.

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

One ECHO project focusing on Chronic Lung Disease (CLD) was added in Q2. There were 4 additional (non-ECHO) CEO projects. The Non-ECHO projects include (1) Postpartum anxiety/OCD program, (2) Perioperative Suboxone SUPER-ERAS, (3) Community resources for non-opiate treatment of back pain, and (4) Depression treatment PCORI. Six Network projects were reviewed and accepted (100% approval rate). Services provided for Project Development and Success increased to 48, compared to 12 reported in Q1, which may indicate that more people are aware of these services or service delivery is increasingly efficient.

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

In Q2 there were 5 services provided for Research Translation and Dissemination, however, there were no funding opportunities disseminated in Q2.



### 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 49 pilot project applications were submitted for three categories of competition: open (34), small (10), and launch (5). Early stage investigators submitted 22 of these across categories. 15 services or consultations were provided to potential applicants. Pilot Projects funded 5 small project awards with 2 of those led by ESIs. Mentoring supporting 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.**

Pilots provided funding for 9 ongoing collaborative research projects that focus on priority health areas ranging from addiction to cancer. Collaborators from WVCTSI partner sites included WVU, WVSOM, and Marshall University.

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

Five applications were submitted for Launch Pad Pilots by researchers at WVSOM. One of the 5 was from an ESI.

Pilot Projects
Key Recommendations
<ul style="list-style-type: none"> <li>• Clarify whether ESI and NI should be tracked separately in Specific Aim 1 metrics</li> <li>• Provide more detailed information regarding collaborative projects addressing WVCTSI priority health areas</li> <li>• Increase participation across sites in Launch Pad Pilots</li> <li>• Identify targets for all appropriate metrics</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.

Eleven Letters of Intent (LOI's) were submitted for Research Scholars. One service was provided to assist with the application process. WVCTSI-supported scientists mentored 11 students in the INTRO program and 27 students engaged in research within the past 12 months. There were 17 active members in the SACS program. There were 17 trained mentors, 12 mentoring teams, and two female clinician scientists being mentored.



### 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.

For the WVU MS in CTS program, there were 13 students enrolled: 3 were fellows or residents and 4 were professional students. While there were no new degrees granted in Q2, there were 3 new degrees granted in Q1. One student was enrolled in the CTS certificate program and 6 students were enrolled in the CTS Ph.D. program. No information was provided for the Marshall University MS in CTS program.

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

In Q2, 32 participants attended six C/T research seminars and four research workshops or short courses. Of those participants, 30 originated from WVU and 2 were from WVSOM.

No data were reported for several metrics, including but not limited to disclosures, patent/license applications, study section services, honors/awards, national society/organization services, and professional development activities.

Professional Development Key Recommendation
<ul style="list-style-type: none"> <li>• Consider focused evaluation of mentoring, degree programs, and educational opportunities</li> <li>• Increase participation across partner sites</li> <li>• Clarify metric applicability and alignment to specific aims where no activity was reported</li> <li>• Identify targets for all appropriate metrics</li> </ul>

## Technology and Resources for Core Laboratories

Narrative data for the annual report suggest progress was made toward developing necessary infrastructure, but no activity was reported on most tracking and evaluation metrics.

**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).**

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

**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 no data provided that reflect activity related to this specific aim during the current reporting period.

**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.

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

One educational session on imaging was provided this quarter with 30 attendees.



### Technology & Resources for Core Labs

#### Key Recommendations

- Identify targets for all appropriate metrics
- Clarify metric applicability and alignment to specific aims

## 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.**

In Q2, 4 meetings/evaluation consultations with other WVCTSI cores were reported with a focus on Specific Aim 1 with a total of 4.5 hours dedicated.

**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.**

In Q2, 7 meetings/evaluation consultations with other WVCTSI cores regarding Specific Aim 2 took place for a total of 7 hours. While there were no reports; generated during Q2, there were 6 meetings/evaluation consultations with other WVCTSI cores regarding quarterly reporting for a total of 10 hours of time. There were 8 meetings/evaluation consultations with other WVCTSI cores regarding value added projects resulting in 8 hours of dedicated time.

The TEC supported five projects in Q2. These value added projects included qualitative data analysis of focus group discussions regarding the opioid epidemic, the development of an evaluation plan for Lisa Salati's external funding proposal, the development of a survey to support baseline and social network analysis data collection for CEO, the development of quarterly report data collection instruments collaboratively with all cores, and the development of an evaluation of proposal development services.

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

There was one meeting/evaluation consultation with other WVCTSI cores regarding Specific Aim 3 for a total of one hour.



Tracking & Evaluation Key Recommendations	
<ul style="list-style-type: none"> <li>• Identify targets for all appropriate metrics</li> <li>• Consider more robust metrics aligned to TEC efforts</li> <li>• Track and evaluate change across time and activity relative to targets in future quarterly reports</li> <li>• Streamline quarterly reporting data collection from iLab and OnCore systems</li> <li>• Improve efficiency to disseminate future quarterly report on deadline</li> </ul>	