

Connecting with the WVCTSI

PARTNERING FOR BETTER HEALTH



West Virginia
Clinical and Translational Science Institute

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Overall WVCTSI Objectives

- Build sustainable research infrastructure that contributes to improving WV health outcomes.
- Recruit, train, and position for success the next generation of clinician scientists and translational researchers.
- Engage with multiple stakeholders, including communities, medical providers, and policy makers to drive research

Cross-Cutting Themes

① The “endangered” clinician scientist

- Train and support tomorrow’s clinician scientists, able to frame the right questions and work in teams to find answers

② Rural Populations

- Rural populations historically underrepresented in clinical research.
- Health concerns of individuals residing in rural communities are critical to WVCTSI mission

③ Commercialization

- Innovative strategies to maximize external investment and successful commercialization

Building the Infrastructure



- Increase research capacity through collaborations, recruitment, training
- Offers services that strengthen the quality of clinical and translational research
- Engage communities in the research agenda

WVCTSI ORGANIZATION



WVCTSI Partners and Practice-Based Research Network



CAMC / WVU
Charleston



Marshall University



West Virginia School of
Osteopathic Medicine



WV Veterans Affairs



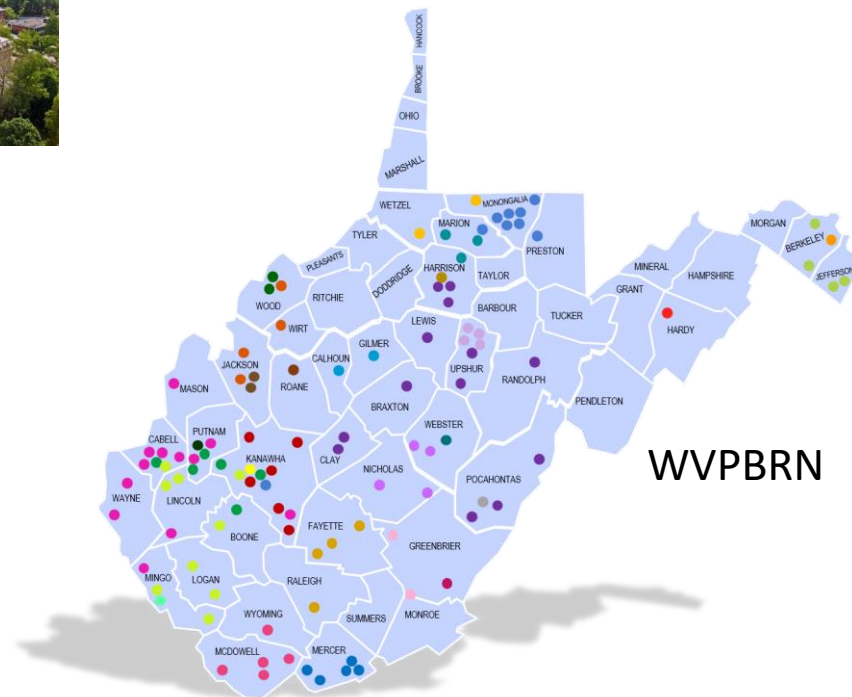
National Institute for
Occupational Safety and
Health



West Virginia
University



WVU Medicine



Health Priority Areas

- Addiction and resultant emerging epidemics
- Cancer
- Cardiovascular disease
- Chronic lung disease
- Neuroscience, including stroke & Alzheimer's Disease



Professional Development

Academic Programs in Clinical and Translational Science



CTS PhD Students

Certificate Program— one year didactic program; 15CH- ONLINE PROGRAM

Master's of Science Program —1-2 year didactic & experiential program; 34 CH -Written grant proposal is a graduation requirement

PhD Program — 4-5 year didactic & experiential; Students complete semester-long research rotations in three domains: basic science, clinical, and population

Professional Development



Research Scholars Program – A program with the mission to support junior faculty to become independent clinical and translational investigators.

- Offers financial support, faculty mentoring, professional development seminars, and opportunities for the scholars to present their scientific work



FACTS - A professional development and networking group focused on empowering women conducting clinical and translational science.

- An appointed steering committee meets quarterly to plan the professional development and networking opportunities.
- Hosts annual outreach events



Workshops and Seminars – The Professional Development Core hosts Seminar Series and Workshops to address needs of faculty, fellows, residents, health professionals, and graduate students.

- Faculty development, grantsmanship, and mentoring are just a few of the topics covered during these professional development opportunities

Proposal Development

Career Development (K-award) Grant Writing Club

- Provides guidance and advice to early-stage clinical and translational investigators planning to apply for a National Institutes of Health (NIH) Mentored Career Development Award
- Structured as a facilitated group writing process

Research Club (R-series) Grant Writing Club

- An intensive grant writing program for clinical and translational investigators developing R03/R21 applications for submission to the National Institutes of Health (NIH).
- Structured as a facilitated group writing process

Consulting and Coaching

- Dr. Joan M. Lakoski, Director of Proposal Development, offers individualized grant writing consultation and coaching through the Professional Development Core



Pilot Projects Program

Small

- 5K for 6 months
- **Applications due September 7, 2020**

Collaborative

- Closed

Launch

- 50K for 9 months
- Focus on commercialization and technology development
- **LOIs Due August 3, 2020**

Open

- 50K for 12 months
- Single PI
- **LOIs Due August 3, 2020**



Overview
Clinical Trials Center of Excellence

Goals of the Clinical Trials Center of Excellence

1

Provide oversight
infrastructure for all
WVU HSC Clinical
Trials

2

Assure regulatory
compliance through
institution of consistent
training, audit and
monitoring systems

3

Improve efficiency

Clinical Trials Center of Excellence

Provided Services

- Training
- Internal Quality Audit
- Regulatory Audit/Monitoring
- OnCore Clinical Trial Management

Optional Services

- Budget Development; Financial Management
- Regulatory Support – IRB Submission
- Study Coordination
- Recruitment Services
- Data Management; CRF Completion
- Communication liaison for IRB, sponsor, CRO

**CTSI
Clinical
Trials**

**Cancer
Institute**

**Heart &
Vascular
Institute**

**Rockefeller
Neuroscience
Institute**

**Pediatric
Clinical
Trials
Group**

**Other
Clinical
Trial
Groups**



Benefits

All investigators receive:

- Centralized SOPs and templates for research conduct
- FDA or Sponsor audit readiness
- OnCore support
- Clinicaltrials.gov support
- Research personnel training
- Internal regulatory monitoring and auditing
- IND/IDE Support
- Improved contract efficiency (in partnership with Legal)

MISSION

The WVCTSI Principal Investigators (PI) Academy will:

- **Provide training** to investigators to enable them to be effective, efficient, and in compliance with both federal and local regulations
- **Serve as a catalyst** and home for investigators conducting clinical research as well as a central communication hub to disseminate training, policies, and best practices
- **Educate** investigators on their responsibilities as PI of a clinical trial

SCOPE

To **provide** WVCTSI-affiliated faculty researchers conducting clinical trials, as defined by the NIH, the **appropriate infrastructure for successful trial conduct**.



OPPORTUNITIES

- **Idea Lab-** PI Academy members can sign up to present their planned, current, or closing clinical trials to the group, and receive feedback from our PI Academy panel of experts. **Held the 1st Wednesday of every month 4-5pm.**
- **Relevant coursework** designed to suit your experience levels and needs **Earn a certificate via SOLE (free and self-paced).**
- **Quarterly dinners with invited speakers** – During pandemic- moved to **webinar format**

WV Project ECHO Overview

Project ECHO is a lifelong learning and guided practice model that revolutionizes medical education and exponentially increases workforce capacity to provide best-practice specialty care and reduce health disparities. The heart of the ECHO model™ is its hub-and-spoke knowledge-sharing networks, led by expert teams who use multi-point video conferencing to conduct virtual clinics with community providers. In this way, primary care doctors, nurses, and other clinicians learn to provide excellent specialty care to patients in their own communities.

The WV Project ECHO program was developed and implemented in May 2016 through funding and support from the West Virginia Clinical & Translational Science Institute (WVCTSI), Claude Worthington Benedum Foundation, WVU School of Medicine, Cabin Creek Health Systems, Anthem, and The WV Primary Care Association in partnership with Project ECHO®



WV Project ECHO Projects and Stats

Current WV Project ECHO Projects

- HCV/HIV
- Chronic Pain
- Medication-Assisted Treatment
- Psychiatry
- Chronic Lung Disease
- Endocrine
- Cardiac Health
- COVID-19

Current WV Project ECHO Stats

- WV Project ECHO currently has over **120** Spoke sites in WV and **10** surrounding states. WV Project ECHO also has had over **350** case presentations and over **4,700** attendees **819** which are unique attendees since its launch in May 2016.

Technology and Resources for Core Labs

Resources Available

- Inhalation Lab
- Genomics Shared Facilities
- State of the art imaging (MRI, EPR, etc)
- Microscope and Animal Imaging
- Flow Cytometry and Single Cell Analysis
- Electron Paramagnetic Resonance Imaging (EPRI)



TRCL: Biospecimen Repository

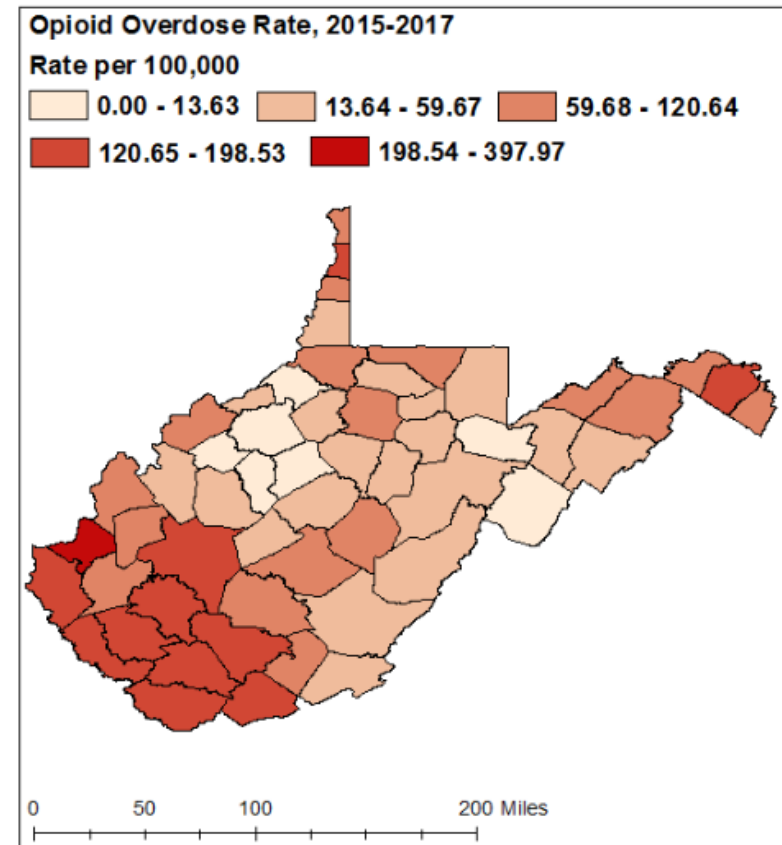
- Tissue Bank
 - Solid tissue may be collected prospectively per protocol needs, or researchers can access bank of stored samples
 - Sample processing and preparation also available
- Biospecimen Processing
 - On-demand collection of non-tissue biospecimens

Clinical Research Design, Epidemiology, and Biostatistics

- PhD-level statistical experts provide consultations on range of biostatistical and epidemiological services
- Data analysis, data management, sample size and power calculations, study design, spatial analysis
- Assistance with methods sections for manuscripts and presentations

Spatial Modeling and Analysis

- Spatial modeling services, cluster studies, and health services accessibility/capacity estimation
- Recent example: Modeling spatial variation in community level risk of fatal or non-fatal overdose and geographic access to prevention and treatment services
- Current project looking at instances of Congestive Heart Failure (CHF) in relation to patient proximity to active and non active coal mines.



Integrated Data Repository (IDR)

- Real-time copy of WVU Medicine electronic patient health record (EPIC) data on >1.5M patients
- Custom datasets can be created for research
- Highlights
 - Geocoding of addresses for geospatial analyses
 - Enhanced data security measures
 - Decedent data incorporated (NDI, & WV Vital Statistics)
 - Patient research registries with ongoing updates

COVID-19 Registry

- Custom-built registry containing information on everyone tested for COVID-19 in the WVU Medicine system
 - Nearly 30,000 patients
- Variables added based on investigator demand
 - ICU stays, ventilator usage, etc.

TriNetX Global Health Research Network

The Fastest Growing Global Health Research Network

400M+

Patients

25

Countries

26,000+

Protocols Analyzed

7,000+

Trials Presented

- Healthcare organizations, biopharma and contract research organizations collaborate to improve existing treatments & to expedite bringing new therapies to market
- Members have access to:
 - Run queries across fully de-identified data from WVU Medicine (1.4M patients) or Research Network (~61M patients)
 - Explore feasibility, cohort characteristics and rate of arrival
 - Utilize Analytics feature for data insights

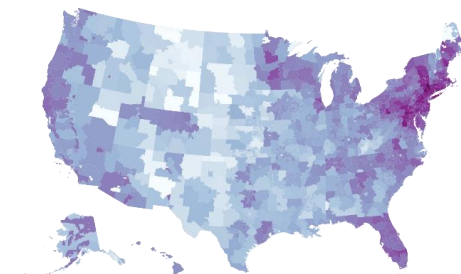
<https://live.trinetx.com/>

TriNetX Global Health Research Network

- Mechanism in place for re-identification of WVU Medicine patients with IRB approval for further research
- Upcoming enhancements include:
 - Diamond Network: patient linking to 3rd-party dataset with payer/claims, pharmaceutical data
 - Natural Language Processing: incorporate information from free-text notes into discrete fields



TriNetX



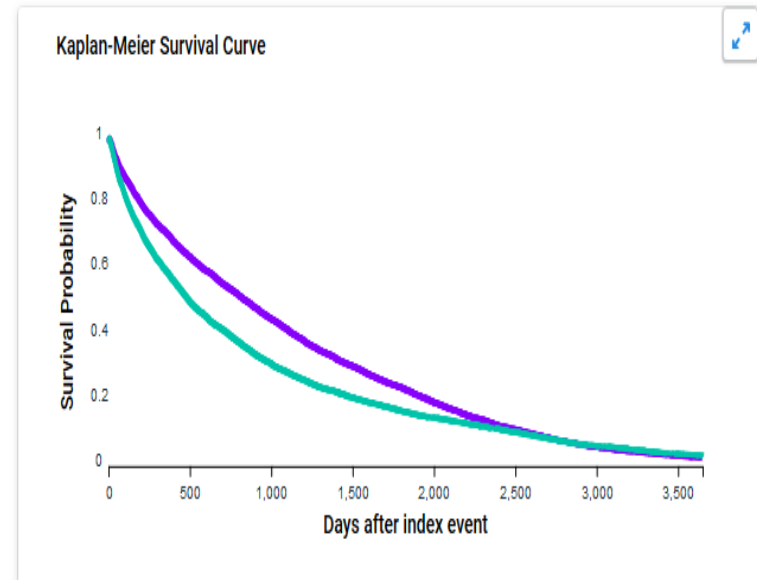
TriNetX Analytics

- Analyze outcomes over time or compare cohorts using measures of association, Kaplan-Meier survival analysis
- Easily balance cohorts with built-in propensity score matching

1b : Kaplan-Meier Analysis Excluding Patients with Outcome Prior to the Time Window

Cohort Statistics				
Cohort	Patients in Cohort	Patients with Outcome	Median Survival (Days)	Survival Probability at End of Time Window
1 Citalopram	5,668	5,524	858	2.541%
2 Escitalopram	5,184	5,017	501	3.221%

Log-Rank Test		
χ^2	df	p
90.142	1	< 0.0001



REDCap: Research Electronic Data Capture

- Secure, web-based application for data capture and storage
- Build and send surveys to participants, or enter data directly into a database
- User-friendly interface, data quality and protection measures, and audit trails
- Download data in formats suitable for all major statistical analysis software platforms



Agilent iLab

- iLab: streamlined service management system
- Comprehensive service request, tracking, and reporting capabilities
- All CTSI services should be requested via iLab
- Sign in with your WVU username and password to create an account



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Members at WVCTSI



Marshall University

Core Name	Primary Contact	Email	Phone Number/Ext
Marshall University Genomic and Bioinformatics Core (GABC)			



West Virginia University

Core Name	Primary Contact	Email	Phone Number/Ext
Bio-Nano Research Facilities - Shared Research Facilities	Callee Walsh	callee.walsh@mail.wvu.edu	304.293.0747
Biospecimen Processing Core	April Lenhart	biospeccore@hsc.wvu.edu	304-293-4016 (or pager 2197)
Cleanrooms - Shared Research Facilities	Harley Hart	harleyhart@mail.wvu.edu	(304) 293-9973, (304) 293-5847

<https://wvctsi.ilab.agilent.com>

WVCTSI Membership

Benefits of Membership for Faculty, Clinicians, Associates and Trainees:

- Access to WVCTSI training and mentoring opportunities
- Access to research support services & resources such as the Integrated Data Repository & Biostatistics Consulting Services
- Information on clinical and translational research opportunities, including pilot funding

[Become a WVCTSI Member](#)

Click **JOIN NOW** on homepage or go to <http://wvctsi.org/membership/>

Thank you!

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www.wvctsi.org