

Background:

- KS veterans: Rural residents (34%); non-Hispanic Whites (66.9%); Blacks (16%)¹
- Black veterans younger, less likely married, and more likely in higher poverty areas, with less college education, and lower median income compared to Whites¹
- Early phase clinical trials (EPCT), an important step in developing novel therapies of the future
- Veterans disproportionately understudied in clinical trials (CT) and, more profoundly, in EPCT
- Kansas City VA Medical Center (KCVAMC)
 - Included in University of Kansas Cancer Center (KUCC) catchment area
 - Serves ~200,000 veterans with access to late phase CTs (NCTN and NCORP) but not to precision medicine EPCT Experimental Therapeutics Clinical Trials Network (ETCTN)
- No clear guidance to open ETCTN at VAs. CCs rely on referrals. Barriers: Strict data sharing rules, insufficient funding, lack of infrastructure for EPCT at VA

Goals:

- Primary: Access and participation to ETCTN CTs to veterans from understudied populations
- Secondary: a) Build a roadmap for bringing ETCTN to veterans; b) Share best practices to other cancer centers (CC)

Solutions and Methods:

- Table 1: Tools used, including lessons from NCI **CATCH-UP.2020** (Create Access to Targeted Cancer Therapy for Underserved Populations) in which KUCC was the lead enrolling site
- KUCC commitment:
 - salary support for study coordinator;
 - training, education, and mentorship in implementation of efficiency to build EPCT infrastructure for investigators and research staff;
 - KUCC ETCTN PI (JB) has VA without compensation (WOC) for oversight

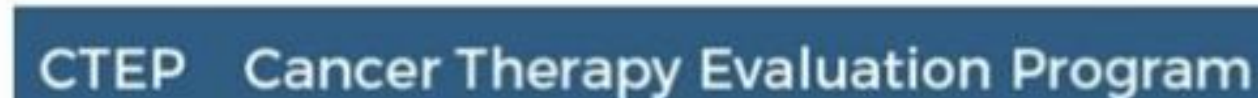
Table 1. Tools used in partnering with the VA in Clinical Trials

A. Before KUCC-KCVAMC Research MOU
Evaluated need for access among veterans using RURAL lens (VA catchment area demographics, common and uncommon cancers, National Veteran Health Equity Report, survey of other CCs)
Established KUCC institutional commitment, additional support/funding
KUCC engagement with KCVAMC stakeholders
KUCC engagement with NCI
KUCC engagement with UM1 consortium
KUCC-KCVAMC team meeting (weekly):
Addressed data sharing
Addressed requirements to be an ETCTN site
Review of ETCTN trials for feasibility at KCVAMC
KUCC ETCTN PI granted VA privileges without compensation (WOC)
KUCC-KCVAMC Collaborations Meet-and-Greet Reception
B. After KUCC-KCVAMC Research MOU Finalized
Training, education, and mentoring of KCVAMC staff
Yale UM1 PI approval of including KCVAMC as KUCC subsite
NCI leadership alignment
KCVAMC rostered as first VA ETCTN site (KUCC subsite)
KUCC-KCVAMC Collaborations Kick-Off meeting and site visit of KCVAMC
KCVAMC ETCTN trial selection according to patient needs and research capabilities
Established assessment of metrics at KCVAMC:
Number of trials activated
Number of veterans accrued
Activation timelines
Deviations
ETCTN audit and monitoring
Continued identification of strengths and weaknesses and mitigation tools implemented
Publish results to share best practices to other CCs and VAs

MOU; Memorandum of Understanding; KUCC: University of Kansas Cancer Center; KCVAMC: Kansas City Veterans Administration Medical Center; ETCTN: Experimental Therapeutics Clinical Trials Network; CCs: Cancer Centers; PI: Principal Investigator



A program of the National Cancer Institute of the National Institutes of Health



Outcomes:

- In October 2024, **KCVAMC became the first ETCTN VA site** as KUCC subsite in Yale UM1 consortium
- KCVAMC now has access to ETCTN EPCTs according to patient needs and research capabilities
- New research staff hired for ETCTN at KCVAMC
- ETCTN trials activation and workflow development initiated
- Project raising awareness of EPCTs among cancer care and primary care providers at KCVAMC
- NAVIGATE (CH), Precision Oncology Program-Clinical Research Center “Hub-and-Spoke” (SK), and NCI R50 Clinician Scientist (JB) grants all aligned

Lessons Learned and Future Directions:

This project is ongoing. Although it is unlikely to conduct First-in-Human and dose escalation EPCTs at VA in the short-term, we will focus on less complicated EPCTs (dose expansion and phase 2 ETCTN) to increase access to innovative therapies for veterans in our catchment area.

Successful collaboration between KUCC and KCVAMC will impact CT practices, demonstrating such collaborations are feasible. These efforts may establish guidelines to Cancer Centers and VAs on streamlined strategies to bring early phase clinical trials ETCTN and institutional Investigator-Initiate Trials to veterans.

Reference: 1. 2021 National Veteran Health Equity Report

Supported by R50CA290098

The George and Floreine Lieberman Family Endowment

