

How to Partner with the Veterans' Administration on Early Phase Clinical Trials

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1. Background

In 2021 National Veteran Health Equity Report, 66.9 percent of veterans identify as non-Hispanic White, 16 percent Black, 34 percent have rural residence. Compared to Whites, Black veterans are younger, less likely to be married, and more likely to reside in higher poverty areas, with less college education, and lower median income. Veterans are disproportionately underrepresented in clinical trials (CT) and, more profoundly, in early phase clinical trials (EPCT), a crucial step in developing novel therapies. University of Kansas Cancer Center (KUCC) catchment area includes Kansas City VA Medical Center (KCVAMC) serving 200,000 veterans with access to late phase CTs (National Clinical Trials Network and NCI Community Oncology Research Program) but not to Experimental Therapeutics Clinical Trials Network (ETCTN) EPCTs.

2. Goals

Our primary goal is to provide precision medicine access to veterans via EPCTs and secondary goals are to build a roadmap for bringing EPCTs close to veterans and share best practices with other cancer centers (CC).

3. Solutions and Methods

There is no clear guidance for CCs to open their EPCTs to VAs. We surveyed leaders from 15 National Cancer Institute (NCI)-designated CCs and found they have been unable to do this, relying on referrals to CCs. Barriers include strict data sharing rules, insufficient funding, and lack of infrastructure for EPCT at VA. Table 1 outlines tools we used including lessons learned in CATCH-UP.2020 (Create Access to Targeted Cancer Therapy for Underserved Populations), where KUCC was the lead enrolling site. Successful strategies included decentralized and streamlined EPCT processes in activation, site and trial selection, prescreening/screening, and quality assurance and monitoring. We engaged stakeholders and entered a Memorandum of Understanding for research collaborations with KCVAMC (including VA non-profit research foundation). KUCC committed to 1) salary support for dedicated EP study coordinator; 2) training and education for investigators and research staff and, 3) mentoring in implementation of efficiency to build EPCT research infrastructure. KUCC ETCTN PI acquired VA appointment without compensation (WOC) for oversight. The KUCC-KCVAMC Collaborations team met weekly. KCVAMC agreed to provide quarterly progress reports.

4. 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 needs of veterans, research capabilities and in formulation of intentional and sustainable processes in EPCTs conduct. Two ETCTN trials have been identified for activation and workflow in development. These raise awareness of EPCTs among cancer care and primary care providers at KCVAMC.

5. Learned and Future Directions

This project is ongoing. Although it is unlikely to conduct First-in Human and dose escalation phases of EPCTs at VA in the short-term, we will focus on less complicated EPCTs (dose expansion and phase 2

ETCTN), increasing access to innovative therapies to veterans in our catchment area. Successful collaboration between KUCC and KCVAMC will impact on CT practices, demonstrating that such collaborations are feasible. These efforts can provide a roadmap to other CCs, VAs, and industry partners on streamlined strategies to bring ETCTN, IITs and industry-sponsored EPCTs to veterans.

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Figure

Table 1. Tools used in partnering with the VA in Clinical Trials
Before the KUCC-KCVAMC Research Memorandum of Agreement (MOU)
Establishing the need for KUCC to open early phase trials at the KCVAMC to address disparities in clinical trials access among the veterans (VA catchment area demographics, common and uncommon cancers, National Veteran Health Equity Report, survey other CCs)
Institutional commitment, additional support/funding from KUCC Director
KUCC engagement with KCVAMC stakeholders
KUCC engagement with NCI
KUCC engagement with UM1 consortium
KUCC-VA collaborations team meeting (weekly): Data sharing, requirements to be an ETCTN site, review of ETCTN trials for feasibility assessment at the KCVAMC, KUCC ETCTN PI granted VA privileges without compensation (WOC)
KUCC-KCVAMC Collaborations Meet-and-Greet Reception
After KUCC-KCVAMC Research MOU finalized
Training, education, and mentoring of KCVAMC staff
UM1 approval of including KCVAMC as KUCC subsite
NCI leadership alignment with the project
KCVAMC rostered as an ETCTN site (KUCC subsite)
Identification of points of contact
KUCC-VAMC Collaborations Kick-off meeting to check workflows
KCVAMC ETCTN trial selection according to patient needs and research capabilities
Assessment of metrics at KCVAMC: Number of trials activated, number of veterans accrued, activation timelines, deviations, guide VA for ETCTN audit and monitoring results
Continued identification of strengths and weaknesses and mitigation tools implemented
Publish results to share best practices with other CCs and VAs

KUCC: University of Kansas Cancer Center; KCVAMC Kansas City VA Medical Center