SESSION PROPOSAL 29

PLANNING, PRIORITIZING, AND CONDUCTING CLINICAL RESEARCH IN THE VA LEARNING HEALTHCARE SYSTEM DURING THE COVID-19 PANDEMIC

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Description of Session:

The Veterans Affairs (VA) Cooperative Studies Program (CSP) and Clinical Science Research and Development (CSRD) are both divisions of the VA Office of Research and Development (ORD) that is responsible for the planning and conduct of clinical trials and epidemiological studies within the VA's learning healthcare system. Since the outbreak of the COVID-19 pandemic in the US, the VA has been facing some new and evolving challenges in clinical research, especially in planning, prioritizing, and conducting new clinical research projects aimed at preventing and/or treating SARS CoV-2 infection/COVID-19 disease.

In considering clinical research projects, different stakeholders of the VA research enterprise assess needs using numerous parameters: (a) CSP and CSRD leadership: VAMC network infrastructure, financial support, available funding, and enterprise-wide impact. (b) Clinical researchers: clinical perspectives and needs, as they relate to study design and operations, in the context of an ever-evolving epidemiological picture and disease knowledgebase (c) VA research Coordinating Center(s): the challenges that reside in aspects of trial design and planning, in an effort to account for frequent changes in the COVID-19 epidemiology, and its impact on project feasibility/participant recruitment, choice of study endpoints, safety of both healthcare providers, research personnel and study participants.

Notwithstanding these evolving challenges, the VA ORD stood up the VA CoronavirUs Research and Efficacy Studies (VA CURES) network in a coordinated effort to develop a master protocol framework that could efficiently utilize the VA's clinical research infrastructure to address the COVID-19 pandemic. The VA CURES framework has been serving as the umbrella structure encompassing numerous COVID-19 clinical research activities.

Both CSP and CSRD have an established clinical research infrastructure, including Coordinating Centers, a Network Of Enrollment Dedicated Sites (NODES) and over 150 VA Medical Centers across the US, with a clear and streamlined process of submission and review of research proposals (Letters of Intent; LOI), subsequent trial planning leading up to scientific review and, once approved, conduct of research projects.

In this session, we will present the VA clinical research infrastructure and share its mobilization in this pandemic. Further, we will share lessons learned in conducting research in emergency situations and how the research infrastructure pivoted and adapted to fulfil its mission of providing the best healthcare to Veterans.

The following four areas will be the focus of this session: • The VA ORD leadership perspective: Infrastructure/support/funding/priorities: • Clinical research perspectives: Study design in the face of evolving epidemiological picture • Trial design and planning: Protocol drafting/timelines/shifting priorities/feasibility/VAMC networks • Organizing and operationalizing the VA CURES umbrella/platform: CURES-1, and CURES-2.

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