ACT for Veterans
Program Objectives & Milestones
January 1- December 31, 2019

The Access to Clinical Trials (ACT) for Veterans initiative was launched by VA ORD and NAVREF with the goal of providing Veterans in the VA health care system with more opportunities to participate in a diverse set of clinical trials and contribute to the national clinical trials enterprise. Since then, many key strides have been made and 2019 will be an exciting and active year for the Initiative! Many of the efforts from 2018 will bear fruit this year as we finalize deliverables and take tangible steps to improve the start-up process for industry-sponsored multi-site trials.

We kicked off the ACT initiative with a widely attended Stakeholder Summit in April 2018. The ACT Steering Committee consolidated input and identified 13 priority efforts, forming cross-disciplinary work groups to address the top five priorities. The work groups have been diligently tackling these issues with the goal of finalizing initial deliverables for the Work Group Summit at the end of February 2019.

The focus of ACT efforts will continue to be placed on operational efficiency, improved communication throughout the VA clinical research community, and bringing in high quality trials that represent unique opportunities to leverage VA capabilities. Specifically, activities will emphasize:

- An operational Single Point of Contact (SPOC) office to efficiently coordinate all multi-site industry trials
- A single IRB process that may include use of VA Central IRB, commercial IRB, or existing VA IRBs
- Pilot testing of 2 studies through the new start-up process
- Establishing agreed upon start-up timelines and meet or exceed them.

Detailed objectives and milestones are laid out by priority in the following tables.

Priority #1: Complete and integrate workgroup deliverables into an operational framework.

Specific Objectives	Estimated timeline for completion
Establish an operational Single Point of Contact office for coordinating new trials (WG#1)	July 2019
Establish a standard set of information that informs stakeholders about the capabilities of the VA clinical research enterprise (WG#2). • Site profiles populated	March 2019 August 2019
Establish a set of requirements that outlines the specific information that VA needs from industry for facilitating interest and initiation of new multi-site trials (WG#3).	March 2019
Establish a living process map that informs and guides all stakeholders through a standardized, streamlined start-up process (WG#4).	May 2019
Establish a single, efficient IRB process that meets the highest standards for human subject protections (may include central IRB, commercial IRB and expanded use of existing VA IRBs) (WG#5). • Pilot the Single IRB process • Finalize the Single IRB process	July 2019 Jul - Nov 2019 January 2020

Priority 2: Identify 2 multisite clinical trials to pilot through the study start up process; efforts will also help establish timelines and key performance indicators to enable continual improvement.

Specific Objectives	Estimated timeline for completion
Establish criteria (e.g., phase, therapeutic area, desired enrollment period, etc.) for case studies appropriate for testing	May 2019
Establish key performance indicators as agreed upon by VA and industry.	May 2019
Identify and test 2 clinical trial opportunities through the established start up workflow process. Compare results with the expected timelines and key performance indicators. Use the data to revise workflow, procedures, tools, etc., if needed.	Jul - Nov 2019
Identify 3rd opportunity to serve as the final case to formalize the new start-up process in 2020 and establish benchmarks	November 2019

Priority #3: Review priorities previously identified at the Stakeholder Summit and incorporate new priorities; Develop and implement a plan to address top remaining priorities. These priorities may include:

- Determine current barriers to a VA Medical Center's ability to consider participation in a trial (e.g., costs/fees for initial review, investigator time, etc.).
- Develop budget models that may be utilized for VA multi-site studies.
- Establish a standard process for obtaining Information Security review and approval. As part of this effort, the feasibility of establishing VA approved data portals and/or vendors for use in clinical trials will also be explored.
- Develop a lead site model for all Administrative, Budget, Contracting, and Regulatory (ABCR) functions (assuming the VA Central IRB is the IRB of record). This will also include the development of workflow and communication processes for the lead site.
- Determine the key performance indicators related to initial start-up processes (e.g., reviews, approvals, completion of deliverables)
- Develop procedural guidance for sites participating in industry sponsored multisite trials to facilitate efficient local site approvals including, but not limited to, CRADA, budget, and IRB. This will include identifying processes that can be done in parallel as well as those that must be done sequentially.
- Develop training materials for stakeholders at local and central levels regarding key procedures and requirements for successful completion.
- Work towards streamlined processes for completing agreements

Specific Objectives	Estimated timeline for completion
Establish workgroups and assign responsibility to leaders empowered to carry out the work necessary to address these priorities.	April 2019
Drive 4 of these priorities to completion	October 2019

Priority #4: Establish a communications plan designed to educate and inform all stakeholders (VA investigators, staff and leadership, NPCs, industry partners, patient advocacy groups, etc.) on policies and procedures related the successful start-up of an industry sponsored multisite clinical trial within VA.

Specific Objectives	Estimated timeline for completion
Determine the individuals or entities responsible for education/information dissemination regarding policies, procedures, etc.	June 2019
Create training and educational materials (print and online) (multi-venue)	August 2019 and Ongoing
Identify and participate in opportunities (meetings, workshops, conferences) to share information.	Ongoing