ACT for Veterans Initiative

ACCESS TO CLINICAL TRIALS FOR VETERANS

NAVREF

Dear ACT for Veterans Stakeholders:

We are pleased to provide you with the following summary on efforts to bring quality clinical trials to our Veterans. Workgroups continue towards established 60- and 90-day goals from our second summit with some highlights below.

- Workgroup 1 (Single Point of Contact): Standard Operating Procedures (SOPs) for the SPOC have been drafted which address (1) key responsibilities of the SPOC (2) ways in which the products of the other workgroups will be utilized by the SPOC, and (3) interactions between the SPOC, industry partners, VA sites, NPCs, and other stakeholders. These SOPs are currently being reviewed by Steering Committee members and are expected to be completed in June.
- Workgroup 2 (VA Assets): Workgroup 2 has completed both the site profile template and a catalog of VA clinical assets. These tools will allow partners to learn more about the VA research sites, capabilities, and strengths. They are currently working to identify a platform, which would be accessible to both internal and external partners, that can host this information.
- Workgroup 3 (VA Requirements): The workgroup has finalized the list of key information needed from industry to facilitate discussions regarding a new trial and to determine if it would be a good fit with VA. In this context, the workgroup is also in the process of establishing guidelines for specialty review committees that may be involved in the evaluation of a given protocol. Those guidelines are expected to be finalized in June. They have also identified the metrics used by industry to help with conceptualizing timelines and benchmarks for study start up activities within VA.
- Workgroup 4 (Workflow): The process to allow for single VA sign-off of Non-Disclosure Agreements (NDAs) for the agency is under consideration by VA leadership for approval. The workgroup has also asked NAVREF's clinical trials committee to help develop a centralized budgeting framework while addressing lead site capabilities and responsibilities. Those efforts are progressing well. NAVREF anticipates the committee will have a final product to Workgroup 4 by the end of the month.
- Workgroup 5 (Single IRB): The group continues to focus its efforts on those activities related to VA compliance with the upcoming single IRB. These efforts include:
    - Identifying VA internal IRBs to become part of a multisite network.
    - Initiating the steps necessary for obtaining a commercial platform to manage and track projects across the multisite network.
    - Optimizing current Central IRB functionality and obtaining approvals to acquire an electronic platform for tracking and managing research projects across a multisite network.
    - Securing the necessary resources to begin hiring additional VA Central IRB staff.
    - Exploring Master Service Agreements for potential future collaboration with commercial IRBs.

It has been inspiring to watch the metamorphosis of this project over the past few months and the dedication of people to this effort. We appreciate the contributions of our workgroup members and leads and their shared commitment toward a larger vision. Thank you for continuing to follow and support our efforts. As always, please contact Krissa Caroff, ACT for Veterans Program Coordinator, by email at clinicaltrials@navref.org should you have any questions.

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