ACT for Veterans Initiative

ACCESS TO CLINICAL TRIALS FOR VETERANS

NAVREF

Dear ACT for Veterans Stakeholders:

As we enter Summer, we're glad to present the latest updates on our efforts particularly towards goals set up earlier this year.

Next week, the Office of Research and Development will be hosting a national meeting for the research Administrative Officers (AOs) at VA medical centers from across the country. In addition to topics related to general operations, policies, and fiscal practices, Grant will be presenting on ACT for Veterans, its goals and the implications for VA facilities who are interested in doing industry-sponsored clinical trials. Given their important roles in the administrative, operational and regulatory activities for research at their site, we are glad that this presentation was requested to help with their efforts.

Regarding the workgroups, progress continues towards each of their respective deliverables and the Steering Committee continues to meet to discuss efforts, common challenges and/or ways to ensure each of the groups are working in a coordinated manner. Some highlights include:

- Workgroup 1 (Single Point of Contact): Activities center on the completion of Standard Operating Procedures (SOPs) that will also provide guidance and lay out expectations for an industry partner. A final version for review is expected by the end of the month that will also incorporate products from the other workgroups.
- Workgroup 2 (VA Assets): Priorities are identifying a platform to host information on sites and developing a database that will facilitate the exchange of information on sites and assets with external partners. Additionally, the group is exploring data sources that may provide more information about site-specific data regarding prevalent diseases/conditions.
- 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 and will be rolled up into the SPOC workflow. They are also reviewing industry start-up timelines which will inform benchmarks for start-up activity timelines within VA.
- Workgroup 4 (Workflow): VA leadership has approved the use of single central VA sign-off of Non-Disclosure Agreements (NDAs). Members of the ACT for Veterans Steering Committee will be working over the next month to develop a process and communication plan for how to execute this authority across VA facilities. We anticipate the plan will be operational by September 2019. NAVREF's clinical trials committee has drafted and submitted proposed guidance on lead site capabilities, including a centralized budgeting framework, that is currently under review by the workgroup.
- Workgroup 5 (Single IRB): The group continues to make headway on initiating the steps necessary for potential future collaboration with commercial IRBs and securing the necessary resources to begin hiring additional VA Central IRB staff. The group is also identifying VA internal IRBs to become part of a multi-site network. One expansion panel is currently in the process of being established.

Thank you again for your continued interest and commitment to this effort. As a reminder, anyone interested in being added to our distribution list should contact Krissa Caroff, Program Coordinator, by email at clinicaltrials@navref.org. Any questions or comments can also be sent using the same email address.

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