ACT for Veterans Initiative

ACCESS TO CLINICAL TRIALS FOR VETERANS

NAVREF

Dear ACT for Veterans Stakeholders:

It's hard to believe, but last Friday marked the one- year anniversary when ACT for Veterans kicked off. Since then, a lot of effort has gone into helping to enhance access to quality clinical trials for Veterans. Thank you to everyone for your dedication and interest. Workgroups continue to move forward with established action plans as summarized below. Furthermore, activities are more focused on bringing the respective workstreams together.

Workgroup 1 (Single Point of Contact): For this central aspect of study start up efforts, individuals met from all workgroups to develop Standard Operating Procedures (SOPs) from the initial contact to submission to the IRB. A draft of the SOPs will be created in the next week and a mock study will be used to test these procedures from the SPOC perspective. The goal is to have SOPs finalized in about six weeks' time to enable a true pilot to be tested starting around Summer 2019

Workgroup 2 (VA Assets): Efforts are focused on finalizing the site profile template to enable partners to learn about VA research sites and strengths. Efforts also are exploring both existing and new options for how best to maintain this information and make it available.

Workgroup 3 (VA Requirements): The group is reviewing the list of VA requirements and getting perspectives that will facilitate initial discussions on possible opportunities for a new trial. The goal is to finalize a checklist with these requirements to be completed later this month. Subsequently, the workgroup will focus on a list of criteria needed to evaluate whether a potential clinical trial would be a good fit for VA capabilities. A list of metrics is also being reviewed to help with setting time expectations for completion of VA review.

Workgroup 4 (Workflow): A process to allow for single VA sign-off of Non-Disclosure Agreements (NDAs) for the agency has been proposed and is currently working through the VA approval process. The workgroup has also started to identify those aspects of the local review committee process that could be accelerated and/or conducted in parallel. NAVREF's clinical trial committee is developing a centralized budgeting framework for multi-site studies and addressing lead site capabilities and responsibilities. These activities are working in coordination with Workgroup 1 with a target completion date at the end of May.

Workgroup 5 (Single IRB): Activities are focused on ensuring VA compliance with the single IRB mandate. Steps include:

- Putting SOPs in place to allow for a VA IRB multisite IRB network and identifying the IRBs to be integrated into it.
- Exploring electronic platforms for tracking and managing research projects.
- Meeting with Human Resources regarding staffing needs.
- Exploring Master Service Agreements for potential future collaboration with commercial IRBs.

Progress is continuing, but there is still work to be done as we are halfway into this two-year process. Please contact Krissa Caroff, ACT for Veterans Program Coordinator, by email at clinicaltrials@navref.org should you have any questions.

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