ACT for Veterans Initiative

ACCESS TO CLINICAL TRIALS FOR VETERANS

NAVREF

Dear ACT for Veterans Stakeholders:

Summer is often a time for relaxation and we hope that you are enjoying it. On the ACT for Veterans front, many of the efforts summarized below are being taken on by VA staff as we continue to work toward facilitating partnerships with others.

While workgroups are wrapping up efforts, there has been a shift toward integrating their products into a single framework for initiating interest to the point of where a study can begin. The intent is to create a clear document describing steps and responsible parties to help with understanding processes and expectations. However, we expect that industry partners will not all work similarly and therefore, we are focusing mainly on essential requirements.

Among the workgroups, much is being driven through the Single Point of Contact (SPOC) model (Workgroup 1). A mature draft of the framework has been completed with discussions focused on how to transition activities from the SPOC to sites/VA facilities once a study has been deemed to be a good fit for VA capabilities.

Workgroups 2 and 3 continue to identify platforms and requirements that will feed into the SPOC process. These tasks have required some information gathering regarding resources, benchmarks and data to better inform these discussions. Efforts to help with establishing topic/disease review committees to assist with evaluating clinical relevance to a VA population and feasibility are also in progress.

As we mentioned in June, Workgroup 4 has successfully obtained VA leadership approval for a central VA sign-off of Non-Disclosure Agreements (NDAs) on behalf of the agency. This approval will eliminate the need for each medical center to execute its own CDA for a multisite clinical trial. The Steering Committee is now working with the Office of General Counsel/Specialty Team Advising Research to map the steps for efficiently carrying out this process. A work flow diagram has been drafted and the proposed process is currently being piloted. Our goal is to have multi-site NDAs negotiated, approved and executed within two weeks (if not less). We anticipate more information to be available by September 2019. A guidance document for the selection of the lead site NPC and evaluating various billing models is also being reviewed.

Finally, efforts regarding IRB processes are focused on ensuring compliance with the single IRB mandate that will be effective in 2020. This includes conducting reviews of relevant internal policies, determining the types of research Privacy and Information Security Officers will review and developing review requirements. Ethical and legal considerations are also being explored by the appropriate VA entities. The group continues with the steps necessary to collaborate with commercial IRBs and non-VA affiliated IRBs. Hiring actions for the VA Central IRB are pending as activities to establish a new panel are underway. These efforts will be critically reliant on the ability to establish an electronic platform for a multisite IRB network which are in discussion.

As word of ACT for Veterans activities spreads, we have observed growing interest from industry collaborators seeking opportunities to engage VA in a variety of other topics and clinical research activities. While we are highly encouraged by this interest, we remain committed to the primary objectives of ACT for Veterans and want to bring them to completion. We urge those interested in future partnerships to stay informed via this monthly newsletter. Feel free to encourage interested colleagues to contact Krissa Caroff, ACT Program Coordinator, at clinicaltrials@navref.org to receive this newsletter or for any questions or comments.

Rick Starrs
CEO, NAVREF

Grant Huang
VA Office of Research and Development