



Dear ACT for Veterans Stakeholders:

This month has provided no shortage of evidence that word about the ACT for Veterans initiative is spreading and that there is shared interest from multiple stakeholders to bring more clinical trials to our nation's veterans. Several companies have approached us with the desire to either learn more about the work being undertaken or to expand their current business with VA to include new or additional clinical trial opportunities. We sincerely appreciate the growing interest and your ongoing patience as we work to ensure that VA is poised to be a partner of choice within the clinical research space. With each month, we move closer to that goal and are pleased share the following summary of recent "ACT"ivities:

1. As was first announced in the August update, this October marks the beginning of pilot testing of the Single Point of Contact (SPOC) framework. As the first step, our workgroup managers will be meeting next week to begin a walkthrough of a previously approved multisite protocol. The purpose of this walkthrough is to conduct a focused review of each of the procedures outlined in the framework. Key objectives of this exercise include: 1) ensuring that proposed procedures are clearly written and understandable to those unfamiliar with the SPOC concept, 2) identifying potential gaps/opportunities for improvement and 3) fine tuning the framework before transitioning to the piloting of live trials.
2. The Society for Clinical Research Sites (SCRS) held its Global Site Solutions Summit October 11th – 13th. Our program coordinator and clinical trials facilitator, Krissa Caroff, attended the meeting and had the opportunity to not only hear from sponsors and CROs about the value of partnerships, but also used the meeting as an opportunity to touch base with current stakeholders and introduce ACT to new contacts.
3. Efforts are in progress with VA Specialty Care Service groups to establish mechanisms to have clinical leadership input on trials to help ensure proposed trials would be good fits with VA strengths and need. Using ideas put forth by the National Oncology Program as a model, we are working to establish a few more Clinical Evaluation Committees in other priority areas for VA. In addition to clinical strengths and needs, the "fit" of a potential trial may consider patient characteristics, equipment/clinical procedure requirement and other factors contributing to success. We anticipate more information to be available in the coming weeks.
4. We continue to pilot the central Non-Disclosure Agreement (NDA) sign off process and to fine tune internal procedures related to the execution of these documents. Efforts have highlighted a potential challenge related to the heterogeneity with how industry partners handle NDAs. We are working with the Office of General Counsel, Specialty Team Advising Research (OGC STAR) to define the role of the SPOC in negotiation and execution of these NDAs. Once these challenges are addressed, we will develop guidance for the VA field and VA-affiliated Non-Profit Corporations.
5. An enterprise wide research committee software management program has been identified and a contract executed by the Office of Research Policy, Protections and Education. A tiered, phased-in rollout of the platform is anticipated over the next two to three years. VHA research programs will use the software for both research reporting and potentially as a tool to promote opportunities for cross-institutional collaboration. This effort will allow for the harmonization and standardization of processes across VA research. A public announcement regarding the contract will be forthcoming.

Thank you again for your support and commitment to this initiative. Please contact Krissa Caroff, ACT for Veterans Program Coordinator, by email at clinicaltrials@navref.org should you have any questions.