



Dear ACT for Veterans Stakeholders:

Happy Holidays! As we prepare to turn the page on another year, we wanted to provide you with a few key developments relative to the ACT for Veterans initiative.

Our recent activities have been focused heavily on organizational and operational requirements. A key concept from the start of the ACT initiative has been to increase efficiencies in the interactions between VA (including its facilities/sites and various offices), VA affiliated non-profit corporations and industry partners. To this end, the establishment of a Single Point of Contact (SPOC) should be familiar. Specifically, SPOC responsibilities have been envisioned to include serving as the initial contact for industry, connecting potential partners with interested sites, working with sponsors and the Office of General Counsel/Specialty Team Advising Research (OGC STAR) to facilitate the negotiation various agreements. While discussions may have conceptualized the SPOC as an individual, we are working towards having a team of individuals to facilitate discussions and coordinate activities involved in the start-up processes. To do so, activities need to address organizational changes within VA, types of personnel and skills needed, processes for hiring, and potential sources of support. The intent is to create a “Partnered Studies Program” office that would have immediate and longer terms capabilities in facilitating partnerships and get trials more rapidly started in VA.

Simultaneously, we have been finishing the walkthroughs of standard operating procedures for how a SPOC would interact with potential partners and other stakeholders to move a project from initial contact through study initiation. The results of the walkthroughs identified a few gaps and/or improvement opportunities in our initial draft process. We are developing standard tools to help with communication and to ensure repeatable and measurable processes with various stakeholders.

The ongoing pilot of the central NDA sign off process has been proceeding well. In general, we have found that by using a central VA signature, we have been able to reduce the time to a matter of days from when the NDA is fully signed to when a protocol is received for further consideration. However, this process is best applied to instances where there is not an existing Master NDA. Currently, we are working with the OGC STAR to determine how to apply processes to those situations when a Master NDA with a company exists. We will keep piloting this process and incorporate details as part of a larger roll out of procedures.

Overall, our efforts are moving us toward the culmination of this initiative in 2020. We are counting on our stakeholders for your continued support- be it time, effort, or other resources, as we work to achieve our collective goal. We look forward to many exciting things in the new year, including the ability to increase Veterans’ access to clinical trials. Have a joyful and safe holiday season. Please feel free to contact Krissa Caroff, ACT for Veterans Program Coordinator, by email at clinicaltrials@navref.org should you have any questions.

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