ACT for Veterans Initiative

ACCESS TO CLINICAL TRIALS FOR VETERANS

NAVREF

Dear ACT for Veterans Stakeholders:

We hope that you are safe and doing well as Coronavirus Disease 2019 (COVID-19) affects our nation. This communication is brought with mixed sentiments given the situation. However, when we started the Access to Clinical Trials initiative almost two years ago, we could not have envisioned the role our work could play as part of the large-scale efforts being undertaken to understand and combat this disease.

As an update, the VA Office of Research and Development anticipates its April launch of the newly formed "Partnered Research Program" (PRP) to be dedicated to carrying out the key priorities identified by this initiative. As we meet our two-year goal to start this effort, the PRP will serve as the single point of contact for potential industry sponsors interested in partnering with VA on multisite clinical trials. The PRP team will have the ability to share trial opportunities with VA investigators via field research offices and non-profit corporations. They will facilitate the identification of potential sites, collect key information regarding interest and share this with industry sponsors. In addition, the team will work in close concert with other offices within VA to ensure that critical start up processes such as NDA negotiation and execution, IRB review and approval, and privacy and information security concerns are addressed in a timely fashion. The PRP will collect key metrics relative to study start up as well. Over time, as we establish more partnerships, we expect that the PRP team will grow, not only in size, but in capability. Information will be shared with stakeholders regarding the PRP-including key contacts, procedures, and tools for interfacing with the program staff. In the meantime, questions can continue to be directed to clinicaltrials@navref.org.

With the COVID-19 pandemic, many capabilities that the ACT initiative helped establish were rapidly kicked into action this past month. As VA sought to provide Veterans with access to COVID-19 trials, the previously reported capabilities for executing a centralized/single non-disclosure agreement and coordination of multiple VA sites with available investigators and processes for a single contact for VA were all engaged. The ability to organize and have key information ready was due in large part to what was achieved by the workgroups as they helped anticipate needs for working with industry partners. Furthermore, VA completed its first reliance agreement to use a commercial IRB. With the help of the Office of General Counsel/Specialty Team Advising Research, Office of Information Technology, Research Support Division, Privacy Office and Office of Research Oversight and others, VA quickly brought trials to allow Veterans to have access to promising therapies. In short, because of the efforts and commitments of our stakeholders, we have been able to employ the processes borne out of this initiative to get a clinical trial site started in a matter of days. We recognize that this circumstance was exceptional, but it provides evidence that the goals that ACT for Veterans set out to achieve can be accomplished.

We want to convey a huge message of thanks to the members of our ACT for Veterans Steering Committee, workgroup members and supporters of this initiative since Day 1. As COVID-19 will take priority for VA for the foreseeable future, VA, its Veterans and investigators now will have opportunities to contribute to overcoming the pandemic. While this note effectively closes the book on this chapter, we recognize that there are additional aspects of clinical trial conduct, such as recruitment and enrollment, that have yet to be explored. We want to assure you that "ACT 2' is on the horizon and we look forward to sharing more details once available.

Stay safe and healthy.

Rick Starrs
CEO, NAVREF

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VA Office of Research and Development