Dear ACT for Veterans Stakeholders:

With Spring just around the corner, we are not only excited about the warmer weather, but also about the great work that came out of our ACT for Veterans Workgroup Summit, which was held February 27th and 28th, in Washington, DC. The Summit was a fantastic opportunity for our five workgroups to come together and to share their ideas and products. An impressive amount of work has been accomplished attendees got the chance to talk and work with each other on ACT for Veterans priorities. Feedback reflected the energy and achievements observed at the meeting, and we want to capitalize on the momentum generated.

Summaries of workgroup process are below. Additionally, each workgroup was tasked with 30, 60, and 90-day action plans that are to be reported to and monitored by the ACT steering committee. Altogether, these efforts will be the main focus for the upcoming months:

1. Workgroup 1 efforts focused on establishing an "Industry Sponsored Clinical Trials Office" (CTO). This office would be responsible for key study start up activities and serve as the initial point of contact to bridge industry and VA investigators. The Office would also have responsibilities related to required start-up procedures including: non-disclosure agreement negotiation and execution; facilitating communication between industry partners and VA; assisting with site identification; IRB submissions and providing an information service to stakeholders. Resources, including staffing, funding, and technology still need to be addressed. Therefore, the workgroup is considering a pilot to better understand the all major requirements and processes. The pilot will closely monitor the progress of up to 10 multi-site industry sponsored trials 6 months after launch. During which time, data will be collected to build the business plan for the establishment of the office. As short- term goals, the workgroup will be creating job descriptions for key CTO functions, identifying existing VA and NPC staff that may be able to perform CTO duties, reviewing existing project management software and determining additional needs, and identifying an IT specialist who may be able to assist with the design of such software.
2. Workgroup 2 has created a catalog of VA clinical research capabilities and expertise (i.e., clinical networks/centers of excellence, clinical trials infrastructure, data resources/informatics, administrative, regulatory and legal). The group also working on developing VA trial site profiles using a templated approach. Efforts will focus on how to best populate such a site profile registry and maintain it. This information is being developed for the Clinical Trials Office in its early discussions with potential industry partners.
3. Workgroup 3 developed a list of key information that VA needs from industry to begin and facilitate initial discussions to determine VA's interest and fit for a trial. Efforts involve a two-step process where information would be provided by industry initially to allow the VA to conduct an initial evaluation by clinical experts familiar with patient needs and VA capabilities. Afterwards, assuming VA participation is appropriate, additional information could be submitted by industry for further advancing efforts.

   Workgroup 3 is also looking to benchmark times to evaluate efforts for future start up activities. Industry volunteers will work together to collect and share metrics on VA activities. Workgroup 3 is planning to meet with workgroup 1 to determine the specific information that the CTO will need to obtain from industry partners in conjunction with their pilot activities.

4. Workgroup 4 shared the key steps involved in different parts of the study start up process, including: assessing VA interest, negotiating and executing non-disclosure agreements, negotiating and executing Cooperative Research and Development Agreements, budget negotiations, IRB review, and local assurance committee reviews at individual VA medical centers. The workgroup is focused on those steps that can be pursued concurrently, identifying constriction points and hurdles, and identifying opportunities to speed up the process to avoid an overly restrictive process and avoid bottlenecks. Procedures also involve the role of a CTO to facilitate activities. Other challenges identified were associated with budgeting and contracting, including identifying who (i.e., which non-profit corporation) should lead efforts related to budgets and CRADA, the lack of standardized costs for research procedures and clinical services and the lack of utilization of Master CRADA and CDA documents. These areas will be further evaluated after initial targets are addressed. Additionally, it should be noted that proposed processes would be applied to those multi-site trials for which VA would concentrate its resources on facilitating. They would not prohibit other activities within VA that others may wish to pursue through other available mechanisms involving facility-level contacts (e.g., investigators, VA affiliated non-profit corporations).

5. Workgroup 5 highlighted a general strategy for helping align VA to the single IRB mandate. These efforts involve addressing policies related to the use of commercial IRBs or any non-affiliated IRB . Models for a network of central VA IRBs is also being explored. Several challenges related to communication, staffing, funding, policy, and the need for an authority to operate an electronic platform for managing IRB processes were identified. Next steps will focus on gathering relevant information, identifying resources and tools for achieving this strategy.

We are very encouraged by the efforts the workgroups have put forth and greatly value their commitment. We will continue to keep you informed as we move into this next phase. Please contact Krissa Caroff, ACT for Veterans Program Coordinator, by email at clinicaltrials@navref.org should you have any questions.

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