ACT for Veterans Initiative

ACCESS TO CLINICAL TRIALS FOR VETERANS

NAVREF

Dear ACT for Veterans Stakeholders:

With Fall officially upon us, we are pleased to share the following updates.

1. The Steering Committee met twice to discuss workgroup activities, ongoing efforts to inform additional stakeholders about ACT, and future Summit planning. A summary of the progress made to date by each of the five workgroups is provided below.
    a. Workgroup 1 (Developing the Single Point of Contact model to facilitate efficiencies in start-up; Lead: Krissa Caroff): Workgroup 1 members have had detailed discussions regarding the role and responsibilities of the Single Point of Contact (SPOC). A set of "wish lists" outlining the responsibilities that would be imperative for a SPOC has been developed. The group is looking specifically at how the SPOC can be used throughout the initial start-up period to improve timelines, communication, education and more. It is anticipated that by the end of October the workgroup will have a comprehensive list of responsibilities enabling discussions to focus on the resources and tools needed for execution.
    b. Workgroup 2 (Providing fuller information about VA assets and processes; Lead: Grant Huang): Workgroup 2 members have been compiling a list of the broad set of abilities and resources that could be beneficial for conducting clinical trials. Items are being categorized at national and local/site levels. Non-VA members have also shared the types of information that they would find desirable. Given the significant amount of information, it is anticipated that a framework can be established to systematically present VA strengths to partners.
    c. Workgroup 3 (Establishing requirements that VA needs from industry; Co- Leads: Tim Morgan & Mark Klein): Workgroup 3 has focused on creating a list of key information that VA would need from industry at the point of initial conversation and subsequently if a trial is determined to be worth pursuing. The workgroup has framed its conversations around a vetting process whereby VA clinical experts and other leaders determine if a trial is an appropriate fit for VA. This workgroup has also begun to discuss establishing criteria to identify whether a trial meets key priorities for VA, developing templates and/or forms and SOPs for making determinations, and evaluating the feasibility and utility of establishing a repository for key industry information.
    d. Workgroup 4 (Process map related to study start up; Lead: Holly Birdsall): This workgroup has focused on drafting a flow diagram depicting the current models being employed by VA to initiate clinical trials. Next steps are to pose specific questions to stakeholders and other workgroups to identify opportunities to improve upon the current process and to create a process map of the ideal model(s) to be used.
    e. Workgroup 5 (Developing the capability for the VA Central IRB to accommodate more industry- sponsored trials; Co-Leads: Stephen Bartlett & Fred Hendler): Workgroup 5 has benefitted from the addition of a member from VA's Center for Strategic Partnerships. Some potential investment funding for VA Central IRB is being considered for supporting initial set up and educational activities. The group is also exploring the use of an "off-the shelf" IRB software to manage submissions, communications, etc.

2. In addition to the workgroup activities, there have also been ongoing efforts undertaken to share information regarding the ACT for Veterans Initiative. These include:
    a. Rachel Ramoni and Grant Huang presented at a recent national meeting of the VA clinical leads/national clinical program directors to explain the work being done as part of ACT. The group is supportive, and some have expressed interest in helping.
    b. Rick Starrs presented information regarding ACT at the Association of VA Hematology/Oncology (AVAHO) in late September. Attendees included VA investigators and staff, as well as various industry representatives.
    c. A research special interest meeting was also held at AVAHO and this provided another opportunity for ACT to be highlighted and for feedback to be provided.
    d. VA investigator (and workgroup member), William Boden, shared a brief presentation at the Duke University/Duke Clinical Research Institute "Think Tank" forum in early October. The purpose of this meeting was to engage and educate various attendees and stakeholders about the many complex issues relating to clinical trials design and execution, the advent of pragmatic trials, and the importance of creating effective partnerships and coalitions among government agencies, universities, and industry to promote joint research initiatives.
3. Other brief updates regarding information mentioned in our September letter:
    a. We are still actively working to get our website "live" and addressing technical requirements for it.
    b. We are continuing to work on the logistics for our next ACT for Veterans Stakeholder Summit. We anticipate the focus of this event will be on presenting and finalizing workgroup deliverables. We are planning for meeting activities to take place in DC over two days in late February. Invitations and additional details will be shared as soon as possible.

As always, we are open to input and welcome you to share information or materials that you think may be informative to the workgroups. Examples may include papers, tools, or examples of activities aimed at making partnerships more efficient. Please feel free to forward those materials to Krissa Caroff, ACT for Veterans Program Coordinator, by email at clinicaltrials@navref.org.

Thank you.

Rick Starrs
CEO, NAVREF

Grant Huang
VA Office of Research and Development (ORD)