ACCESS TO CLINICAL TRIALS FOR VETERANS



Dear ACT for Veterans Stakeholders:

We hope you had a nice summer. We are glad to report on our most recent efforts since our last update.

- 1. The Steering Committee met to discuss workgroup progress, communication strategies, and future Summit planning. A summary of the progress made to date by each of the five workgroups is provided below.
 - a. Overall, the Steering Committee provided the workgroups with general operating principles to facilitate communication and direction. They have also been staffed by managers to support activities and products.
 - b. Workgroup 1 (Develop the Single Point of Contact model to facilitate the communication of trial opportunities, processes, and requirements; Lead: Krissa Caroff): Members of workgroup 1 met in late August to discuss the current methods by which clinical trials come into VA and the advantages and disadvantages of each. They also discussed the advantages of having a single point of contact within each sponsor organization and Contract Research Organization. Members of the workgroup determined that they will need to define the Single Point of Contact (SPOC) role, including the specific responsibilities assigned to the SPOC. They will also be exploring the current volume of trials that come into the VA to understand the capacity needs of the SPOC. The group will be meeting again in late September to begin to address specific responsibilities.
 - c. Workgroup 2 (Establishing basic information VA can provide to industry regarding VA assets and processes; Lead Grant Huang): The workgroup held its first teleconference with team members meeting each other and discussing their interests and expertise. Efforts have begun to start collecting information that will help achieve workgroup goals. Additionally, the diversity of the group has helped with starting to understand how VA can help others know what they don't know.
 - d. Workgroup 3 (Establishing requirements that outline the information VA needs from industry; Co-Leads: Tim Morgan & Mark Klein): Team leads for this workgroup were identified and two introductory meetings were held between the leads and the ACT Lead and Program Coordinator to help orient the leads and draft an agenda. The first workgroup meeting was held, and members began to compile a list detailing the types of information they believed VA would need from industry and will be fine tuning that list over the next few weeks.
 - e. Workgroup 4 (Process map related to study start up; Lead: Holly Birdsall): In advance of convening the full workgroup, the lead obtained information regarding the current models by which industry sponsored multisite trials are initiated within VA. Workgroup members will use this information as a starting point for identifying the aspects of the process that may be adopted for the future state that the workgroup will be mapping.
 - f. Workgroup 5 (Develop the capability for the VA Central IRB to accommodate more industry-sponsored trials; Co-Leads: Stephen Bartlett & Fred Hendler): Workgroup members met and were provided with background and information to help understand the current state and other operational considerations. The workgroup also discussed some barriers to be considered and will be discussing concerns identified moving forward.
- 2. A website has been developed which will provide visitors with details related to history and purpose of ACT for Veterans, initiative progress, and some resources for partners. We are working through some technical requirements for accessibility and hope to have it go live in the next month.
- 3. NAVREF held its annual conference September 9th- 12th in Washington DC. During the conference, a panel comprised of representatives of NAVREF, VHA's Office of Research and Development (ORD), industry, VA investigators, and the VA affiliated non-profit corporations (NPCs) introduced ACT for Veterans to an audience of NPC executive directors and staff, industry representatives and VA Associate Chief of Staffs for Research. The panelists shared their unique perspectives and welcomed attendees to share information

- with their respective organizations and to participate, if able. Members from the VA Office of General Counsel/Specialty Team Advising Research were also present and contributed to the discussion.
- 4. Discussions have begun regarding the next ACT for Veterans Stakeholder Summit with a tentative plan to hold the meeting in early 2019. We will keep you informed as more details become available.

We are pleased to see the workgroups convening and are enthusiastic about the activities they are undertaking. We look forward to hearing their next updates and will continue to share. We are also excited that word continues to spread about this initiative. As always, should you have any questions or comments, please contact 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)