ACT for Veterans Initiative

ACCESS TO CLINICAL TRIALS FOR VETERANS

NAVREF

Calendar Year 2018: Progress Report

(As of November 15, 2018)

In December 2017, under the leadership of Dr. Rachel Ramoni, VA's Chief Research & Development Officer (CRADO) and NAVREF CEO, Rick Starrs, a new effort to increase veterans access to clinical trials began to take shape. As a first step, a steering committee was developed. The steering committee provides the strategic direction for a two-year plan to improve clinical trial start-up efficiency. The initial charge to the steering committee was to determine the goals and objectives for a workshop which would bring together VA and non-VA stakeholders interested in improving the efficiency of VA clinical trials. Members of the steering committee were responsible for identifying individuals both within and outside of VA who would be appropriate to participate in the workshop and the subsequent workgroups that would be created. Initial members of the steering committee included:

- Steve Bartlett, VA Central IRB Co-chair
- Holly Birdsall, VA ORD Senior Medical Officer
- Krissa Caroff, NAVREF Clinical Trial Facilitator and Clinical Trial Initiative Program Coordinator
- Marisue Cody, VA ORD Director of Operations
- Scott Duvall (ad hoc), Director, VA Informatics and Computing Infrastructure (VINCI)
- Grant Huang, Director, Cooperative Studies Program
- Karen Jeans, Associate Director of Regulatory Affairs, CSR&D
- Rick Starrs, NAVREF CEO
- Rachel Ramoni, VA CRADO

During December, potential sponsors were approached with a proposal to financially support both the Program Coordinator position as well as the clinical trial workshop. 3 sponsors graciously offered financial support: Cohen Veterans Bioscience, the Lungevity Foundation, and Veterans Against Alzheimer's.

January 2018- April 2018

Between January and April 2018, steering committee members met several times per month to focus on workshop planning, objectives and goals. The workshop was given the name "Stakeholder Summit" and was scheduled for April 12, 2018. Specific activities occurring during this time included:

- Meeting logistics (i.e., meeting space identification, registration website, arranging hotel accommodations)
- Identifying potential VA and non-VA stakeholders
- Sending invitations
- Creation of a pre-summit survey to help inform meeting discussion and ensure that the Summit focused on the issues deemed most vital.
- Preparation of read-ahead materials to provide significant background information to those registered to attend the Summit.

The Clinical Trials Stakeholder Summit was held on April 12, 2018. Over 60 individuals representing industry, VA Central Office, VA medical centers, patient advocacy groups, and the NPCs convened in Arlington, Virginia with a common goal: enhancing Veteran access to clinical trials. Attendees spent much of the day participating in facilitated discussions centered around three key areas: Initiating Partnerships, Business Operations, and Study Approvals and Considerations. During each of the sessions, attendees shared their own experiences, challenges, and best practices related to such issues as finding an initial point of contact, confidentiality disclosures and other agreements, and understanding and

navigating the study approval process. The Summit concluded with an interactive session wherein participants were asked to review the eight main topics identified through the discussions and to make recommendations regarding actions that could be taken relative to those priorities.

Post Summit activities included:

- The compilation of detailed notes from the Summit discussions (provided by Deloitte consulting staff which facilitated the Summit).
- The establishment of an email distribution list (CTSummitGroup@navref.org) as a mechanism to communicate with Summit attendees.
- The creation of a dedicated email address (clinicaltrials@navref.org) to allow individuals to pose questions or concerns regarding industry-partnered clinical trials with VA.
- A post summit survey was created and disseminated to all attendees within 5 days of the Summit to evaluate satisfaction. The results of the Post Summit survey indicated strong satisfaction with the meeting and interest in holding a future meeting.

May 2018:

The Steering Committee held a face-to-face meeting in Washington DC to review the notes and comments provided by Deloitte and the post-meeting survey. Based upon this information, a list of proposed action items was created. All Summit attendees were then contacted and asked to complete an online questionnaire designed to determine which of a series of proposed actions should serve as the initial priorities for the initiative.

Steering Committee members also met with the VA Office of General Counsel/Specialty Team Advising Research to discuss possible opportunities for efficient practices and metrics for agreements related to clinical trials.

June 2018:

The Clinical Trials Steering Committee met in early June to review the results of the prioritization questionnaire. Considering such factors as: a) the level of resources required, b) complexity, and c) estimated timeframe for completion, the committee identified 5 key priorities. These priorities, along with some recommended next steps, as well as 8 other priority activities, were outlined and shared.

Dr. Rachel Ramoni hosted a webinar in mid-June to discuss progress relative to the clinical trials initiative, including a detailed overview of the priorities and next steps. During the webinar, participants provided feedback and some stakeholders volunteered to participate as workgroup members.

Steering Committee members also began targeted discussions with various VA offices involved with processes related to the initiation of industry clinical trials (including VA Office of General Counsel, VA Office of Information and Technology, VHA Privacy, VHA Office of Specialty Care Services and the VHA Office of Informatics and Information Governance).

July 2018:

Due to an increased interest in the initiative, efforts were undertaken to emphasize communication. As a starting point, a summary document was created explaining the history and rationale for the initiative. Furthermore, work began on a dedicated website- the purpose of which would be to serve as a single point of reference for current initiative participants as well as for those interested in learning more about conducting clinical trials within VA.

The clinical trials initiative also was formally designated as “Access to Clinical Trials (ACT) for Veterans”.

The Steering Committee finalized the group composition, roles, responsibilities and expectations for the five work groups designated to tackle the top five initial priorities previously identified for improving trial initiation activities.

August 2018:

The five work groups were commissioned with designated leads and managers to help with organizational activities. Additional activities continued to occur outside of the workgroups on other topics such as central budgeting, engaging other individuals and offices within VA, and sharing information regarding the initiative with other stakeholders. Workgroup activities began.

September 2018- October 2018:

Workgroups continued to meet and provide progress reports to the Steering Committee. Steering Committee membership was expanded to include all workgroup leads to ensure adequate workgroup representation at each Steering Committee meeting.

A number of efforts were also undertaken to share information regarding ACT for Veterans:

- During the NAVREF annual 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. This provided the first opportunity for such a varied audience to hear about the initiative, ask questions and volunteer to participate.
- Rachel Ramoni and Grant Huang presented at a national meeting of the VA clinical leads/national clinical program directors to explain the work being done as part of ACT.
- Rick Starrs presented information regarding ACT at the Association of VA Hematology/Oncology (AVAHO) in late September.
- 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.
- 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.
- Rick Starrs presented information regarding ACT at the Annual Meeting of the Society of Research Administrators International in late October.

Preliminary planning for a follow-up Summit also began during this time.

In mid-October due to concerns regarding the Federal Advisory Committee Act, workgroup activities had to be put on hold pending resolution of a mechanism allowing VA to interact routinely with industry representatives. In order to ensure that the initiative continued to gain momentum, Grant Huang, Program Lead, and Krissa Caroff, Program Coordinator, communicated with all workgroup members and continued to meet with workgroup leads.

November 2018:

As of this report, the activities of the 5 workgroups has resulted in the establishment of foundational information regarding:

- The roles and responsibilities for the Single Point of Contact (Workgroup 1).
- VA assets and capabilities both at a national and local level that can benefit how trials are done (Workgroup 2).
- The materials and information that VA needs from industry to evaluate the appropriateness and interest in committing resources to a given proposal for VA (Workgroup 3).
- Current workflows for how trials can be initiated and the processes and people involved (Workgroups 4 and 5).

With this information now in place, workgroup efforts are shifting toward defining the future state- focusing on more complex matters such as financial resources needed, key players and their roles, communications, tools and materials, and key principles for prioritizing activities that will need to be created to ensure efficiency.

The Program Coordinator has worked closely with each of the workgroup managers to establish workspaces via a SharePoint site for all workgroups. Key drafts of documents have been uploaded.

Office of Research and Development staff are working with the Office of General Counsel to outline processes to allow more efficient Non-Disclosure Agreement (NDA) sign off. Efforts are focused on identifying a central authority and policy requirements involved. Key personnel critical to this process have been identified and steps are currently being undertaken to seek leadership support and prepare materials for these efforts.

The Act for Veterans website (www.actforveterans.org) is now live. The current purpose of the website is to raise awareness of the initiative, while serving the long-term goal of becoming a key resource and source of information, tools, and other materials for both VA and non-VA stakeholders seeking information on industry-VA multisite trial partnerships.

Planning activities for the next Summit are well underway. The meeting will take place over two days (February 27th and 28th) and is designed to bring together the work products of the workgroups, obtain feedback, and make adjustments. It will also provide the opportunity to assess overall efforts and refine as necessary. "Save the Date" notices were recently sent to all workgroup members.

Ongoing:
A monthly update has been provided to interested stakeholders since May 2018.
The distribution list has grown from ~ 60 people in April to just over 200 as of November 15th.
Work continues to address concerns regarding FACA. This is expected to be resolved by December 5th - at which point workgroups will be able to resume meetings with VA and non-VA members.
Website content will continue to be revised and fine-tuned in order to fully explain the work of the ACT for Veterans Initiative to internal and external audiences.