Dear VA Clinical Trials Stakeholders:

Our most recent set of updates is below. We continue to make progress and remain excited about the changes being made in support of industry-partnered trials within VA.

1. To help with "branding" this effort, members of the Steering Committee have now agreed to name this effort "Access to Clinical Trials (ACT) for Veterans". We hope that you agree that it simply and accurately captures the mission of the initiative and helps make things more inclusive of the growing list of stakeholders (see below). In the coming weeks, we hope to create an ACT for Veterans logo (the "Stakeholder Summit" letterhead will no longer continue) and look forward to seeing the website, bearing the same name, go live.

2. The Steering Committee met in late July to discuss 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. These efforts resulted in a guidance and principles document to help with orienting and coordinating the work groups.

3. Just before this update, the five work groups were commissioned with designated leads and managers to help with organizational activities. As a reminder, each of these work groups will focus on one of the following priorities:

   - Developing the single point of contact (SPOC) model to facilitate the communication of trial opportunities, processes, and requirements.
   - Establishing a standard set of basic information that VA can provide to industry regarding VA assets (e.g., patients, investigators, capabilities, etc.) and processes (e.g., approvals, requirements, etc.) in order to initiate partnerships.
   - Establishing a set of requirements that outlines the specific information that VA needs from industry to initiate conversations.
   - Creating and maintaining a process map related to study start up (from initiation of the relationship through site initiation) which includes and delineates centralized functions from those that are local responsibilities.
   - Developing the capability for the VA Central IRB to accommodate more industry-sponsored trials.

   In the upcoming weeks, we expect these work groups to have their first meetings to go over their scope and begin their efforts. It is anticipated that groups will have key deliverables completed in about 6 months (early 2019). We are extremely grateful to those of you who volunteered. Any questions regarding the work groups should be directed to Krissa Caroff (contact information provided below).

4. Within the Veterans Health Administration (VHA), there continues to be changes as part of modernization efforts. While details are still forthcoming, the Office of Research and Development will be part of a VHA division that includes the Office of Academic Affiliations and the VHA Innovation Ecosystem. This group will be headed by Dr. Carolyn Clancy (who Summit attendees may recall spoke at the April meeting), as the Deputy Under Secretary for Discovery, Education and Affiliate Networks.

5. Additional work continues "behind the scenes" on other topics such as central budgeting, engaging other individuals and offices within VA, and sharing information regarding the initiative with other stakeholders. Since the April Summit, we have added nearly 125 new contacts!

Thank you again for your continued interest and commitment to this effort. As a reminder, anyone interested in being added to our distribution list should contact Krissa Caroff, Program Coordinator, by email at clinicaltrials@navref.org. Any questions or comments can also be sent using the same email address.

Thank you.

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