ACT for Veterans Initiative

ACCESS TO CLINICAL TRIALS FOR VETERANS

NAVREF

Dear ACT for Veterans Stakeholders:

Thank you for your continued interest and commitment to ACT for Veterans. The "buzz" is most definitely spreading. Recently, we've seen an increase in outreach from various companies expressing interest in partnering with VA on a number of opportunities, including ones that are not specific to multisite clinical trials. While we appreciate this enthusiasm and help in communicating our efforts, we remain committed to the primary goal to increase Veterans' access to multisite industry sponsored clinical trials by creating a streamlined study start up process. Your continued patience will be appreciated, particularly given the progress described below.

Since the last update, we have continued to focus efforts on integrating prior work into a streamlined operational framework. This framework is designed to capture key players and responsibilities from the point of initial interest up to study initiation. As mentioned previously, the Single Point of Contact (SPOC) is an integral component of this framework and as such, a significant amount of time and energy have been devoted to defining its role and responsibilities; tools are being developed to assist the SPOC and to enable a "customer focus" in its dealings with partners. Over the next several weeks, we anticipate that a final draft of the framework will be complete, resources for the pilot will be identified, and pilot testing of the process will commence in October!

Speaking of pilot testing, the first test of using the central VA authority for signing Non-Disclosure Agreements (NDAs) was recently conducted. The goal of this newly approved process is to eliminate the need for each medical center to execute its own NDA for a multisite trial. The Steering Committee recently reviewed the results of this first test. Some targets for procedural changes were identified and we highlighted steps where VA is reliant on its partner's actions. We will continue to pilot this process to seek areas for improvement. As work progresses, we will provide a combined summary of key efforts, lessons and proposed benchmarks in future updates.

Significant activity is occurring with respect to policies and procedures related to human subjects research. Most noteworthy is a meeting in Washington DC (occurring as we write this update) of over 160 IRB administrators, Research and Development Committee (R&DC) coordinators, and other facility leaders representing over 90 VA medical centers. Goals of this meeting include: 1) training attendees on policy related to the single IRB mandate, 2) sharing tools that have been developed to assist staff- including a checklist that will be used in industry partnered clinical trials, and 3) identifying opportunities to improve R&DC related activities.

Once again, thank you for your support, and enjoy these final weeks of summer! Please contact Krissa Caroff, ACT Program Coordinator, at clinicaltrials@navref.org with any questions or comments. You may also subscribe to this newsletter by sending an email to that address.

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