Top 5 Priorities & Recommended Tasks

The following represent the 5 priorities identified by the Clinical Trials Steering Committee, along with some recommended next steps. Please note that these are the priorities that will receive the highest level of attention and resources, however the other items (listed after the top five) can and will proceed as best possible given time/resources. In addition to the recommended tasks, we have outlined some general tasks that will be applicable regardless of the priority. Please take the time to review these, and give some consideration as to how you, or others within your organization, may be able to contribute.

General tasks:

1) Identify/solicit potential work group members and leads for each priority area.
2) Develop standards for work processes related to progress reporting, communication (internally and with other groups), interactions with the Steering Committee, etc.
3) Discuss task framework with work groups to ensure that plans/activities address resource, policy, operational/procedural and stakeholder engagement requirements.
4) Establish milestones and timelines

Priority	Recommended Tasks Associated with Priority
1. Develop the single point of contact (SPOC) model to facilitate the communication of trial opportunities, processes, and requirements.	a. Survey current methods being utilized by VA and by industry to initiate partnerships (e.g., NAVREF, sponsor contacting investigator, Oncology ABCR model, reliance on past relationships, etc.) and: • Analyze strengths and weaknesses (including efficiencies or lack thereof) associated with those methods. • Estimate approximate contacts per defined period of time to estimate workload. b. Establish the roles and responsibilities of the SPOC related to the initial contact regarding new clinical trial opportunities including: • Communications – with industry partners, VAMCs/NPCs, VA Central Office • Project management / tracking – following requests to point of agreement • Stakeholder engagement for specific trials • Facilitate CDA process – negotiation and execution • Monitoring performance/timelines • Managing resource needs c. Establish roles and responsibilities for further engaging VA sites/investigators on clinical trials deemed of high interest to VA. d. Develop communication tools including:

	• General information about SPOC resource and procedures • Intake form for initial inquiries on interest for new trials • Communications mechanisms for VA/NPCs e. Develop project management tools for receiving, tracking and bringing initial requests to closure. f. Determine resources (e.g., space, staff, IT) needed by the SPOC to complete assigned responsibilities. • Determine how to obtain resources for meeting identified needs. g. Develop operational processes for fulfilling responsibilities. • E.g., develop operational/procedural guidelines, tools (such as intake forms) for how the SPOC will communicate with all stakeholders (external partners, VA investigators/facilities, affiliated non-profits, etc.).
2. Establish 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.	a. Collect/survey current examples of requirements that industry requests from non-VA sites/partners. • Delineate between "critical" and "preferred" information • Determine what are common items that can be promoted for all VA medical centers and/or for VHA overall. • Determine what, if any, VA offices/programs already have capabilities and or data that addresses needs. b. Refine/obtain input from industry regarding the types of additional unique information needed from VA regarding site, healthcare system, informatics, and other capabilities. • Delineate processes for obtaining site-specific vs. health care system/national information. c. Develop data collection tool(s) for assessing current assets from VA/NPC stakeholders. d. Develop solicitation for VA medical centers/NPCs for providing info for profile development. e. Create a database to catalog those assets and capabilities. • Establish mechanism for updating information (e.g., site accounts) f. Create documents, worksheets, materials that include this information and can easily be shared. g. Establish a website/repository for this information to be accessed and shared and determine who is responsible

	for maintaining this information and ensuring that it is up to date.
3. Establish a set of requirements that outlines the specific information that VA **needs from** industry to initiate conversations.	a. Work with individual VA medical centers, VA non-profits, therapeutic leads, etc., to identify the information needed for VA to determine initial interest. • Determine common elements that can be systematically requested from industry. • Evaluate requirements from requests involving non-VA settings (e.g., academic medical center, community clinics) • Obtain/Identify tools and procedures already being utilized by sites to collect this information. b. Establish the key criteria that would identify a trial as a high priority for VA (e.g., the value of the trial to Veterans/VA, ability to deliver/complete requirements, etc.). c. Identify key criteria that would suggest VA is not an ideal partner in participating in a trial (e.g., lack of feasibility, resource requirements, etc.). d. Establish an industry panel to a) understand the type of information that industry typically provides site partners, b) share what has been proposed as needs with industry to solicit feedback and assess the feasibility of gathering such information. e. Develop templates and/or forms needed to obtain such information. f. Evaluate the feasibility and utility of establishing a repository for key industry information to be accessed and shared. • Determine what that information would be, who would be responsible for maintaining and updating it and where it would be stored.
4. Create and maintain 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.	a. Organize a diverse group of stakeholders with expertise in various procedural aspects of the workflow to: • Map the current process(es) • Conduct workflow analyses of the current state to identify best practices and inefficiencies, and opportunities to eliminate redundancy. • Propose the future state • Test and fine tune the future state proposal to create a living version of process map.

	b. Obtain any program office/leadership support and/or changes in policies to enable processes to occur. c. Develop training and education materials that can be shared with stakeholders relative to steps in the process map.
5. Develop the capability for the VA Central IRB to accommodate more industry-sponsored trials.	a. Identify current VA Central IRB review timelines for: • Administrative Review • Lead Site Application Approval • Local Site Application Approvals b. With industry input, determine recommended timelines/performance expectations for VA Central IRB c. Analyze current CIRB process flow to identify inefficiencies, bottlenecks, and opportunities to improve timelines and/or performance. d. Establish communication channels with Office of Research Oversight and their review activities for sites to ensure compliance standards are consistent. e. Determine which performance goals are "required" and what are "recommended". Compare goals to what occurs with non-VA sites. f. Determine resources (time, money, staff, industry specific 2nd panel, training, information systems, etc.) needed to allow VA Central IRB to achieve those acceptable timelines/performance expectations. g. Secure needed resources for achieving performance goals. h. Assess the cost/fee structure of VA Central IRB and make those fees publicly available. i. Assess procedures for submission/receipt of VA Central IRB protocols. j. Determine what requirements for VA Central IRB use are specific to VA and what can be adopted from other models. k. Develop training/education materials that can be shared with stakeholders relative to VA Central IRB review procedures, timelines, and costs.

The other key tasks for this initiative identified at the Stakeholder Summit and rated by Summit participants are listed below. When possible, we will seek to optimize efforts from the top five priorities to facilitate actions that will help address these tasks.

6. Determine current barriers to a VA Medical Center's ability to consider participation in a trial (e.g., costs/fees for initial review, investigator time, etc.). Sub-steps may include:

   - Working with VA affiliated non-profits to understand operational and fiscal requirements.
   - Working with VA research offices (e.g., Associate Chiefs of Staff for Research) to understand local requirements / procedures.
   - Identifying methods for protecting investigator time for industry-sponsored trials.
   - Working with VA clinical leadership to determine challenges and identify solutions to balancing clinical versus research responsibilities.

7. Develop budget models that may be utilized for VA multi-site studies. Sub-steps may include:

   - Developing a standard set of basic costs for conducting a trial within a VAMC.
   - Developing a rate card for common research related tests and procedures.

8. Establish a standard process for obtaining Information Security review and approval. As part of this effort, the feasibility of establishing VA approved data portals and/or vendors for use in clinical trials will also be explored.

9. Develop a lead site model for all Administrative, Budget, Contracting, and Regulatory (ABCR) functions (assuming the VA Central IRB is the IRB of record). This will also include the development of workflow and communication processes for the lead site.

10. Determine the key performance indicators related to initial start-up processes (e.g., reviews, approvals, completion of deliverables) including:

    - Understanding industry norms relative to such processes as feasibility, IRB review, CDA execution, budget and CRADA negotiation.
    - Obtaining existing targets/metrics relative to such processes as legal review, IRB review, etc.
    - Establishing shared expectations for key performance indicators.
    - Determining who will be responsible for collecting KPI data.
    - Anticipating KPIs for later stages.

11. Develop procedural guidance for sites participating in industry sponsored multisite trials to facilitate efficient local site approvals including, but not limited to, CRADA, budget, and IRB. This will include identifying processes that can be done in parallel as well as those that must be done sequentially.

12. Develop training materials for stakeholders at local and central levels regarding key procedures and requirements for successful completion. Sub-steps may include:

- Identifying an entity/office responsible for implementing the plan,
- Establishing priorities for the various areas requiring education (e.g., human subjects protection/VA Central IRB, agreements including CRAs and CRADAs, budgeting)

13. Work towards streamlined processes for completing agreements. Sub-steps may include
    - Assessing template agreements and developing instructions/training for completing them.
    - Identifying appropriate single signatory authorities for Confidential Disclosure Agreements.
    - Standardizing procedures and/or delegations of authority for Cooperative Research and Development Agreements