*Category: Clinical Trial Operations (Trial Start-up, Regulatory, Data Management, IITs) – Work in Progress*

**Enhanced Activation of Multicenter Investigator- Initiated Trials with Dedicated Multicenter Activation Team**

C. Friedman, J. Walkley, M. Warren, K. Muenkel, J. Migliacci, M. Kehoe, A. Mayer, P. Nolan, C. Houston

*Memorial Sloan Kettering Cancer Center*

**1. Background**

Memorial Sloan Kettering (MSK) Multicenter (MCT) Office is a centralized team dedicated to multicenter investigator-initiated trials (IIT) where MSK is the sponsor and/or data coordinating center. MCT is comprised of three specialized teams, Activation, Compliance, and Protocol Operations, which each serve a role in providing oversight. Typically, IITs come with funding restraints and use of the MCT Office is more cost-effective than an external contract research organization (CRO).

All MSK protocols are activated by the MSK Protocol Activation Core (PAC), regardless of sponsor and protocol type.

To open a multicenter IIT at MSK, a prime contract with the funder(s) is executed, institutional review board (IRB) approval must be granted, and Food and Drug Administration (FDA) Study May Proceed letter is received, before the participating site activation may begin. Historically, and in some cases currently, MSK will open an IIT as a single center study and then amend to become multicenter.

When the protocol is a therapeutic multicenter investigator-initiated trial, involvement of MCT Activation early and throughout the MSK activation process ensures greater success when working with participating sites.

**2. Goals**

Goals for MCT Activation involvement during MSK activation:

- Ensure feasibility of protocols as multicenter studies
- Ensure MCT Activation involvement does not adversely affect time to activation for MSK
- Provide MCT feedback during MSK activation to ensure participating site activation initiates once MSK is OTA
- Collaborate seamlessly with PAC

**3. Solutions and Methods**

MCT works with a Clinical Research Budget Manger aligned to multicenter IIT budgets. When asked to work on budget drafts pre-PAC submission, MCT Activation is included and provides input early on.

MCT Activation collaborates with MSK's Legal team to ensure contract terms in prime agreement(s) with funders would be acceptable to participating sites in sub-contracts and align with multicenter operational and regulatory requirements.

MCT Activation staff members are assigned to studies during MSK activation to ensure expertise in the protocol. During MSK activation, these staff complete multicenter feasibility reviews in parallel to institutional committee reviews.

Complexity, disease area, and trial type are considered for staff assignments. Expertise and specialization in international collaborations and relying site management guide staff involvement.

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**4. Outcomes**

MCT Activation involvement earlier in the process does not impact ability to activate at MSK and aims to reduce protocol and contract amendments required to initiate external site activation.

This minimizes the participating sites' need to submit protocol amendments to their local IRBs during their own activation process. In addition, contract amendments are reduced by incorporating known site requirements during MSK negotiation of prime agreement(s).

**5. Lessons Learned and Future Directions**

MCT should be looped in as early in the process as possible when the PI is drafting initial concept and submitting to funders. Establishing strong working relationships with PIs and funding entities, ensures multicenter considerations are discussed early on, setting all teams up for success.

Integrations of MCT in the PAC processes and collaboration with various MSK teams involved in the activation process improves outcomes for MSK as well as participating sites.

Moving forward, international collaborations are a high priority. Involving research teams and PIs at international sites early in development ensures country specific requirements and solutions are identified and addressed.

**Figure**