Category: Regulatory – Work In Progress

MSKCC INDs Multicenter IITs: A Centralized Model in Regulatory Oversight

H. Pham, W. Blouin, S. Yoon, J. Walkley, R. Ellis, M. Warren

Memorial Sloan Kettering Cancer Center

1. Background

Multicenter clinical trials require extensive management and oversight. The use of Investigational New Drug (INDs) in trials require additional reporting and regulatory requirements set forth by the Food and Drug Administration (FDA). Historically, expansive IND multicenter clinical trials were industry-sponsored, and the only feasible option for many investigators to participate in. However, these industry-sponsored trials, focused on commercialized drug development, largely overlooked research questions focused on clinician-based interests and needs. In addition, participation in industry-sponsored trials are costly for sites, which includes adequate clinical research staffing, training, monitoring and data management needs. As a result, investigator-sponsored IITs have become an attractive option for clinicians.

Here, we discuss how MSKCC's Clinical Research Administration has implemented a structured centralized model in the management of MSKCC INDs multicenter IITs and the challenges faced on an increasingly robust and expanding research portfolio.

2. Goals

MSKCC has two dedicated offices in the management of MSKCC INDs multicenter IITs: the IND Office and Multicenter Compliance. Together, the offices' goal is to provide centralized regulatory oversight and quality management of MSKCC INDs multicenter IITs through several measures:

- Streamline FDA communication amongst MSKCC, investigators and participating sites through a centralized IND office
- Reduce reporting lag and maintain consistency in regulatory reporting, including amendment posting and adverse reporting events
- Increase trial activations at participating sites, including community health centers through the MSK Clinical Research Strategic Partnership Program

3. Solutions and Methods

As lead coordinating site and the sponsor of the IND, MSKCC reduces the burden of regulatory oversight on participating sites, allowing them to focus on other components of trial management, including patient accrual and protocol operations.

- We have performed gap assessments and identified areas of improvement within the quality and compliance programs for both the IND Office and Multicenter compliance office
- We have developed a risk-based monitoring quality system to provide proactive multicenter support in: research staff training, Corrective and Preventive Actions (CAPA), audits and inspection preparedness

- Introduction of new technological enhancements in MSK's protocol information system for real-time reporting, such as electronic submission of documents rather than e-mail attachments, as well as automatically generated notifications to study teams on protocol status updates

4. Outcomes

Since implementing the strategies, we have preliminary data to demonstrate the following trends:

- Increased volume of MSKCC INDs multicenter IITs activations
- Increased number of participating sites, including MSK Clinical Research Strategic Partnership Program
- Expected decrease time in regulatory reporting processing, such as adverse event reporting and annual reports to the FDA

5. Lessons Learned

- Apply our knowledge and experience to recognize areas of growth, adjust and recommend changes to infrastructure model structure
- As our multicenter partnerships continue to expand internationally, streamlining adherence to the EU's General Data Protection Regulation (GDPR) enacted in May 2018.
- Continue to enhance our information technology systems, including automated data collection for study accrual breakdown in annual reports
- Capture important clinical, regulatory or scientific milestones that aid in the transition of products to our industry partners