

## **Enhancing Collaboration, Streamlining Submissions, and Achieving Regulatory Excellence for MSK Sponsored INDs**

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### **1. Background**

The Investigational New Drug/Device (IND) centralized office plays a pivotal role in supporting our researchers in developing regulatory strategies that help to advance cancer therapies through pre-IND and post approval-IND stages. Through collaborative engagements with regulatory bodies, research teams, and additional stakeholders, our office ensures a comprehensive and patient-centric approach, navigating the complexities of cancer therapeutic development with a commitment to regulatory excellence. The evolving regulatory landscape demands a nuanced understanding of regulatory compliance, strategic planning, regulatory submission requirements, and the intricacies of product development specific to cancer research while balancing technological advancements to support positive clinical outcomes.

### **2. Goals**

- a. Enhance regulatory strategy development
- b. Proactive and adaptive regulatory submission approach
- c. Efficient communication and collaboration between regulatory bodies, external collaborators, and interdepartmental teams
- d. Stakeholders engagement
- e. Streamlining post-IND approval activities and managing the IND lifecycle

### **3. Solutions and Methods**

- From interpreting regulatory requirements to staying abreast of the latest guidelines, our office crafts regulatory strategies that align with both business objectives and compliance standards.
- Our office plays a pivotal role in modernizing and optimizing the regulatory submission process. It aligns with global standards, enhances efficiency, promotes collaboration, and ensures compliance with regulatory requirements, expediting the delivery of safe and effective investigational products to our patients.
- The centralized IND office model helps collaborate and communicate effectively with internal and external stakeholders, which helps drive pre-IND regulatory strategies and manage the post-IND approval activities.
- Effectively manage IND/IDE portfolios by proactively communicating regulatory requirements to all stakeholders, ensuring comprehensive institutional compliance.
- Our office coordinates and prioritizes all compassionate use requests, addressing patient treatment needs while ensuring compliance with regulatory requirements.

### **4. Outcomes**

- Effective pre/post IND approval collaboration and communications contributed to our regulatory success, risk management, strategic planning, resource optimization, stakeholder alignment, and ultimately the delivery of safe and effective investigational products to our patients.
- Transitioning to Electronic Common Technical Document (eCTD) submission platforms helped us in achieving higher degree of regulatory compliance. It also helped with enhanced document

management, faster submission processing, data accuracy, version control, faster Food and Drug Administration acceptance and tracking.

- Post-IND approval activities play a pivotal role in advancing clinical development, ensuring regulatory compliance, monitoring safety, collecting data for subsequent submissions, and supporting potential commercialization activities. These activities contribute to the overall success of the drug development program and the eventual availability of novel treatments for patients.
- A centralized regulatory model of communication provides a structured and organized approach that supports overall effectiveness and success of the organization.

#### **5. Lessons Learned and Future Directions**

- Keeping the relevant stakeholders informed about regulatory requirements through training programs and disseminating regulatory updates.
- Evaluate and enhance regulatory strategies to adapt to changing institution needs and evolving regulatory landscapes. Provide regulatory guidance and advice to cross-functional teams internally and externally.
- Fully convert all our submissions to eCTD format to simplify the submission process and enhance regulatory efficiency. Improving document tracking, enhancing the quality of submissions, and reducing regulatory submission timelines will ensure timely fulfillment of patient treatment needs.