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

Richard Ellis, Alan Ho, Shengquan Duan, Stephen Carlin, Ashish Dhir, Alan Burke, Hanh Pham, Anil Yadav, Sylvia Grigsby, Lamont Meeks, Chamandeep Kaur

Memorial Sloan-Kettering Cancer Center

INTRODUCTION

The Investigational New Drug/Device centralized office (INDO) is vital in supporting researchers from pre-IND to post-approval stages. Through collaborations with regulatory bodies, research teams, and additional stakeholders, INDO ensures a comprehensive and patient-centric approach, navigating the complexities of cancer therapeutic development with a commitment to deliver advanced world-class cancer treatments to our patients. The evolving regulatory landscape demands a nuanced understanding of regulatory compliance and strategic planning, as well as having a flexible approach for the intricacies in cancer research product development while balancing technological advancements to support positive clinical outcomes.

OBJECTIVES

Our centralized office model aims to enhance our work through:

- Regulatory Strategy Development from the pre-IND (pre-clinical) to post IND approval
- Proactively monitoring regulatory landscape changes, adapting new regulatory submission approaches appropriately
- Continuous engagement through efficient communication and collaboration between stakeholders
- Streamlining post-IND approval activities and managing the IND lifecycle

PRE-IND TO POST-IND LIFECYCLE MANAGEMENT

The INDO and Product Development team work closely together on our MSK-manufactured, Phase I clinical trials.

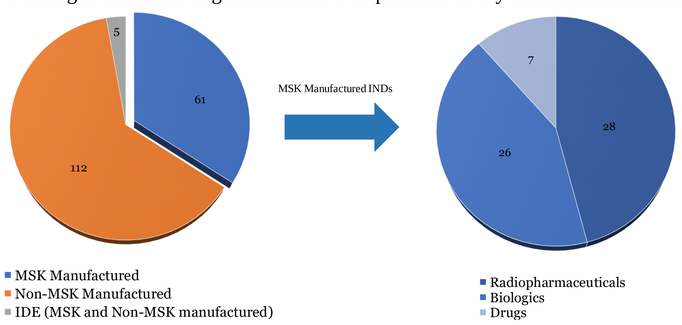
Preclinical Development
- Provide scientific expertise and product development strategies to key stakeholders, from ideation to Phase I clinical trials
- Facilitate the transition of novel therapies to the clinic by providing guidance on CMC and Pharmacology & Toxicology

IND Preparation in Collaboration with various stakeholders
- Provide Technical Writing Services for Pre-IND meeting requests, briefing packages and IND/IDE applications

Pre & Post FDA Approval
- Respond to agency questions
- Track manufacturing changes throughout IND lifecycle
- Report changes via Information amendments and Annual Reports

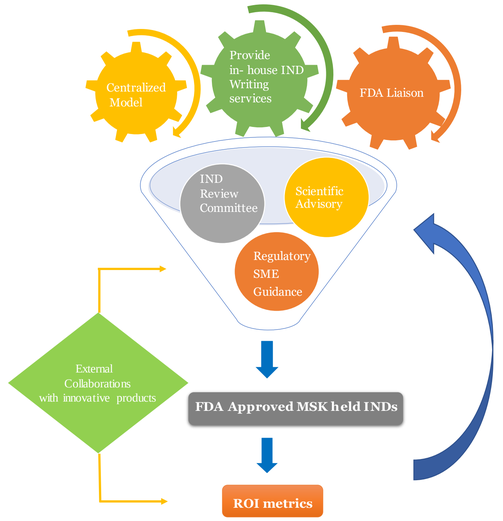
PORTFOLIO MANAGEMENT

INDO manages one of the largest Research IND portfolio of any academic institution.



COLLABORATION AND COMMUNICATION

- Effective pre/post IND approval collaboration and communication promotes collaboration, mitigate risks, align stakeholders, and ensure safe product delivery.
- The centralized IND office model helps to drive clinical development by ensuring regulatory compliance, monitoring safety, collecting data, while supporting commercialization activities.

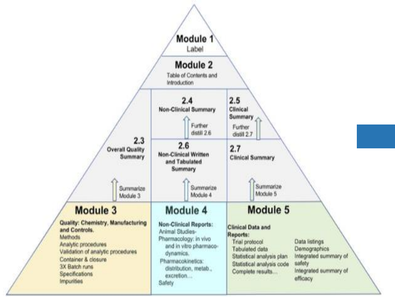


STREAMLINING PORTFOLIO'S TRANSITION TO eCTD

- To align with industry best practices and to remain a leader in academic IND portfolio management, we began transitioning our IND portfolio to eCTD submissions in June 2022.
- Implemented new suite of eCTD applications: GlobalSubmit, Document loading, Document review, Submission validation and FDA ESG – Electronic Submission Gateway.
- Developed eCTD implementation workflows including: Document Management, eCTD submission tracking, QC/QA approval processes, and SOP creation.
- Collaborated with Product Development to map eCTD structure to existing IND applications, insure all MSK manufactured IND applications meets all eCTD requirements.

eCTD SUBMISSION STATISTICS

- Since June 2022, completed and processed over 1000 eCTD submissions to the FDA.
- Compared to paper submissions, we achieved a 30% increase in processing efficiency after transitioning to eCTD format.
- Minimal rejections and technical queries related to FDA submissions.



FUTURE GOALS

- Adhering to regulatory compliance involves keeping relevant stakeholders informed about regulatory requirements through training programs and reviewing and disseminating regulatory updates, while simultaneously evaluating and enhancing regulatory strategies to adapt to changing institutional needs and evolving regulatory landscapes and providing regulatory guidance and advice to cross-functional teams both 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.

CONCLUSION

- 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 FDA 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 regulatory compliance and strategic mission of the organization.