**INTRODUCTION**

When it comes to regulatory and product development, innovation is the holy grail. The magic happens when barriers are eliminated, while maintaining institutional compliance and driving change within clinical research. The Regulatory Oversight and Product Development unit at MSK has developed a sustainable, centralized model to provide expert guidance to investigators, clinical research staff, and external collaborators throughout the Investigational New Drug (IND) lifecycle that enables us to also drive innovation within the space.

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**CENTRALIZED REGULATORY MODEL**

- **Investigational Drugs**
- **Us**
- **Drug to maintaining and strategic plays staff**
- **Time from INDC Approval to FDA Approval**
- **Devices**
- **Time from INDC Submission to FDA Approval**
- **How strategic for Drug we our unit investigational (Committee)**
- **will be able**
- **This decision**
- **within**
- **implementing regulatory**
- **of INDO application submission**
- **Drug partners’**
- **Development**
- **relationships**
- **core**
- **The requirements and process**
- **an**
- **consultancy**
- **drive**
- **institutional**
- **applying**
- **supporting**
- **lifecycle**
- **rate**
- **number**
- **regulatory**
- **Regulatory**
- **the agency**
- **several**
- **leverage**
- **factors**
- **MSK**
- **Protocol Team**
- **formal**
- **liaise**
- **industry**
- **compliance**
- **are**
- **have**
- **on**
- **in**
- **MSK**
- **Oversight**
- **and**
- **FDA**
- **and**
- **for**
- **is**
- **We**
- **Drug**
- **Clinical Research**
- **Partners**
- **Licensing**
- **Clinical Research Administration**
- **Investigational New Drug Committee (INDC)**
- **Protocol Activation Core (PAC)**
- **Licensing Managers and external industry/biotechnology partners**.

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**REGULATORY METRICS AND SUCCESSES**

- **We have established processes for regulatory and product development strategies for MSK-manufactured products.**
- **A formal structure has been developed for requesting specialty designations such as breakthrough therapy, that helps to expedite the drug development process.**
- **INDO has been able to decrease the time from FDA submission to activation by half, while an increased number of IND/IDE applications are being submitted to FDA, resulting in patients having access to investigational products in record time.**
- **MSK has a 96% success rate in applying for breakthrough therapy designations compared to industry 32% (for drug applications) and 39% (for biologics) based on current FDA data.**

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**IND/OE LIFECYCLE MANAGEMENT**

The Investigational New Drug Office (INDO) is responsible for ensuring that investigators and clinical research staff adhere to institutional standards and federal regulatory requirements regarding investigational drugs, devices and biologics. The Product Development Team implements in-house writing services and consultancy to investigators, core facilities and biotechnology partners.

- **Create and implement pre-clinical product development project plans**
- **Provide expert guidance in Chemistry, Manufacturing and Controls (CMC), Pharmacology/Toxicology and Regulatory Strategy**
- **Author technical documents (CMC and pharm/hox sections of IND)**
- **Manage the submission process which includes, editing, assembling, publishing, quality and document tracking**
- **Final document review**
- **IND application submission**
- **Provide timely responses to FDA in addressing regulatory, clinical or product related queries**
- **Lead all meetings and discussions with the FDA on behalf of MSK**
- **Communicate all.gov to issues to investigators and center leadership**
- **Ensure that regulatory requirements set by the FDA are managed and followed by the institution**
- **Overview the review and/or management of regulatory reporting activities, including but not limited to: doxers, annual reports, drug safety updates, post-approval manufacturing changes and stability updates**
- **Maintain all regulatory documentation for MSK sponsored trials**
- **Manage and controls regulatory and product development SOPs (Standard Operating Procedures)**
- **Review and submit final study reports to the FDA**
- **Work cross functionally with internal colleagues to facilitate the transition of MSK manufactured products to industry**
- **Responsibilities for initiating the IND transfer process**
- **Wilderness/Terminate IND with FDA**

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**FUTURE GOALS**

- **Acquire eCTD publishing software**
- **Optimize Digital Solutions**
- **Create FDA Dashboard**

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**CONCLUSION**

- **The Regulatory Oversight and Product Development unit at MSK plays an integral role in developing innovation that occurs within the regulatory space.**
- **As one of the first academic institutions to have a centralized IND office, we continue to leverage our relationship with the FDA and utilize several strategic tools to enhance our decision-making processes involving MSK-sponsored IND trials.**
- **We focus on several factors that support a positive return on innovation in a field that is rapidly changing and growing increasingly complex.**

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**Driving Innovation Through Regulatory and Product Development Magic**

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