Driving Innovation Through Regulatory and Product Development Magic

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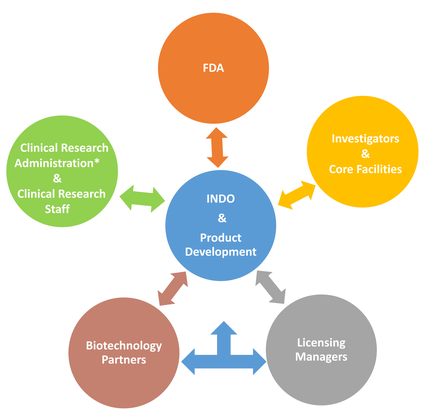
INTRODUCTION

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.

CENTRALIZED REGULATORY MODEL

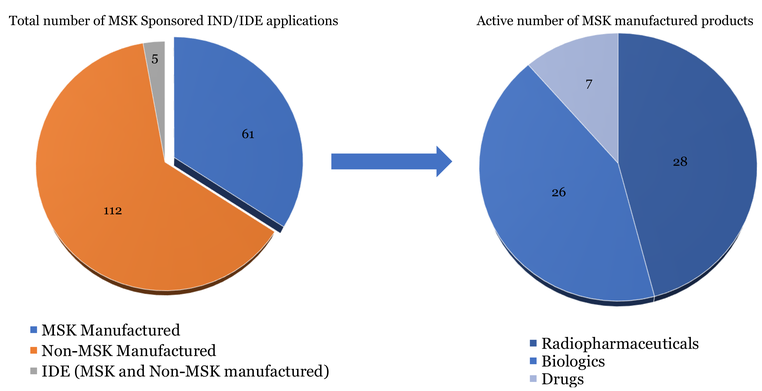


*Clinical Research Administration also includes HRPP, PAC and INDC

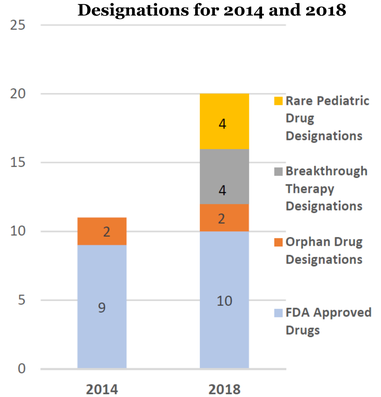
- This centralized communication model helps us to effectively liaise with our Human Research Protection Program (HRPP), Investigators, Clinical Research Staff, Core Facilities, Investigational New Drug Committee (INDC), Protocol Activation Core (PAC), Licensing Managers and external industry/biotechnology partners.
- The Regulatory Oversight and Product Development unit has streamlined communication with the Food and Drug Administration (FDA) where the Investigational New Drug Office (INDO) acts as MSK's primary liaison to the agency in answering questions and queries relating to MSK sponsored IND trials, decreasing the lag time in completing scientific and regulatory reviews.

PORTFOLIO MANAGEMENT

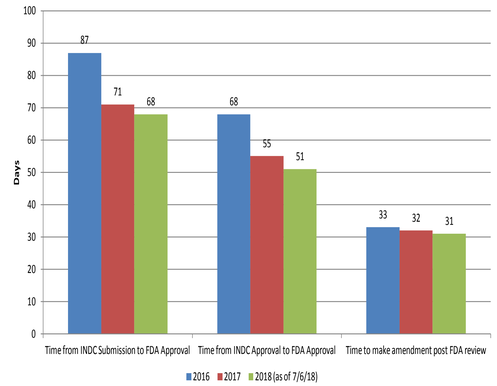
INDO manages one of the largest IND portfolio of any academic institution.



Cumulative FDA Approvals and Specialty Designations for 2014 and 2018



IND Time to Activation



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 66% success rate in applying for breakthrough therapy designations compared to industry 32% (for drug applications) and 34% (for biologics) based on current FDA data.

IND/IDE 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.

Pre-Clinical Development (Day 1)
- 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/tox sections of IND)

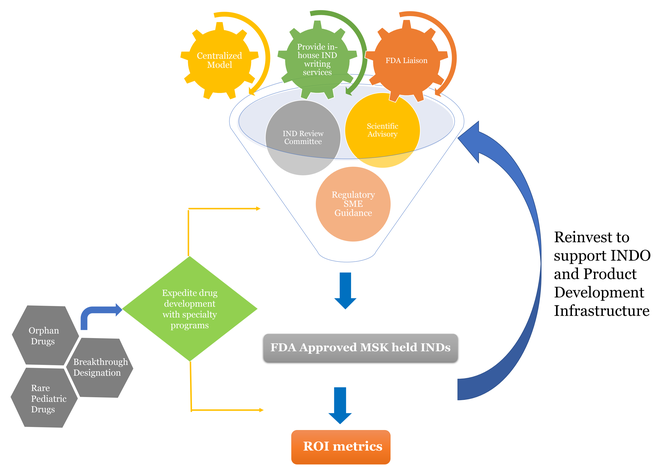
Initial Submission (Day 0)
- Manage the submission process which includes, editing, assembling, publishing, quality and document tracking
- Final document review
- IND application submission

FDA Review (Day 30)
- 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 go/no go issues to investigators and center leadership

IND Portfolio Maintenance
- Ensure that regulatory requirements set by the FDA are managed and followed by the institution
- Oversee the review and/or management of regulatory reporting activities, including but not limited to: dossiers, 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)

IND/IDE termination
- 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
- Responsible for initiating the IND transfer process
- Withdraw/Terminate IND with FDA

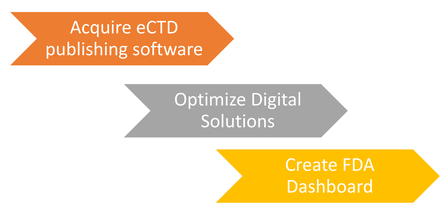
STRATEGIC TOOLS THAT SUPPORT RETURN ON INNOVATION



The return on innovation (ROI) is unique to the core of how the unit functions.

- We utilize several strategic tools that support a return on innovation.
- We continue to reinvest by supporting the infrastructure of the unit by optimizing the processes that drive the regulatory and product development space.
- Additionally, we are utilizing FDA fast track and accelerated programs, which were exclusively being used by industry to leverage our relationships with our biotechnology collaborators.

FUTURE GOALS



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.