

Driving Innovation Through Regulatory and Product Development Magic

R. Ellis, S. Oliver, L. Shrestha, A. Yadav, O. Hauke;

Memorial Sloan Kettering Cancer Center

1. Background

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 (ROPD) unit 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.

2. Goals

- Centralize communication within the regulatory and product development space
- Utilize regulatory and product development strategic tools to enhance decision making processes
- Develop a formal structure to utilize FDA fast track and accelerated programs

3. Solutions and Methods

Our recipe of innovation and success focused on four key areas to drive a culture of institutional innovation:

- (a) centralized IND office
- (b) streamlined FDA communication
- (c) established process for regulatory and product development strategies
- (d) culture of diversity and inclusion.

4. Outcomes and Future Directions

- We have established processes for regulatory and product development strategies for MSK-manufactured products.
- We have developed a formal structure 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 increasing the number of IND/IDE applications submitted to FDA, resulting in patients having access to investigational products in record time.
- MSK has achieved 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.

Category: Regulatory – Completed Project

- 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.
- We are utilizing FDA fast track and accelerated programs, which were exclusively being used by industry to leverage our relationships with our biotechnology collaborators.