Category: Regulatory – Work In Progress

The Regulatory and Product Development Road to the Future of Cancer Care

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1. Background

The world around cancer research and treatment is evolving rapidly. While unmet medical need will continue to drive future cancer research and development, the core values of any cancer treatment will remain the same – Safety, Efficacy, and ultimately Cure. Advances in cancer research to terminal disease prevalence are causing a shift in paradigm, for both regulatory and product development teams within the organizations. At MSKCC, the Investigational New Drug & Device office (INDO) and Product Development (PD) Units review regulatory trends, advancing science and technology to develop the study drug candidates from the bench to first-in-human trials

2. Goals

- **Regulatory balance** – It is important to understand the regulatory standards and guidelines at an early stage of drug development for any cancer therapy. Regulatory surveillance will ensure balancing change in regulatory trends with advancing technological and scientific breakthroughs.
- **Product Development (PD)** – The product development team at MSKCC translates the investigator's therapeutic discovery to required clinical, non-clinical, and critical quality attributes of the medical product that will be used in our IND applications.
- **Communication** – The INDO and PD team is involved with the investigators at early stages of the preclinical drug development process to explain the regulatory requirements that will drive innovative therapy in the right direction to obtain regulatory approvals and to meet crucial milestones.
- **Time** - Time is a critical factor while developing cancer therapies to ensure that treatment is accessible to patients as early as possible in a clinical trial.

3. Solutions and Methods

- **IND oversight and strategy** – The INDO's comprehensive regulatory strategy helps to eliminate all the potential hurdles that could impact the successful IND application from submission to approval stage.
- **Product development collaboration** - The PD team's collaboration with our core facilities, investigators, and regulatory team helps to achieve all the preclinical requirements for MSK's IND/IDE studies including the preparation of IND applications/technical documents for regulatory submissions.
- **Internal review committees** – The Investigational New Drug and Device committee reviews and addresses both the clinical and regulatory component of the new IND application that is submitted to the FDA.
- **Expedited drug development programs** – MSKCC continues to effectively utilize FDA's expedited drug development programs such as breakthrough therapy drug designation, orphan

drug designation, and rare pediatric disease designation to expedite development of therapies for unmet medical needs.

- **Developing internal SOP's and regulatory resources for investigators.**
- **External collaborations with biotechnology partners.**

4. Outcomes

- **Improved regulatory compliance and decision-making process** - We continue to learn from FDA's feedback during IND review process and have successfully managed to improve our IND submission for both clinical and regulatory components of IND applications.
- **Enhanced pace of product development** – Effective regulatory strategy and cross-functional collaborations have helped us to reduce the time-lag between "aha" moment of an idea for a therapy to development of the medical product in a clinical trial.
- **Return on Innovation (ROI)** - MSKCC continues to deliver ROI and utilize it to support the INDO and PD unit.

5. Lessons Learned

- **Supporting innovation.**
- **Enhancing the current protocol management systems to streamline regulatory operations.**
- **Digital solutions to internal tracking systems.**