INTRODUCTION

Multicenter clinical trials require extensive management and oversight. In addition, the use of Investigational New Drug (INDs) in trials require additional reporting and regulatory requirements set forth by the Food and Drug Administration (FDA). Historically, expansive IND multicenter clinical trials were industry-sponsored, and the only feasible option for many investigators to participate in. However, these industry-sponsored trials, focused on commercialized drug development, largely overlooked research questions focused on clinician-based interests and needs. In addition, participation in industry-sponsored trials are costly for sites, additional considerations have to be made for adequate clinical research staffing, training, monitoring and data management. As a result, investigator-initiated multicenter trials have become an alternative attractive for clinicians.

MSKCC’s Clinical Research Administration has implemented a structured model in the management of MSKCC Multicenter IND IITs, which has led to a continuous and successful growth of our research portfolio.

CENTRALIZED REGULATORY MODEL

- Ensuring adherence to institutional standards and federal regulatory requirements set forth by the FDA, NIH, and OHRP
- Liaison for all FDA communications
- Providing expert guidance to MSK investigators on FDA trends and regulatory strategy

MSK is the sponsor of 55 active INDs that involve several participating sites. These INDs include both drugs and biologics and devices. The majority of these INDs are for lymphoma indications.

MSKCC reduces the burden of regulatory oversight on participating sites, allowing them to focus on study development, activation, finance, and streamlined centralized clinical trial execution.

SOLUTIONS & METHODS IMPLEMENTED

In 2018, MSKCC restructured specialized units to focus on specific components of the clinical trial life cycle, including study development, activation, finance, and streamlined centralized clinical trial management. These enhancements have resulted in an increase in partnering site collaborations, successful trial activations and a decrease in time to study activation.

CONCLUSIONS AND FUTURE DIRECTIONS

As we continue to expand our robust portfolio, we aim to implement the following goals:

- Apply our knowledge and experience to recognize areas of growth, including protocol volume and staffing needs. We will continue to reevaluate these areas, and recommend changes to infrastructure model structure as appropriate
- As our multicenter partnerships continue to expand internationally, we will continue to evaluate adherence to the EU’s General Data Protection Regulation (GDPR) in May 2018
- Continue to enhance our information technology systems, including automated data collection for study accrual breakdown in annual reports
- Capture important clinical, regulatory or scientific milestones that aid in the transition of products to our industry partners

Since 2015, there has been a generally steady increase in multicenter MSKCC IND IITs open to accrual activations, as well as an increased unique collaborating institutions. These numbers are inclusive of trials that are approved in 2019.

YEAR AVERAGE DAYS
2016 100
2017 98
2018 81
2019 45

*Data does not include 2019 trials that were FDA approved in 2020