Multicenter IND IITs – A Centralized Model in Regulatory Oversight

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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 attractive alternative 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

IND Office (INDO)

Responsible for all investigational Drugs, devices and biologics, including INDs that are MSKCC manufactured

- 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

Multicenter Trials (MCT) Office

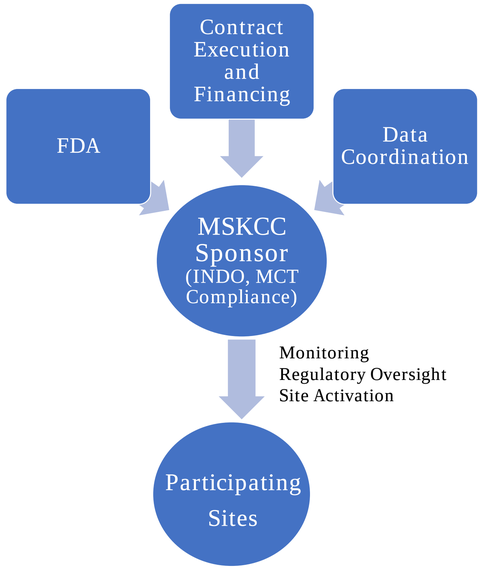
Oversees multicenter protocols on which MSK is the sponsor and data coordinating center

- Managing external site review and IRB approval, including budget and contract execution
- Monitoring, auditing and overseeing external site compliance
- Streamlining communications between MSK and participating institutions

Clinical Research Strategic Partnerships (CRSP)

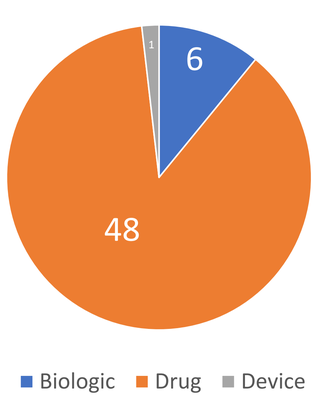
Expands MSKCC's participating sites to community healthcare providers

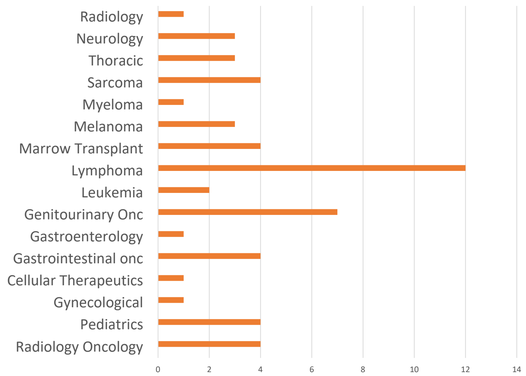
- Fostering the rapid adoption of the newest standards in the community setting
- Improving the quality of care and outcomes for cancer patients in an accelerated and cost- effective model that does not require building new facilities
- Expanding access to MSKCC's clinical trials, cutting- edge cancer research, and conduct multicenter trials amongst CRSP members



ACTIVE IND PORTFOLIO

MSKCC 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.





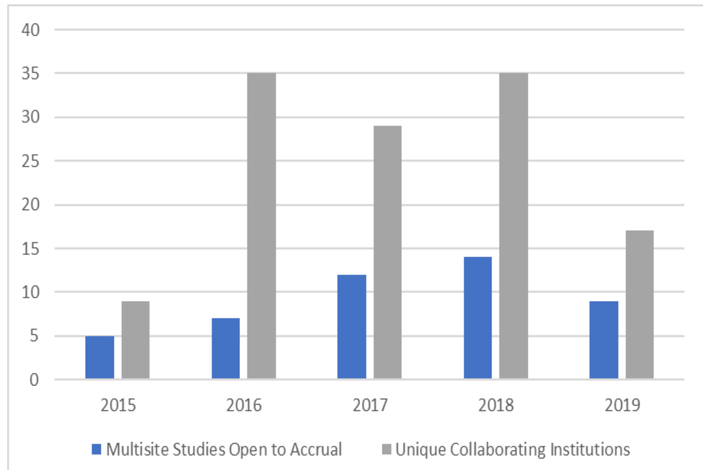
SOLUTIONS & METHODS IMPLEMENTED

MSKCC reduces the burden of regulatory oversight on participating sites, allowing them to focus on other components of trial management, including patient accrual and trial activation and operations. We have performed gap assessments and identified areas of improvement within the quality and compliance programs in Clinical Research Administration to continue to expand and successfully grow our research portfolio.

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.

MULTICENTER TRIAL ACTIVATIONS

Since 2015, there has been a generally steadily 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 opened at Strategic Partnership sites.



IRB APPROVAL TO FDA APPROVAL

The introduction of a streamline clinical trial activation approach in 2018 reduced the time between initial MSKCC IRB approval to FDA IND approval in multicenter trials .

Year	Average days
2016	100
2017	98
2018	81
2019*	45

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

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, streamlining 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