Category: Trial Start-up and Activation – Completed Project

One Committee to Review Them All: A Single, Multidisciplinary COVID-19 Research Committee

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1. Background

On January 20, 2020, when the first case of a novel coronavirus (COVID-19) was confirmed in Washington, its major impact was unknown. Memorial Sloan Kettering's (MSK) Hospital Incident Command System (HICS) was activated on February 5, with our first COVID-19 case identified in early March. By March 17, our Protocol Activation and Human Research Protection Program was fully remote and on March 23, MSK leadership requested the creation of the COVID-19 Research Committee.

2. Goals

Given the race to identify safe and effective treatments for COVID-19, modifications to MSK's workflows and review processes were needed. The goal was to create a COVID-19 Committee as a "one-stop" committee, providing comprehensive review of clinical research related to COVID-19, including scientific review mandated by the Cancer Center Support Grant (CCSG) guidelines, prior to review by the institutional review board. This committee would be charged includes prioritizing the research portfolio to prevent overlap of efforts.

3. Solutions and Methods

Figure 1 illustrates the quick timeline of events leading up to and after the creation of the COVID-19 committee. Our Protocol Information Management System (PIMS) was leveraged to efficiently manage and track COVID-19 research. The COVID-19 committee was created within seven days, as opposed to the several months it typically takes for such enhancements. The charge of the new committee was to prioritize and expedite all clinical research related to COVID-19 in support of the institutional effort to rapidly activate therapeutic and other COVID-19 related research. These changes were implemented by the Protocol Review Core (PRC). Members included faculty from multiple disciplines, disease management groups and departments. From March to June, the committee held 18 meetings, sometimes twice a week, and continued to review protocols through September outside of meetings: in total, reviewing 22 prospective, 42 retrospective, and 4 biospecimen protocols.

4. Outcomes

Of the 22 prospective protocols, 8 were removed from the activation pipeline for various reasons. The remaining 14 protocols (100 percent) opened to accrual (OTA) at the time of this data lock, in a median of 44 days. In comparison, the medicine committees reviewed 58 protocols in a similar timeframe, only 43 percent of which were OTA. This unique single committee structure enabled protocols to open in an unprecedented timeframe. Notably, 5 of the 7 therapeutic protocols have enrolled 136 participants (in total), with first patients enrolled in ≤ 1 day.

5. Lessons Learned

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Observing how this new "one-stop" committee has enabled such quick activation; our unit is now exploring how to utilize multidisciplinary committees to reduce the time to activation for all research protocols. Some considerations have been sustainability of review timelines. The time commitment and quick turn-around demand from a single committee to review all 300+ protocols in our activation pipeline each year needs to be considered. An idea we hope to explore further is to group protocols by disease and create a group of committees by disease management team.

Figure: