What’s in a Pre-Review? Establishing a Streamlined Method for Ensuring Quality Submissions to Protocol Review Committees

Jocelyn Migliacci, MA, Ashley Motta, Andrew McKeown, MPH, Diana Diaz-Leyton, MHA, Christina Kolenut, MPH, Xhenete Lekperic, Krista Napolitano, MA, Carly Ryan, Ann Rodavitch, MA, Sara Hanley, MSW

BACKGROUND
- Memorial Sloan Kettering Cancer Center (MSK) has a robust clinical research portfolio that is vital to MSK’s mission.
- Before opening for patient enrollment, each protocol must undergo a series of committee reviews based on the participating investigators and resources needed to conduct the protocol.
- Approximately 300 new prospective protocols go through the review and activation process each year.
- Historically, individual clinical departments were responsible for managing their own protocol review committee (N=18) and additional groups were responsible for managing MSK’s institutional committees (N=7).
- Protocols were reviewed in an asynchronous manner, one at a time.
- The previous structure inherently created vague and inconsistent review requirements, incomplete submissions, lack of transparency, unclear scope, inaccurate data entry and repetitive reviews from various committees. All these factors contributed to delays in the protocol review process.
- MSK leadership charged Clinical Research Administration with optimizing protocol review and activation to decrease Time to IRB Approval (TTIA).
- Two new centralized sub-units, the Protocol Review Core (PRC) and Protocol Activation Core (PAC) were created.
- PRC is charged with managing 25 departmental and institutional review committees, including MSK’s PRMS, and increasing efficiencies within the review process while maintaining the quality of protocol reviews.

GOALS
- In support of the institution initiative to decrease TTIA, our goal was to develop and implement a new comprehensive pre-review process that increases efficiency, reduces bottlenecks, and ensures protocols are ready for committee reviews.
- In conjunction with this overarching goal, we identified the following sub-goals:
  - Define review requirements (i.e., required documents, required committee reviews)
  - Improve quality of regulatory protocol data in the Protocol Information Management System (PIMS)
  - Ensure complete submissions for committee reviews
  - Focus committee scope & streamline review flows
  - Increase transparency and communication
  - Conduct pre-reviews within 24 hours of receipt

IMPACT
- PRC conducted 289 pre-reviews in 2018 (Figure 5).
- Eighty percent of pre-review comments were sent to PAC within 24 hours of receipt, with a median time of 7.5 hours. Median time to pre-review approval was 2 days (Figure 1).
- Rapid turnaround results in prompt placement of protocols on committee meeting agendas.
- Revised workflows and resources developed by PRC expedite turnaround time, ensures consistent and high quality PIMS data, facilitates confirmation of review type (full or expedited) and allows for concurrent reviews.
- Improved compliance with institutional and regulatory requirements. One of the most notable examples has been the 50% increase in Committee on Radiation (COR) submissions from 2017 to 2018, which demonstrates PRC’s effectiveness in determining required committee reviews.

CHANGES INTRODUCED
The Protocol Review Core developed and implemented a comprehensive, standardized pre-review process:

- Protocol Review Core (PRC) receives protocol submission from PAC in the Protocol Information Management System (PIMS).
- One of two PRC members who are “on call” for the day conducts pre-review using comprehensive resources.
- Median Time - Comments to PAC = 7.5 hrs.
- Median Time - Pre-Review Approval = 2 days.
- PRC provides PAC with pre-review comments based on review of the documents and data entered in PIMS.
- PRC’s comments are addressed and resolved by PAC.
- PRC approves the protocol for committee reviews.

RESOURCES
- PRC developed multiple resources to ensure consistency and transparency to enable a standardized pre-review process.
  - Committee Determination Form, which is a smart form with guided questions to ensure protocols are reviewed by all appropriate departmental and institutional committees.
  - Best Practices Guidance.
  - PIMS Library that defines data fields in our institutional database.
- Pre-Review Guide, which extensively details standardized requirements for pre-review, such as required documents and naming conventions (Figure 2).
- New PIMS Functionality, including snapshots of required reviews/statuses available (Figure 3).
- Efficient Review Flows that help maximize the number of concurrent reviews and minimize TTIA (Figure 4).

DISCUSSION
- PRC’s new pre-review process has contributed to reducing MSK’s median TTIA from 135 days in 2017 to 80 days in 2018 by streamlining workflows throughout the review process and across committees.
- Collaboration between centralized groups (PRC and PAC) as well as shared resources have been instrumental in our successful first year.
- Continued improvements and adaptability are essential with the ever-changing landscape of clinical research.
- Improved quality of PIMS data ensures institutional leadership is utilizing accurate data in their reporting and decision making. In the future, we hope to utilize our experience to increase the percentage of pre-reviews completed within 24 hours, further decrease time to approval at review committees, increase quality of protocol submissions, and inform future collaborations within the clinical research community.
- We will continually assess the needs of our stakeholders (PAC, PI, committee members) as well as the value added in our processes and incorporate changes to improve our workflows.