Category: Trial Start-up and Activation – Completed Project

Four Years and Beyond: Progress With the Committee on Radiation

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1. Background

- The protocol review core (PRC) within Memorial Sloan Kettering Cancer Center's (MSK) clinical research administration (CRA) was established in 2018 to provide centralized oversight of protocol review committees, including the committee on radiation (COR), with a goal of decreasing time to activation (TTA) (time from primary department submission to activation)
    - PRC is charged with increasing efficiencies within the review process, while maintaining the quality of protocol reviews
- COR has jurisdiction over all ionizing radiation use in accordance with applicable regulations and MSK's broad scope license, which includes reviewing protocols where participants receive any investigational radiation exposure; COR is also responsible for non-clinical/research uses of radiation
- PRC and COR leadership identified challenges with protocol reviews at COR such as:
    - Ambiguity of criteria identifying protocols requiring COR review resulting in missed reviews
    - Anticipation of an increased submission volume with fixed resources, while supporting the center's TTA goals
    - PRC operating outside of scope since COR is a unique committee reviewing clinical and non-clinical research activities and subject to regulatory oversight

2. Goals

- Streamline COR's review process while ensuring regulatory compliance
- Improve access to COR resources
- Align responsibilities for COR administration

3. Solutions and Methods

- In collaboration with COR leadership, PRC streamlined the review process and ensured regulatory compliance by:
    - Establishing clear criteria to identify protocols requiring COR review
    - Implementing an expedited review process for low-dose, low-radiation risk protocols
    - Collaborating with consent editors to create template informed consent language regarding applicable risks
    - Creating template letter text for review letters
    - Developing an amendment workflow to ensure applicable protocols are routed for COR review
    - Updating COR SOPs to align with expedited review process and other internal workflows
- Improved access to COR resources
    - Updated the clinical research portal page (MSK's intranet) to include resources for the clinical research community (e.g., dosimetry tables, review criteria, consent language, etc.) to improve quality of protocol submissions
- Aligned responsibilities for COR administration

  - PRC offboarded non-clinical research related tasks to a newly created regulatory specialist position in the Medical Health Physics office using the RACI (Responsible, Accountable, Consulted, Informed) matrix to define scope of different teams

4. Outcomes

- 325 percent increase in COR protocol reviews from 2017-2021, demonstrating the improved compliance with institutional and regulatory requirements
- Median days (9 in 2020 and 12 in 2021) for COR review remained consistent despite increase in volume
- Since implementing expedited reviews in July 2019, most protocols are expedited at COR (86 percent in 2020 and 83 percent in 2021)
- 79 percent increase in protocols approved as-is (no comments to investigators) since launching the portal page updates in 2021
- Seamless transition of committee management responsibilities

5. Lessons Learned and Future Directions

- Lessons Learned:
  - Establishing clear review criteria in the initial stage of protocol submissions was effective for ensuring regulatory compliance
  - Incorporating RACI tool was critical for realigning administrative responsibilities
- Future Directions:
  - More effectively manage committee user work and reduce manual tasks (2022) through enhancements with MSK's homegrown protocol information management systems (PIMS)
  - Automate amendment submissions and reviews in PIMS
  - Continue to increase efficiencies within the review process