Category: Trial Start-up, Activation, Regulatory, and Protocol Development – Completed project

Accepted! Refining Minimal Submission Requirements for Protocol Review and Activation

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1. Background

Memorial Sloan Kettering (MSK) receives approximately 300 prospective and 150 retrospective biospecimen protocol submissions for activation each year. Providing the minimal critical information up front is a key component for successful trial activation. MSK's Minimal Submission Requirements (MSR) were developed by leadership to ensure activation readiness and includes a comprehensive list of items that, if missing, will delay trial activation. The Protocol Review Core (PRC) is a sub-unit within the Protocol Activation, Review & Human Research Protection Program (HRPP) Office, responsible for providing the resources and education necessary for the Principal Investigator (PI) and study teams to submit protocols that meet MSK's MSR. If the MSRs are not met, PRC requests additional information and returns the submission to the study team. Since November 2020, PRC has implemented improvements to resources, workflows, and trainings in support of activation goals.

2. Goals

- Streamline the MSRs to improve transparency and understanding
- Improve education for clinical research staff
- Standardize process for completing MSR reviews

3. Solutions and Methods

- Since 2020, PRC collaborated with stakeholders to modify the MSRs:
    - Categorized based on sponsor type
    - Simplified requirements
    - Redefined budget and contract requirements
    - Leveraged technology to prompt submitters in providing documentation:
        - Appropriate IND/IDE plan
        - Funding deadlines
        - Timeline to activate MSK cohorts
    - Support institutional initiatives:
        - NCTN TTA goals
        - Priority categorization
    - Revised based on trends in activation delays:
        - Pharmacy administration/preparation documentation
        - Confirmation of nursing support
- Expanded centralized team who review MSR from 3 to 6 and standardized processes:
    - Redesigned internal checklist, created templated comments for returning incomplete submissions
    - Ensured MSR turn-around within 2 days
    - Weekly MSR check-in team meetings
- In January 2022, PRC launched bi-monthly MSR trainings for study teams.
    - Collaborated with study team leadership to identify staff for trainings
    - Highlighted common submission roadblocks and communication best practices
    - Created Tableau dashboard to assess frequency of returned submissions

4. Outcomes

- Median days per year from last submission to acceptance was one day between 2021-2023, across 1,417 total submissions (940 prospective and 477 BRPs/RRPs).
- January 2022 - December 2023: PRC trained 140 research staff over 18 sessions, including 44 study teams across 14 departments and 14 unique positions.
- Since November 2020, 16 updates made to the MSR document, demonstrating commitment to meet needs of the Center.
- In 2023, 47 percent of prospective trials were accepted as is and 43 percent of trials were returned once, 10 percent of trials were returned more than once.
- MSK sponsored trials accepted as is improved from 21 percent in 2021 to 38 percent in 2023.

5. Lessons Learned and Future Directions

- A centralized team who specializes in the review of new protocol submissions is critical in managing ambiguous and complex submissions across numerous departments.
- Collaboration with stakeholders was key in refining the requirements.
- Goal of improving submission completeness is ongoing. Magnitude of varying study teams present a training challenge.
- Utilize Tableau dashboard to conduct targeted trainings.
- Enhance staff education:
    - Obtain feedback from staff
    - Consider MSR office hours
    - Develop additional resources
- Continue collaboration with stakeholders and regularly assess requirements.
- Leverage technology to ensure complete submissions.