Automating and Streamlining the 2-Stage Scientific Review Process

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BACKGROUND

In 2020, the Mayo Clinic Comprehensive Cancer Center (MCCC) began planning for implementation of a formal 2-stage scientific review process. This effort was necessary to meet new requirements described in the NCI P30 Cancer Center Support Grant (CCSG) Guidelines (PAR-21-321). A review of the current state Protocol Review and Monitoring System (PRMS) process highlighted further opportunities to standardize, automate and reduce administrative burden.

OBJECTIVES/GOALS

- Implement a 2-stage scientific protocol review process for MCCC
- Differentiate between 1st-stage disease group (DG) review and 2nd-stage Protocol Review Monitoring Committee (PRMC) review
- Eliminate redundant data entry and improve first time quality
- Develop electronic system to facilitate review process and store documents

METHODS/SOLUTIONS

MCCC developed a 2-stage scientific protocol review process and defined the elements and criteria to be used by the 22 MCCC DGs and four PRMCs. To support the process, a scientific review e-committee tool was developed. The tool includes a REDCap database enhanced by an independent and interactive online dashboard as shown in the figure to the right. The tool features electronic forms for data capture, storage, metrics tracking, branching logic and automated email communications. Branching logic directs the user to the type of review required (e.g., full, expedited, administrative) and appropriate routing of the protocol for review by one or more committees.

RESULTS/OUTCOMES

The scientific review e-committee tool and 2-stage review process was piloted in three DGs from May to July 2021. As of January 2022, the tool was implemented in 14 of 22 MCCC DGs. 180 protocols have been entered with 20 completing the full scientific review process. Prior to implementation, first-time quality on entry of critical PRMS data was: 89% for capturing DG review date; 74% for PRMC submission date; and 79% for PRMC approval date. Leveraging automation, the tool is now capturing these data points at 100%.

DISCUSSION

Lessons learned through implementation include the value of standardized protocol review forms for data capture as well as DG structure and support to assist study team and committees with a more robust process. A Senior Program Coordinator has been assigned to each DG to support implementation. This additional resource is a main point of contact for Investigators and sponsors to help steward protocols from DG submission to PRMC approval. In addition, a protocol review requirement table with definitions was created to aid the entry of protocols into the tool.