Category: Finance/CCSH/PRMS – Work in Progress

Automating and Streamlining the 2-Stage Scientific Review Process

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1. Background

In 2020, the Mayo Clinic 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.

2. Goals

- Implement a 2-stage scientific protocol review process for MCCC
- Differentiate between first-stage disease group (DG) review and second-stage protocol review monitoring committee (PRMC) review
- Improve communication and flow of data through the 2-stage review process
- Eliminate redundant data entry and improve first time quality
- Develop electronic system to facilitate review process and store documents
- Improve tracking of PRMS metrics

3. Solutions and Methods

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. The tool features electronic forms for data capture, storage, metrics tracking, branching logic and automated email communications. The e-committee tool optimizes protocol review through standardization of workflow and process automation while reducing data entry. It applies standardized review criteria for an initial scientific review, feasibility assessment, and prioritization at the DG. 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.

4. 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. One hundred-eighty 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 percent for capturing DG review date; 74 percent for PRMC submission date; and 79 percent for PRMC approval date. Leveraging automation, the tool is now capturing these data points at 100 percent.

5. Lessons Learned and Future Directions

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.