Category: Finance/CCSG/PRMS – Work In Progress

Capturing Metrics for the First Stage of Protocol Review at a Consortium Cancer Center

K. Hoy[1], A. Firstencel[1], H.J. Pounardijian[1], J. Chan[1], K. Jenkins[2], L. Mooney[2], M. Kilbane[2]

[1]Case Comprehensive Cancer Center; [2]Cleveland Clinic Cancer Center

1. Background

In November of 2019 new CCSG P30 guidelines were published. These guidelines changed the reporting Requirements for the PRMS for the first time in over 10 years. The FOA delineated two stages of protocol review, the first stage is at the disease team/hospital level and the second stage is at the PRMC level. Though the first stage of review was happening before the most recent FOA, the formal documentation this process is novel.

Cleveland Clinic implemented formal, first stage, disease-focused scientific review through a feasibility process with an approved Standard Operating Procedure (SOP) on October 15, 2009. University Hospitals implemented formal, first stage disease-focused scientific review on through a feasibility process with an approved Standard Operating Procedure (SOP) on January 8, 2018. The lead, non-clinical research coordinator (RC) distributes the protocol and associated documents to the entire research team, inclusive of research nurses (RN) and non-licensed clinical coordinators (CRCs and CRAs), pharmacy personnel, additional non-clinical research coordinators (RC), all disease team physicians, and financial analysts, at least 2 weeks prior to the regular Disease Oriented Group (DOG) meeting in which first review will occur. At the DOG meeting the PI presents the trial and physicians each have time to comment on the scientific merit and viability of the trial. In addition, all team members have time and are expected to discuss any issues discovered. The Program Leader then has authority to approve or deny opening the clinical trial. Implemented in 2019, team members are expected to have identified the issues, reported them to the lead RCs and developed solutions as appropriate before the meeting. The meeting then consists of discussion about both issues and solutions and decisions on whether it is feasible or not to open the study. Many of the teams have implemented PowerPoint presentations of the potential trials to support the discussion of feasibility.

2. Goals

- What percentage of trials are rejected at each stage of the process.
- How effective is each stage?
- What is the best practice to capture all of the studies being offered at each consortium partner?
- Can the first stage of review be used to further joint trials?

3. Solutions and Methods

- **Engaged CTUs and Disease teams from both consortium partners to develop standard metrics.**
- **Developed common timelines for data collection.**
- **Shared best practices among consortium members to provide best practices.**

4. Outcomes

- Data collection is ongoing.

- Metrics will be established for each step in the process: Pre-CDA, CDA, Feasibility, Disease Group

5. Lessons Learned

- Develop standard review processes across disease teams.
- Track which trials are being offered at each site.
- Use descriptive statistics to show how selective the vetting process is for each step of the first stage of review.