Category: Prioritization and Scientific Review – Work in Progress

Implementation of the Protocol Review Committee's Low Accrual Guidance

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1. Background

The Clinical Trials Office (CTO) Protocol Review Committee (PRC) reviews ~400 studies per year. Our 2020 Cancer Center Support Grant (CCSG) review identified a lack in closure of poorly or non-accruing studies by the PRC. Our PRC charter guidance at the time indicated that during annual renewal, low accruing studies (accrual of less than 40% of annual target) were required to provide justification for low accrual and delineate measures taken to improve accrual. The PRC decides if the studies should receive a Six-Month Re-Review (6MRR) with a goal; and then, closure is considered if the study does not meet the goal stipulated by PRC.

However, often, PRC reviewers hesitated to close under-performing studies, recognizing the efforts in opening and maintaining a study. To facilitate increased closure of poorly or non-accruing studies, a need to educate CTO investigators and reviewers on clearer low accrual guidelines was determined.

2. Goals

- Track trends for low accruing studies.
- Collaborate with PRC Chairs to establish defined process addressing low accruing studies
- Disseminate low accrual guidelines to the CTO and PRC reviewers

3. Solutions and Methods

We analyzed trends for renewal submissions in 2023. Out of 222 renewal submissions, 139 studies were low accruing.

We found that 90 percent of low accruing studies received a one-year approval and 7 percent received a 6MRR. We sorted the percentages of low accruing studies based on study type; 35 percent were pharmaceutical studies, 30 percent were Investigator-Initiated Trials (IITs), and 21 percent were cooperative group studies. Lastly, we categorized the reasons for low accrual provided by study teams. Notable categories of low accrual justification were studies having been open to accrual for less than or for six months and studies not yet being open to accrual (combined percentage of 29%), rare disease involvement (12%), and strict eligibility criteria (10%).

4. Outcomes

We determined that a point of intervention would be with IITs that have strict eligibility criteria. We also determined that closure guidelines would not apply to rare disease studies, studies open to accrual less than a year, or studies that are not yet open to accrual. Based on this information, we created updated guidance for low accruing studies, implemented in August 2024. PRC reviewers are provided with these guidelines prior to review. This guidance would equip PRC reviewers to make more definitive recommendations for closure. The updated guidelines were disseminated to the CTO via disease group meetings and office-wide meetings.

5. Learned and Future Directions

- Continue educating reviewers and investigators about the need to provide appropriate low accrual justification and to provide efficient plans of improving accrual

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- Consider using automated accrual reports in Oncore in the future:
  - To highlight under-performing studies prior to PRC review so study teams can proactively prepare their explanation for low accrual and efforts to improve accrual
  - To alert investigators ahead of time of at-risk studies that will be subjected to low accrual monitoring

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