The YODA Project
Research Proposal Review - Revisions Requested
(Protocol #: 2020-4359)

Reviewers:
☒ Nihar Desai
☒ Joshua Wallach
☐ Harlan Krumholz
☐ Richard Lehman
☒ Joseph Ross

Review Questions:          Decision:
1. Is the scientific purpose of the research proposal clearly described?  Yes
2. Will request create or materially enhance generalizable scientific and/or medical knowledge to inform science and public health?  Yes
3. Can the proposed research be reasonably addressed using the requested data?  Unsure, further clarification from requestor is needed
4. Recommendation for this data request:  Not Approve

Comments:

Although this project, which focuses on evaluating how a previously developed model performs on trial patients receiving enzalutamide or abiraterone acetate, appears to be realistic, there are two areas where some (brief) additional information is necessary:

1. Under the section 'Main Predictor/Independent Variable and how it will be categorized/defined for your study', the authors note that one of their aims is to check for new independent predictors of OS in patients receiving abiraterone acetate or enzalutamide. It would be helpful if the authors provided a brief description of the types of predictors that are of interest and that are available in the specific trial.

2. Under the 'Statistical Analysis' section, the authors briefly describe their previously developed methodology. For the current project, can the authors provide additional information: how will predictors be established and what does 'suboptimal performance' mean?