The YODA Project
Research Proposal Review - Final
(Protocol #: 2020-4416)

Reviewers:
☑ Nihar Desai
☐ Cary Gross
☐ Harlan Krumholz
☐ Richard Lehman
☑ Joseph Ross
☑ Joshua Wallach

Review Questions:

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? Yes, or it's highly likely

4. Recommendation for this data request: Approve

Comments:

The one other piece that would be good to sort out is what is the power to show a difference? Is that realistic with the sample size available?

In this proposal, the authors aim to assess the effect of canagliflozin compared to placebo on liver-related outcomes in patients with T2DM and to identify subgroups that benefit most from such treatments. This is a realistic proposal; however, in order to help improve clarity, the authors should provide more information about how they will develop the prediction score - how will variables be selected, etc.