

**The YODA Project
Research Proposal Review**

The following page contains the final YODA Project review
approving this proposal.

The YODA Project
Research Proposal Review - Final
(Protocol #: 2020-4409)

Reviewers:

- Nihar Desai
- Cary Gross
- Harlan Krumholz
- Richard Lehman
- Joseph Ross
- Joshua Wallach

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? | Yes, or it's highly likely |
| 4. Recommendation for this data request: | Approve |

Comments:

No additional comments.

**The YODA Project
Research Proposal Review**

Revisions were requested during review of this proposal.
The following pages contain the original YODA Project review and
the original submitted proposal.

The YODA Project
Research Proposal Review - Revisions Requested
(Protocol #: 2020-4409)

Reviewers:

- Nihar Desai
- Cary Gross
- Harlan Krumholz
- Richard Lehman
- Joseph Ross
- Joshua Wallach

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:

In this request, the authors outline a study focused on assessing the effect of canagliflozin vs. placebo on liver related outcomes in patients with T2DM and identifying subgroups that are most likely to benefit from treatment. Could the requestors clarify that the trials that are being requested contain the outcomes of interest for this study? In particular, do both trials have information for the primary and/or secondary outcomes outlined in the data request?