

The YODA Project
Research Proposal Review - Final
(Protocol #: 2019-4035)

Reviewers:

- Nihar Desai
- Cary Gross
- 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? | Yes, or it's highly likely |
| 4. Recommendation for this data request: | Approve |

Comments:

The authors are likely to identify additional trials besides the 2 requested that assess the efficacy of SGLT-2 inhibitors and GLP-1 agonists versus placebo in patient with type 2 diabetes mellitus on cardiovascular outcomes. Will all the data be uploaded to the platform? Or is the purpose to use these data from the 2 trials, conduct the appropriate analyses, and then merge the summary data with already calculated estimates from previously acquired trials? I believe it's the latter, which should just be explained a bit more clearly.