

**The YODA Project**  
**Research Proposal Review - Final**  
**(Protocol #: 2019-4071 )**

**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:**

Interesting study to compare change in HbA1c, all-cause mortality, micro- and macro-vascular complications, patient-reported symptoms and quality of life and specific adverse outcomes reported for Canagliflozin / SGLT2s including renal impairment, diabetic ketoacidosis, volume depletion, furnier's gangrene and lower limb amputation relevant to diabetes reported in published articles versus those in CSRs.

The authors should clarify how they will interpret their comparisons. For a comparison of published reports to CSRs, for all of the many outcomes they've specified, do the numbers need to be an exact match to be considered equivalent, or within a certain % of one another, etc.?