

The YODA Project
Research Proposal Review - Final
(Protocol #: 2016-0912)

Reviewers:

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

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 |

Decision:

Comments:

This is an excellent proposal and an important study. Investigators may consider providing additional background on the other cardiovascular trials on which they are testing the replication of results, if there are others. Similarly, the investigators plan to replicate the results of the trial by explicitly following the methods laid out within the text of the article, as well as any online supplements. However, a secondary aim might be to consider replicating the results by explicitly following the methods laid out in the Statistical Analysis Plan, which contains more detail than the manuscript text, and to compare the results to the Clinical Study Report (or CSR summary), which will contain more granular findings, particularly for safety endpoints and adverse events.

I don't quite understand the 2nd aim. With regard to the first aim, the primary endpoint of the study seems to be an arrhythmia related endpoint, I am not sure whether survival was part of the primary analysis. The goal of this analysis (replication of this trial) is important and the authors should specify that their approach will be to replicate the primary analysis of the trial.