

The YODA Project
Research Proposal Review - Final
(Protocol #: 2021-4764)

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:

Investigators plan to compare SAE reporting in publications, trial registries and CSRs. The CSRs for these 15 trials are being requested from both the EMA and the YODA Project. I expect that they will provide the same information, but the investigators should consider what they will do if the CSRs from the two sources differ.