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

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

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.