

The YODA Project
Research Proposal Review - Final
(Protocol #: 2021-4812)

Reviewers:

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

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:

Useful proposal to obtain information on important subgroups from the full CSR of 3 clinical trials for meta-analysis. I expect the data to be available for the endpoints of interest stratified by age 65 years, but worry that the info will not be available stratified by age 75 years (which might then require the requesting investigators to perform their own analysis).