

**The YODA Project  
Research Proposal Review**

The following page contains the final YODA Project review  
approving this proposal.

**The YODA Project**  
**Research Proposal Review - Final**  
**(Protocol #: 2020-4275 )**

**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:**

No additional comments.

**The YODA Project  
Research Proposal Review**

Revisions were requested during review of this proposal.  
The following pages contain the original YODA Project review and  
the original submitted proposal.

**The YODA Project**  
**Research Proposal Review - Revisions Requested**  
**(Protocol #: 2020-4275 )**

**Reviewers:**

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

**Review Questions:**

1. Is the scientific purpose of the research proposal clearly described?
2. Will request create or materially enhance generalizable scientific and/or medical knowledge to inform science and public health?
3. Can the proposed research be reasonably addressed using the requested data?
4. Recommendation for this data request:

**Decision:**

- No
- Unsure, further clarification from requestor is needed
- Unsure, further clarification from requestor is needed
- Not Approve

**Comments:**

Data are only made available via the YODA Project for scientific purposes and, to that end, approved investigators are required to sign a Data Use Agreement (DUA) which requires the Data User to grant JANSSEN a fully paid, perpetual, worldwide, non-exclusive, royalty-free license for all purposes to each such Invention. Examples of the DUA can be found here. Please clarify the scientific purpose of this work, and commitment to disseminate knowledge gained.

There are a number of confusing aspects of this application, which proposes to improve & validate our prototype ADAS-Cog 11 model and develop & validate ADAS-Cog 13 & MMSE models. Chief concern is that the authors do not specify how they will make use of the 3 clinical trials being made available via the YODA Project, but instead discuss their use of data being made available from the Critical Path Institute, including the CAMD and ADNI datasets. The research proposal should be tailored to the data being requested. My guess is that the CAMD and ADNI datasets are being used for development, these 3 trials for validation. But if so, how will the results be compared? Will the CAMD and ADNI data sets be uploaded to the virtual environment used by YODA Project, or kept separate? Have the predictor variables been identified yet? They should be pre-specified.