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 #: 2023-5218)

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:

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 #: 2023-5218   )

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?	No
2. Will request create or materially enhance generalizable scientific and/or medical knowledge to inform science and public health?	Unsure, further clarification from requestor is needed
3. Can the proposed research be reasonably addressed using the requested data?	Unsure, would defer to Data Holder Due Diligence Assessmen
4. Recommendation for this data request:	Not Approve

Comments:

1. Could the investigator provide greater clarity regarding the approach to comparing visual vs computational reads of the images?

2. Data available through the YODA Project can only be used for research purposes, not education. The proposal should be revised to focus on the empiric aspects of the work (ie, compare traditional visual reads versus computational methods for ARIA detection, predict treatment response in subgroups). Any incorporation of the findings from this work into an online education portal should be separated from the YODA Project research proposal and should be based on the published findings.

3. This request seems to make several assumptions- especially that ARIA are the most important surrogate for adverse clinical outcomes and that their significance is already known. Other assumptions are that this agent will be widely used in Alzheimer's disease and that patients will be followed up with regular imaging. However, little supporting evidence is included. Could the investigator provide a careful and evidenced account of current clinical uncertainty and a clear explanation of how they would address this, both in broad terms and with clear statistical description?