

**The YODA Project**  
**Research Proposal Review - Final**  
**(Protocol #: 2022-4981 )**

**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:**

1. The investigators have specified 10 primary outcome measures in their protocol and then list 6 additional outcomes measures (3 remission-based and 3 response-based) in the section for 'main predictor/independent variable(s)', but the main predictor/independent variable is the disease distribution (left-sided vs. extensive disease). Please clarify.
2. Will this study really include 10 co-primary endpoints/will the results for all these endpoints be emphasized equally?
3. Are Poisson regressions appropriate for all 10 outcomes? Additional information is necessary regarding the methods for the different endpoints.