

**The YODA Project**  
**Research Proposal Review - Final**  
**(Protocol #: 2023-5534 )**

**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? | No                          |
| 3. Can the proposed research be reasonably addressed using the requested data?  | No, or it's highly unlikely |
| 4. Recommendation for this data request:  | Not Approve                 |

**Comments:**

The YODA Project has determined that your request for data, titled Quality tolerance limit and duplicated patient investigation in clinical trials, has not been approved, for the following reason(s):

1. It appears that the intended use is to support a commercial interest and the YODA Project data request requirements specifically preclude the sharing of data for commercial purposes
2. Your proposal was reviewed by our scientific team, who concluded that there was insufficient information to evaluate the integrity of the research project. It was not clear how the trials would be used to assess the proposed objectives, what variables would be used and how the main outcomes would be defined for each of the objectives, nor how the analyses would be conducted.
3. Anonymized data is shared with external research teams. During the anonymization process, the clinical data are transformed to ensure that the risk of re-identification is below the required threshold. This results in a loss of data utility which will impact the research described in the proposed project. For example, the amount of geographical information is limited. Country may be available, but the site location is always suppressed. In addition, demographic characteristics are generally considered indirect identifiers and may be suppressed or generalized, making it difficult to identify duplicate patients. Please refer to the dataset specification available for NCT01032629 for more details on the Johnson & Johnson anonymization approach.

As described in the Policies and Procedures documentation, the YODA Project will only approve requests to use data in a way that will promote scientific research that may advance science or lead to improvements in individual and public health and healthcare delivery.