

**The YODA Project**  
**Research Proposal Review - Final**  
**(Protocol #: 2022-4952 )**

**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. Will summary data from trials of either treatment identified from literature search also be included (step 1 in 'data source'); if so, how will the estimates derived from IPD be combined with estimates derived from summary data?
2. Please provide more information on "study group of oral gepants". Is this one trial or data from multiple trials? Is it a cohort of patients treated at the investigator's institution? More detail is required to understand the comparison between the data from 13 trials and "study group of oral gepants".
3. Please clarify if the 6 variables listed as 'main predictor variables' or 'other variables of interest' are the variables to be used for propensity matching. Any information on how these variables will be categorized for matching would also be helpful.