

**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 #: 2020-4276)

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:

Systematic review and meta-analysis to examine the risk of psychiatric AEs associated with topiramate use. Investigators are requesting access to CSRs of 38 RCTs via the YODA Project, not IPD. From the CSR AE summaries, they will ascertain psychiatric AE counts for their meta-analysis. Results of this work will be informative to patients and clinicians alike. I would only recommend that they register their review protocol in PROSPERO, so others can know they are working on this question and provide feedback as appropriate.

Project to meta-analyze psychiatric adverse event data among users of topiramate. Investigator is not analyzing participant-level data. Data made available for this project need only be CSRs.

**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 #: 2020-4276)

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? | 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? | Unsure, further clarification from requestor is needed |
| 4. Recommendation for this data request: | Not Approve |

Comments:

Given that the investigators are not requesting patient-level data and are not proposing to conduct analyses on the YODA platform, they should specify that the request is for the CSR data only. The analytic approach for the meta-analysis is lacking detail in assessment of heterogeneity and appropriateness of pooling data to provide summary estimates.

No analytics are described which would justify the release of IPD or CSRs. It is not clear that the investigators could carry out a useful quantitative analysis of the published data.

In response to the proposal ("In the systematic review, data will be analyzed qualitatively. In the meta-analysis, odds-ratios will be calculated for the different adverse effects occurring under Topiramate vs. Placebo // Topiramate vs. active comparator using RevMan 5."), the reviewer's response: The wording here suggests that this will be a basic exercise to form part of a MSc project, rather than a substantive scientific project.

The kind of proposal described is worthwhile but would need to involve a team and many months of skilled analytic work.