

The YODA Project
Research Proposal Review - Final
(Protocol #: 2018-3156)

Reviewers:

- Nihar Desai
- Cary Gross
- Harlan Krumholz
- Richard Lehman
- Joseph Ross

Review Questions:

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:

This proposal is a useful investigation of the pharmacokinetics of bedaquiline among patients with type 2 diabetes mellitus using either metformin or a sulfonylurea. My only concern with the proposal is whether pharmacokinetic data are available for the 2 trials requested. If available, this research will provide useful information for patients using bedaquiline concomitantly with either metformin or a sulfonylurea.