

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

**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:**

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.