The YODA Project
Research Proposal Review - Final
(Protocol #: 2019-4001)

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?	Unsure, further clarification from requestor is needed
3. Can the proposed research be reasonably addressed using the requested data?	Unsure, would defer to Data Holder Due Diligence Assessmen
4. Recommendation for this data request:	Not Approve

Comments:

It is unclear why the researchers wish to use such a complex control strategy: "there may be as many as three sources of controls, prospective concurrent controls, retrospective controls, and historical controls or LimiFlex subjects." Earlier the proposal states that "This is a multi-center, prospective, concurrently controlled, non-blinded study. Balance between groups will be achieved through sub classification using propensity scores." A standard form of randomized allocation may be preferable.

Further, the response to the query regarding why this analysis must be conducted outside the YODA platform is insufficient and suggests this data request is out-of-scope for the YODA Project.

Ultimately, this data request cannot be approved, for the following reasons:

1. Data access methods: there are additional privacy considerations for the individuals in the trial given that the data would need to be directly transferred to the researcher outside the secure platform and, further, that the data would then need to be submitted to a third party regulatory authority.

2. Clear commercial use: The YODA Project shares data for general scientific research purposes or to advance medical knowledge. Use of the data for any commercial purposes is expressly prohibited in our Data Use Agreement (DUA).

3. License to inventions: The YODA Project DUA requires that Medical Device & Diagnostics Global Services (acting on behalf of the Johnson & Johnson Family of Medical Device Companies) is granted a fully paid, perpetual, worldwide, non-exclusive, royalty-free license for all purposes to any invention or discovery resulting from analyses of the Data.

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.