The YODA Project
Research Proposal Review - Final
(Protocol #: 2021-4638 )

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:
Potentially valuable study to understand the impact of frailty on treatment outcomes for patients with multiple myeloma enrolled in NCT02252172. My only minor comment is that I expect the authors intended to propose that frailty, defined according to Facon et al using a composite score of age, ECOG performance status and Charlson comorbidity score, is their main independent/predictor variable. I expect they will conduct an interaction analysis to know if the effect of daratumumab in combination with lenalidomide and dexamethasone versus lenalidomide and dexamethasone alone is any different, or an analysis stratified by frailty.