

**The YODA Project**  
**Research Proposal Due Diligence Assessment**

<b>Part 1: General Information</b>	
<b>YODA Project (Protocol) ID:</b>	2021-4638
<b>Date:</b>	18 March 2021
<b>Product Name:</b>	Daratumumab
<b>Therapeutic Area:</b>	Oncology
<b>Product Class:</b>	Monoclonal antibody
<b>Condition(s) Studied:</b>	Multiple Myeloma
<b>Protocol Number(s) and Title(s):</b>	<b>NCT02252172 - 54767414MMY3008</b> - A Phase 3 Study Comparing Daratumumab, Lenalidomide, and Dexamethasone (DRd) vs Lenalidomide and Dexamethasone (Rd) in Subjects With Previously Untreated Multiple Myeloma Who Are Ineligible for High Dose Therapy
<b>Part 2: Data Availability</b>	
Data Holder has authority to provide clinical trial data or development partner has agreed to share clinical trial data.	Yes
Comments:	
Data Holder has sharable electronic clinical trial data or data can be converted to electronic format.	Yes
Comments:	
De-identification and redaction of clinical trial data in accordance with current HIPAA and EU criteria allows protection of participant privacy and confidentiality.	Yes
Comments:	
The product and relevant indication studied has either been approved by regulators in the US and EU, or terminated from development.	Yes
Comments:	
Data Holder has completed the clinical trial and trial has been completed for a period of at least 18 months (or results published in peer-reviewed biomedical literature).	Yes
Comments:	
<b>Part 3: Data Availability Summary</b>	
Based on the responses to the above Data Availability questions, the requested clinical trial data are available for a data sharing request.	Yes
<b>Part 4: Proposal Review</b>	
Question:	Response:
Summary-level CSR data is appropriate for the proposed analysis.	Yes
Participant-level data is appropriate for the proposed analysis.	Yes
A similar analysis is underway or completed/pending disclosure by Janssen.	Yes
Comments:	Janssen, in collaboration with external experts, have conducted post hoc analyses to explore the impact of frailty and related baseline variables on response to daratumumab/lenalidomide and other combinations. Janssen et al plan to publish these results at upcoming symposiums and leading journals, including recent presentation at European Myeloma Network and at ASH 2019.