The YODA Project
Research Proposal Due Diligence Assessment

Part 1: General Information	
YODA Project (Protocol) ID:	2021-4660
Date:	27 April 2021
Product Name:	Daratumumab
Therapeutic Area:	Oncology
Product Class:	Monoclonal antibody
Condition(s) Studied:	Multiple Myeloma
Protocol Number(s) and Title(s):	**NCT02076009 - 54767414MMY3003** - Phase 3 Study Comparing Daratumumab, Lenalidomide, and Dexamethasone (DRd) vs Lenalidomide and Dexamethasone (Rd) in Subjects With Relapsed or Refractory Multiple Myeloma **NCT02136134 - 54767414MMY3004** - Phase 3 Study Comparing Daratumumab, Bortezomib and Dexamethasone (DVd) vs Bortezomib and Dexamethasone (Vd) in Subjects With Relapsed or Refractory Multiple Myeloma

Part 2: Data Availability		
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:		

Part 3: Data Availability Summary	
Based on the responses to the above Data Availability questions, the requested clinical trial data are available for a data sharing request.	Yes

Part 4: Proposal Review	
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:	Individual patient-level data has been used to investigate the potential correlation between the IMWG-based response and PFS/OS via various statistical approaches (e.g., Cox proportional hazards model, subset analysis, etc.). Along with data from other studies in RRMM patients, Janssen team is developing/evaluating the potential analysis plan to further assess the patient-level and/or trial-level associations between response and PFS/OS with different statistical methods (e.g., landmark analysis, Cox model with time-varying covariate, meta-analytical approach, etc.).