Part 1: General Information	
YODA Project (Protocol) ID:	2018-3321
Date:	17 November 2023
Product Name:	Daratumumab
Therapeutic Area:	Oncology
Product Class:	Monoclonal antibody
Condition(s) Studied:	Multiple Myeloma
Protocol Number(s) and Title(s):	**NCT00574288/**54767414GEN501-Daratumumab (HuMax®-CD38) Safety Study in Multiple Myeloma - Open Label, Dose-escalation Followed by Open Label, Single-arm Study **NCT01985126/**54767414MMY2002- An Open-label, Multicenter, Phase 2 Trial Investigating the Efficacy and Safety of Daratumumab in Subjects With Multiple Myeloma Who Have Received at Least 3 Prior Lines of Therapy (Including a Proteasome Inhibitor and IMiD) or Are Double Refractory to a Proteasome Inhibitor and an IMiD **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 **NCT01615029/**DARA-GEN503 -An Open Label, International, Multicenter, Dose Escalating Phase I/II Trial Investigating the Safety of Daratumumab in Combination With Lenalidomide and Dexamethasone in Patients With Relapsed or Relapsed and Refractory Multiple Myeloma **NCT03180736/**54767414MMY3013 - A Phase 3 Study Comparing Pomalidomide and Dexamethasone With or Without Daratumumab in Subjects With Relapsed or Refractory Multiple Myeloma Who Have Received at Least One Prior Line of Therapy With Both Lenalidomide and a Proteasome Inhibitor

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:	"Modeling longitudinal profile of M-protein and its association with survival in multiple myeloma" with potential journal submissions to clinical journals and/or clinical pharmacology journals

Part 5: Cost		
Estimated cost to share the requested clinical trial data.		Tier 3
Tier 1: < $5,000	Tier 2: $5,000 - $25,000	Tier 3: > $25,000