The YODA Project
Research Proposal Due Diligence Assessment

Part 1: General Information	
YODA Project (Protocol) ID:	2019-3936
Date:	8 August 2019
Product Name:	Paliperidone palmitate/Abiraterone acetate/Galantamine/Daratumumab
Therapeutic Area:	Oncology/Neuroscience
Product Class:	Atypical antipsychotics/ CYP17 inhibitor/AZ Disease - Cholinesterase Inhibitors/ Monoclonal Antibody
Condition(s) Studied:	Schizophrenia/Neoplasms, Prostatic/Alzheimer Disease/Multiple Myeloma
Protocol Number(s) and Title(s):	**Paliperidone palmitate:** NCT00589914-R092670PSY3006 *A Randomized, Double-Blind, Parallel-Group, Comparative Study of Flexible Doses of Paliperidone Palmitate and Flexible Doses of Risperidone Long-Acting Intramuscular Injection in Subjects With Schizophrenia* **Abiraterone acetate:** NCT00638690-COU-AA-301 *A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study of Abiraterone Acetate (CB7630) Plus Prednisone in Patients With Metastatic Castration-Resistant Prostate Cancer Who Have Failed Docetaxel-Based Chemotherapy* NCT00887198-COU-AA-302 *A Phase 3, Randomized, Double-blind, Placebo-Controlled Study of Abiraterone Acetate (CB7630) Plus Prednisone in Asymptomatic or Mildly Symptomatic Patients With Metastatic Castration-Resistant Prostate Cancer* **Galantamine:** NCT00679627-GALALZ3005 *A Randomized, Double-Blind, Placebo-controlled Trial of Long-term (2-year) Treatment of Galantamine in Mild to Moderately-Severe Alzheimer's Disease* **Daratumumab:** 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	
Question:	**Response:**
Data Holder has authority to provide clinical trial data or development partner has agreed to share clinical trial data.	Yes
Comments:	N/A

The YODA Project
Research Proposal Due Diligence Assessment

Data Holder has sharable electronic clinical trial data or data can be converted to electronic format.	Yes
Comments:	N/A
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:	N/A
The product and relevant indication studied has either been approved by regulators in the US and EU, or terminated from development.	Yes
Comments:	N/A
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:	N/A
Part 3: Data Availability Summary	
Based on the responses to the above Data Availability questions, the requested clinical trial data can be made available for data sharing.	Yes
Part 4: Proposal Review	
Question:	**Response:**
Summary-level CSR data is appropriate for the proposed analysis.	No
Participant-level data is appropriate for the proposed analysis.	Yes
A similar analysis is underway or completed/pending disclosure by Janssen.	No
Comments:	