The YODA Project
Research Proposal Due Diligence Assessment

Part 1: General Information	
YODA Project (Protocol) ID:	2022-4951
Date:	10 May 2022
Product Name:	Abiraterone Acetate/Epoetin Alfa/Golimumab/Macitentan/ Topiramate
Therapeutic Area:	Immunology/Oncology/NS/Respiratory Tract Diseases
Product Class:	Anticonvulsants/Endothelin Receptor Antagonist/Antirheumatic Agents - Biologic Response Modifiers/ Colony-Stimulating Factors
Condition(s) Studied:	Metastatic Breast Carcinoma/Rheumatoid Arthritis/Idiopathic Pulmonary Fibrosis/Prostate Cancer/Migraine
Protocol Number(s) and Title(s):	**NCT00211133 - EPO-INT-76** DOUBLE BLIND - A Double-blind, Randomized, Placebocontrolled Study to Evaluate the Impact of Maintaining Hemoglobin Using Eprex (Epoetin Alfa) in Metastatic Breast Carcinoma Subjects Receiving Chemotherapy **NCT01004432 - CNTO148ART3002** - Golimumab in Rheumatoid Arthritis Participants With an Inadequate Response to Etanercept (ENBREL) or Adalimumab (HUMIRA) **NCT00903331 - AC-055B201** - A Double-blind, Randomized, Placebo-controlled, Multicenter, Parallel Group Study to Evaluate the Efficacy, Safety, and Tolerability of Macitentan in Patients With Idiopathic Pulmonary Fibrosis **NCT01715285 - 212082PCR3011** - A Randomized, Double-blind, Comparative Study of Abiraterone Acetate Plus Low-Dose Prednisone Plus Androgen Deprivation Therapy (ADT) Versus ADT Alone in Newly Diagnosed Subjects With High-Risk, Metastatic Hormone-naive Prostate Cancer (mHNPC) **NCT00210496 - CAPSS-334** - Efficacy of AXERT (Almotriptan Malate) in the Acute Treatment of Migraine: A Pilot Study of the Potential Impact of Preventive Therapy With TOPAMAX (Topiramate)

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	
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	

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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:	