The YODA Project
Research Proposal Due Diligence Assessment

Part 1: General Information	
YODA Project (Protocol) ID:	**2016-1136**
Date:	19 December 2016
Product Name:	Abiraterone acetate
Therapeutic Area:	Oncology
Product Class:	CYP17 inhibitor
Condition(s) Studied:	Prostatic Neoplasms
Protocol Number(s) and Title(s):	**NCT00638690** - 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**- 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

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 shareable 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

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Participant-level data is appropriate for the proposed analysis.		Yes
A similar analysis is underway or completed/pending disclosure by Janssen.		Yes
Comments:	We are looking at on impact of the use of statins on outcomes with patients treated with ZYTIGA.	