The YODA Project Research Proposal Due Diligence Assessment

VODA Project (Protocol) ID: 2016-1103	Part 1: General Information				
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. Comments: N/A Data Holder has shareable electronic clinical trial data or data can be converted to electronic format. 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. Comments: N/A The product and relevant indication studied has either been approved by regulators in the US and EU, or terminated from development. 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. Part 4: Proposal Review Question: Response: Summary-level CSR data is appropriate for the proposed analysis. No	YODA Project (Protocol) ID:	2016-1103			
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The YODA Project Research Proposal Due Diligence Assessment

A similar analysis is underway or completed/pending disclosure by Janssen.		No
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