

The YODA Project
Research Proposal Due Diligence Assessment

Part 1: General Information	
YODA Project (Protocol) ID:	2016-1058
Date:	23 August 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
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
Participant-level data is appropriate for the proposed analysis.	Yes
A similar analysis is underway or completed/pending disclosure by Janssen.	Yes
Comments:	Multiple manuscripts on predictive factor modeling in mCRPC have been published, some of which used the Cou-AA-301 data sets. Among manuscripts published are: Scher et al Journal Clin Oncol 2011; 28(18-suppl): LBA4517

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	Afshar et al Anticancer Res 2015; 35(2):1057 Loriot et al Journal Clin Oncol 2012; 30(5-suppl):213 De Bono et al New Engl Journal Med 2011; 364:1995-2005 and most importantly (and recently): Chi et al Ann Oncol 2016; 27(3):454-460
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