The YODA Project Research Proposal Due Diligence Assessment

Product Name: Abiraterone acetate 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. 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 elevant indication 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 Summary Based on the responses to the above Data Availability Summary Part 4: Proposal Review Question: Response: Question: Response: Question: Response: 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. 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, sone of which used the Cou-AA-301 data sets. Among manuscripts published are: Scher et al Journal Clin Oncol 2011; 28(18-suppl): LBAA517			Part 1: General Information		
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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	