

The YODA Project

Research Proposal Due Diligence Assessment

Part 1: General Information	
YODA Project (Protocol) ID:	2024 – 0136
Date:	January 31 2024
Product Name:	Apalutamide
Therapeutic Area:	Oncology
Product Class:	Androgen receptor inhibitors
Condition(s) Studied:	Prostate Cancer
Protocol Number(s) and Title(s):	1. NCT02489318 - A Phase 3 Randomized, Placebo-controlled, Double-blind Study of Apalutamide Plus Androgen Deprivation Therapy (ADT) Versus ADT in Subjects With Metastatic Hormone-sensitive Prostate Cancer (mHSPC)
Part 2: Data Availability	
Data Holder has authority to provide clinical trial data or development partner has agreed to share clinical trial data.	Yes
Comments:	
Data Holder has sharable electronic clinical trial data or data can be converted to electronic format.	Yes
Comments:	
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:	
The product and relevant indication studied has either been approved by regulators in the US and EU, or terminated from development.	Yes
Comments:	
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:	
Part 3: Data Availability Summary	
Based on the responses to the above Data Availability questions, the requested clinical trial data are available for a data sharing request.	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:	Similar analysis just published: Axel S. Merseburger, Neeraj Agarwal, Amitabha Bhaumik, Florence Lefresne, Laurence I. Karsh, Andrea J. Pereira de Santana Gomes, Álvaro Juárez Soto, Robert W. Given, Sabine D. Brookman-May, Suneel D. Mundle, Sharon A. McCarthy, Hirotsugu Uemura, Simon Chowdhury, Kim N. Chi, Anders Bjartell,

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	Apalutamide plus androgen deprivation therapy in clinical subgroups of patients with metastatic castration-sensitive prostate cancer: A subgroup analysis of the randomised clinical TITAN study, <i>European Journal of Cancer</i> , Volume 193, 2023, 113290, ISSN 0959-8049, https://doi.org/10.1016/j.ejca.2023.113290
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