# The YODA Project
# Research Proposal Due Diligence Assessment

| Part 1: General Information | |
|---|---|
| **YODA Project (Protocol) ID:** | 2022-4868 |
| **Date:** | 2 February 2022_Updated 29Jul22 |
| **Product Name:** | Apalutamide / Abiraterone acetate |
| **Therapeutic Area:** | Oncology |
| **Product Class:** | Nonsteroidal antiandrogen / CYP17 inhibitor |
| **Condition(s) Studied:** | Prostatic Neoplasms Prostate Cancer |
| **Protocol Number(s) and Title(s):** | **NCT02257736 - 56021927PCR3001 -** A Phase 3 Randomized, Placebo-controlled Double-blind Study of JNJ-56021927 in Combination With Abiraterone Acetate and Prednisone Versus Abiraterone Acetate and Prednisone in Subjects With Chemotherapy-naive Metastatic Castration-resistant Prostate Cancer (mCRPC)<br>**NCT00887198 - COU-AA-302** - 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 | |
|---|---|
| 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. | No |

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| Comments: | |