

Johnson & Johnson Innovative Medicine	Data Sharing Request Due Diligence Assessment
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General Information	
YODA Project (Protocol) ID:	2025-0508
Date Proposal Received by YODA Project:	14-JUL-2025
Product Name(s):	Apalutamide (Erleada) Abiraterone acetate (ZYTIGA®)
Condition(s) Studied:	Prostate Cancer
NCT Numbers(s), Protocol Number(s) and Title(s):	<p>1. NCT02489318 - 56021927PCR3002 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)</p> <p>2. NCT01715285 - 212082PCR3011 A Randomized, Double-blind, Comparative Study of Abiraterone Acetate Plus Low-Dose Prednisone Plus Androgen Deprivation Therapy (ADT) Versus ADT Alone in Newly Diagnosed Subjects With High-Risk, Metastatic Hormone-naïve Prostate Cancer (mHNPC)</p> <p>3. NCT02236637 - 212082PCR4001 A Prospective Registry of Patients With a Confirmed Diagnosis of Adenocarcinoma of the Prostate Presenting With Metastatic Castrate-Resistant Prostate Cancer</p>
Proposal Review	
Question 1: The clinical trial data from the study/studies listed above were previously identified and approved as being available for a data sharing request. Is there any reason why the study/studies listed should no longer be shared?	No
Comments if 'Yes':	
Question 2: On review of the proposal, is there any data that has been requested that may be missing from the clinical database?	No
Comments if 'Yes':	
Question 3: Is a similar analysis underway, or completed and pending disclosure by J&J?	No
Comments if 'Yes':	