

Johnson&Johnson Innovative Medicine	Data Sharing Request Due Diligence Assessment
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General Information	
YODA Project (Protocol) ID:	2024-0948
Date Proposal Received by YODA Project:	7-Feb-2025
Product Name(s):	Abiraterone acetate (ZYTIGA®) Apalutamide (ERLEADA®)
Condition(s) Studied:	Prostate Cancer, Prostatic Neoplasms
NCT Number(s), Protocol Number(s) and Title(s):	<p>1. 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-naïve Metastatic Castration-resistant Prostate Cancer (mCRPC)</p> <p>2. 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':	