Johnson&Johnson Innovative Medicine	**Data Sharing Request Due Diligence Assessment**

General Information	
YODA Project (Protocol) ID:	2025-0340
Date Proposal Received by YODA Project:	12-May-2025
Product Name(s):	Apalutamide (Erleada) Abiraterone acetate (ZYTIGA®)
Condition(s) Studied:	Prostate Cancer, Prostate Neoplasms
NCT Numbers(s), Protocol Number(s) and Title(s):	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) 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)

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':	