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

General Information	
YODA Project (Protocol) ID:	2025-0120
Date Proposal Received by YODA Project:	15-Feb-2025
Product Name(s):	Paliperidone (INVEGA®) paliperidone palmitate (INVEGA® SUSTENNA®)
Condition(s) Studied:	Schizophrenia
NCT Numbers(s), Protocol Number(s) and Title(s):	1. NCT01662310 - **R076477-SCH-3041** Paliperidone Extended Release Tablets for the Prevention of Relapse in Subjects With Schizophrenia: A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study 2. NCT01529515 - **R092670PSY3012** A Randomized, Multicenter, Double-Blind, Relapse Prevention Study of Paliperidone Palmitate 3 Month Formulation for the Treatment of Subjects With Schizophrenia 3. NCT00086320 - **R076477-SCH-301** A Randomized, Double-blind, Placebo-controlled, Parallel-group Study With an Open-label Extension Evaluating Paliperidone Extended Release Tablets in the Prevention of Recurrence in Subjects With Schizophrenia 4. NCT00111189 - **R092670PSY3001** A Randomized Double-blind Placebo-controlled Parallel Group Study Evaluating Paliperidone Palmitate in the Prevention of Recurrence in Patients With Schizophrenia. Placebo Consists of 20% Intralipid (200 mg/mL) Injectable Emulsion

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':	