The YODA Project
Research Proposal Due Diligence Assessment

Part 1: General Information	
YODA Project (Protocol) ID:	2019-3821
Date:	17 January 2019
Product Name:	Risperidone/ Paliperidone palmitate/Paliperidone
Therapeutic Area:	Neuroscience
Product Class:	atypical antipsychotics
Condition(s) Studied:	Schizophrenia
Protocol Number(s) and Title(s):	**Paliperidone palmitate/Paliperidone:** NCT00397033 R076477SCA3001 NCT00412373 R076477SCA3002 NCT00086320 R076477-SCH-301 NCT00334126 R076477SCH3015 NCT00085748 R076477-SCH-302 NCT00077714 R076477-SCH-304 NCT00083668 R076477-SCH-305 NCT00524043 R076477-SCH-4012 NCT00645307 R076477-SCH-701 NCT00210548 R092670PSY3003 NCT00101634 R092670PSY3004 NCT00590577 R092670PSY3007 NCT00074477 R092670-SCH-201 NCT01299389 PALM-JPN-4 N/A OPTICS Bundle NCT00752427 R076477-SCH-702 NCT00650793 R076477-SCH-703 **Risperidone:** N/A RIS-USA-1 (RIS-USA-9001)

Part 2: Data Availability	
Question:	**Response:**
Data Holder has authority to provide clinical trial data or development partner has agreed to share clinical trial data.	Yes
Comments: N/A	
Data Holder has sharable electronic clinical trial data or data can be converted to electronic format.	Yes
Comments: N/A	
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: N/A	
The product and relevant indication studied has either been approved by regulators in the US and EU, or terminated from development.	Yes
Comments: N/A	
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: N/A	

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Part 3: Data Availability Summary	
Based on the responses to the above Data Availability questions, the requested clinical trial data can be made available for data sharing.	Yes

Part 4: Proposal Review	
Question:	**Response:**
Summary-level CSR data is appropriate for the proposed analysis.	Yes*
Participant-level data is appropriate for the proposed analysis.	Yes
A similar analysis is underway or completed/pending disclosure by Janssen.	No
Comments:	*some of the paliperidone analyses can be done with CSR data, others require patient level data