The YODA Project
Research Proposal Due Diligence Assessment

Part 1: General Information	
YODA Project (Protocol) ID:	2019-4080
Date:	23 January 2020
Product Name:	Risperidone/ Paliperidone/ Paliperidone palmitate
Therapeutic Area:	Neuroscience
Product Class:	atypical antipsychotics
Condition(s) Studied:	Schizophrenia Bipolar I Disorder
Protocol Number(s) and Title(s):	**Paliperidone/ palmitate:** NCT00299715 R076477-BIM-3001 NCT00309699 R076477-BIM-3002 NCT00309686 R076477-BIM-3003 NCT00488319 R076477PSZ3002 NCT00397033 R076477SCA3001 NCT00412373 R076477SCA3002 NCT00334126 R076477SCH3015 NCT00645099 R076477SCH3020 NCT00083668 R076477-SCH-305 NCT00650793 R076477-SCH-703 NCT00111189 R092670PSY3001 NCT00210548 R092670PSY3003 NCT00119756 R092670PSY3005 NCT00604279 R092670PSY3008 NCT00074477 R092670-SCH-201 **Risperidone:** NCT00094926 RIS-BIP-302 NCT00249236 RIS-IND-2 NCT00253162 RIS-INT-69 NCT00495118 RIS-INT-80 NCT00299702 RISSCH4060 NCT00253136 RIS-USA-121 NCT00034749 RIS-USA-231 NCT00257075 RIS-USA-239

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	

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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
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.	No
Participant-level data is appropriate for the proposed analysis.	Yes
A similar analysis is underway or completed/pending disclosure by Janssen.	No
Comments:	