The YODA Project
Research Proposal Due Diligence Assessment

Part 1: General Information	
YODA Project (Protocol) ID:	2019-3978
Date:	2 October 2019
Product Name:	Paliperidone/Risperidone
Therapeutic Area:	Neuroscience
Product Class:	Atypical Antipsychotics
Condition(s) Studied:	Schizophrenia/Schizoaffective Disorder/Bipolar I Disorder
Protocol Number(s) and Title(s):	**Paliperidone/Paliperidone palmitate:** NCT01299389 PALM-JPN-4 NCT00309699 R076477BIM3002 NCT00309686 R076477BIM3003 NCT00490971 R076477-BIM-3004 NCT00518323 R076477PSZ3001 NCT00105326 R076477-SCH-1010 NCT00086320 R076477-SCH-301 NCT00334126 R076477SCH3015 NCT00085748 R076477-SCH-302 NCT00078039 R076477-SCH-303 NCT00077714 R076477-SCH-304 NCT01662310 R076477-SCH-3041 NCT00083668 R076477-SCH-305 NCT00645307 R076477-SCH-701 NCT00752427 R076477-SCH-702 NCT00299715 R076477BIM3001 NCT00397033 R076477SCA3001 NCT00412373 R076477SCA3002 NCT00111189 R092670PSY3001 NCT00210548 R092670PSY3003 NCT00101634 R092670PSY3004 NCT00590577 R092670PSY3007 NCT01529515 R092670PSY3012 NCT01193153 R092670-SCA-3004 NCT00074477 R092670SCH201 **Risperidone:** NCT00132678 RISBIM3003 NCT00076115 RIS-BIM-301 NCT00094926 RIS-BIP-302 NCT00391222 RISBMN3001 NCT00236457 RIS-INT-62 NCT00253162 RIS-INT-69 NCT00088075 RIS-SCH-302 NCT00992407 RISSCH4178 NCT00061802 RIS-SCP-402 NCT00253149 RIS-USA-102 NCT00253136 RIS-USA-121 NCT00257075 RIS-USA-239 NCT00236379 RIS-USA-275 N/A RIS-USA-72

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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	
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.	No
A similar analysis is underway or completed/pending disclosure by Janssen.	No
Comments:	