The YODA Project
Research Proposal Due Diligence Assessment

Part 1: General Information	
YODA Project (Protocol) ID:	2021-4705
Date:	9 July 2021
Product Name:	Risperidone/ Paliperidone
Therapeutic Area:	Neuroscience
Product Class:	Atypical antipsychotics
Condition(s) Studied:	Schizophrenia/ Schizoaffective Disorder
Protocol Number(s) and Title(s):	**Paliperidone/Paliperidone Palmitate:** NCT01299389 PALM-JPN-4 NCT01258920 PALM-JPN-5 NCT00334126 R076477SCH3015 NCT00086320 R076477-SCH-301 NCT00650793 R076477-SCH-703 NCT00460512 R076477SCH3017 NCT00566631 R076477SCH3018 NCT00645099 R076477SCH3020 NCT00078039 R076477-SCH-303 NCT01662310 R076477-SCH-3041 NCT00083668 R076477-SCH-305 NCT00524043 R076477-SCH-4012 NCT00645307 R076477-SCH-701 NCT01157351 R092670SCH3006 NCT00589914 R092670PSY3006 NCT01606228 R076477SCH3033 NCT00111189 R092670PSY3001 NCT00210717 R092670PSY3002 NCT00210548 R092670PSY3003 NCT00101634 R092670PSY3004 NCT00119756 R092670PSY3005 NCT00590577 R092670PSY3007 NCT00604279 R092670PSY3008 NCT01515423 R092670PSY3011 NCT01529515 R092670PSY3012 NCT00074477 R092670-SCH-201 NCT01081769 R092670SCH3005 NCT01051531 R092670SCH3009 NCT01281527 R092670SCH3010 NCT01527305 R092670SCH4009 NCT02713282 R092670SCH3015 **Risperidone:** NCT01299389 PALM-JPN-4 NCT01258920 PALM-JPN-5 NCT00334126 R076477SCH3015 NCT00086320 R076477-SCH-301 NCT00650793 R076477-SCH-703

	NCT00460512 R076477SCH3017 NCT00566631 R076477SCH3018 NCT00645099 R076477SCH3020 NCT00078039 R076477-SCH-303 NCT01662310 R076477-SCH-3041 NCT00083668 R076477-SCH-305 NCT00524043 R076477-SCH-4012 NCT00645307 R076477-SCH-701 NCT01157351 R092670SCH3006 NCT00589914 R092670PSY3006 NCT01606228 R076477SCH3033 NCT00111189 R092670PSY3001 NCT00210717 R092670PSY3002 NCT00210548 R092670PSY3003 NCT00101634 R092670PSY3004 NCT00119756 R092670PSY3005 NCT00590577 R092670PSY3007 NCT00604279 R092670PSY3008 NCT01515423 R092670PSY3011 NCT01529515 R092670PSY3012 NCT00074477 R092670-SCH-201 NCT01081769 R092670SCH3005 NCT01051531 R092670SCH3009 NCT01281527 R092670SCH3010 NCT01527305 R092670SCH4009 NCT02713282 R092670SCH3015

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