The YODA Project
Research Proposal Due Diligence Assessment

Part 1: General Information	
YODA Project (Protocol) ID:	2019-3827
Date:	1 February 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:** N/A OPTICS Bundle NCT00299715 R076477-BIM-3001 NCT00309699 R076477-BIM-3002 NCT00309686 R076477BIM3003 NCT00490971 R076477-BIM-3004 NCT00518323 R076477PSZ3001 NCT00488319 R076477PSZ3002 NCT01009047 R076477PSZ3003 NCT00397033 R076477SCA3001 NCT00412373 R076477SCA3002 NCT00105326 R076477-SCH-1010 NCT00086320 R076477-SCH-301 NCT00334126 R076477SCH3015 NCT00085748 R076477-SCH-302 NCT00645099 R076477SCH3020 NCT00078039 R076477-SCH-303 NCT01606228 R076477SCH3033 NCT00077714 R076477-SCH-304 NCT01662310 R076477-SCH-3041 NCT00083668 R076477-SCH-305 NCT00524043 R076477-SCH-4012 NCT00645307 R076477-SCH-701 NCT00752427 R076477-SCH-702 NCT00650793 R076477-SCH-703 NCT01157351 R092670SCH3006 NCT01299389 PALM-JPN-4 NCT01258920 PALM-JPN-5 NCT00111189 R092670PSY3001 NCT00210717 R092670PSY3002 NCT00210548 R092670PSY3003 NCT00101634 R092670PSY3004 NCT00119756 R092670PSY3005 NCT00589914 R092670PSY3006 NCT00590577 R092670PSY3007 NCT00604279 R092670PSY3008

	NCT01529515 R092670PSY3012 NCT01193153 R092670-SCA-3004 NCT00074477 R092670SCH201 NCT01081769 R092670SCH3005 NCT01051531 R092670SCH3009 NCT01281527 R092670SCH3010 NCT01527305 R092670SCH4009 **Risperidone:** NCT00132678 RISBIM3003 NCT00076115 RIS-BIM-301 NCT00246246 RIS-BIP-301 NCT00094926 RIS-BIP-302 NCT00391222 RISBMN3001 NCT00249236 RIS-IND-2 NCT00249132 RIS-INT-3 NCT00250367 RIS-INT-46 NCT00249223 RIS-INT-61 NCT00253162 RIS-INT-69 NCT00216580 RIS-PSY-301 NCT00216476 RISSCH3001 NCT00088075 RIS-SCH-302 NCT00378092 RISSCH3024 NCT00216632 RISSCH4026 NCT00369239 RISSCH4043 NCT00216671 RISSCH4045 N/A RIS-USA-1 (RIS-USA-9001) NCT00253149 RIS-USA-102 NCT00253136 RIS-USA-121 NCT00034749 RIS-USA-231 NCT00257075 RIS-USA-239 N/A RIS-USA-240 NCT00236379 RIS-USA-275 N/A RIS-USA-72

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:	