The YODA Project
Research Proposal Due Diligence Assessment

Part 1: General Information	
YODA Project (Protocol) ID:	2017-1846
Date:	12 July 2017
Product Name:	Paliperidone/ Paliperidone palmitate
Therapeutic Area:	Neuroscience
Product Class:	atypical antipsychotics
Condition(s) Studied:	Schizophrenia
Protocol Number(s) and Title(s):	**NCT00299715** R076477BIM3001 **NCT00309699** R076477BIM3002 **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 **OPTICS Bundle** **NCT00111189** R092670PSY3001 **NCT00210717** R092670PSY3002 **NCT00210548** R092670PSY3003 **NCT00101634** R092670PSY3004 **NCT00119756** R092670PSY3005 **NCT00589914** R092670PSY3006 **NCT00590577** R092670PSY3007 **NCT00604279** R092670PSY3008 **NCT01529515** R092670PSY3012 **NCT01193153** R092670-SCA-3004 **NCT00074477** R092670SCH201

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

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Research Proposal Due Diligence Assessment

Part 1: General Information	
YODA Project (Protocol) ID:	2017-1846
Date:	12 Jul 2017
Product Name:	Risperidone
Therapeutic Area:	Neuroscience
Product Class:	atypical antipsychotics
Condition(s) Studied:	Schizophrenia
Protocol Number(s) and Title(s):	**NCT00132678** RISBIM3003 **NCT00076115** RIS-BIM-301 **NCT00246246** RIS-BIP-301 **NCT00094926** RIS-BIP-302 **NCT00391222** RISBMN3001 **NCT00250354** RIS-CAN-19 **NCT00261508** RIS-CAN-23 **NCT00249236** RIS-IND-2 **NCT00249132** RIS-INT-3 **NCT00250367** RIS-INT-46 **NCT00253162** RIS-INT-69 **NCT00236444** RIS-INT-79 **NCT00236470** RIS-INT-84 **NCT00216580** RIS-PSY-301 **NCT00216476** RISSCH3001 **NCT00088075** RIS-SCH-302 **NCT00378092** RISSCH3024 **N/A** RIS-USA-1 **NCT00253149** RIS-USA-102 **NCT00253136** RIS-USA-121 **N/A** RIS-USA-150 **NCT00034749** RIS-USA-231 **NCT00257075** RIS-USA-239 **N/A** RIS-USA-240 **N/A** RIS-USA-72 **NCT00266552** RIS-USA-93

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
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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	Yes

regulators in the US and EU, or terminated from development.	
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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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:	