The YODA Project
Research Proposal Due Diligence Assessment

Part 1: General Information	
YODA Project (Protocol) ID:	2020-4521
Date:	7 December 2020
Product Name:	Risperidone/ Paliperidone/ Topiramate
Therapeutic Area:	Neuroscience
Product Class:	Atypical antipsychotics
Condition(s) Studied:	Schizophrenia/Bipolar I Disorder
Protocol Number(s) and Title(s):	**Paliperidone:** **NCT00309699** R076477-BIM-3002 **NCT00309686** R076477-BIM-3003 **NCT00086320** R076477-SCH-301 **NCT00334126** R076477SCH3015 **NCT00645099** R076477SCH3020 **NCT00077714** R076477-SCH-304 **NCT00083668** R076477-SCH-305 **NCT00752427** R076477-SCH-702 **NCT00650793** R076477-SCH-703 **NCT00299715** R076477-BIM-3001 **NCT00111189** R092670PSY3001 **NCT00210717** R092670PSY3002 **NCT00210548** R092670PSY3003 **NCT00101634** R092670PSY3004 **NCT00119756** R092670PSY3005 **NCT00589914** R092670PSY3006 **NCT00590577** R092670PSY3007 **NCT00604279** R092670PSY3008 **NCT00074477** R092670-SCH-201 **NCT00078039** R076477-SCH-303 **Risperidone:** **NCT00132678** RISBIM3003 **NCT00094926** RIS-BIP-302 **NCT00391222** RISBMN3001 **NCT00249132** RIS-INT-3 **NCT00253162** RIS-INT-69 **NCT00378092** RISSCH3024 **Topiramate:** **NCT00237289** CAPSS-168 **NCT00037674** TOPMAT-PDMD-004 **NCT00240721** TOPMAT-PDMD-005 **NCT00035230** TOPMAT-PDMD-008

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

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