The YODA Project
Research Proposal Due Diligence Assessment

Part 1: General Information	
YODA Project (Protocol) ID:	2017-1966
Date:	8 August 2017
Product Name:	Risperidone/ Paliperidone palmitate
Therapeutic Area:	Neuroscience
Product Class:	atypical antipsychotics
Condition(s) Studied:	Schizophrenia
Protocol Number(s) and Title(s):	**Paliperidone palmitate:** NCT00111189 R092670PSY3001 NCT00210717 R092670PSY3002 NCT00210548 R092670PSY3003 NCT00101634 R092670PSY3004 NCT00119756 R092670PSY3005 NCT00589914 R092670PSY3006 NCT00590577 R092670PSY3007 NCT00604279 R092670PSY3008 NCT01529515 R092670PSY3012 NCT01193153 R092670-SCA-3004 NCT00074477 R092670SCH201 **Risperidone:** NCT00216580 RIS-PSY-301 NCT00216476 RISSCH3001

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

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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.	Yes
Comments:	**Factors associated with relapse in schizophrenia despite adherence to long-acting injectable antipsychotic therapy** Alphs, Larry; Nasrallah, Henry A.; Bossie, Cynthia A.; Fu, Dong-Jing; Gopal, Srihari; Hough, David; Turkoz, Ibrahim