

**The YODA Project**  
**Research Proposal Due Diligence Assessment**

<b>Part 1: General Information</b>	
<b>YODA Project (Protocol) ID:</b>	2020-4517
<b>Date:</b>	7 December 2020
<b>Product Name:</b>	Risperidone/ Paliperidone
<b>Therapeutic Area:</b>	Neuroscience
<b>Product Class:</b>	Atypical antipsychotics
<b>Condition(s) Studied:</b>	Schizophrenia
<b>Protocol Number(s) and Title(s):</b>	<a href="#">NCT01009047</a> <a href="#">R076477PSZ3003</a> <a href="#">NCT00086320</a> <a href="#">R076477-SCH-301</a> <a href="#">NCT00645099</a> <a href="#">R076477SCH3020</a> <a href="#">NCT01662310</a> <a href="#">R076477-SCH-3041</a> <a href="#">NCT00111189</a> <a href="#">R092670PSY3001</a> <a href="#">NCT00210717</a> <a href="#">R092670PSY3002</a> <a href="#">NCT01529515</a> <a href="#">R092670PSY3012</a> <a href="#">NCT01193153</a> <a href="#">R092670SCA3004</a> <a href="#">NCT00236457</a> <a href="#">RIS-INT-62</a> <a href="#">NCT00216476</a> <a href="#">RISSCH3001</a> <a href="#">NCT00299702</a> <a href="#">RISSCH4060</a> <a href="#">NCT00992407</a> <a href="#">RISSCH4178</a> <a href="#">NCT00236379</a> <a href="#">RIS-USA-275</a>
<b>Part 2: Data Availability</b>	
<b>Question:</b>	<b>Response:</b>
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	
<b>Part 3: Data Availability Summary</b>	
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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<b>Part 4: Proposal Review</b>	
<b>Question:</b>	<b>Response:</b>
Summary-level CSR data is appropriate for the proposed analysis.	Yes
Participant-level data is appropriate for the proposed analysis.	No
A similar analysis is underway or completed/pending disclosure by Janssen.	No
Comments:	