

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

<b>Part 1: General Information</b>	
<b>YODA Project (Protocol) ID:</b>	2021-4754
<b>Date:</b>	6 October 2021
<b>Product Name:</b>	Risperidone/ Paliperidone
<b>Therapeutic Area:</b>	Neuroscience
<b>Product Class:</b>	Atypical antipsychotics
<b>Condition(s) Studied:</b>	Schizophrenia/ Schizoaffective Disorder
<b>Protocol Number(s) and Title(s):</b>	<p><b>Paliperidone/Paliperidone Palmitate:</b></p> <p>NCT01299389 PALM-JPN-4  NCT01258920 PALM-JPN-5  NCT00518323 R076477PSZ3001  NCT00488319 R076477PSZ3002  NCT01009047 R076477PSZ3003  NCT00397033 R076477SCA3001  NCT00412373 R076477SCA3002  NCT00105326 R076477-SCH-1010  NCT00086320 R076477-SCH-301  NCT00334126 R076477SCH3015  NCT00460512 R076477SCH3017  NCT00566631 R076477SCH3018  NCT00085748 R076477-SCH-302  NCT00645099 R076477SCH3020  NCT00078039 R076477-SCH-303  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  NCT00111189 R092670PSY3001  NCT00210717 R092670PSY3002  NCT00210548 R092670PSY3003  NCT00101634 R092670PSY3004  NCT00119756 R092670PSY3005  NCT00589914 R092670PSY3006  NCT00590577 R092670PSY3007  NCT00604279 R092670PSY3008  NCT01515423 R092670PSY3011  NCT01529515 R092670PSY3012  NCT01193153 R092670SCA3004  NCT00074477 R092670-SCH-201  NCT01081769 R092670SCH3005  NCT01157351 R092670SCH3006  NCT01051531 R092670SCH3009  NCT01281527 R092670SCH3010</p>

## The YODA Project

### Research Proposal Due Diligence Assessment

	<p>NCT02713282 R092670SCH3015 NCT01527305 R092670SCH4009</p> <p><b>Risperidone:</b></p> <p>NCT00249145 RIS-INT-24 NCT00249132 RIS-INT-3 NCT00249223 RIS-INT-61 NCT00236457 RIS-INT-62 NCT00236444 RIS-INT-79 NCT00495118 RIS-INT-80 N/A RIS-INT-85 NCT00044681 RIS-INT-93 NCT01050582 RISNAP4022 NCT00216580 RIS-PSY-301 NCT00821600 RIS-SCH-1012 NCT00216476 RISSCH3001 NCT00088075 RIS-SCH-302 NCT00378092 RISSCH3024 NCT00297388 RIS-SCH-401 NCT00216632 RISSCH4026 NCT00369239 RISSCH4043 NCT00216671 RISSCH4045 NCT00299702 RISSCH4060 NCT00253136 RIS-USA-121 NCT00034749 RIS-USA-231 NCT00034775 RIS-USA-259 NCT00236587 RIS-USA-265 NCT00236379 RIS-USA-275 N/A RIS-USA-72 NCT00266552 RIS-USA-93</p>
<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

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

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	
<b>Part 4: Proposal Review</b>		
<b>Question:</b>	<b>Response:</b>	
Summary-level CSR data is appropriate for the proposed analysis.	No	
Participant-level data is appropriate for the proposed analysis.	Yes/No*	
No* list of studies includes studies in patients who did not have schizophrenia: RIS-INT-79 RIS-USA-93 RIS-INT-24 RIS-INT-93		
A similar analysis is underway or completed/pending disclosure by Janssen.	No	
Comments:		