

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

<b>Part 1: General Information</b>	
<b>YODA Project (Protocol) ID:</b>	2019-3958
<b>Date:</b>	19 August 2019
<b>Product Name:</b>	Methylphenidate HCl/Paliperidone/Risperidone/Topiramate
<b>Therapeutic Area:</b>	Neuroscience
<b>Product Class:</b>	Stimulants/ADHD/Anorexiant/Atypical Antipsychotics/Anticonvulsants
<b>Condition(s) Studied:</b>	Attention Deficit Hyperactivity Disorder/Schizophrenia/Anxiety, Autistic, Bipolar, Major Depressive Disorders/Epilepsy
<b>Protocol Number(s) and Title(s):</b>	<p><b>Methylphenidate HCl:</b></p> <p><b>NCT00326391</b> 02-159  <b>NCT00866996</b> 12-101  <b>NCT00326300</b> 12-304  <b>NCT00246220</b> 42603ATT3002  <b>NCT00307684</b> 42603ATT3004  <b>NCT00714688</b> 42603ATT3013  <b>NCT00246233</b> 42603MDD3001 (CON-CAN-3)  <b>NCT00269815</b> C98012  <b>NCT00937040</b> CONCERTA-ATT-3014  <b>NCT00799409</b> CONCERTA-ATT-4069  <b>NCT00799487</b> CONCERTA-ATT-4080  <b>NCT01323192</b> JNS001-JPN-A01</p> <p><b>Paliperidone/Paliperidone palmitate:</b></p> <p>N/A OPTICS Bundle  <b>NCT00299715</b> R076477BIM3001  <b>NCT00309699</b> R076477BIM3002  <b>NCT00309686</b> R076477BIM3003  <b>NCT00490971</b> R076477-BIM-3004  <b>NCT00518323</b> R076477PSZ3001  <b>NCT00488319</b> R076477PSZ3002  <b>NCT01009047</b> R076477PSZ3003  <b>NCT00397033</b> R076477SCA3001  <b>NCT00412373</b> R076477SCA3002  <b>NCT00105326</b> R076477-SCH-1010  <b>NCT00086320</b> R076477-SCH-301  <b>NCT00334126</b> R076477SCH3015  <b>NCT00085748</b> R076477-SCH-302  <b>NCT00645099</b> R076477SCH3020  <b>NCT00078039</b> R076477-SCH-303  <b>NCT01606228</b> R076477SCH3033  <b>NCT00077714</b> R076477-SCH-304  <b>NCT01662310</b> R076477-SCH-3041  <b>NCT00083668</b> R076477-SCH-305  <b>NCT00524043</b> R076477-SCH-4012  <b>NCT00645307</b> R076477-SCH-701</p>

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<b>NCT00752427</b>	R076477-SCH-702
<b>NCT00650793</b>	R076477-SCH-703
<b>NCT01157351</b>	R092670SCH3006
<b>NCT01299389</b>	PALM-JPN-4
<b>NCT01258920</b>	PALM-JPN-5
<b>NCT00111189</b>	R092670PSY3001
<b>NCT00210717</b>	R092670PSY3002
<b>NCT00210548</b>	R092670PSY3003
<b>NCT00101634</b>	R092670PSY3004
<b>NCT00119756</b>	R092670PSY3005
<b>NCT00589914</b>	R092670PSY3006
<b>NCT00590577</b>	R092670PSY3007
<b>NCT00604279</b>	R092670PSY3008
<b>NCT01529515</b>	R092670PSY3012
<b>NCT01193153</b>	R092670-SCA-3004
<b>NCT00074477</b>	R092670SCH201
<b>NCT01081769</b>	R092670SCH3005
<b>NCT01051531</b>	R092670SCH3009
<b>NCT01281527</b>	R092670SCH3010
<b>NCT01527305</b>	R092670SCH4009
<b>Risperidone:</b>	
<b>NCT00086112</b>	RIS-ANX-301
<b>NCT00576732</b>	RISAUT4002
<b>NCT00132678</b>	RISBIM3003
<b>NCT00076115</b>	RIS-BIM-301
<b>NCT00246246</b>	RIS-BIP-301
<b>NCT00094926</b>	RIS-BIP-302
<b>NCT00391222</b>	RISBMN3001
<b>NCT00250354</b>	RIS-CAN-19
<b>NCT00261508</b>	RIS-CAN-23
<b>NCT00249236</b>	RIS-IND-2
<b>NCT00249132</b>	RIS-INT-3
<b>NCT00250367</b>	RIS-INT-46
<b>NCT00249223</b>	RIS-INT-61
<b>NCT00236457</b>	RIS-INT-62
<b>NCT00253162</b>	RIS-INT-69
<b>NCT00236444</b>	RIS-INT-79
<b>NCT00495118</b>	RIS-INT-80
<b>NCT00236470</b>	RIS-INT-84
<b>NCT00044681</b>	RIS-INT-93
<b>NCT00269919</b>	RIS-KOR-64
<b>NCT00216528</b>	RIS-KOR-66
<b>NCT01050582</b>	RISNAP4022
<b>NCT00216580</b>	RIS-PSY-301
<b>NCT00821600</b>	RIS-SCH-1012
<b>NCT00216476</b>	RISSCH3001
<b>NCT00088075</b>	RIS-SCH-302
<b>NCT00378092</b>	RISSCH3024

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	<p><b>NCT00297388</b> RIS-SCH-401  <b>NCT00216632</b> RISSCH4026  <b>NCT00369239</b> RISSCH4043  <b>NCT00216671</b> RISSCH4045  <b>NCT00299702</b> RISSCH4060  <b>NCT00526877</b> RISSCH4119  <b>NCT00992407</b> RISSCH4178  <b>NCT01855074</b> RISSCH4186  <b>N/A</b> RIS-USA-1 (RIS-USA-9001)  <b>NCT00253149</b> RIS-USA-102  <b>NCT00253136</b> RIS-USA-121  <b>N/A</b> RIS-USA-150  <b>NCT00034749</b> RIS-USA-231  <b>NCT00257075</b> RIS-USA-239  <b>N/A</b> RIS-USA-240  <b>NCT00236587</b> RIS-USA-265  <b>NCT00236379</b> RIS-USA-275  <b>NCT00236353</b> RIS-USA-305  <b>N/A</b> RIS-USA-72  <b>NCT00266552</b> RIS-USA-93</p> <p><b>Topamax:</b>  <b>NCT00210782</b> CAPSS-272  <b>NCT00237289</b> CAPSS-168  <b>NCT00240721</b> TOPMAT-PDMD-005  <b>NCT00037674</b> TOPMAT-PDMD-004  <b>NCT00035230</b> TOPMAT-PDMD-008  <b>N/A</b> TOPMAT-PDMD-006  <b>N/A</b> YP</p>
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<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	

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<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>	
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:	