### Part 1: General Information

<table>
<thead>
<tr>
<th>YODA Project (Protocol) ID:</th>
<th>2022-4992</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date:</td>
<td>8 July 2022</td>
</tr>
<tr>
<td>Product Name:</td>
<td>Risperidone/ Paliperidone</td>
</tr>
<tr>
<td>Therapeutic Area:</td>
<td>Neuroscience</td>
</tr>
<tr>
<td>Product Class:</td>
<td>Atypical antipsychotics</td>
</tr>
<tr>
<td>Condition(s) Studied:</td>
<td>Schizophrenia/ Schizoaffective Disorder</td>
</tr>
</tbody>
</table>
| Protocol Number(s) and Title(s): | NCT00077714 R076477-SCH-304  
NCT00078039 R076477-SCH-303  
NCT00083668 R076477-SCH-305  
NCT00085748 R076477-SCH-302  
NCT00086320 R076477-SCH-301  
NCT00105326 R076477-SCH-1010  
NCT00309686 R076477-BIM-3003  
NCT00309699 R076477-BIM-3002  
NCT00334126 R076477SCH3015  
NCT00397033 R076477SCA3001  
NCT00412373 R076477SCA3002  
NCT00460512 R076477SCH3017  
NCT00488319 R076477PSZ3002  
NCT00490971 R076477-BIM-3004  
NCT00518323 R076477PSZ3001  
NCT00524043 R076477-SCH-4012  
NCT00566631 R076477SCH3018  
NCT00645099 R076477SCH3020  
NCT00645307 R076477-SCH-701  
NCT00650793 R076477-SCH-703  
NCT00752427 R076477-SCH-702  
NCT01009047 R076477PSZ3003  
NCT01258920 PALM-JPN-5  
NCT01299389 PALM-JPN-4  
NCT01662310 R076477-SCH-3041  
NCT0299715 R076477-BIM-3001  
NCT0074477 R092670-SCH-201  
NCT00101634 R092670PSY3004  
NCT00111189 R092670PSY3001  
NCT00119756 R092670PSY3005  
NCT00210548 R092670PSY3003  
NCT00210717 R092670PSY3002  
NCT00589914 R092670PSY3006  
NCT00590577 R092670PSY3007  
NCT00604279 R092670PSY3008  
NCT01051531 R092670SCH3009  
NCT01081769 R092670SCH3005  
NCT01157351 R092670SCH3006  
NCT01193153 R092670-SCA-3004 |
| NCT01281527 | R092670SCH3010 |
| NCT01515423 | R092670PSY3011 |
| NCT01527305 | R092670SCH4009 |
| NCT01529515 | R092670PSY3012 |
| NCT01606228 | R076477SCH3033 |
| NCT01624675 | R092670SCH3015 |
| NCT01624675 | RIS-AUT-JPN-01 |
| NCT N/A      | RIS-INT-85     |
| NCT0034749   | RIS-USA-231    |
| NCT0034762   | RIS-USA-232    |
| NCT0034775   | RIS-USA-259    |
| NCT0044681   | RIS-INT-93     |
| NCT0061802   | RIS-SCP-402    |
| NCT0076115   | RIS-BIM-301    |
| NCT0086112   | RIS-ANX-301    |
| NCT0088075   | RIS-SCH-302    |
| NCT0094926   | RIS-BIP-302    |
| NCT0095134   | RIS-DEP-401    |
| NCT0132678   | RISBIM3003     |
| NCT0216476   | RISSCH3001     |
| NCT0216528   | RIS-KOR-66     |
| NCT0216580   | RIS-PSY-301    |
| NCT0216632   | RISSCH4026     |
| NCT0216671   | RISSCH4045     |
| NCT0236353   | RIS-USA-305    |
| NCT0236379   | RIS-USA-275    |
| NCT0236444   | RIS-INT-79     |
| NCT0236457   | RIS-INT-62     |
| NCT0236470   | RIS-INT-84     |
| NCT0236587   | RIS-USA-265    |
| NCT0246246   | RIS-BIP-301    |
| NCT0249132   | RIS-INT-3      |
| NCT0249145   | RIS-INT-24     |
| NCT0249158   | RIS-AUS-5      |
| NCT0249223   | RIS-INT-61     |
| NCT0249236   | RIS-IND-2      |
| NCT0250354   | RIS-CAN-19     |
| NCT0250367   | RIS-INT-46     |
| NCT0253123   | RIS-USA-63     |
| NCT0253136   | RIS-USA-121    |
| NCT0253149   | RIS-USA-102    |
| NCT0253162   | RIS-INT-69     |
| NCT0257075   | RIS-USA-239    |
| NCT0261508   | RIS-CAN-23     |
| NCT0266552   | RIS-USA-93     |
| NCT0269919   | RIS-KOR-64     |
| NCT0297388   | RIS-SCH-401    |
| NCT0299702   | RISSCH4060     |
| NCT0369239   | RISSCH4043     |
| NCT0378092   | RISSCH3024     |
### The YODA Project
#### Research Proposal Due Diligence Assessment

<table>
<thead>
<tr>
<th>NCT00391222</th>
<th>RISBMN3001</th>
</tr>
</thead>
<tbody>
<tr>
<td>NCT00495118</td>
<td>RIS-INT-80</td>
</tr>
<tr>
<td>NCT00526877</td>
<td>RISSCH4119</td>
</tr>
<tr>
<td>NCT00576732</td>
<td>RISAUT4002</td>
</tr>
<tr>
<td>NCT00821600</td>
<td>RIS-SCH-1012</td>
</tr>
<tr>
<td>NCT00992407</td>
<td>RISSCH4178</td>
</tr>
<tr>
<td>NCT01050582</td>
<td>RISNAP4022</td>
</tr>
<tr>
<td>NCT01855074</td>
<td>RISSCH4186</td>
</tr>
<tr>
<td>NCT N/A</td>
<td>RIS-INT-83</td>
</tr>
<tr>
<td>NCT N/A</td>
<td>RIS-USA-1</td>
</tr>
<tr>
<td>NCT N/A</td>
<td>RIS-USA-150</td>
</tr>
<tr>
<td>NCT N/A</td>
<td>RIS-USA-240</td>
</tr>
<tr>
<td>NCT N/A</td>
<td>RIS-USA-72</td>
</tr>
<tr>
<td>NCT N/A</td>
<td>RIS-BEL-14</td>
</tr>
<tr>
<td>NCT N/A</td>
<td>RIS-USA-70</td>
</tr>
</tbody>
</table>

### Part 2: Data Availability

<table>
<thead>
<tr>
<th>Question</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data Holder has authority to provide clinical trial data or development partner has agreed to share clinical trial data.</td>
<td>Yes</td>
</tr>
<tr>
<td>Comments: N/A</td>
<td></td>
</tr>
<tr>
<td>Data Holder has sharable electronic clinical trial data or data can be converted to electronic format.</td>
<td>Yes</td>
</tr>
<tr>
<td>Comments: N/A</td>
<td></td>
</tr>
<tr>
<td>De-identification and redaction of clinical trial data in accordance with current HIPAA and EU criteria allows protection of participant privacy and confidentiality.</td>
<td>Yes</td>
</tr>
<tr>
<td>Comments: N/A</td>
<td></td>
</tr>
<tr>
<td>The product and relevant indication studied has either been approved by regulators in the US and EU, or terminated from development.</td>
<td>Yes</td>
</tr>
<tr>
<td>Comments: N/A</td>
<td></td>
</tr>
<tr>
<td>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).</td>
<td>Yes</td>
</tr>
<tr>
<td>Comments: N/A</td>
<td></td>
</tr>
</tbody>
</table>

### 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

<table>
<thead>
<tr>
<th>Question</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Summary-level CSR data is appropriate for the proposed analysis.</td>
<td>No</td>
</tr>
<tr>
<td>Participant-level data is appropriate for the proposed analysis.</td>
<td>Yes</td>
</tr>
<tr>
<td>A similar analysis is underway or completed/pending disclosure by Janssen.</td>
<td>No</td>
</tr>
<tr>
<td>Comments:</td>
<td></td>
</tr>
</tbody>
</table>