# The YODA Project
## Research Proposal Due Diligence Assessment

### Part 1: General Information

<table>
<thead>
<tr>
<th>YODA Project (Protocol) ID:</th>
<th>2020-4517</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date:</td>
<td>7 December 2020</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</td>
</tr>
</tbody>
</table>

**Protocol Number(s) and Title(s):**

- NCT01009047 R076477PSZ3003
- NCT00086320 R076477-SCH-301
- NCT00645099 R076477SCH3020
- NCT01662310 R076477-SCH-3041
- NCT00111189 R092670PSY3001
- NCT00210717 R092670PSY3002
- NCT01529515 R092670PSY3012
- NCT01193153 R092670SCH3004
- NCT00236457 RIS-INT-62
- NCT00216476 RISSCH3001
- NCT00299702 RISSCH4060
- NCT00992407 RISSCH4178
- NCT00236379 RIS-USA-275

### Part 2: Data Availability

**Question:** Data Holder has authority to provide clinical trial data or development partner has agreed to share clinical trial data.  
**Response:** Yes  
**Comments:** N/A

**Question:** Data Holder has sharable electronic clinical trial data or data can be converted to electronic format.  
**Response:** Yes  
**Comments:** N/A

**Question:** De-identification and redaction of clinical trial data in accordance with current HIPAA and EU criteria allows protection of participant privacy and confidentiality.  
**Response:** Yes  
**Comments:** N/A

**Question:** The product and relevant indication studied has either been approved by regulators in the US and EU, or terminated from development.  
**Response:** Yes  
**Comments:** N/A

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

Comments: