# The YODA Project
# Research Proposal Due Diligence Assessment

| Part 1: General Information | |
|---|---|
| **YODA Project (Protocol) ID:** | 2022-4854 |
| **Date:** | 2 February 2022 |
| **Product Name:** | Paliperidone Palmitate |
| **Therapeutic Area:** | Neuroscience |
| **Product Class:** | Atypical antipsychotics |
| **Condition(s) Studied:** | Schizophrenia |
| **Protocol Number(s) and Title(s):** | **NCT00589914 - R092670PSY3006 -** A Randomized Double-Blind Parallel-Group Comparative Study of flexible Doses of Paliperidone Palmitate and flexible Doses of Risperidone Long Acting Intramuscular Injection in Subjects With Schizophrenia<br>**NCT00604279 - R092670PSY3008 -** A Randomized Open-Lable Parallel Group Comparaitve Study of Paliperidone PaImitate (50 100 150 mg eg) and Risperidone LAI (25 37.5 or 50 mg) in Subjects with Schizophrenia<br>**NCT00210717 - R092670PSY3002 -** A Randomized Double-Blind Parallel Group Comparative Study of flexibly Dosed Paliperidone Palmitate (25 50 75 or 100 mg eg) Administered Every 4 Weeks and Flexibly Dosed RISPERDAL CONSTA (25 37.5 or 50 mg) Administered every 2 Weeks in Subjects With Schizophrenia |

| Part 2: Data Availability | |
|---|---|
| **Question:** | **Response:** |
| 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 | |

| 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 |
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| 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: | |