# The YODA Project
# Research Proposal Due Diligence Assessment

| Part 1: General Information | |
|---|---|
| **YODA Project (Protocol) ID:** | 2019-4078 |
| **Date:** | 11 December 2019 |
| **Product Name:** | Paliperidone Palmitate |
| **Therapeutic Area:** | Neuroscience |
| **Product Class:** | Atypical Antipsychotics |
| **Condition(s) Studied:** | Schizophrenia/Schizoaffective Disorder |
| **Protocol Number(s) and Title(s):** | NCT00111189 R092670PSY3001<br>NCT01529515 R092670PSY3012<br>NCT01193153 R092670-SCA-3004 |

| 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 | |
|---|---|
| **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: | |