# The YODA Project
# Research Proposal Due Diligence Assessment

| Part 1: General Information | |
|---|---|
| **YODA Project (Protocol) ID:** | 2021-4637 |
| **Date:** | 27 April 2021 |
| **Product Name:** | Esketamine |
| **Therapeutic Area:** | Neuroscience |
| **Product Class:** | NMDA receptor antagonist |
| **Condition(s) Studied:** | Treatment Resistant Depressive Disorder |
| **Protocol Number(s) and Title(s):** | **NCT02417064** ESKETINTRD3001 A Randomized, Double-blind, Multicenter, Active-controlled Study to Evaluate the Efficacy, Safety, and Tolerability of Flexible Doses of Intranasal Esketamine Plus an Oral Antidepressant in Adult Subjects With Treatment-resistant Depression<br>**NCT02493868** ESKETINTRD3003 A Randomized, Double-blind, Multicenter, Active-Controlled Study of Intranasal Esketamine Plus an Oral Antidepressant for Relapse Prevention in Treatment-resistant Depression<br>**NCT02497287** ESKETINTRD3004 An Open-label, Long-term, Safety and Efficacy Study of Intranasal Esketamine in Treatment-resistant Depression |

| 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 |
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| 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: | |