# The YODA Project
## Research Proposal Due Diligence Assessment

### Part 1: General Information

<table>
<thead>
<tr>
<th>YODA Project (Protocol) ID:</th>
<th>2016-1005</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date:</td>
<td>16Aug16</td>
</tr>
<tr>
<td>Product Name:</td>
<td>INVEGA, INVEGA SUSTENNA, RISPERDAL</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>
<tr>
<td>Protocol Number(s) and Title(s):</td>
<td></td>
</tr>
<tr>
<td>NCT00391222 - A Randomized, Double Blind, Placebo and Active Controlled Parallel Group Study to Evaluate the Efficacy and Safety of Risperidone Long-acting Injectable (LAI) for the Prevention of Mood Episodes in the Treatment of Subjects With Bipolar I</td>
<td></td>
</tr>
<tr>
<td>NCT00034749 - The Efficacy and Safety of Risperidone in Adolescents With Schizophrenia: a Comparison of Two Dose Ranges of Risperidone</td>
<td></td>
</tr>
<tr>
<td>NCT00076115 - Research on the Effectiveness of Risperidone in Bipolar Disorder in Adolescents and Children (REACH): A Double-Blind, Randomized, Placebo-Controlled Study of the Efficacy and Safety of Risperidone for the Treatment of Acute Mania in Bipolar</td>
<td></td>
</tr>
<tr>
<td>NCT00132678 - A Randomized, Double-blind, Placebo-controlled Study to Explore the Efficacy and Safety of Risperidone Long-acting Intramuscular Injectable in the Prevention of Mood Episodes in Bipolar 1 Disorder, With Open-label Extension</td>
<td></td>
</tr>
<tr>
<td>NCT00249132 - A Canadian multicenter placebo-controlled study of fixed doses of risperidone and haloperidol in the treatment of chronic schizophrenic patients</td>
<td></td>
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<tr>
<td>NCT00216476 - CONSTATRE: Risperdal® Consta® Trial of Relapse Prevention and Effectiveness</td>
<td></td>
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<tr>
<td>NCT00216580 - An Open-label Trial of Risperidone Long-acting Injectable in the Treatment of Subjects With Recent Onset Psychosis</td>
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<tr>
<td>NCT00253162 - The Efficacy And Safety Of Flexible Dose Ranges Of Risperidone Versus Placebo Or Haloperidol In The Treatment Of Manic Episodes Associated With Bipolar I Disorder.</td>
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<tr>
<td>NCT00378092 - A Prospective Study of the Clinical Outcome Following Treatment Discontinuation After Remission in First-Episode Schizophrenia</td>
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<tr>
<td>NCT00488319 - A 2-Year, Open-Label, Single-Arm Safety Study of Flexibly Dosed Paliperidone Extended Release (1.5-12 mg/day) in the Treatment of Adolescents (12 to 17 Years of Age) With Schizophrenia</td>
<td></td>
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<tr>
<td>NCT01009047 - A Randomized, Multicenter, Double-Blind, Active-Controlled, Flexible-Dose, Parallel-Group Study of the Efficacy and Safety of Prolonged Release Paliperidone for the Treatment of Symptoms of Schizophrenia in Adolescent Subjects, 12 to 17 Years</td>
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<tr>
<td>NCT00645099 - A Prospective Randomized Open-label 6-Month Head-To-Head Trial to Compare Metabolic Effects of Paliperidone ER and Olanzapine in Subjects With Schizophrenia</td>
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<tr>
<td>NCT00518323 - A Randomized, Multicenter, Double-Blind, Weight-Based, Fixed-Dose, Parallel-Group, Placebo-Controlled Study of the</td>
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Efficacy and Safety of Extended Release Paliperidone for the Treatment of Schizophrenia in Adolescent Subjects, 12 to 17 Years

NCT00334126- A Randomized, Double-blind, Placebo-controlled, Parallel Group Study to Evaluate the Efficacy and Safety of Paliperidone ER Compared to Quetiapine in Subjects With an Acute Exacerbation of Schizophrenia

NCT00086320- A Randomized, Double-blind, Placebo-controlled, Parallel-group Study With an Open-label Extension Evaluating Paliperidone Extended Release Tablets in the Prevention of Recurrence in Subjects With Schizophrenia

NCT00650793- A Randomized, DB, PC and AC, Parallel Group, Dose-Response Study to Evaluate the Efficacy and Safety of 3 Fixed Dosages of Extended Release OROS Paliperidone (6, 9, 12 mg/Day) and Olanzapine (10mg/Day), With Open-Label Extension, in the T

NCT00589914- 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

NCT00604279- A Randomized, Open-Label, Parallel Group Comparative Study of Paliperidone Palmitate (50,100, 150 mg eq) and Risperidone LAI (25, 37.5, or 50 mg) in Subjects with Schizophrenia

NCT00590577- A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Dose Response Study to Evaluate the Efficacy and Safety of 3 Fixed Doses (25 mg eq., 100 mg eq., and 150 mg eq.) of Paliperidone Palmitate in Subjects With Schizophrenia

NCT00111189- A Randomized Double-blind Placebo-controlled Parallel Group Study Evaluating Paliperidone Palmitate in the Prevention of Recurrence in Patients With Schizophrenia. Placebo Consists of 20% Intralipid (200mg/mL) Injectable Emulsion

NCT00210717- A Randomized, Double-Blind, Parallel Group, Comparative Study of Flexibly Dosed Paliperidone Palmitate (25, 50, 75, or 100 mg eq.) Administered Every 4 Weeks and Flexibly Dosed RISPERDAL CONSTA (25,37.5, or 50 mg) Administered Every 2 Weeks

NCT00119756- A Randomized, Crossover Study to Evaluate the Overall Safety and Tolerability of Paliperidone Palmitate Injected in the Deltoid or Gluteus Muscle in Patients With Schizophrenia

NCT00210548- A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Dose-Response Study to Evaluate the Efficacy and Safety of 3 Fixed Doses (50 mg eq., 100 mg eq., and 150 mg eq.) of Paliperidone Palmitate in Subjects With Schizophrenia

NCT00101634- A Randomized, Double-blind, Placebo-controlled, Parallel-group, Dose-response Study to Evaluate the Efficacy and Safety of 3 Fixed Doses (25 mg eq, 50 mg eq, and 100 mg eq) of Paliperidone Palmitate in Patients With Schizophrenia

NCT00397033- A Randomized, Double-blind, Placebo-controlled, Parallel-group Study to Evaluate the Efficacy and Safety of Two Dosages of Paliperidone ER in the Treatment of Patients With Schizoaffective Disorder

NCT00412373- A Randomized, Double-blind, Placebo-controlled, Parallel-Group Study to Evaluate the Efficacy and Safety of Flexible-
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dose Paliperidone ER in the Treatment of Patients With Schizoaffective Disorder

**NCT00299715** - A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Dose-Response, Multicenter Study to Evaluate the Efficacy and Safety of Three Fixed Doses of Extended-Release Paliperidone in the Treatment of Subjects With Acute Manic and Mi

**NCT00309699** - A Randomized, Double-Blind, Active- and Placebo-Controlled, Parallel-Group, Multicenter Study to Evaluate the Efficacy and Safety of Flexibly-Dosed, Extended-Release Paliperidone Compared With Flexibly-Dosed Quetiapine and Placebo in the T

**NCT00309686** - A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multicenter Study to Evaluate the Efficacy and Safety of Flexibly-Dosed Extended-Release Paliperidone as Adjunctive Therapy to Mood Stabilizers in the Treatment of Acute Manic

**NCT00752427** - 24 week extension of NCT00085748: A Randomized, 6-Week Double-Blind, Placebo-Controlled Study With an Optional 24-Week Open-Label Extension to Evaluate the Safety and Tolerability of Flexible Doses of Paliperidone Extended Release in the T

**NCT00083668** - A Randomized, Double-blind, Placebo- and Active-controlled, Parallel-group, Dose-response Study to Evaluate the Efficacy and Safety of 3 Fixed Dosages of Paliperidone Extended Release (ER) Tablets and Olanzapine, With Open-label Extension,

**NCT00074477** - A Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of 50 and 100 Mg-eq of Paliperidone Palmitate in Patients With Schizophrenia

**NCT00078039** - Trial Evaluating Three Fixed Dosages of Paliperidone Extended-Release (ER) Tablets and Olanzapine in the Treatment of Patients With Schizophrenia

**NCT00085748** - A Randomized, 6-Week Double-Blind, Placebo-Controlled Study With an Optional 24-Week Open-Label Extension to Evaluate the Safety and Tolerability of Flexible Doses of Paliperidone Extended Release in the Treatment of Geriatric Patients Wit

**NCT01529515** - A Randomized, Multicenter, Double-Blind, Relapse Prevention Study of Paliperidone Palmitate 3 Month Formulation for the Treatment of Subjects With Schizophrenia

**NCT01193153** - A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study of Paliperidone Palmitate Evaluating Time to Relapse in Subjects With Schizoaffective Disorder

**NCT01662310** - Paliperidone Extended Release Tablets for the Prevention of Relapse in Subjects With Schizophrenia: A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study


<table>
<thead>
<tr>
<th>Part 2: Data Availability</th>
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<tbody>
<tr>
<td><strong>Question:</strong> Data Holder has authority to provide clinical trial data or development partner has agreed to share clinical trial data.</td>
</tr>
<tr>
<td>Comments:</td>
</tr>
</tbody>
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<thead>
<tr>
<th>Question</th>
<th>Response</th>
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<tbody>
<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>
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<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>
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<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>
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<tr>
<td>Comments: N/A</td>
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<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>
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<td>Comments: N/A</td>
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#### 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.

#### Part 4: Proposal Review

<table>
<thead>
<tr>
<th>Question</th>
<th>Response</th>
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</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>
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</table>