The YODA Project
Research Proposal Due Diligence Assessment

Part 1: General Information	
YODA Project (Protocol) ID:	2024-0556
Date:	May 30, 2024
Product Name:	INVEGA SUSTENNA/Xeplion, INVEGA TRINZA/Trevicta, INVEGA HAFYERA/Byannli and RISPERDAL Consta
Therapeutic Area:	Neuroscience
Product Class:	Antipsychotics
Condition(s) Studied:	Schizophrenia/Schizoaffective disorder
Protocol Number(s) and Title(s):	1. NCT03345342 - R092670PSY3015: A Double-blind, Randomized, Active-controlled, Parallel-group Study of Paliperidone Palmitate 6-Month Formulation 2. NCT01559272 - R092670PSY1005: A Single-Dose, Open-Label, Randomized, Parallel-Group Study to Assess the Pharmacokinetics, Safety, and Tolerability of a Paliperidone Palmitate 3-Month Formulation in Subjects With Schizophrenia 3. NCT02713282 - R092670SCH3015: A 52-Week, Open-Label, Prospective, Multicenter, International Study of a Transition to the Paliperidone Palmitate 3-Month Formulation In Patients With Schizophrenia Previously Stabilized on the Paliperidone Palmitate 1-Month Formulation 4. NCT01515423 - R092670PSY3011 - A Randomized, Multicenter, Double-Blind, Non-inferiority Study of Paliperidone Palmitate 3 Month and 1 Month Formulations for the Treatment of Subjects With Schizophrenia 5. NCT01157351 - R092670SCH3006 - A Fifteen-month, Prospective, Randomized, Activecontrolled, Open-label, Flexible Dose Study of Paliperidone Palmitate Compared With Oral Antipsychotic Treatment in Delaying Time to Treatment Failure in Adults With Schizophrenia Who Have Been Incarcerated 6. NCT00111189 - R092670PSY3001 - 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 (200 mg/mL) Injectable Emulsion 7. NCT00210717 - R092670PSY3002 - 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 in Subjects With Schizophrenia 8. NCT00119756 - R092670PSY3005 - 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 9. NCT01529515 - R092670PSY3012 - A Randomized, Multicenter, Double-Blind, Relapse Prevention Study of Paliperidone Palmitate 3 Month Formulation for the Treatment of Subjects With Schizophrenia 10. NCT01193153 - R092670SCA3004 - A Randomized, Double-Blind, Placebo-Controlled, Parellel- Group Study of Paliperidone Palmitate Evaluating Time to Relapse in Subjects With Schizoaffective Disorder 11. NCT01081769 - R092670SCH3005 - A 24-month, Prospective, Randomized, Active-Controlled, Open-Label, Rater-Blinded, Multicenter, International Study of the Prevention of Relapse Comparing Long-Acting Injectable Paliperidone Palmitate to Treatment as Usual With Oral Antipsychotic Monotherapy in Adults With Schizophrenia 12. NCT01051531 - R092670SCH3009 - Safety, Tolerability, and Treatment Response of Paliperidone Palmitate in Subjects With Schizophrenia When Switching From Oral Antipsychotics 13. NCT01258920 - PALM-JPN-5 - A Long-Term, Open-Label Study of Flexibly Dosed Paliperidone Palmitate Long-Acting Intramuscular Injection in Japanese Patients With Schizophrenia 14. NCT00216476 - RISSCH3001 - CONSTATRE: Risperdal® Consta® Trial of Relapse Prevention and Effectiveness 15. NCT00216671 - RISSCH4045 - Early Versus Late Initiation of Treatment With Risperdal Consta in Subjects With Schizophrenia After an Acute Episode 16. NCT00369239 - RISSCH4043 - Is Premorbid Functioning a Predictor of Outcome in Patients With Early Onset Psychosis Treated With Risperdal Consta? 17. NCT00216632 - RISSCH4026 - Treatment Success in Patients Requiring Treatment Change From Olanzapine to Risperidone Long Acting Injectable (TRESOR) 18. NCT00216528 - RIS-KOR-66 - A Prospective, Open-Label Study to Evaluate Symptomatic Remission in Schizophrenia With Long Acting Risperidone Microspheres (Risperdal Consta) 19. NCT00269919 - RIS-KOR-64 - Effect on Efficacy, Safety and Quality of Life by Long-Term Treatment of Long-

	Acting Risperidone Microspheres in Patients With Schizophrenia 20. NCT00992407 - RISSCH4178 - A Randomized, Open-label, Active-controlled Study to Evaluate Social Functioning of Long Acting Injectable Risperidone and Oral Risperidone in the Treatment of Subjects With Schizophrenia or Schizoaffective Disorder 21. NCT00236353 - RIS-USA-305 - An Open-label Study of the Efficacy and Safety of RISPERDAL Long-acting Microspheres (RISPERDAL CONSTA) Administered Once Monthly in Adults With Schizophrenia or Schizoaffective Disorder 22. NCT00495118 - RIS-INT-80 - Risperidone Depot (Microspheres) in the Treatment of Subjects With Schizophrenia or Schizoaffective Disorder - an Open-label Follow-up Trial of RIS-INT-62 and RIS-INT-85 23. NCT01855074 - RISSCH4186 - Evaluation of Efficacy and Safety of Risperidone in Long-acting Microspheres in Patients With Schizophrenia, Schizophreniform or Schizoaffective Disorders Diagnosed According to the DSM-IV Criteria, After Switching Treatment With Any Antipsychotic Therapy With Long-acting Microspheres of Risperidone 24. NCT00236457 - RIS-INT-62 - Randomized, Multi-center, Open Label Trial Comparing Risperidone Depot (Microspheres) and Olanzapine Tablets in Patients With Schizophrenia or Schizoaffective Disorder 25. NCT00236587 - RIS-USA-265 - An Open Label, Long Term Trial of Risperidone Long Acting Microspheres in the Treatment of Patients Diagnosed With Schizophrenia 26. NCT00297388 - RIS-SCH-401 - A 52-wk Prospective, Randomized, Double-blind, Multicenter Study of Relapse Following Transition From Oral Antipsychotic Medication to 2 Different Doses (25 or 50 mg Every 2 Wks) of Risperidone Long-acting Microspheres (RISPERDAL CONSTA) in Adults With Schizophrenia or Schizoaffective Disorder 27. NCT00299702 - RISSCH4060 - A 2-year, Prospective, Blinded-rater, Open-label, Activecontrolled, Multicenter, Randomized Study of Long-term Efficacy and Effectiveness Comparing Risperdal® Consta® and Abilify® (Aripiprazole) in Adults With Schizophrenia 28. NCT00526877 - RISSCH4119 (RISC-TWN-MA10) - Evaluation of Efficacy and Safety of Long acting Risperidone Microspheres in Patients With Schizophrenia or Schizoaffective Disorders, Who is Receiving Psychiatric Home-care Treatment, When Switching From

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	Typical Depot or Oral Antipsychotics to Long-acting Risperidone Microspheres

Part 2: Data Availability	
Data Holder has authority to provide clinical trial data or development partner has agreed to share clinical trial data.	Yes
Comments:	
Data Holder has sharable electronic clinical trial data or data can be converted to electronic format.	Yes
Comments:	
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:	
The product and relevant indication studied has either been approved by regulators in the US and EU, or terminated from development.	Yes
Comments:	
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:	
Part 3: Data Availability Summary	
Based on the responses to the above Data Availability questions, the requested clinical trial data are available for a data sharing request.	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:	Better if they avoided open label studies