The YODA Project
Research Proposal Due Diligence Assessment

Part 1: General Information	
YODA Project (Protocol) ID:	2021-4575
Date:	26 February 2021
Product Name:	Risperidone
Therapeutic Area:	Neuroscience
Product Class:	Stimulants/ADHD/Anorexiants/Atypical Antipsychotics/Anticonvulsants
Condition(s) Studied:	Anxiety Disorder/Schizophrenia/Autistic disorder, Bipolar I Disorder/Alzheimer's Disease/ Dementia
Protocol Number(s) and Title(s):	**1. NCT00391222 - RISBMN3001** - 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 Disorder **2. NCT00034749 - RIS-USA-231** - The Efficacy and Safety of Risperidone in Adolescents With Schizophrenia: a Comparison of Two Dose Ranges of Risperidone **3. NCT00132678 - RISBIM3003** - 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 **4. NCT00094926 - RIS-BIP-302** - A Prospective, Randomized, Double-blind, Placebo-controlled Study of the Effectiveness and Safety of RISPERDAL CONSTA Augmentation in Adult Patients With Frequently relapsing Bipolar Disorder **5. NCT00249132 - RIS-INT-3** - A Canadian multicenter placebo-controlled study of fixed doses of risperidone and haloperidol in the treatment of chronic schizophrenic patients **6. NCT00216476 - RISSCH3001** - CONSTATRE: Risperdal® Consta® Trial of Relapse Prevention and Effectiveness **7. NCT00253162 - RIS-INT-69** - 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 **8. RIS-INT-83** - Efficacy and safety of a flexible dose of risperidone versus placebo in the treatment of psychosis of Alzheimer's disease. A double-blind, placebo-controlled, parallel-group study. **9. NCT00088075 - RIS-SCH-302/CR003370** - A Randomized, Double-Blind, Placebo-Controlled Clinical Study of the Efficacy and Safety of Risperidone for the Treatment of Schizophrenia in Adolescents **10. RIS-USA-1 (RIS-USA-9001)** - Risperidone versus haloperidol versus placebo in the treatment of schizophrenia **11. NCT00253149 - RIS-USA-102/CR006040** - The Safety And Efficacy Of Risperdal (Risperidone) Versus Placebo Versus Haloperidol As Add-On Therapy To Mood Stabilizers In The Treatment Of The Manic Phase Of Bipolar Disorder **12. NCT00253136 - RIS-USA-121/CR006055** - Risperidone Depot (Microspheres) vs. Placebo in the Treatment of Subjects With Schizophrenia **13. RIS-USA-150** - A double-blind, placebo-controlled study of risperidone in children and adolescents with autistic disorder

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	14. NCT00034762 - RIS-USA-232/CR002764 - Efficacy And Safety Of A Flexible Dose Of Risperidone Versus Placebo In The Treatment Of Psychosis Of Alzheimer's Disease **15. NCT00257075 - RIS-USA-239/CR006052** - The Efficacy And Safety Of Flexible Dosage Ranges Of Risperidone Versus Placebo In The Treatment Of Manic Episodes Associated With Bipolar I Disorder **16. NCT00253123 - RIS-USA-63/CR006022** - A Randomized, Double-Blind, Placebo-Controlled Study of Risperidone for Treatment of Behavioral Disturbances in Subjects With Dementia **17. RIS-USA-72** - The safety and efficacy of risperidone 8 mg qd and 4 mg qd compared to placebo in the treatment of schizophrenia **18. NCT00216671 - RISSCH4045** - Early Versus Late Initiation of Treatment With Risperdal Consta in Subjects With Schizophrenia After an Acute Episode **19. NCT00086112 - RIS-ANX-301** - A Double-blind, Randomized, Prospective Study to Evaluate Adjunctive Risperidone Versus Adjunctive Placebo in Generalized Anxiety Disorder Sub-optimally Responsive to Standard Psychotropic Therapy **20. NCT00236457 - RIS-INT-62** - Randomized, Multi-center, Open Label Trial Comparing Risperidone Depot (Microspheres) and Olanzapine Tablets in Patients With Schizophrenia or Schizoaffective Disorder

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:	