The YODA Project
Research Proposal Due Diligence Assessment

Part 1: General Information	
YODA Project (Protocol) ID:	2024 – 0492
Date:	May 7, 2024
Product Name:	Risperdal
Therapeutic Area:	Neuroscience
Product Class:	Atypical antipsychotics
Condition(s) Studied:	Dementia/Alzheimer Disease
Protocol Number(s) and Title(s):	1. NCT00249158 - RIS-AUS-5/CR006010: Risperidone in the Treatment of Behavioural and Psychological Signs and Symptoms in Dementia (BPSSD): a Multicentre, Double-blind, Placebo-controlled Parallel-group Trial 2. RIS-BEL-14 3. NCT00249145 - RIS-INT-24/CR006046: Risperidone in the Treatment of Behavioral Disturbances in Demented Patients: an International, Multicenter, Placebo-controlled, Double-blind, Parallel-group Trial Using Haloperidol as Internal Reference 4. NCT00253123 - RIS-USA-63/CR006022: A Randomized, Double-Blind, Placebo-Controlled Study of Risperidone for Treatment of Behavioral Disturbances in Subjects With Dementia 5. RIS-USA-70 (EXTENSION OF RIS-USA-63) CR003361, RIS-USA-T216 6. RIS-INT-83 7. 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.

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:	

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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:	Janssen completed several analyses of these trials (some at patient level) to address the question of the risk of stroke and mortality with risperidone. These are marked UNPUBLISHED STRICTLY CONFIDENTIAL and were conducted to support labeling. They have not been published.