

General Information	
YODA Project (Protocol) ID:	2025-0168
Date Proposal Received by YODA Project:	20-Mar-2025
Product Name(s):	Risperidone (RISPERDAL)
Condition(s) Studied:	Dementia, Alzheimer Disease, Behavior Disorder in Demetia of the Alzheimer type
NCT Numbers(s), Protocol Number(s) and Title(s):	<ol style="list-style-type: none"> 1. NO NCT#- RIS-USA-70 (EXTENSION OF RIS-USA-63) CR003361, RIS-USA-T216 An open-label, long-term study of risperidone for the treatment of behavioral disturbances in patients with dementia 2. NO NCT#- RIS-INT-83 Efficacy and safety of a flexible dose of risperisone versus placebo in the treatment of psychosis of Alzheimer’s disease. A double-blind, placebo-controlled, parallel-group study. 3. 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 4. NCT00249145 - RIS-INT-24/CR006046 Risperidone in the Treatment of Behavioral Disturbances in Demented Patients: an International, Multicenter, Placebo-controlled, Doubleblind, Parallel-group Trial Using Haloperidol as Internal Reference 5. 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 6. NCT00253123 - RIS-USA-63/CR006022 A Randomized, Double-Blind, Placebo-Controlled Study of Risperidone for Treatment of Behavioral Disturbances in Subjects With Dementia 7. RIS-BEL-14 Risperidone in the treatment of behavioural disturbances in patients with Alzheimer's dementia: a double-blind placebo-controlled trial
Proposal Review	
Question 1: The clinical trial data from the study/studies listed above were previously identified and approved as being available for a data sharing request. Is there any reason why the study/studies listed should no longer be shared?	No
Comments if 'Yes':	
Question 2: On review of the proposal, is there any data that has been requested that may be missing from the clinical database?	No

Johnson & Johnson Innovative Medicine	Data Sharing Request Due Diligence Assessment
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Comments if 'Yes':		
Question 3:	Is a similar analysis underway, or completed and pending disclosure by J&J?	No
Comments if 'Yes':		