The YODA Project
Research Proposal Due Diligence Assessment

Part 1: General Information	
YODA Project (Protocol) ID:	2024-0840
Date:	8-Oct-2024
Product Name:	RAZADYNE (galantamine)
Therapeutic Area:	Neuroscience
Product Class:	Alzheimer's Disease – Cholinesterase Inhibitors
Condition(s) Studied:	Alzheimer Disease
Protocol Number(s) and Title(s):	1. NO NCT# : **GAL-USA-10** Placebo-controlled evaluation of galantamine in the treatment of Alzheimer's disease: Evaluation of safety and efficacy under a slow titration regimen 2. NCT00645190 : **GAL-CHN-T100** A Randomized, Double Blind, Active Control, Flexible Dose, Multicenter Study to Evaluate Galantamine HBr in the Treatment of Alzheimer's Disease:Safety and Effectiveness of an Immediate-release Table Formulation. 3. NCT00216593 : **GAL-ALZ-302** Treatment of Severe Alzheimer's Disease in a Residential Home, Nursing Home, or Geriatric Residential Setting: Evaluation of Efficacy and Safety of Galantamine Hydrobromide in a Randomised, Doubleblind, Placebo-Controlled Study 4. NCT00679627 : **GALALZ3005** A Randomized, Double-Blind, Placebo-controlled Trial of Long-term (2-year) Treatment of Galantamine in Mild to Moderately-Severe Alzheimer's Disease 5. NCT00253214 : **GAL-INT-10** Placebo-Controlled Evaluation of Galantamine in the Treatment of Alzheimer's Disease: Safety and Efficacy of a Controlled-Release Formulation 6. NO NCT# : **GAL-93-01** A group comparative, placebo-controlled, double-blind trial of the efficacy and safety of galantamine hydrobromide, 7.5 mg (6 mg galantamine base) TID, 10 mg (8 mg galantamine base) TID and 15 mg (12 mg galantamine base) TID taken orally for 12 weeks in patients with a diagnosis of senile dementia of the Alzheimer's type 7. NCT00253227 : **GAL-INT-2** Galantamine in the Treatment of Alzheimer's Disease: Flexible Dose Range Trial

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:	