The YODA Project
Research Proposal Due Diligence Assessment

Part 1: General Information	
YODA Project (Protocol) ID:	2016-0765
Date:	8 June 2016 (Updated 15Jun16)
Product Name:	Galantamine
Therapeutic Area:	Neuroscience
Product Class:	Acetylcholinesterase
Condition(s) Studied:	Alzheimer's
Protocol Number(s) and Title(s):	**NCT00253201**- Efficacy, Tolerability and Safety of Galantamine in the Treatment of Alzheimer's Disease **NCT00304629** - Long Term Safety and Efficacy of Galantamine in Alzheimer's Disease (Extension INT-8) **NCT00253227** - Galantamine in the Treatment of Alzheimer's Disease: Flexible Dose Range Trial **No NCT#/**GAL-INT-3-Long Term Safety and Efficacy of Galantamine in the treatment of Alzheimer's Disease **No NCT#/**GAL-INT-7- Long Term Safety and Efficacy of Galantamine in the treatment of Alzheimer's Disease **NCT00261573** - The Safety and Efficacy of Galantamine in the Treatment of Vascular and Mixed Dementia **NCT00253188** - Efficacy, Tolerability and Safety of Galantamine in the Treatment of Alzheimer's Disease **NCT00253214** - Placebo-Controlled Evaluation of Galantamine in the Treatment of Alzheimer's Disease: Safety and Efficacy of a Controlled-Release Formulation **NCT00236574** - A Randomized Double Blind Placebo-Controlled Trial to Evaluate the Efficacy and Safety of Galantamine in Patients With Mild Cognitive Impairment (MCI) Clinically at Risk for Development of Clinically Probable Alzheimer's Disease **NCT00236431** - A Randomized Double-Blind Placebo-Controlled Trial to Evaluate the Efficacy and Safety of Galantamine in Patients With Mild Cognitive Impairment (MCI) Clinically at Risk for Development of Clinically Probable Alzheimer's Disease **No NCT#/** GAL-MVD-301-A long-term comparison of galantamine and donepezil in the treatment of Alzheimer's disease **No NCT#/** GAL-MVD-302-Galantamine treatment of vascular dementia: a randomized trial

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 shareable electronic clinical trial data or data can be converted to electronic format.	Yes
Comments: N/A	

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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.	Yes
Participant-level data is appropriate for the proposed analysis.	Yes
A similar analysis is underway or completed/pending disclosure by Janssen.	No
Comments:	