

The YODA Project
Research Proposal Due Diligence Assessment

Part 1: General Information	
YODA Project (Protocol) ID:	2020-4324
Date:	21 July 2020
Product Name:	Galantamine
Therapeutic Area:	Neuroscience
Product Class:	AZ Disease - Cholinesterase Inhibitors
Condition(s) Studied:	Alzheimer Disease
Protocol Number(s) and Title(s):	<p>NCT00253214 GAL-INT-10 Placebo-Controlled Evaluation of Galantamine in the Treatment of Alzheimer's Disease: Safety and Efficacy of a Controlled-Release Formulation</p> <p>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</p> <p>NCT00253227 GAL-INT-2 Galantamine in the Treatment of Alzheimer's Disease: Flexible Dose Range Trial</p>
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.	Yes
Participant-level data is appropriate for the proposed analysis.	Yes
A similar analysis is underway or completed/pending disclosure by Janssen.	No

The YODA Project
Research Proposal Due Diligence Assessment

Comments:	
-----------	--