The YODA Project
Research Proposal Due Diligence Assessment

Part 1: General Information	
YODA Project (Protocol) ID:	2017-1746
Date:	12 Jul 2017
Product Name:	Galantamine/Risperidone/Topiramate/Ustekinumab/ Infliximab/ Golimumab/ Canagliflozin
Therapeutic Area:	Neuroscience/Immunology/ Metabolism
Product Class:	Acetylcholinesterase inhibitor/ atypical antipsychotics/ antiepileptic (AED) agent/ mAB anti-IL12 / anti-IL23/ Tumor necrosis factor (TNF) blocker/ SGLT-2 inhibitor/
Condition(s) Studied:	Alzheimer's, Dementia, Migraine, Psoriasis, Crohn's Disease, Psoriatic Arthritis, Rheumatoid Arthritis/ Type 2 Diabetes
Protocol Number(s) and Title(s):	**Galantamine/Risperidone/Topiramate:** NCT00216593 GAL-ALZ-302 NCT00236574 GAL-INT-11 NCT00236431 GAL-INT-18 NCT00034762 RIS-USA-232 NCT00210912 CAPSS-276 NCT00212810 CAPSS-381 NCT00236509 TOPMAT-MIGR-001 NCT00231595 TOPMAT-MIGR-002 NCT00236561 TOPMAT-MIGR-003 **Ustekinumab:** NCT00267969 C0743T08 NCT00307437 C0743T09 NCT01369329 CNTO1275CRD3001 NCT01369342 CNTO1275CRD3002 NCT01369355 CNTO1275CRD3003 NCT01009086 CNTO1275PSA3001 NCT01077362 CNTO1275PSA3002 **Golimumab:** NCT00264537 C0524T05 NCT00264550 C0524T06 NCT00265096 C0524T08 NCT00265083 C0524T09 NCT00299546 C0524T11 NCT00361335 C0524T12 NCT00487539 C0524T17 NCT00488631 C0524T18 NCT00973479 CNTO148ART3001 **Infliximab:** NCT00207662 C0168T21 NCT00207766 C0168T26 NCT00236028 C0168T29 NCT00036439 C0168T37 NCT00096655 C0168T46 NCT00094458 C0168T67 **Canagliflozin:**

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	NCT01106625 28431754DIA3002 NCT01081834 28431754DIA3005 NCT01106677 28431754DIA3006 NCT00968812 28431754DIA3009 NCT01106651 28431754DIA3010 NCT01106690 28431754DIA3012 NCT01137812 28431754DIA3015

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