The YODA Project
Research Proposal Due Diligence Assessment

Part 1: General Information	
YODA Project (Protocol) ID:	2020-4276
Date:	10 July 2020
Product Name:	Topiramate
Therapeutic Area:	Neuroscience
Product Class:	Anticonvulsants
Condition(s) Studied:	Bipolar Disorder/Epilepsy/Migraine/Seizures/Obesity/Alcohol Dependence
Protocol Number(s) and Title(s):	**NCT00237302** CAPSS-122 **NCT00253175** CAPSS-155 **NCT00237289** CAPSS-168 **NCT00210808** CAPSS-220 **NCT00210782** CAPSS-272 **NCT00210912** CAPSS-276 **NCT00210821** CAPSS-277 **NCT00210925** CAPSS-278 **NCT00210496** CAPSS-334 **NCT00212810** CAPSS-381 (INTREPID) **NCT00230698** TOPMAT-EPMN-104 **NCT00231556** TOPMAT-EPMN-106 **NCT00216606** TOPMAT-MIG-201 **NCT00210535** TOPMATMIG3006 **NCT00236509** TOPMAT-MIGR-001 **NCT00231595** TOPMAT-MIGR-002 **NCT00236561** TOPMAT-MIGR-003 **NCT00231647** TOPMAT-OBD-202 **NCT00231621** TOPMAT-OBDL-001 **NCT00236626** TOPMAT-OBDM-001 **NCT00231660** TOPMAT-OBDM-002 **NCT00231530** TOPMAT-OBDM-003 **NCT00231634** TOPMAT-OBDM-004 **NCT00236639** TOPMAT-OBES-002 **NCT00236600** TOPMAT-OBES-004 **NCT00236665** TOPMAT-OBHT-001 **NCT00231608** TOPMAT-OBMA-001 **NCT00037674** TOPMAT-PDMD-004 **NCT00240721** TOPMAT-PDMD-005 **N/A** TOPMAT-PDMD-006 **NCT00035230** TOPMAT-PDMD-008 **NCT00035802** TOPMAT-PDMD-009 **NCT00113815** TOPMATPEP3001 **NCT00236860** Y3 (CC2604-C-103) **NCT00236756** YL **N/A** YP **NCT00236704** YTC **NCT00236418** YTCE

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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.	No
A similar analysis is underway or completed/pending disclosure by Janssen.	No
Comments:	