The YODA Project
Research Proposal Due Diligence Assessment

Part 1: General Information	
YODA Project (Protocol) ID:	2023-5226
Date:	12 September 2023
Product Name:	Topiramate
Therapeutic Area:	Neuroscience
Product Class:	Antiepileptic (AED) agent
Condition(s) Studied:	Epilepsy
Protocol Number(s) and Title(s):	1. NCT00231556 – A Randomized, Double-Blind, Parallel-Group, Monotherapy Study to Compare the Safety and Efficacy of Two Doses of Topiramate in the Treatment of Newly Diagnosed or Recurrent Epilepsy 2. NCT00236418 – Topiramate Clinical Trial in Primary Generalized Tonic-Clonic Seizures 3. NCT00236704 – Topiramate Clinical Trial in Primary Generalized Tonic-Clonic Seizures 4. NCT00236847 – Double-Blind, Parallel Comparison of Topiramate 300mg Twice Daily to Placebo in Patients With Refractory Partial Epilepsy 5. NCT00236756 – A Double-Blind Trial of Topiramate in Subjects with Lennox-Gastaut Syndrome 6. NCT00236730 – Double-Blind Parallel Comparison of Three Doses of Topiramate and Placebo in Refractory Partial Epilepsy 7. NCT00236873 - Double-Blind Parallel Comparison of Topiramate 200 mg Twice Daily to Placebo in Patients With Refractory Partial Epilepsy 8. NCT00236860 - Double-Blind Parallel Comparison of Topiramate 400 mg Twice Daily to Placebo in Patients With Refractory Partial Epilepsy

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:	

The YODA Project
Research Proposal Due Diligence Assessment

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:	