Due Diligence Assessment – Research Proposal

Part 1: General Information	
YODA Project (Protocol) ID:	2022-4952
Date:	3 May 2022
Product Name:	Topiramate
Therapeutic Area:	Neuroscience
Product Class:	Anticonvulsants
Condition(s) Studied:	Migraine
Protocol Number(s) and Title(s):	**NCT00210535 - TOPMATMIG3006** - A Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Topiramate for the Prophylaxis of Migraine in Pediatric Subjects 12 to 17 Years of Age **NCT00210860 - CAPSS-296** - An Open-label Study of the Safety and Efficacy of Topiramate for Migraine Prophylaxis: Extension Study to CAPSS-277 **NCT00236509 - TOPMAT-MIGR-001** - A Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Dose-Response Study to Evaluate the Efficacy and Safety of Topiramate in the Prophylaxis of Migraine **NCT00231595 - TOPMAT-MIGR-002** - A Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Dose-Response Study to Evaluate the Efficacy and Safety of Topiramate in the Prophylaxis of Migraine **NCT00236561 - TOPMAT-MIGR-003** - A Randomized, Double-Blind, Parallel-Group, Dose-Response Study to Evaluate the Efficacy and Safety of Two Doses of Topiramate Compared to Placebo and Propranolol in the Prophylaxis of Migraine **NCT00216606 - TOPMAT-MIG-201** - A Randomized Double-Blind Placebo Controlled Trial to Investigate the Efficacy and Tolerability of Topiramate in the Prophylaxis of Chronic Migraine **NCT00212810 - CAPSS-381 (INTREPID)** - TOPAMAX (Topiramate) Intervention to Prevent Transformation of Episodic Migraine: The Topiramate INTREPID Study **NCT00210912 - CAPSS-276** - A Comparison of the Efficacy and Safety of Topiramate Versus Placebo for the Prophylaxis of Chronic Migraine **NCT00216619 - TOPMAT-MIG-303** - A Double-Blind, Randomized, Placebo-Controlled, Multicenter Trial to Investigate the Efficacy and Tolerability of Topiramate in Prolonged Migraine Prevention **NCT00237302 - CAPSS-122** - A Comparison of the Efficacy and Safety of Topiramate Versus Placebo for the Prophylaxis of Migraine in Pediatric Subjects **NCT00210821 - CAPSS-277** - A Comparison of Topiramate Versus Amitriptyline in Migraine Prophylaxis **NCT00210496 - CAPSS-334** - Efficacy of AXERT (Almotriptan Malate) in the Acute Treatment of Migraine: A Pilot Study of the Potential Impact of Preventive Therapy With TOPAMAX (Topiramate) **NCT00253175 - CAPSS-155** - A Comparison Of The Efficacy And Safety Of Topamax® (Topiramate) Tablets Versus Placebo For The Prophylaxis Of Migraine
Part 2: Data Availability	

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