

Johnson & Johnson Innovative Medicine	Data Sharing Request Due Diligence Assessment
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General Information	
YODA Project (Protocol) ID:	2025-0260
Date Proposal Received by YODA Project:	01-May-2025
Product Name(s):	INVOKANA and TOPAMAX®
Condition(s) Studied:	Obesity, Obesity Diabetes Mellitus, Type 2 Diabetes Mellitus, Adult Onset Obesity Hypertension Obesity/Binge-Eating Disorder
NCT Numbers(s), Protocol Number(s) and Title(s):	<p>1. NCT00650806 - 28431754OBE2001 A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Dose-Ranging Study to Investigate the Safety and Efficacy of JNJ-28431754 in Nondiabetic Overweight and Obese Subjects</p> <p>2. NCT02243202 - 28431754OBE2002 A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Investigate the Safety and Efficacy of the Co-administration of Canagliflozin 300 mg and Phentermine 15 mg Compared With Placebo for the Treatment of Non-diabetic Overweight and Obese Subjects</p> <p>3. NCT00236639 - TOPMAT-OBES-002 A Randomized, Double-Blind, Placebo-Controlled, Multicenter, Parallel Group, Dose-Response Study to Assess the Efficacy and Safety of Topiramate in the Treatment of Patients With Obesity</p> <p>4. NCT00236600 - TOPMAT-OBES-004 A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study of Efficacy and Safety of Topiramate in Weight Loss Maintenance in Obese Patients Following Participation in an Intensive, Non-Pharmacologic Weight Loss Program</p> <p>5. NCT00231530 - TOPMAT-OBDM-003 A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Assess the Safety and Efficacy of Topiramate in the Treatment of Obese, Type 2 Diabetic Patients on a Controlled Diet</p> <p>6. NCT00236665 - TOPMAT-OBHT-001 A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel Group Study of the Efficacy and Safety of Topiramate in the Treatment of Obese Patients With Mild to Moderate Essential Hypertension</p> <p>7. NCT00210808 - CAPSS-220 A Multicenter, Randomized, Double-blind, Placebo-controlled,</p>

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	<p>Flexible-dose Study to Assess the Safety and Efficacy of Topiramate in the Treatment of Moderate to Severe Binge-eating Disorder Associated With Obesity</p> <p>8. NCT00231647 - TOPMAT-OB2-202 A Randomized, Double-Blind, Placebo-Controlled, Multicenter, Parallel-Group Study to Assess the Efficacy and Safety of Topiramate OROS Controlled-Release in the Treatment of Obese, Type 2 Diabetic Subjects Managed With Diet or Metformin</p> <p>9. NCT00231621 - TOPMAT-OB2L-001 A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel Group, One-year Study of the Efficacy and Safety of Topiramate in the Treatment of Obese Subjects With Dyslipidemia</p> <p>10. NCT00236626 - TOPMAT-OBDM-001 A 9 Month, Double-Blind, Placebo-Controlled Study With a Blinded Crossover Transition to Open-Label Extension, Evaluating the Safety and Effectiveness of Topiramate on Insulin Sensitivity in Overweight or Obese Type 2 Diabetes Patients</p> <p>11. NCT00231660 - TOPMAT-OBDM-002 A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study of the Efficacy and Safety of Topiramate in the Treatment of Obese, Type 2 Diabetic Patients Treated With Metformin</p> <p>12. NCT00231634 - TOPMAT-OBDM-004 A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel Group Study of the Efficacy and Safety of Topiramate in the Treatment of Obese, Type 2 Diabetic Patients Inadequately Controlled on Sulfonylurea Therapy</p> <p>13. NCT00231608 - TOPMAT-OBMA-001 The Safety and Efficacy of Topiramate in Male Patients With Abdominal Obesity: A 6-Month Double-Blind, Randomized, Placebo-Controlled Study With a 6-Month Open-Label Extension</p> <p>14. NCT00236613 - TOPMAT-OBES-001 A Randomized, Double-Blind, Placebo-Controlled, Multicenter, Parallel Group, Dose-Response Study to Assess the Efficacy and Safety of Topiramate in the Treatment of Patients With Obesity</p>
Proposal Review	
Question 1:	No

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The clinical trial data from the study/studies listed above were previously identified and approved as being available for a data sharing request. Is there any reason why the study/studies listed should no longer be shared?		
Comments if 'Yes':		
Question 2: On review of the proposal, is there any data that has been requested that may be missing from the clinical database?		No
Comments if 'Yes':		
Question 3: Is a similar analysis underway, or completed and pending disclosure by J&J?		No
Comments if 'Yes':		