

<b>General Information</b>	
<b>YODA Project (Protocol) ID:</b>	2025-0088
<b>Date Proposal Received by YODA Project:</b>	6-Feb-2025
<b>Product Name(s):</b>	Canagliflozin (INVOKANA®)
<b>Condition(s) Studied:</b>	Diabetes Mellitus, Type 2 Obesity
<b>NCT Numbers(s), Protocol Number(s) and Title(s):</b>	<ol style="list-style-type: none"> <li>1. NCT00642278 - <b>28431754DIA2001</b> A Randomized, Double-Blind, Placebo-Controlled, Double-Dummy, Parallel Group, Multicenter, Dose-Ranging Study in Subjects With Type 2 Diabetes Mellitus to Evaluate the Efficacy, Safety, and Tolerability of Orally Administered SGLT2 Inhibitor JNJ-28431754 With Sitagliptin as a Reference Arm</li> <li>2. NCT01106625 - <b>28431754DIA3002</b> A Randomized, Double-Blind, Placebo-Controlled, 3-Arm, Parallel-Group, Multicenter Study to Evaluate the Efficacy, Safety, and Tolerability of Canagliflozin in the Treatment of Subjects With Type 2 Diabetes Mellitus With Inadequate Glycemic Control on Metformin and Pioglitazone Therapy</li> <li>3. NCT01064414 - <b>28431754DIA3004</b> A Randomized, Double-Blind, Placebo-Controlled, 3-Arm, Parallel-Group, 26-Week, Multicenter Study With a 26-Week Extension, to Evaluate the Efficacy, Safety and Tolerability of Canagliflozin in the Treatment of Subjects With Type 2 Diabetes Mellitus Who Have Moderate Renal Impairment</li> <li>4. NCT01081834 - <b>28431754DIA3005</b> A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multicenter Study to Evaluate the Efficacy, Safety, and Tolerability of Canagliflozin as Monotherapy in the Treatment of Subjects With Type 2 Diabetes Mellitus Inadequately Controlled With Diet and Exercise</li> <li>5. NCT01106677 - <b>28431754DIA3006</b> A Randomized, Double-Blind, Placebo and Active-Controlled, 4-Arm, Parallel Group, Multicenter Study to Evaluate the Efficacy, Safety, and Tolerability of Canagliflozin in the Treatment of Subjects With Type 2 Diabetes Mellitus With Inadequate Glycemic Control on Metformin Monotherapy</li> <li>6. NCT00968812 - <b>28431754DIA3009</b> A Randomized, Double-Blind, 3-Arm Parallel-Group, 2-Year (104-Week), Multicenter Study to Evaluate the Efficacy, Safety, and Tolerability of JNJ-28431754 Compared With Glimepiride in the Treatment of Subjects With Type 2 Diabetes Mellitus Not Optimally Controlled on Metformin Monotherapy</li> <li>7. NCT01106651 - <b>28431754DIA3010</b> A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multicenter Study to Evaluate the Efficacy, Safety, and Tolerability</li> </ol>

of Canagliflozin Compared With Placebo in the Treatment of Older Subjects With Type 2 Diabetes Mellitus Inadequately Controlled on Glucose Lowering Therapy

8. NCT01106690 - **28431754DIA3012**

A Randomized, Double-Blind, Placebo-Controlled, 3-Arm, Parallel-Group, Multicenter Study to Evaluate the Efficacy, Safety, and Tolerability of Canagliflozin in the Treatment of Subjects With Type 2 Diabetes Mellitus With Inadequate Glycemic Control on Metformin and Sulphonylurea Therapy

9. NCT01137812 - **28431754DIA3015**

A Randomized, Double-Blind, Active-Controlled, Multicenter Study to Evaluate the Efficacy, Safety, and Tolerability of Canagliflozin Versus Sitagliptin in the Treatment of Subjects With Type 2 Diabetes Mellitus With Inadequate Glycemic Control on Metformin and Sulphonylurea Therapy

10. NCT01809327 - **28431754DIA3011**

A Randomized, Double-Blind, 5-Arm, Parallel-Group, 26-Week, Multicenter Study to Evaluate the Efficacy, Safety, and Tolerability of Canagliflozin in Combination With Metformin as Initial Combination Therapy in the Treatment of Subjects With Type 2 Diabetes Mellitus With Inadequate Glycemic Control With Diet and Exercise

11. NCT01381900 - **28431754DIA3014**

A Randomized, Double-Blind, Placebo-Controlled, Parallel Group, 18-Week Study to Evaluate the Efficacy, Safety, and Tolerability of Canagliflozin in the Treatment of Subjects With Type 2 Diabetes Mellitus With Inadequate Glycemic Control on Metformin Alone or in Combination With a Sulphonylurea

12. NCT01340664 - **28431754DIA2003**

A Randomized, Double-Blind, Placebo-Controlled, 3-Arm, Parallel-Group, Multicenter Study to Evaluate the Efficacy, Safety, and Tolerability of Canagliflozin in the Treatment of Subjects With Type 2 Diabetes Mellitus With Inadequate Glycemic Control on Metformin

13. NCT02025907 - **28431754DIA4004**

A Randomized, Double-blind, Placebo Controlled, 2-arm, Parallel-group, 26-week, Multicenter Study to Evaluate the Efficacy, Safety, and Tolerability of Canagliflozin in the Treatment of Subjects With Type 2 Diabetes Mellitus With Inadequate Glycemic Control on Metformin and Sitagliptin Therapy

14. NCT01032629 - **28431754DIA3008**

A Randomized, Multicenter, Double-Blind, Parallel, Placebo-Controlled Study of the Effects of JNJ-28431754 on Cardiovascular Outcomes in Adult Subjects With Type 2 Diabetes Mellitus

15. NCT01989754 - **28431754DIA4003**

A Randomized, Multicenter, Double-Blind, Parallel, Placebo-Controlled Study of the Effects of Canagliflozin on Renal Endpoints in Adult Subjects With Type 2 Diabetes Mellitus

**Data Sharing Request Due Diligence Assessment**

	<p><b>16. NCT00650806 - 28431754OBE2001</b> 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><b>17. NCT00650806 - 28431754OBE2001</b> 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><b>18. NCT02065791 - 28431754DNE3001</b> A Randomized, Double-blind, Event-driven, Placebo-controlled, Multicenter Study of the Effects of Canagliflozin on Renal and Cardiovascular Outcomes in Subjects With Type 2 Diabetes Mellitus and Diabetic Nephropathy</p> <p><b>19. NCT03267576 - 28431754DIA4026</b> Canagliflozin Continuous Glucose Monitoring (CANA CGM) Trial: A Pilot Randomized, Double-Blind, Controlled, Crossover Study on the Effects of the SGLT-2 Inhibitor Canagliflozin (vs. the DPP-4 Inhibitor Sitagliptin) on Glucose Variability in Mexican Patients With Type 2 Diabetes Mellitus Inadequately Controlled on Metformin</p> <p><b>20. NCT02139943 - 28431754DIA2004</b> A Randomized Phase 2, Double-blind, Placebo-controlled, Treat-to-Target, Parallel-group, 3-arm, Multicenter Study to Assess the Efficacy and Safety of Canagliflozin as Add-on Therapy to Insulin in the Treatment of Subjects With Type 1 Diabetes Mellitus</p>
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**Proposal Review**

<p>Question 1: The clinical trial data from the study/studies listed above were previously identified and approved as being available for a data sharing request. <b>Is there any reason why the study/studies listed should no longer be shared?</b></p>	No
Comments if 'Yes':	
<p>Question 2: On review of the proposal, is there any data that has been requested that may be <b>missing</b> from the clinical database?</p>	No
Comments if 'Yes':	
<p>Question 3: Is a similar analysis underway, or completed and pending disclosure by J&amp;J?</p>	No
Comments if 'Yes':	