The YODA Project
Research Proposal Due Diligence Assessment

Part 1: General Information	
YODA Project (Protocol) ID:	2024-0248
Date:	May 24, 2024
Product Name:	Invokana
Therapeutic Area:	CVM
Product Class:	Sodium-glucose co-transporter 2 (SGLT2) inhibitors
Condition(s) Studied:	Diabetes Mellitus, Type 2
Protocol Number(s) and Title(s):	1. **NCT03267576 - 28431754DIA4026**: 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 2. **NCT02139943 - 28431754DIA2004:** 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

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:	
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

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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:	