The YODA Project
Research Proposal Due Diligence Assessment

Part 1: General Information

YODA Project (Protocol) ID:	2019-3995
Date:	30 September 2019
Product Name:	Canagliflozin
Therapeutic Area:	Metabolism
Product Class:	SGLT-2 inhibitor
Condition(s) Studied:	Type 2 Diabetes
Protocol Number(s) and Title(s):	**NCT00642278 -** 28431754DIA2001 **NCT01106625 -** 28431754DIA3002 **NCT01064414 -** 28431754DIA3004 **NCT01081834 -** 28431754DIA3005 **NCT01106677 -** 28431754DIA3006 **NCT00968812 -** 28431754DIA3009 **NCT01106651 -** 28431754DIA3010 **NCT01106690 -** 28431754DIA3012 **NCT01137812 -** 28431754DIA3015 **NCT01340664 -** 28431754DIA2003 **NCT01032629 -** 28431754DIA3008 **NCT01989754 -** 28431754DIA4003

Part 2: Data Availability

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