

The YODA Project
Research Proposal Due Diligence Assessment

Part 1: General Information	
YODA Project (Protocol) ID:	2019-4071
Date:	9 January 2020
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 NCT01340664 28431754DIA2003 NCT01106625 28431754DIA3002 NCT01064414 28431754DIA3004 NCT01081834 28431754DIA3005 NCT01106677 28431754DIA3006 NCT01032629 28431754DIA3008 NCT00968812 28431754DIA3009 NCT01106651 28431754DIA3010 NCT01809327 28431754DIA3011 NCT01106690 28431754DIA3012 NCT01381900 28431754DIA3014 NCT01137812 28431754DIA3015 NCT01989754 28431754DIA4003 NCT02025907 28431754DIA4004
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.	No
A similar analysis is underway or completed/pending disclosure by Janssen.	No
Comments:	