

**The YODA Project**  
**Research Proposal Due Diligence Assessment**

<b>Part 1: General Information</b>	
<b>YODA Project (Protocol) ID:</b>	2019-4077
<b>Date:</b>	19 December 2019
<b>Product Name:</b>	Canagliflozin
<b>Therapeutic Area:</b>	Metabolism
<b>Product Class:</b>	SGLT-2 inhibitor
<b>Condition(s) Studied:</b>	Type 2 Diabetes
<b>Protocol Number(s) and Title(s):</b>	<a href="#">NCT01106625 - 28431754DIA3002</a> <a href="#">NCT01081834 - 28431754DIA3005</a> <a href="#">NCT01106677 - 28431754DIA3006</a> <a href="#">NCT00968812 - 28431754DIA3009</a> <a href="#">NCT01106651 - 28431754DIA3010</a> <a href="#">NCT01137812 - 28431754DIA3015</a> <a href="#">NCT01032629 - 28431754DIA3008</a> <a href="#">NCT01989754 - 28431754DIA4003</a> <a href="#">NCT02025907 - 28431754DIA4004</a>
<b>Part 2: Data Availability</b>	
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	
<b>Part 3: Data Availability Summary</b>	
Based on the responses to the above Data Availability questions, the requested clinical trial data can be made available for data sharing.	Yes
<b>Part 4: Proposal Review</b>	
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:	