

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

Part 1: General Information	
YODA Project (Protocol) ID:	2015-0416
Date:	16 February 2015
Product Name:	Canagliflozin / INVOKANA
Therapeutic Area:	Metabolism
Product Class:	SGLT-2 inhibitor
Condition(s) Studied:	Type 2 Diabetes
Protocol Number(s) and Title(s):	NCT00642278 NCT01106625 NCT01064414 NCT01081834 NCT01106677 NCT00968812 NCT01106651 NCT01106690 NCT01137812
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.	No
Participant-level data is appropriate for the proposed analysis.	Yes
A similar analysis is underway or completed/pending disclosure by Janssen.	Yes

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Comments:	Two manuscripts on bone safety are underway. The integrated fracture analyses and the bone data of the elderly subjects were assessed in these papers.
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