

The YODA Project
Research Proposal Due Diligence Assessment

Part 1: General Information	
YODA Project (Protocol) ID:	2016-0767
Date:	30 Mar 2016
Product Name:	Bedaquiline
Therapeutic Area:	IDV
Product Class:	Diarylquinoline
Condition(s) Studied:	Tuberculosis
Protocol Number(s) and Title(s):	<p>NCT00449644 - A Phase II, Placebo-controlled, Double-blind, Randomized Trial to Evaluate the Anti-bacterial Activity, Safety, and Tolerability of TMC207 in Subjects With Newly Diagnosed Sputum Smearpositive Pulmonary Infection With Multi-drug Resistant</p> <p>NCT00910871 - A Phase II, Open-label Trial With TMC207 as Part of a Multi-drug Resistant Tuberculosis (MDRTB) Treatment Regimen in Subjects With Sputum Smear-positive Pulmonary Infection With MDR-TB.</p>
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

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