

Due Diligence Assessment – Research Proposal

Part 1: General Information	
YODA Project (Protocol) ID:	2015-0514
Date:	8May2015
Product Name:	Levofloxacin/LEVAQUIN
Therapeutic Area:	IDV
Product Class:	Antibiotic
Condition(s) Studied:	Urinary Tract Infection and Acute Pyelonephritis
Protocol Number(s) and Title(s):	CAPSS-349 / NCT00210886
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.	No
Comments: Just like any post hoc analysis, the proposed study may not have sufficient power to draw a definite conclusion.	