

The YODA Project
Research Proposal Due Diligence Assessment

Part 1: General Information	
YODA Project (Protocol) ID:	2016-0738
Date:	29 Feb 2016
Product Name:	Olysis
Therapeutic Area:	IDV
Product Class:	Simeprevir
Condition(s) Studied:	Hepatitis C
Protocol Number(s) and Title(s):	NCT02278419 - A Phase 2a, Partly Randomized, Open-label Trial to Investigate the Efficacy and Safety of an 8 or 12-Week Treatment Regimen of Simeprevir in Combination With Sofosbuvir in Treatment-Naive and Experienced Subjects With Chronic Genotype 4 Hepatitis C Infection
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:	
Data Holder has sharable electronic clinical trial data or data can be converted to electronic format.	Yes
Comments:	
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:	
The product and relevant indication studied has either been approved by regulators in the US and EU, or terminated from development.	No
Comments:	Phase 2 Study; not submitted to HA for labeling consideration at this time.
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).	No
Comments:	The due diligence assessment for the inquiry regarding availability of NCT02278419 has been completed. Goal is to make the OSIRIS data available to requestor through YODA upon request of Janssen EMEA. While the trial falls out of scope for sharing based on our existing policy, it has been reviewed and discussed at multiple sub-team meetings and there is complete alignment from CDT, legal and regional medical, regulatory and legal to move forward with sharing the data.
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:

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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:	