

The YODA Project
Research Proposal Due Diligence Assessment

Part 1: General Information	
YODA Project (Protocol) ID:	2018-3765
Date:	30 November 2018
Product Name:	Golimumab
Therapeutic Area:	Immunology
Product Class:	Antirheumatic Agents - Biologic Response Modifiers
Condition(s) Studied:	Ankylosing Spondylitis/Arthritis, Rheumatoid/ Arthritis, Psoriatic/ Colitis, Ulcerative
Protocol Number(s) and Title(s):	NCT00264537 C0524T05 NCT00264550 C0524T06 NCT00265096 C0524T08 NCT00265083 C0524T09 NCT00299546 C0524T11 NCT00361335 C0524T12 NCT00487539 C0524T17 NCT00488631 C0524T18 NCT01248780 C0524T28 NCT01248793 C0524T29 NCT02186873 CNT0148AKS3001 NCT00973479 CNT0148ART3001 NCT01004432 CNT0148ART3002 NCT02181673 CNT0148PSA3001 NCT00975130 P06129 NCT01453725 P07642
Part 2: Data Availability	
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.	Yes
Comments:	
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:	
Part 3: Data Availability Summary	
Based on the responses to the above Data Availability questions, the requested clinical trial data are available for a data sharing request.	Yes

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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:	