The YODA Project
Research Proposal Due Diligence Assessment

Part 1: General Information	
YODA Project (Protocol) ID:	2018-2931
Date:	19 April 2018 (Updated 28 September 2018)
Product Name:	Infliximab/ Golimumab
Therapeutic Area:	Immunology
Product Class:	Tumor necrosis factor (TNF) blocker
Condition(s) Studied:	Rheumatoid Arthritis
Protocol Number(s) and Title(s):	**Infliximab:** NCT# N/A C0168T14 NCT00269867 C0168T22 NCT00236028 C0168T29 NCT00202852 P04280 **Golimumab:** NCT00207714 C0524T02 NCT00264537 C0524T05 NCT00264550 C0524T06 NCT00299546 C0524T11 NCT00361335 C0524T12 NCT01248780 C0524T28 NCT00973479 CNTO148ART3001

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:	