The YODA Project
Research Proposal Due Diligence Assessment

Part 1: General Information	
YODA Project (Protocol) ID:	2019-4092
Date:	17 December 2019
Product Name:	Golimumab/Infliximab
Therapeutic Area:	Immunology
Product Class:	Antirheumatic Agents - Biologic Response Modifiers
Condition(s) Studied:	Active Ulcerative Colitis Rheumatoid Arthritis
Protocol Number(s) and Title(s):	**Golimumab:** **NCT00264550 -** C0524T06 **NCT00361335 -** C0524T12 **NCT00487539 -** C0524T17 **NCT00973479 -** CNTO148ART3001 **NCT00488631 -** C0524T18 **NCT00488774 -** C0524T16 **Infliximab:** **NCT00036439 -** C0168T37 **NCT00096655 -** C0168T46 **NCT00269867 -** C0168T22 **NCT00236028 -** C0168T29 **NCT01551290 -** REMICADEUCO3001

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

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:	