The YODA Project
Research Proposal Due Diligence Assessment

Part 1: General Information	
YODA Project (Protocol) ID:	2018-3556
Date:	13 September 2018
Product Name:	Infliximab/ Ustekinumab/ Golimumab
Therapeutic Area:	Immunology
Product Class:	Antirheumatic Agents - Biologic Response Modifiers
Condition(s) Studied:	Crohn's Disease, Ulcerative Colitis
Protocol Number(s) and Title(s):	**Infliximab:** **NCT00036439** C0168T37 **NCT00096655** C0168T46 **NCT00207675** C0168T47 **NCT00094458** C0168T67 **NCT00336492** C0168T72 **NCT00207662** C0168T21 **NCT00207766** C0168T26 **NCT00004941** C0168T20 **NCT00537316** P04807 **NCT01551290** CR018769; REMICADEUCO3001 **NCT00269854** C0168T16 (initial treatment phase and repeated treatment phase studies) **Ustekinumab:** **NCT00771667** C0743T26 **NCT01369329** CNTO1275CRD3001 **NCT01369342** CNTO1275CRD3002 **NCT01369355** CNTO1275CRD3003 **NCT00265122** C0379T07 **Golimumab:** **NCT00487539** C0524T17 **NCT00488631** C0524T18 **NCT00488774** C0524T16 **NCT01863771** CNTO148UCO3001 **NCT01988961** CNTO148UCO2001

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:		

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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:	