The YODA Project
Research Proposal Due Diligence Assessment

Part 1: General Information	
YODA Project (Protocol) ID:	2017-1856
Date:	19 Jul 2017
Product Name:	Infliximab/ Golimumab/ Ustekinumab
Therapeutic Area:	Immunology
Product Class:	mAB anti-IL12 / anti-IL23; Tumor necrosis factor (TNF) blocker
Condition(s) Studied:	Crohn's Disease, Ulcerative Colitis
Protocol Number(s) and Title(s):	**Infliximab:** NCT00269854 C0168T16 (ITP and RTP studies) NCT00004941 C0168T20 NCT00207662 C0168T21 NCT00207766 C0168T26 NCT00036439 C0168T37 NCT00096655 C0168T46 NCT00094458 C0168T67 NCT00537316 P04807 NCT01190839 REMICADECRD3001 NCT01551290 REMICADEUCO3001 **Golimumab:** NCT00487539 C0524T17 NCT00488631 C0524T18 **Ustekinumab:** NCT00771667 C0743T26 NCT01369329 CNTO1275CRD3001 NCT01369342 CNTO1275CRD3002 NCT01369355 CNTO1275CRD3003

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:	

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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:	

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