The YODA Project
Research Proposal Due Diligence Assessment

Part 1: General Information	
YODA Project (Protocol) ID:	2020-4341
Date:	10 June 2020
Product Name:	Golimumab/Infliximab
Therapeutic Area:	Immunology
Product Class:	Antirheumatic Agents - Biologic Response Modifiers
Condition(s) Studied:	Active Ulcerative Colitis/Active Rheumatoid Arthritis/Active Ankylosing Spondylitis/Active/Fistulizing CROHN'S Disease/ Active Psoriatic Arthritis
Protocol Number(s) and Title(s):	**NCT00036439 -** C0168T37 **NCT00096655 -** C0168T46 **NCT00264537 -** C0524T05 **NCT00264550 -** C0524T06 **NCT00265083 -** C0524T09 **NCT00299546 -** C0524T11 **NCT00361335 -** C0524T12 **NCT00487539 -** C0524T17 **NCT01248780 -** C0524T28 **NCT01248793 -** C0524T29 **NCT00207662 -** C0168T21 - ACCENT I **NCT00207766 -** C0168T26 - ACCENT II **NCT00004941 -** C0168T20 **NCT00269867 -** C0168T22 **NCT00265096 -** C0524T08 **NCT01551290 -** REMICADEUCO3001 **NCT01190839 -** REMICADECRD3001 **NCT00269854 -** C0168T16 **NCT00973479 -** CNTO148ART3001 **NCT00488631 -** C0524T18 **NCT00207714 -** C0524T02 **NCT00488774 -** C0524T16 **NCT02186873 -** CNTO148AKS3001 **NCT02181673 -** CNTO148PSA3001 **NCT01863771 -** CNTO148UCO3001

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.	Yes
Participant-level data is appropriate for the proposed analysis.	Yes
A similar analysis is underway or completed/pending disclosure by Janssen.	No
Comments:	