The YODA Project
Research Proposal Due Diligence Assessment

Part 1: General Information	
YODA Project (Protocol) ID:	2019-4067
Date:	11 December 2019
Product Name:	Infliximab/ Ustekinumab/ Golimumab/Guselkumab
Therapeutic Area:	Immunology
Product Class:	Antirheumatic Agents - Biologic Response Modifiers
Condition(s) Studied:	Crohn's Disease, Ulcerative Colitis, Rheumatoid Arthritis, Plaque Psoriasis
Protocol Number(s) and Title(s):	**Infliximab:** **NCT N/A** C0168T14 **NCT00269854** C0168T16 **NCT00004941** C0168T20 **NCT00207662** C0168T21 **NCT00269867** C0168T22 **NCT00207766** C0168T26 **NCT00236028** C0168T29 **NCT00036374** C0168T32 **NCT00036439** C0168T37 **NCT00036387** C0168T41 **NCT00096655** C0168T46 **NCT00207675** C0168T47 **NCT00094458** C0168T67 **NCT00336492** C0168T72 **NCT01551290** REMICADEUCO3001 **NCT00202852** P04280 **NCT00537316** P04807 **NCT00732875** P05645 **NCT01190839** REMICADECRD3001 **Ustekinumab:** **NCT00320216** C0379T04 **NCT01008995** C0743T23 **NCT00747344** C0743T25 **NCT01090427** CNTO1275PSO3006 **NCT00723528** JNS009-JPN-02 **NCT00267969** C0743T08 **NCT00307437** C0743T09 **NCT00454584** C0743T12 **NCT01009086** CNTO1275PSA3001 **NCT01077362** CNTO1275PSA3002 **NCT01550744** CNTO1275PSO3009 **NCT01059773** CNTO1275PSO4004 **Golimumab:** **NCT01962974** CNTO148ART3003 **NCT01230827** CNTO148JIA3001 **NCT00207714** C0524T02 **NCT00264537** C0524T05 **NCT00264550** C0524T06

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	NCT00299546 C0524T11 **NCT00361335** C0524T12 **NCT01248780** C0524T28 **NCT00973479** CNTO148ART3001 **NCT01004432** CNTO148ART3002 **NCT02181673** CNTO148PSA3001 **NCT00975130** P06129 **Guselkumab:** **NCT02203032** CNTO1959PSO3003

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:	