The YODA Project
Research Proposal Due Diligence Assessment

Part 1: General Information	
YODA Project (Protocol) ID:	2019-3842
Date:	4 March 2019
Product Name:	Ustekinumab
Therapeutic Area:	Immunology
Product Class:	Antirheumatic Agents - Biologic Response Modifiers
Condition(s) Studied:	Crohn's Disease
Protocol Number(s) and Title(s):	**NCT00771667** -C0743T26 - A Phase 2b, Multicenter, Randomized, Double-blind, Placebo-controlled, Parallel Group Study to Evaluate the Efficacy and Safety of Ustekinumab Therapy in Subjects With Moderately to Severely Active Crohn's Disease Previously Treated With TNF Antagonist Therapy **NCT01369329** - CNTO1275CRD3001 - A Phase 3, Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Study to Evaluate the Safety and Efficacy of Ustekinumab Induction Therapy in Subjects With Moderately to Severely Active Crohn's Disease Who Have Failed or Are Intolerant to TNF Antagonist Therapy (UNITI-1) **NCT01369342** -CNTO1275CRD3002 - A Phase 3, Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Study to Evaluate the Safety and Efficacy of Ustekinumab Induction Therapy in Subjects With Moderately to Severely Active Crohn's Disease (UNITI-2)

Part 2: Data Availability	
Question:	**Response:**
Data Partner has authority to provide clinical trial data or development partner has agreed to share clinical trial data.	Yes
Comments:	
Data Partner 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 Partner 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 can be made available for data sharing.	Yes

Part 4: Proposal Review

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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.		Yes
Comments:	Abstract previously presented at DDW (Fistula Healing in Pivotal Studies of Ustekinumab in Crohn's Disease) *Bruce E Sands1, Christopher Gasink2 Douglas Jacobstein2, Long-Long Gao2 Jewel Johanns2 Jean Frederic Colombel1, Willem de Villiers3, William J Sandborn4)* There is an additional presentation planned at DDW May 2019 evaluating fistulas and drug levels	