The YODA Project
Research Proposal Due Diligence Assessment

Part 1: General Information	
YODA Project (Protocol) ID:	2021-4822
Date:	8 November 2021
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):	**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) **NCT01369355 -CNTO1275CRD3003** A Phase 3, Randomized, Double-blind, Placebo-controlled, Parallel group, Multicenter Study to Evaluate the Safety and Efficacy of Ustekinumab Maintenance Therapy in Subjects With Moderately to Severely Active Crohn's Disease

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

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A similar analysis is underway or completed/pending disclosure by Janssen.	No
Comments:	