The YODA Project
Research Proposal Due Diligence Assessment

Part 1: General Information	
YODA Project (Protocol) ID:	2016-1176
Date:	15 Dec 2016
Product Name:	Ustekinumab
Therapeutic Area:	Immunology
Product Class:	mAB anti-IL12 / anti-IL23
Condition(s) Studied:	Crohn's Disease
Protocol Number(s) and Title(s):	**NCT01369329**-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**-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	
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.		YES –
Comments:	we are looking at ustekinumab concentration correlation with clinical response, as well as a number of biomarkers that could be predictive of response to Stelara.	

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YODA Project (Protocol) ID:	2016-1176
Date:	15 Dec 2016-Updated 14 Feb 17
Product Name:	Ustekinumab
Therapeutic Area:	Immunology
Product Class:	mAB anti-IL12 / anti-IL23
Condition(s) Studied:	Crohn's Disease
Protocol Number(s) and Title(s):	**NCT01369355** 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		
1. Data Holder has authority to provide clinical trial data or development partner has agreed to share clinical trial data.		Yes
Comments:		
2. Data Holder has sharable electronic clinical trial data or data can be converted to electronic format.		Yes
Comments:		
3. 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:		
4. The product and relevant indication studied has either been approved by regulators in the US and EU, or terminated from development.		Yes
Comments:		
5. 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).		No
Comments:	Estimated completion date- November 2019 as there is a Long-term extension ongoing. Primary analysis after 44 weeks of maintenance treatment for global regulatory submission has been completed and published and can be shared.	

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

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