The YODA Project
Research Proposal Due Diligence Assessment

Part 1: General Information	
YODA Project (Protocol) ID:	2015-0560
Date:	10 Jul 15
Product Name:	STELARA /SIMPONI
Therapeutic Area:	Immunology
Product Class:	mAB anti-IL12 / anti-IL23 and Tumor necrosis factor (TNF) blocker
Condition(s) Studied:	Psoriasis Arthritis
Protocol Number(s) and Title(s):	**CNTO1275PSA3001 /// NCT01009086** A Study of the Safety and Effectiveness of Ustekinumab in Patients With Psoriatic Arthritis **CNTO1275PSA3002 /// NCT01077362** A Study of the Safety and Efficacy of Ustekinumab in Patients With Psoriatic Arthritis With and Without Prior Exposure to Anti-TNF Agents **C0524T08 /// NCT00265096** A Multicenter, Randomized, Double-blind, Placebo controlled Trial of Golimumab, a Fully Human Anti-TNFa Monoclonal Antibody, Administered Subcutaneously in Subjects with Active Psoriatic Arthritis

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: N/A or add comments if answered No.	
Data Holder has sharable electronic clinical trial data or data can be converted to electronic format.	Yes
Comments: N/A or add comments if answered No.	
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: N/A or add comments if answered No.	
The product and relevant indication studied has either been approved by regulators in the US and EU, or terminated from development.	Yes
Comments: N/A or add comments if answered No.	
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: N/A or add comments if answered No.	

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

The YODA Project
Research Proposal Due Diligence Assessment

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