The YODA Project
Research Proposal Due Diligence Assessment

Part 1: General Information	
YODA Project (Protocol) ID:	2024 – 0436
Date:	May 29, 2024
Product Name:	Simponi/Stelara/Remicade/Tremfya
Therapeutic Area:	Immunology
Product Class:	Antirheumatic agents/antipsoriatics/interleukin-23 antagonist
Condition(s) Studied:	Psoriatic arthritis/Rheumatoid arthritis/Psoriasis
Protocol Number(s) and Title(s):	1. NCT00265096 - C0524T08: 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 2. NCT02181673 - CNTO148PSA3001: A Multicenter, Randomized, Double-blind, Placebo-controlled Trial of Golimumab, an Anti-TNFα Monoclonal Antibody, Administered Intravenously, in Subjects With Active Psoriatic Arthritis 3. NCT01009086 - CNTO1275PSA3001: A Phase 3 Multicenter, Randomized, Double-blind, Placebo-controlled Trial of Ustekinumab, a Fully Human Aanti-IL-12/23p40 Monoclonal Antibody, Administered Subcutaneously, in Subjects With Active Psoriatic Arthritis 4. NCT01077362 - CNTO1275PSA3002: A Phase 3 Multicenter, Randomized, Double-blind, Placebo-controlled Trial of Ustekinumab, a Fully Human Anti-IL-12/23p40 Monoclonal Antibody, Administered Subcutaneously, in Subjects With Active Psoriatic Arthritis Including Those Previously Treated With Biologic Anti-TNFalpha Agent(s) 5. NCT00267956 - C0743T10: A Phase 2, Multicenter, Randomized, Double-blind, Placebo-controlled Trial of CNTO 1275, a Fully Human Anti-IL-12 Monoclonal Antibody, Administered Subcutaneously, in Subjects With Active Psoriatic Arthritis 6. NCT00051623 - CR004789: A Multicenter, Randomized, Double-blind Trial of Anti-TNFa Chimeric Monoclonal Antibody (Infliximab) for the Treatment of Patients With Psoriatic Arthritis 7. NCT00367237 - P04422: A Randomized, Multicenter, International, Open-label Study of Infliximab Plus Methotrexate Versus Methotrexate (MTX) Alone for the Treatment of MTX naïve Subjects With Active Psoriatic Arthritis

	8. NCT03796858 - CNTO1959PSA3003: Phase 3b, Multicenter, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Efficacy and Safety of Guselkumab Administered Subcutaneously in Participants With Active Psoriatic Arthritis and an Inadequate Response to Anti-Tumor Necrosis Factor Alpha (Anti-TNFα) Therapy 9. NCT02319759 - CNTO1959PSA2001: A Phase 2a, Multicenter, Randomized, Double-blind, Placebo-controlled Study Evaluating the Efficacy and Safety of Guselkumab in the Treatment of Subjects With Active Psoriatic Arthritis 10. NCT03158285 - CNTO1959PSA3002: A Phase 3, Multicenter, Randomized, Double-blind, Placebo-controlled Study Evaluating the Efficacy and Safety of Guselkumab Administered Subcutaneously in Subjects With Active Psoriatic Arthritis 11. NCT03162796 - CNTO1959PSA3001: A Phase 3, Multicenter, Randomized, Double-blind, Placebo-controlled Study Evaluating the Efficacy and Safety of Guselkumab Administered Subcutaneously in Subjects With Active Psoriatic Arthritis Including Those Previously Treated With Biologic Anti-TNF Alpha Agents

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

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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.	Yes
Comments:	