The YODA Project
Research Proposal Due Diligence Assessment

Part 1: General Information	
YODA Project (Protocol) ID:	2022-5060
Date:	18 November 2022
Product Name:	Infliximab/Golimumab/Ustekinumab/Sirukumab
Therapeutic Area:	Immunology
Product Class:	Antirheumatic Agents - Biologic Response Modifiers
Condition(s) Studied:	Rheumatoid Arthritis Psoriatic Arthritis
Protocol Number(s) and Title(s):	**NCT00264537 - C0524T05** - A Multicenter, Randomized, Double-blind, Placebo-controlled Trial of Golimumab, a Fully Human Anti-TNFa Monoclonal Antibody, Administered Subcutaneously, in Methotrexate-naïve Subjects with Active Rheumatoid Arthritis **NCT00264550 - C0524T06** - A Multicenter, Randomized, Double-blind, Placebo-controlled Trial of Golimumab, a Fully Human Anti-TNFa Monoclonal Antibody, Administered Subcutaneously, in Subjects with Active Rheumatoid Arthritis Despite Methotrexate Therapy **NCT00299546 - C0524T11** - A Multicenter, Randomized, Double-blind, Placebo-controlled Trial of Golimumab, a Fully Human Anti-TNFa Monoclonal Antibody, Administered Subcutaneously in Subjects with Active Rheumatoid Arthritis and Previously Treated with Biologic Anti TNFa Agent(s) **NCT00361335 - C0524T12** - A Multicenter, Randomized, Double-blind, Placebo-controlled Trial of Golimumab, a Fully Human Anti-TNFa Monoclonal Antibody, Administered Intravenously, in Subjects with Active Rheumatoid Arthritis Despite Methotrexate Therapy **NCT01248780 - C0524T28** - A Phase 3, Multicenter, Randomized, Double-blind, Placebo-controlled Study Evaluating the Efficacy and Safety of Golimumab in the Treatment of Chinese Subjects with Active Rheumatoid Arthritis Despite Methotrexate Therapy **NCT00269867 - C0168T22** - A Placebo-Controlled, Double-Blinded, Randomized Clinical Trial of Anti-TNF Chimeric Monoclonal Antibody (cA2) in Patients With Active Rheumatoid Arthritis Despite Methotrexate Treatment **NCT00236028 - C0168T29** - A Randomized, Double-blind, Trial of Anti-TNFa Chimeric Monoclonal Antibody (Infliximab) in Combination With Methotrexate Compared With Methotrexate Alone for the Treatment of Patients With Early Rheumatoid Arthritis **NCT00973479 - CNTO148ART3001** - A Multicenter, Randomized, Double-blind, Placebo-controlled Trial of Golimumab, an Anti-TNFalpha Monoclonal Antibody, Administered Intravenously, in Patients With Active Rheumatoid Arthritis Despite Methotrexate Therapy **NCT00207714 - C0524T02** - A Randomized, Double-blind, Dose-ranging Trial of CNTO 148 Subcutaneous Injection Compared With

	Placebo in Subjects With Active Rheumatoid Arthritis Despite Treatment With Methotrexate **C0168T14** - Therapeutic efficacy of multiple intravenous infusions of anti-tumor necrosis factor alpha monoclonal antibody combined with low-dose weekly methotrexate in rheumatoid arthritis **NCT02181673 - CNTO148PSA3001** - A Study of Golimumab in Participants With Active Psoriatic Arthritis **NCT01004432 - CNTO148ART3002** - Golimumab in Rheumatoid Arthritis Participants With an Inadequate Response to Etanercept (ENBREL) or Adalimumab (HUMIRA) **NCT01962974 - CNTO148ART3003** - A Golimumab Phase 3b, Multicenter, Assessment of Intravenous Efficacy in Rheumatoid Arthritis Subjects Who Have Diminished Disease Control Despite Treatment With Infliximab (REMICADE®) **NCT00036387 - C0168T41** - A Randomized, Double-blind Trial of the Safety of Anti-TNF Chimeric Monoclonal Antibody (Infliximab) in Combination With Methotrexate Compared to Methotrexate Alone in Patients With Rheumatoid Arthritis on Standard Disease-modifying Anti-Rheumatic Drug **NCT01689532 - CNTO136ARA3001** - A Study of CNTO 136 (Sirukumab) Administered Subcutaneously in Japanese Patients With Active Rheumatoid Arthritis Unresponsive to Methotrexate or Sulfasalazine **NCT01604343 - CNTO136ARA3002** - A Multicenter, Randomized, Double-blind, Placebo-controlled, Parallel Group Study of CNTO 136 (Sirukumab), a Human Anti-IL-6 Monoclonal Antibody, Administered Subcutaneously, in Subjects With Active Rheumatoid Arthritis Despite DMARD Therapy **NCT01606761 - CNTO136ARA3003** - A Multicenter, Randomized, Double-blind, Placebo-controlled, Parallel Group Study of CNTO 136 (Sirukumab), a Human Anti-IL-6 Monoclonal Antibody, Administered Subcutaneously, in Subjects With Active Rheumatoid Arthritis Despite Anti-TNF-Alpha Therapy **NCT02019472 - CNTO136ARA3005** - A Multicenter, Randomized, Double-blind, Parallel Group Study of Sirukumab Monotherapy Compared With HUMIRA® Monotherapy Administered Subcutaneously, in Subjects With Active Rheumatoid Arthritis **NCT01645280 - CNTO1275ARA2001** - A Phase 2, Multicenter, Randomized, Double-blind, Placebo controlled, Parallel-group, Study Evaluating the Efficacy and Safety of Ustekinumab (STELARA®) and CNTO 1959 Administered Subcutaneously in Subjects With Active Rheumatoid Arthritis Despite Concomitant Methotrexate Therapy

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:	

The YODA Project
Research Proposal Due Diligence Assessment

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