The YODA Project
Research Proposal Due Diligence Assessment

Part 1: General Information	
YODA Project (Protocol) ID:	2015-0339
Date:	13Mar15_updated_16 September 2020
Product Name:	Infliximab/Golimumab/Ustekinumab
Therapeutic Area:	Immunology
Product Class:	Immunomodulators
Condition(s) Studied:	Crohn's disease, ulcerative colitis, rheumatoid arthritis and ankylosing spondylitis
Protocol Number(s) and Title(s):	**NCT00036374** - A Randomized, Double-Blind Trial of Anti-TNF Chimeric Monoclonal Antibody (Infliximab) in Combination With Methotrexate for the Treatment of Patients With Polyarticular Juvenile Rheumatoid Arthritis **NCT00036439** - A Randomized, Placebo-controlled, Double-blind Trial to Evaluate the Safety and Efficacy of Infliximab in Patients With Active Ulcerative Colitis **NCT00096655** - A Randomized, Placebo-controlled, Double-blind Trial to Evaluate the Safety and Efficacy ofInfliximab in Patients With Active Ulcerative Colitis **NCT00207675** - A Randomized, Multicenter, Open-label Study to Evaluate the Safety and Efficacy of Anti-TNF a Chimeric Monoclonal Antibody (Infliximab, REMICADE) in Pediatric Subjects With Moderate to Severe CROHN'S Disease **NCT00094458** - Multicenter, Randomized, Double-Blind, Active Controlled Trial Comparing REMICADE® (infliximab) and REMICADE plus Azathioprine to Azathioprine in the Treatment of Patients with Crohn's Disease Naive to both Immunomodulators and Biologic **NCT00336492** - A Phase 3, Randomized, Open-label, Parallel-group, Multicenter Trial to Evaluate the Safety and Efficacy of Infliximab (REMICADE) in Pediatric Subjects With Moderately to Severely Active Ulcerative Colitis **NCT00264537** - 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** - 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** - 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 **NCT00361335** - 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 **NCT00487539** - A Phase 2/3 Multicenter, Randomized, Placebo-controlled, Double blind Study to Evaluate the Safety and Efficacy of Golimumab Induction Therapy, Administered Subcutaneously, in Subjects with Moderately to Severely Active Ulcerative Colitis **NCT01248780** - 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 **NCT01248793** - A Phase 3, Multicenter, Randomized, Double-blind, Placebo-controlled Study Evaluating the Efficacy and Safety of Golimumab in the Treatment of Chinese Subjects with Ankylosing Spondylitis **NCT00207662** - ACCENT I - A Randomized, Double-blind, Placebo-controlled Trial of Anti-TNFa Chimeric Monoclonal Antibody (Infliximab, Remicade) in the Long-term Treatment of Patients With Moderately to Severely Active Crohn's Disease **NCT00207766** - ACCENT II - A Randomized, Double-blind, Placebo-controlled Trial of Anti-TNF Chimeric Monoclonal Antibody (Infliximab, Remicade) in the Long Term Treatment of Patients With Fistulizing CROHN'S Disease **NCT00004941** - A Placebo-controlled, Repeated-dose Study of Anti-TNF Chimeric Monoclonal Antibody (cA2) in the Treatment of Patients with Enterocutaneous Fistulae as a Complication of Crohn’s Disease **NCT00269867** - 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** - 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 NCT01369329 - CNTO1275CRD3001 NCT01369342 - CNTO1275CRD3002 NCT01369355 - CNTO1275CRD3003 NCT00207740 - C0524T03 NCT00073437 - C0168T48 NCT00060502 - C0168T60 NCT00267956 - C0743T10 NCT02438787 - CNTO1275AKS3002 NCT02437162 - CNTO1275AKS3001 NCT02407223 - CNTO1275AKS3003 NCT01483599 - CNTO1959PSO2001 NCT00723528 - JNS009-JPN-02 NCT01551290 - REMICADEUCO3001

The YODA Project
Research Proposal Due Diligence Assessment

	NCT01190839 - REMICADECRD3001 NCT00320216 - C0379T04 NCT00265122 - C0379T07 NCT00207714 - C0524T02 NCT00265096 - C0524T08 NCT00265083 - C0524T09 NCT00488774 - C0524T16 NCT00488631 - C0524T18 (No NCT) C0168T14 (No NCT) C0168T16 (Same study folder as below) NCT00269854 - C0168T16 NCT00036387 - C0168T41 NCT00207701 - C0168T51 NCT00267969 - C0743T08 NCT00307437 - C0743T09 NCT00454584 - C0743T12 NCT01008995 - C0743T23 NCT00747344 - C0743T25 NCT00771667 - C0743T26 NCT02186873 - CNTO148AKS3001 NCT01962974 - CNTO148ART3003 NCT00973479 - CNTO148ART3001 NCT01004432 - CNTO148ART3002 NCT01230827 - CNTO148JIA3001 NCT02181673 - CNTO148PSA3001 NCT01988961 - CNTO148UCO2001 NCT01863771 - CNTO148UCO3001 NCT01009086 - CNTO1275PSA3001 NCT01077362 - CNTO1275PSA3002 NCT01059773 - CNTO1275PSO4004 NCT01090427 - CNTO1275PSO3006 NCT01550744 - CNTO1275PSO3009 NCT02203032 - CNTO1959PSO3003

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:	

The YODA Project
Research Proposal Due Diligence Assessment

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:	An ACR50 is a good level of response but is not defined as clinical remission in RA. Consider examining other definitions of clinical remission, for eg DAS28 score <2.6, SDAI score <=3.3 Unclear how defining patient sample: study participation or study treatment? If meant to be the controlled portion of data, whole study or other cuts of data?