The YODA Project
Research Proposal Due Diligence Assessment

Part 1: General Information	
YODA Project (Protocol) ID:	2017-2381
Date:	16 November 2017
Product Name:	Infliximab/ Golimumab
Therapeutic Area:	Immunology
Product Class:	Tumor necrosis factor (TNF) blocker
Condition(s) Studied:	Rheumatoid Arthritis
Protocol Number(s) and Title(s):	**Infliximab:** 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 NCT00732875 (P05645) A Placebo-controlled, Double-blinded, Randomized Clinical Trial of Anti-TNF Chimeric Monoclonal Antibody (cA2) in Korean Patients With Active Rheumatoid Arthritis Despite Methotrexate Treatment (Open-label Extension Part) 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 **Golimumab:** 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)

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:	No data available for P05645	
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:		

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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:	*Yes-No (NCT00299546) analyzed ACR 20 response at week 14 for RF in C0524T11 (see Week 24 CSR Figure 9)