The YODA Project
Research Proposal Due Diligence Assessment

Part 1: General Information	
YODA Project (Protocol) ID:	2022-5080
Date:	18 November 2022
Product Name:	Infliximab/Golimumab
Therapeutic Area:	Immunology
Product Class:	Antirheumatic Agents - Biologic Response Modifiers
Condition(s) Studied:	Ankylosing Spondylitis
Protocol Number(s) and Title(s):	**NCT00265083 - C0524T09** - A Multicenter, Randomized, Double-blind, Placebo-controlled Trial of Golimumab, a Fully Human Anti-TNFa Monoclonal Antibody, Administered Subcutaneously, in Subjects with Active Ankylosing Spondylitis **NCT02186873 - CNTO148AKS3001** - A Study of Golimumab in Participants With Active Ankylosing Spondylitis **NCT00207701 - C0168T51** - A Randomized, Double-blind Trial of the Efficacy of REMICADE (Infliximab) Compared With Placebo in Subjects With Ankylosing Spondylitis Receiving Standard Anti-inflammatory Drug 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:	
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

The YODA Project
Research Proposal Due Diligence Assessment

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