

## The YODA Project

### Research Proposal Due Diligence Assessment

<b>Part 1: General Information</b>	
<b>YODA Project (Protocol) ID:</b>	2022-4961
<b>Date:</b>	26 January 2024
<b>Product Name:</b>	Infliximab/Golimumab
<b>Therapeutic Area:</b>	Immunology
<b>Product Class:</b>	Antirheumatic Agents - Biologic Response Modifiers
<b>Condition(s) Studied:</b>	Rheumatoid Arthritis
<b>Protocol Number(s) and Title(s):</b>	<p><b>NCT00269867 - C0168T22</b> - A Placebo-Controlled, Double-Blinded, Randomized Clinical Trial of Anti-TNF Chimeric Monoclonal Antibody (cA2) in Patients With Active Rheumatoid Arthritis Despite Methotrexate Treatment</p> <p><b>NCT00207714 - C0524T02:</b> 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</p> <p><b>NCT00264550 - C0524T06:</b> 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</p>
<b>Part 2: Data Availability</b>	
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:	
<b>Part 3: Data Availability Summary</b>	
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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<b>Part 4: Proposal Review</b>	
<b>Question:</b>	<b>Response:</b>
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:	