

The YODA Project

Research Proposal Due Diligence Assessment

Part 1: General Information	
YODA Project (Protocol) ID:	2024-0748
Date:	16-August-2024
Product Name:	SIMPONI (Golimumab), REMICADE (Infliximab), STELARA (Infliximab)
Therapeutic Area:	Immunology
Product Class:	Antirheumatic agents - biologic response modifiers
Condition(s) Studied:	Ulcerative Colitis
Protocol Number(s) and Title(s):	<p>1. NCT00488631 - C0524T18 A Phase 3, Multicenter, Randomized, Placebo-controlled, Double-blind Study to Evaluate the Safety and Efficacy of Golimumab Maintenance Therapy Administered Subcutaneously in Subjects With Moderately to severely Active Ulcerative Colitis</p> <p>2. NCT00036439 - C0168T37 A Randomized Placebo-controlled, Double-blind Trial to Evaluate the Safety and Efficacy of Infliximab in Patients With Active Ulcerative Colitis</p> <p>3. NCT00096655 - C0168T46 A Randomized Placebo-controlled, Double-blind Trial to Evaluate the Safety and Efficacy of Infliximab in Patients With Active Ulcerative Colitis</p> <p>4. NCT02407236 – CNT01275UCO3001 A Phase 3, Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicentre Protocol to Evaluate the Safety and Efficacy of Ustekinumab Induction and Maintenance Therapy in Subjects with Moderately to Severely Active Ulcerative Colitis</p>
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

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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.		Yes
Comments:	Yes to similar analysis for Ustekinumab	