

The YODA Project
Research Proposal Due Diligence Assessment

Part 1: General Information	
YODA Project (Protocol) ID:	2016-1107
Date:	27 Oct 2016
Product Name:	Infliximab
Therapeutic Area:	Immunology
Product Class:	Tumor necrosis factor (TNF) blocker
Condition(s) Studied:	Crohn's Disease
Protocol Number(s) and Title(s):	<p>NCT00269854/ C0168T16- A Placebo-Controlled, Dose-Ranging Study Followed by a Placebo-Controlled, Repeated-Dose Extension of Anti-TNF Chimeric Monoclonal Antibody (cA2) in the Treatment of Patients With Active Crohn's Disease</p> <p>C0168T16- Efficacy and safety of retreatment with anti-tumor necrosis factor antibody (infliximab) to maintain remission in Crohn's disease.</p> <p>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</p> <p>NCT00207662- ACCENT I - A Randomized, Double-blind, Placebo-controlled Trial of Anti-TNFα Chimeric Monoclonal Antibody (Infliximab, Remicade) in the Long-term Treatment of Patients With Moderately to Severely Active Crohn's Disease</p> <p>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</p> <p>NCT00207675- A Randomized, Multicenter, Open-label Study to Evaluate the Safety and Efficacy of Anti-TNF α Chimeric Monoclonal Antibody (Infliximab, REMICADE) in Pediatric Subjects With Moderate to Severe CROHN'S Disease</p> <p>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 Therapy (Study of Biologic and Immunomodulator Naive Patients in Crohn's Disease)</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 shareable 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

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