

**The YODA Project**  
**Research Proposal Due Diligence Assessment**

<b>Part 1: General Information</b>	
<b>YODA Project (Protocol) ID:</b>	2015-0612
<b>Date:</b>	6Oct 2015
<b>Product Name:</b>	Infliximab (REMICADE)
<b>Therapeutic Area:</b>	Immunology
<b>Product Class:</b>	Tumor necrosis factor (TNF) blocker
<b>Condition(s) Studied:</b>	Crohn's Disease
<b>Protocol Number(s) and Title(s):</b>	<p>NCT00036439 - A Randomized, Placebo-controlled, Double-blind Trial to Evaluate the Safety and Efficacy of Infliximab in Patients With Active Ulcerative Colitis</p> <p>NCT00096655 - A Randomized, Placebo-controlled, Double-blind Trial to Evaluate the Safety and Efficacy of Infliximab in Patients With Active Ulcerative Colitis</p> <p>NCT00207675 - A Randomized, Multicenter, Open-label Study to Evaluate the Safety and Efficacy of Anti-TNF a 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</p> <p>NCT00336492 - A Phase 3, Randomized, Open-label, Parallel-group, Multicenter Trial to Evaluate the Safety and Efficacy of Infliximab (REMICADE) in Pediatric Subjects With Moderately to Severely Active Ulcerative Colitis</p> <p>NCT00487539 - A Phase 2/3 Multicenter, Randomized, Placebo-controlled, Double blind Study to Evaluate the Safety and Efficacy of Golimumab Induction Therapy, Administered Subcutaneously, in Subjects with Moderately to Severely Active Ulcerative Colitis</p> <p>NCT00207662 - ACCENT I - A Randomized, Double-blind, Placebo-controlled Trial of Anti-TNFa 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>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>NCT00537316 - Efficacy &amp; Safety of Infliximab Monotherapy Vs Combination Therapy Vs AZA Monotherapy in Ulcerative Colitis (Part 1) Maintenance Vs Intermittent Therapy for Maintaining Remission (Part 2)</p>
<b>Part 2: Data Availability</b>	

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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:	Confirmed with Merck.
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:	Confirmed with Merck.
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
<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:	The study will evaluate the impact of obesity on disease course and response to biologic therapy in IBD patients. The primary outcome is clinical remission, defined as CDAI < 150 for adults and PCDAI < 10 for children for Crohn's disease patients. Both CDAI and PCDAI have a weight component score, where lower weight compared to the standard weight is assigned to a worse CDAI/PCDAI score. A heavier weigh compared to the standard weight is given a better weight component score in CDAI/PCDAI. Therefore, the outcome measurements for the endpoints have limitations to evaluate the negative impact of obesity on disease. One may consider removing the weight component from PCDAI/CDAI score and adjust the CDAI/PCDAI cutoffs in clinical remission definition.