

The YODA Project
Research Proposal Due Diligence Assessment

Part 1: General Information	
YODA Project (Protocol) ID:	2015-0522
Date:	28 May 2015
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):	NCT00094458 / C0168T67 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
Part 2: Data Availability	
Question:	Response:
Data Holder has authority to provide clinical trial data or development partner has agreed to share clinical trial data.	Yes
Comments: N/A	
Data Holder has sharable electronic clinical trial data or data can be converted to electronic format.	Yes
Comments: N/A	
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: N/A	
The product and relevant indication studied has either been approved by regulators in the US and EU, or terminated from development.	Yes
Comments: N/A	
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: N/A	
Part 3: Data Availability Summary	
Based on the responses to the above Data Availability questions, the requested clinical trial data can be made available for data sharing.	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:	In SONIC, Infliximab level measurements were collected at Weeks 0, 30, and 46. Infliximab concentration measurements were not collected at Week 14.

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	<p>A manuscript on impact of infliximab concentrations on remission based on SONIC data was published this year. Please see reference below:</p> <p>Factors Associated With Short- and Long-Term Outcomes of Therapy for Crohn's Disease Walter Reinisch, Jean-Frederic Colombel, William J. Sandborn, Gerassimos J. Mantzaris, Asher Kornbluth, k Omoniyi J. Adedokun, Michael Miller, Kezhen L. Tang, Paul Rutgeerts, and Freddy Cornillie Clinical Gastroenterology and Hepatology 2015;13:539–547</p>
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