

The YODA Project
Research Proposal Due Diligence Assessment

| Part 1: General Information | |
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| YODA Project (Protocol) ID: | 2020-4234 |
| Date: | 4 March 2020 |
| Product Name: | Infliximab |
| Therapeutic Area: | Immunology |
| Product Class: | Antirheumatic Agents - Biologic Response Modifiers |
| 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 (Study of Biologic and Immunomodulator Naive Patients in Crohn's Disease) |
| 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 |
| 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: | |