# The YODA Project
# Research Proposal Due Diligence Assessment

| Part 1: General Information | |
|---|---|
| **YODA Project (Protocol) ID:** | 2022-4901 |
| **Date:** | 8 March 2022 |
| **Product Name:** | Infliximab |
| **Therapeutic Area:** | Immunology |
| **Product Class:** | Antirheumatic Agents - Biologic Response Modifiers |
| **Condition(s) Studied:** | Ulcerative Colitis |
| **Protocol Number(s) and Title(s):** | **NCT00036439 - C0168T37** - A Randomized, Placebo-controlled, Double-blind Trial to Evaluate the Safety and Efficacy of Infliximab in Patients With Active Ulcerative Colitis<br>**NCT00096655 - C0168T46** - A Randomized, Placebo-controlled, Double-blind Trial to Evaluate the Safety and Efficacy of Infliximab in Patients With Active Ulcerative Colitis |

| 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: | |