# The YODA Project
# Research Proposal Due Diligence Assessment

| Part 1: General Information | |
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| **YODA Project (Protocol) ID:** | 2023 – 5194 |
| **Date:** | February 15, 2024 |
| **Product Name:** | Infliximab/Golimumab/Ustekinumab |
| **Therapeutic Area:** | Immunology |
| **Product Class:** | Tumor necrosis factor-alpha (TNH-alpha) inhibitors/Biologics/Monoclonal antibodies |
| **Condition(s) Studied:** | Ulcerative Colitis |
| **Protocol Number(s) and Title(s):** | 1. **NCT00036439 - C0168T37**: A Randomized, Placebo-controlled, Double-blind Trial to Evaluate the Safety and Efficacy of Infliximab in Patients With Active Ulcerative Colitis<br>2. **NCT00096655 - C0168T46: A** Randomized, Placebo-controlled, Double-blind Trial to Evaluate the Safety and Efficacy of Infliximab in Patients With Active Ulcerative Colitis<br>3. **NCT00487539 - C0524T17:** 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<br>4. **NCT01551290 - CR018769; REMICADEUCO3001:** A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Efficacy and Safety of Infliximab in Chinese Subjects With Active Ulcerative Colitis<br>5. **NCT01369329 - CNTO1275CRD3001**: A Phase 3, Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Study to Evaluate the Safety and Efficacy of Ustekinumab Induction Therapy in Subjects With Moderately to Severely Active Crohn's Disease Who Have Failed or Are Intolerant to TNF Antagonist Therapy (UNITI-1)<br>6. **NCT01369342 - CNTO1275CRD3002:** A Phase 3, Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Study to Evaluate the Safety and Efficacy of Ustekinumab Induction Therapy in Subjects With Moderately to Severely Active Crohn's Disease (UNITI-2)<br>7. **NCT00488631 - C0524T18:** A Phase 3 Multicenter, Randomized, Placebo-controlled, Double-blind Study to Evaluate the Safety and Efficacy of Golimumab Maintenance Therapy, Administered Subcutaneously, in |

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| | Subjects With Moderately to Severely Active Ulcerative Colitis<br>8. **NCT01369355 - CNTO1275CRD3003:** A Phase 3, Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Study to Evaluate the Safety and Efficacy of Ustekinumab Maintenance Therapy in Subjects With Moderately to Severely Active Crohn's Disease<br>9. **NCT00488774 - C0524T16:** A Phase 2/3 Multicenter, Randomized, Placebo-controlled, Double-blind Study to Evaluate the Safety and Efficacy of Golimumab Induction Therapy, Administered Intravenously, in Subjects With Moderately to Severely Active Ulcerative Colitis<br>10. **NCT01863771 - CNTO148UCO3001:** A Safety and Effectiveness Study of Golimumab in Japanese Patients With Moderately to Severely Active Ulcerative Colitis<br>11. **NCT02407236 - CNTO1275UCO3001:** A Phase 3, Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Protocol to Evaluate the Safety and Efficacy of Ustekinumab Induction and Maintenance Therapy in Subjects With Moderately to Severely 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:** |

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| 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: | |