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

### Part 1: General Information

<table>
<thead>
<tr>
<th>YODA Project (Protocol) ID:</th>
<th>2022-5037</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date:</td>
<td>22 September 2022-Updated 4Oct22</td>
</tr>
<tr>
<td>Product Name:</td>
<td>Infliximab/Golimumab/Ustekinumab</td>
</tr>
<tr>
<td>Therapeutic Area:</td>
<td>Immunology</td>
</tr>
<tr>
<td>Product Class:</td>
<td>Antirheumatic Agents - Biologic Response Modifiers</td>
</tr>
<tr>
<td>Condition(s) Studied:</td>
<td>Ulcerative Colitis</td>
</tr>
</tbody>
</table>
| 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  
  NCT02407236 - CNT01275UC03001 - A Phase 3, Randomized, Double-blind, Placebo-controlled, Parallel group, Multicenter Protocol to Evaluate the Safety and Efficacy of Ustekinumab  
  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 Subjects With Moderately to Severely Active Ulcerative Colitis  
  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

<table>
<thead>
<tr>
<th>Data Holder has authority to provide clinical trial data or development partner has agreed to share clinical trial data.</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comments:</td>
<td></td>
</tr>
<tr>
<td>Data Holder has sharable electronic clinical trial data or data can be converted to electronic format.</td>
<td>Yes</td>
</tr>
<tr>
<td>Comments:</td>
<td></td>
</tr>
<tr>
<td>De-identification and redaction of clinical trial data in accordance with current HIPAA and EU criteria allows protection of participant privacy and confidentiality.</td>
<td>Yes</td>
</tr>
<tr>
<td>Comments:</td>
<td></td>
</tr>
<tr>
<td>The product and relevant indication studied has either been approved by regulators in the US and EU, or terminated from development.</td>
<td>Yes</td>
</tr>
<tr>
<td>Comments:</td>
<td></td>
</tr>
<tr>
<td>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).</td>
<td>Yes</td>
</tr>
<tr>
<td>Comments:</td>
<td></td>
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</tbody>
</table>

### Part 3: Data Availability Summary

<table>
<thead>
<tr>
<th>Based on the responses to the above Data Availability questions, the requested clinical trial data are available for a data sharing request.</th>
<th>Yes</th>
</tr>
</thead>
</table>
Part 4: Proposal Review

<table>
<thead>
<tr>
<th>Question</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Summary-level CSR data is appropriate for the proposed analysis.</td>
<td>No</td>
</tr>
<tr>
<td>Participant-level data is appropriate for the proposed analysis.</td>
<td>Yes</td>
</tr>
<tr>
<td>A similar analysis is underway or completed/pending disclosure by Janssen.</td>
<td>No</td>
</tr>
</tbody>
</table>

Comments: