### Part 1: General Information

<table>
<thead>
<tr>
<th>YODA Project (Protocol) ID:</th>
<th>2016-1136</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date:</td>
<td>19 December 2016</td>
</tr>
<tr>
<td>Product Name:</td>
<td>Abiraterone acetate</td>
</tr>
<tr>
<td>Therapeutic Area:</td>
<td>Oncology</td>
</tr>
<tr>
<td>Product Class:</td>
<td>CYP17 inhibitor</td>
</tr>
<tr>
<td>Condition(s) Studied:</td>
<td>Prostatic Neoplasms</td>
</tr>
<tr>
<td>Protocol Number(s) and Title(s):</td>
<td></td>
</tr>
<tr>
<td>NCT00638690 - A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study of Abiraterone Acetate (CB7630) Plus Prednisone in Patients With Metastatic Castration-Resistant Prostate Cancer Who Have Failed Docetaxel-Based Chemotherapy</td>
<td></td>
</tr>
<tr>
<td>NCT00887198 - A Phase 3, Randomized, Double-blind, Placebo-Controlled Study of Abiraterone Acetate (CB7630) Plus Prednisone in Asymptomatic or Mildly Symptomatic Patients With Metastatic Castration-Resistant Prostate Cancer</td>
<td></td>
</tr>
</tbody>
</table>

### Part 2: Data Availability

<table>
<thead>
<tr>
<th>Question</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data Holder has authority to provide clinical trial data or development partner has agreed to share clinical trial data.</td>
<td>Yes</td>
</tr>
<tr>
<td>Comments: N/A</td>
<td></td>
</tr>
<tr>
<td>Data Holder has shareable electronic clinical trial data or data can be converted to electronic format.</td>
<td>Yes</td>
</tr>
<tr>
<td>Comments: N/A</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: N/A</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: N/A</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: N/A</td>
<td></td>
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</tbody>
</table>

### 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

<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>
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<td>--------------------------------------------------</td>
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<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>Yes</td>
</tr>
<tr>
<td>Comments:</td>
<td>We are looking at the impact of the use of statins on outcomes with patients treated with ZYTIGA.</td>
</tr>
</tbody>
</table>