

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

<b>Part 1: General Information</b>	
<b>YODA Project (Protocol) ID:</b>	2015-0649
<b>Date:</b>	12 Jan 2016
<b>Product Name:</b>	Mixed: Paliperidone, Risperidone, Topiramate, Infliximab
<b>Therapeutic Area:</b>	Neuroscience, Immunology
<b>Product Class:</b>	mixed
<b>Condition(s) Studied:</b>	mixed
<b>Protocol Number(s) and Title(s):</b>	NCT00036374 NCT00036439 NCT00096655 NCT00207675 NCT00094458 NCT00119756 NCT00210548 NCT00101634 NCT00076115 NCT00132678 NCT00094926 NCT00207662 NCT00037674 NCT00035230 A Randomized, Double-Blind, Multicenter, Placebo-Controlled, 21-Day Study of the Safety and Efficacy of Topiramate for the Treatment of Acute Manic or Mixed Episodes in Subjects With Bipolar I Disorder With an Optional Open-Label Extension NCT00202865 NCT00077714 NCT00083668 NCT00074477 NCT00078039
<b>Part 2: Data Availability</b>	
<b>Question:</b>	<b>Response:</b>
Data Holder has authority to provide clinical trial data or development partner has agreed to share clinical trial data.	Yes
Comments:   N/A	
Data Holder has sharable electronic clinical trial data or data can be converted to electronic format.	Yes
Comments:   N/A	
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:   N/A	
The product and relevant indication studied has either been approved by regulators in the US and EU, or terminated from development.	Yes
Comments:   N/A	

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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: N/A	
<b>Part 3: Data Availability Summary</b>	
Based on the responses to the above Data Availability questions, the requested clinical trial data can be made available for data sharing.	Yes
<b>Part 4: Proposal Review</b>	
<b>Question:</b>	<b>Response:</b>
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:	