Due Diligence Assessment – Research Proposal

Part 1: General Information	
YODA Project (Protocol) ID:	2015-0539
Date:	30 Jun 15
Product Name:	CONCERTA
Therapeutic Area:	Neuroscience
Product Class:	CNS stimulants
Condition(s) Studied:	Attention Deficit Hyperactivity Disorder
Protocol Number(s) and Title(s):	12-101 A Multi-center Randomized Parallel Group Study Evaluating Treatment Outcomes of Concerta (Extended Release Methylphenidate) and Strattera (Atomoxetine) in Children With Attention-deficit/Hyperactivity Disorder

Part 2: Data Availability		
Question:		**Response:**
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	
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	

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	
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:	