The YODA Project
Research Proposal Due Diligence Assessment

Part 1: General Information	
YODA Project (Protocol) ID:	2024-0860
Date:	1-Oct-2024
Product Name:	CONCERTA (methylphenidate)
Therapeutic Area:	Neuroscience
Product Class:	Stimulants/ADHS/Anorexiants
Condition(s) Studied:	Attention Deficit Hyperactivity Disorder
Protocol Number(s) and Title(s):	1. NCT00307684 - **42603ATT3004** – An Open International Multicentre Long-Term Follow Up Study to Evaluate Safety of Prolonged Release OROS Methlyphenidate in Adults With Attention Deficit Hyperactivity Disorder 2. NCT00326300 - **12-304** - An Open-Label, Dose-Titration, Long-Term Safety Study to Evaluate CONCERTA (Methylphenidate HCL) Extended-release Tablets at Doses of 36 mg, 54 mg, 72 mg, 90 mg, and 108 mg Per Day in Adults With Attention Deficit Hyperactivity Disorder 3. NCT00246220 - **42603ATT3002** - A Multicentre, Randomised, Double-Blind, Placebo-Controlled, Parallel Group, Dose-Response Study To Evaluate the Safety And Efficacy Of Prolonged Release OROS Methylphenidate Hydrochloride (18, 36 and 72 mg/Day), With Open-Label Extension, In Adults With Attention Deficit/Hyperactivity Disorder 4. NCT00714688 - **42603ATT3013** - A Multicentre, Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Dose-Response Study to Evaluate Efficacy and Safety of Prolonged Release (PR) OROS Methylphenidate (54 and 72 mg/Day) in Adults With Attention Deficit/Hyperactivity Disorder 5. NCT00866996 - CR008329 (**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 6. NCT00269815 - **C98012** - Long-term Safety and Effectiveness of OROS (Methylphenidate HCl) in Children With ADHD 7. NCT00799409 - **CONCERTA-ATT-4069** - The ABC Study: A Double-Blind, Randomized, Placebo-Controlled, Crossover Study Evaluating the Academic, Behavioral, and Cognitive Effects of CONCERTA on Older Children With ADHD 8. NCT00799487 - **CONCERTA-ATT-4080** - Double-Blind, Randomized, Placebo-Controlled, Crossover Study Evaluating the Academic, Behavioral and Cognitive Effects of CONCERTA on Older Children With ADHD (The ABC Study) 9. NCT00937040 - CR015058 (**CONCERTA-ATT-3014**) - A Placebo-Controlled Double-Blind, Parallel Group, Individualizing Dosing Study Optimizing Treatment of Adults With Attention Deficit

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	Hyperactivity Disorder to an Effective Response With OROS Methylphenidate 10. NCT00326391 - **02-159**/CR011560 - A Placebo-Controlled, Double-Blind, Parallel-Group, Dose-Titration Study to Evaluate the Efficacy and Safety of CONCERTA (Methylphenidate HCl) Extended-release Tablets in Adults With Attention Deficit Hyperactivity Disorder at Doses of 36 mg, 54 mg, 72 mg, 90 mg, or 108 mg Per Day 11. NCT01323192 - **JNS001-JPN-A01** - A Double-blind, Placebo-controlled, Parallel-Group Study to Evaluate the Efficacy and Safety of JNS001 in Adults With Attention-Deficit/Hyperactivity Disorder at Doses of 18 mg, 36 mg, 54 mg, or 72 mg Per Day

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:
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:	