

## The YODA Project

### Research Proposal Due Diligence Assessment

<b>Part 1: General Information</b>	
<b>YODA Project (Protocol) ID:</b>	2024-0980
<b>Date:</b>	13-December-2024
<b>Product Name:</b>	Jcovden (Ad26.COVID.S), TOPAMAX (Topiramate)
<b>Therapeutic Area:</b>	Infectious Disease & Vaccines, Neuroscience
<b>Product Class:</b>	Monovalent Vaccine, Anticonvulsants
<b>Condition(s) Studied:</b>	COVID-19, Alcoholism
<b>Protocol Number(s) and Title(s):</b>	<p>1. NCT04614948 - <b>VAC31518COV3009</b> A Randomized, Double-blind, Placebo-controlled Phase 3 Study to Assess the Efficacy and Safety of Ad26.COVID.S for the Prevention of SARS-CoV-2-mediated COVID-19 in Adults Aged 18 Years and Older</p> <p>2. NCT00210925 - <b>CAPSS-278</b> A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Flexible Dose Study to Assess the Safety and Efficacy of Topiramate in the Treatment of Alcohol Dependence</p>
<b>Part 2: Data Availability</b>	
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:	
<b>Part 3: Data Availability Summary</b>	
Based on the responses to the above Data Availability questions, the requested clinical trial data are available for a data sharing request.	Yes
<b>Part 4: Proposal Review</b>	
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:	