Sample Due Diligence Assessment

Part 1: General Information	
YODA Project (Protocol) ID:	
Date:	
Product Name:	
Therapeutic Area:	
Product Class:	
Condition(s) Studied:	
Protocol Number(s) and Title(s):	

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/No
Comments: N/A or add comments if answered No.	
Data Holder has sharable electronic clinical trial data or data can be converted to electronic format.	Yes/No
Comments: N/A or add comments if answered No.	
De-identification and redaction of clinical trial data in accordance with current HIPAA and EU criteria allows protection of participant privacy and confidentiality.	Yes/No
Comments: N/A or add comments if answered No.	
The product and relevant indication studied has either been approved by regulators in the US and EU, or terminated from development.	Yes/No
Comments: N/A or add comments if answered No.	
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/No
Comments: N/A or add comments if answered No.	

Part 3: Data Availability Summary	
Based on the responses to the above Data Sharing questions, the requested clinical trial data can be made available for data sharing.	Yes/No

Part 4: Proposal Review	
Question:	**Response:**
Summary level CSR data is appropriate for the proposed analysis.	Yes/No
Participant level data is appropriate for the proposed analysis.	Yes/No
A similar analysis is underway or completed/pending disclosure by the Data Holder.	Yes/No
Comments: N/A or add comments.	