The YODA Project
Research Proposal Due Diligence Assessment

Part 1: General Information	
YODA Project (Protocol) ID:	2016-0960
Date:	4 November 2016
Product Name:	EPOETIN ALFA
Therapeutic Area:	ONC - EP
Product Class:	Hematologic Agents
Condition(s) Studied:	Anemia
Protocol Number(s) and Title(s):	**NCT00211133** - A Double-blind, Randomized, Placebo-controlled Study to Evaluate the Impact of Maintaining Hemoglobin Using Eprex (Epoetin Alfa) in Metastatic Breast Carcinoma Subjects Receiving Chemotherapy **NCT00270127** - Double-Blind, Placebo-Controlled Study to Assess the Effect of Early Intervention and/or Treatment With Epoetin Alfa on Anemia in Cancer Patients Receiving Non-Platinum-Containing Chemotherapy **NCT00270166** - A Placebo-Controlled Study on the Effect of Epoetin Alfa in Patients With Malignancy Receiving Chemotherapy **NCT00270049** - The Effect of Subcutaneous r-HuEPO in Patients With Chronic Lymphocytic Leukemia **NCT00270101** - A Placebo-Controlled Study on the Effect of r-huEPO in Patients With Multiple Myeloma Followed by an Open-Label Extension **NCT00270283** -A Double-Blind, Placebo-Controlled Study With Open-Label Follow-up to Determine the Safety and Efficacy of Subcutaneous Doses of r-HuEPO in AIDS Patients With Anemia Induced by Their Disease and AZT Therapy **NCT00091910**- A Randomized, Double-Blind, Placebo-Controlled Study to Determine the Efficacy and Safety of Epoetin Alfa in Critically Ill Subjects **No NCT** #/ EPO-2 (PR98-15-014)-Efficacy in the rHuEPO (Epoetin Alfa) in the Critically Ill Patient: A Randomized, Double Blind, Placebo-Controlled trial

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	

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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

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.	Yes
Participant-level data is appropriate for the proposed analysis.	Yes
A similar analysis is underway or completed/pending disclosure by Janssen.	No
Comments:	