

The YODA Project
Research Proposal Due Diligence Assessment

Part 1: General Information	
YODA Project (Protocol) ID:	2017-2486
Date:	4 December 2017
Product Name:	EPOETIN ALFA
Therapeutic Area:	ONC - EP
Product Class:	Hematologic Agents
Condition(s) Studied:	Anemia
Protocol Number(s) and Title(s):	<p>NCT00211133 - EPO-INT-76 - 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</p> <p>NCT00270127 - EPO-INT-10- 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</p> <p>NCT00270166 - EPO-INT-3- A Placebo-Controlled Study on the Effect of Epoetin Alfa in Patients With Malignancy Receiving Chemotherapy</p> <p>NCT00269997 -I88-036 - The Effect of Subcutaneous r-HuEPO in Patients With Chronic Anemia Secondary to Cisplatin Chemotherapy</p> <p>NCT00266617 - I88-037 - The Effect of Subcutaneous r-HuEPO in Patients With Chronic Anemia Secondary to Chemotherapy</p>
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

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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:	