The YODA Project
Research Proposal Due Diligence Assessment

Part 1: General Information	
YODA Project (Protocol) ID:	2018-2946
Date:	10 May 2018
Product Name:	Trabectedin
Therapeutic Area:	Oncology
Product Class:	Antineoplastic Agents
Condition(s) Studied:	Liposarcoma|Leiomyosarcoma/ Sarcoma/ Solid Tumor
Protocol Number(s) and Title(s):	**NCT01343277**/ET743-SAR-3007**-** A Study of Trabectedin or Dacarbazine for the Treatment of Patients With Advanced Liposarcoma or Leiomyosarcoma **NCT00060944**/ET743-STS-201**-** A Randomized, Multicenter, Open-label Study of Yondelis (ET-743 Ecteinascidin) Administered by 2 Different Schedules (Weekly for 3 of 4 Weeks vs. q3 Weeks) in Subjects With Locally Advanced or Metastatic Liposarcoma or Leiomyosarcoma Following Treatment With an Anthracycline and Ifosfamide **NCT00210665**/ET743-SAR-3002**-** A Study to Provide Access to Trabectedin in Participants With Locally Advanced or Metastatic Soft Tissue Sarcoma Who Have Persistent or Recurrent Disease and Who Are Not Expected to Benefit From Currently Available Standard of Care Treatment **NCT00786838**/ET743-OVC-1001**-** A Study to Assess the Potential Effects of a Single-Dose Administration of Trabectedin on the QT Intervals of the Electrocardiogram

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:	

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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:	