The YODA Project
Research Proposal Due Diligence Assessment

Part 1: General Information	
YODA Project (Protocol) ID:	2019-3840
Date:	5 April 2019
Product Name:	Ibrutinib
Therapeutic Area:	Oncology
Product Class:	kinase inhibitors
Condition(s) Studied:	Mantle Cell Lymphoma/Recurrent Mature B-cell Neoplasms/Chronic Lymphocytic Leukemia/Chronic Lymphocytic Leukemia With 17p Deletion/Relapsed or Refractory Chronic Lymphocytic Leukemia Marginal Zone Lymphoma/B-cell Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma/Diffuse Large Cell B-lymphoma/Waldenström's Macroglobulinemia
Protocol Number(s) and Title(s):	**NCT01722487**/ PCYC-1115-CA -Randomized, Multicenter, Open-label, Phase 3 Study of the Bruton's Tyrosine Kinase Inhibitor Ibrutinib Versus Chlorambucil in Patients 65 Years or Older With Treatment-naive Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma **NCT01236391**/ PCYC-1104-CA -Multicenter Phase 2 Study of Bruton's Tyrosine Kinase (Btk) Inhibitor, PCI-32765, in Relapsed or Refractory Mantle Cell Lymphoma **NCT01105247**/ PCYC-1102-CA -A Phase 1b/2 Fixed-dose Study of Bruton's Tyrosine Kinase (Btk) Inhibitor, PCI-32765, in Chronic Lymphocytic Leukemia

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:	*scans are not available
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:	

Part 3: Data Availability Summary

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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:	